**3.** Adhvaryu, M. R., N. M. Reddy and B. C. Vakharia (2008). "**Prevention of hepatotoxicity due to anti tuberculosis treatment: A novel integrative approach.**" World Journal of Gastroenterology **14**(30): 4753-4762.

Aim was to evaluate the ability of *Curcuma longa* (CL) and ***Tinospora cordifolia*** (TC) formulation to prevent anti-tuberculosis (TB) treatment (ATT) induced hepatotoxicity. Patients with active TB diagnosis were randomized to a drug control group and a trial group on drugs plus an herbal formulation. Isoniazid, rifampicin, pyrazinamide and ethambutol for first 2 mo followed by continuation phase therapy excluding Pyrazinamide for 4 mo comprised the anti-tuberculous treatment. Curcumin enriched (25%) CL and a hydro-ethanolic extract enriched (50%) TC 1 g each divided in two doses comprised the herbal adjuvant. Hemogram, bilirubin and liver enzymes were tested initially and monthly till the end of study to evaluate the result. Results: Incidence and severity of hepatotoxicity was significantly lower in trial group (incidence: 27/192 vs 2/316, P < 0.0001). Mean aspartate transaminase (AST) (195.93 ± 108.74 vs 85 ± 4.24, P < 0.0001), alanine transaminase (ALT) (75.74 ± 26.54 vs 41 ± 1.41, P < 0.0001) and serum bilirubin (5.4 ± 3.38 vs 1.5 ± 0.42, P < 0.0001). A lesser sputum positivity ratio at the end of 4 wk (10/67 vs 4/137, P = 0.0068) and decreased incidence of poorly resolved parenchymal lesion at the end of the treatment (9/152 vs 2/278, P = i0.0037) was observed. Improved patient compliance was indicated by nil drop-out in trial vs 10/192 in control group (P < 0.0001). The herbal formulation prevented hepatotoxicity significantly and improved the disease outcome as well as patient compliance without any toxicity or side effects.

**4.** Agrawal, A. K., D. M. Tripathi, R. Sahai, N. Gupta, R. P. Saxena, A. Puri, M. Singh, R. N. Misra, C. B. Dubey and K. C. Saxena (1997). "**Management of Giardiasis by a herbal drug 'Pippali Rasayana': A clinical study.**" Journal of Ethnopharmacology **56**(3): 233-236.

Pippali Rasayana (PR), an Indian ayurvedic drug prepared from Palash (*Butea monosperma* (Lamk) Kuntze; Leguminaceae) and Pippali (***Piper longum*** L.; Piperaceae), was administered at a dose of 1 g p.o. three times daily for a period of 15 days to patients (25 treated, 25 placebo controls) suffering from giardiasis with clinical signs and symptoms, and stools positive for trophozoites/cysts of Giardia lamblia. After 15 days of drug treatment there was a complete disappearance of G. lamblia (trophozoites/cysts) from the stools of 23 out of 25 patients. General signs and symptoms of ill health and abdominal discomfort, presence of mucus, pus cells and RBCs were significantly reduced. There was a marked improvement in the clinical and haematological profile of the patients. Spontaneous recovery in 20% cases was recorded in placebo controls.

**5.** Ahmed, A. O., J. S. Tripathi and I. S. Gambhir (2013). "**Comparative clinical evaluation of an ayurvedic regimen in the management of senile dementia.**" International Journal of Research in Ayurveda and Pharmacy **4**(3): 307-311.

An enhanced life expectancy in developed countries has been accompanied by an increased number of people suffering from age-associated dementia. Senile dementia is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, without any impairment in consciousness. Prevalence rates for senile dementia

increase essentially with advancing age. The prevalence rate rises to 54.8% in individuals above 95 years of age. So far, efforts to find a cure for Alzheimer Disease (AD) have been disappointing, and the drugs currently available to treat the disease address only its symptoms and with limited effectiveness. Present study was design to see the efficacy of Saraswata ghrita (includes ***Trikatu*: *Zingiber officinale, Piper longum, Piper nigrum***) along with Shirobasti on Senile dementia. A total number of 34 patients of Senile dementia were recruited by using ICD- 10 criteria of Dementia and MMSE scores and randomly divided in to two groups. Alzheimer's disease assessment scale (cognitive subscale) has been used to evaluate the clinical condition of the patients of Senile dementia. After completion of treatment Saraswata ghrita along with Shirobasti shows statistically significant results on clinical and neuro-cognitive parameters.

**6.** Altman, R. D. and K. C. Marcussen (2001). "**Effects of a ginger extract on knee pain in patients with osteoarthritis.**" Arthritis and Rheumatism **44**(11): 2531-2538.

Objective was to evaluate the efficacy and safety of a standardized and highly concentrated extract of 2 ginger species, ***Zingiber officinale*** and *Alpinia galanga* (EV.EXT 77), in patients with osteoarthritis (OA) of the knee. Two hundred sixty-one patients with OA of the knee and moderate-to-severe pain were enrolled in a randomized, double-blind, placebocontrolled, multicenter, parallel-group, 6-week study. After washout, patients received ginger extract or placebo twice daily, with acetaminophen allowed as rescue medication. The primary efficacy variable was the proportion of responders experiencing a reduction in "knee pain on standing," using an intent-to-treat analysis. A responder was defined by a reduction in pain of ≥15 mm on a visual analog scale. In the 247 evaluable patients, the percentage of responders experiencing a reduction in knee pain on standing was superior in the ginger extract group compared with the control group (63% versus 50%; P = 0.048). Analysis of the secondary efficacy variables revealed a consistently greater response in the ginger extract group compared with the control group, when analyzing mean values: reduction in knee pain on standing (24.5 mm versus 16.4 mm; P = 0.005), reduction in knee pain after walking 50 feet (15.1 mm versus 8.7 mm; P = 0.016), and reduction in the Western Ontario and McMaster Universities osteoarthritis composite index (12.9 mm versus 9.0 mm; P = 0.087). Change in global status and reduction in intake of rescue medication were numerically greater in the ginger extract group. Change in quality of life was equal in the 2 groups. Patients receiving ginger extract experienced more gastrointestinal (GI) adverse events than did the placebo group (59 patients versus 21 patients). GI adverse events were mostly mild. A highly purified and standardized ginger extract had a statistically significant effect on reducing symptoms of OA of the knee. This effect was moderate. There was a good safety profile, with mostly mild GI adverse events in the ginger extract group.

**7.** Ambiye, V. R., D. Langade, S. Dongre, P. Aptikar, M. Kulkarni and A. Dongre (2013). "**Clinical evaluation of the spermatogenic activity of the root extract of Ashwagandha (*Withania somnifera*) in oligospermic males: A pilot study.**" Evidence-based Complementary and Alternative Medicine ID 571420.

Ashwagandha (***Withania somnifera***) has been described in traditional Indian Ayurvedic medicine as an aphrodisiac that can be used to treat male sexual

dysfunction and infertility. This pilot study was conducted to evaluate the spermatogenic activity of Ashwagandha root extract in oligospermic patients. Forty-six male patients with oligospermia (sperm count < 20 million/mL semen) were enrolled and randomized either to treatment (n = 21) with a full-spectrum root extract of Ashwagandha (675 mg/d in three doses for 90 days) or to placebo (n = 25) in the same protocol. Semen parameters and serum hormone levels were estimated at the end of 90-day treatment. There was a 167% increase in sperm count (9.59 ± 4.37 × $10^6$/mL to 25.61 ± 8.6 × $10^6$/mL), 53% increase in semen volume (1.74 ± 0.58 mL to 2.76 ± 0.60 mL), and 57% increase in sperm motility (18.62 ± 6.11% to 29.19 ± 6.31%) on day 90 from baseline. The improvement in these parameters was minimal in the placebo-treated group. Furthermore, a significantly greater improvement and regulation were observed in serum hormone levels with the Ashwagandha treatment as compared to the placebo. The present study adds to the evidence on the therapeutic value of Ashwagandha (*Withania somnifera*), as attributed in Ayurveda for the treatment of oligospermia leading to infertility.

**8.** Anagha, D. N., MythreyR.C and G. Hegde (2013). "**Clinical study on the efficacy of amritadi ghrita and kutaja sooryapaka taila in the management of vicharchika vis-à-vis eczema.**" International Journal of Research in Ayurveda and Pharmacy **4**(6): 820-824.

Vicharchika is explained as one among Ekadasha Kshudra Kustha. The clinical features of vicharchika like Kandu, Pidaka, Shyavavarnata, Srava, Rookshata, Daha, Raji, and Vedana are very much similar with the features of Eczema. This is an inflammatory response produced by various internal and external factors. To manage such inflammatory condition of the skin, shamana chikitsa, in the form of bahya and abhyantara sneha prayoga was planned in order to have a safe and effective result in treating Vicharchika vis-à-vis Eczema. The objective of this study was, to evaluate the efficacy of Amritadi Ghrita as Shamana sneha along with the external application of Kutaja Sooryapaka Taila in the management of Vicharchika vis-à-vis Eczema. It is an observational clinical study with pre, mid and post test design where 30 patients of Vicharchika vis-à-vis Eczema were randomly selected and subjected to deepana and pachana with ***Trikatu*** choorna (***Zingiber officinale, Piper longum, Piper nigrum***) administered in a dose of 2 g thrice daily before food with ushnodaka, until nirama lakshanas were observed. Shamana snehapana by Amritadi Ghritha was advised in the dose of 30 ml, in empty stomach at annakala for 30 days along with external application of Kutajasooryapaka Taila twice a day after thoroughly cleaning the affected area of the skin with lukewarm water. Pathya ahara and Vihara were advised throughout the course of the study. In the present study, results obtained with respect to all the parameters were statistically highly significant with 'P' value of 0.000. Overall assessment showed marked relief in 20 patients, moderate relief in 6 patients followed by complete relief in 4 patients. Significant results in reduction of all the parameters i.e. Kandu (87.5 %), Pidaka (85.8 %), Srava (60.83 %), Rookshata (60.83 %) and Vaivarnyata (89.16 %) were found. Hence Amritadi Ghrita as Shamana sneha along with the external application of Kutaja Sooryapaka Taila was found to be very effective in the management of Vicharchika vis-à-vis Eczema.

**9.** Andallu, B. and B. Radhika (2000). "**Hypoglycemic, diuretic and hypocholesterolemic effect of Winter cherry (*Withania somnifera*, Dunal) root**." Indian Journal of Experimental Biology **38**(6): 607-609.

Hypoglycemic, diuretic and hypocholesterolemic effects of roots of ***Withania somnifera*** (ashvagandha) were assessed on human subjects. Six mild NIDDM subjects and six mild hypercholesterolemic subjects were treated with the powder of roots of *W. somnifera* for 30 days. Suitable parameters were studied in the blood and urine samples of the subjects along with dietary pattern before and at the end of treatment period. Decrease in blood glucose was comparable to that of an oral hypoglycemic drug. Significant increase in urine sodium, urine volume, significant decrease in serum cholesterol, triglycerides, LDL (low density lipoproteins) and VLDL (very low density lipoproteins) cholesterol were observed indicating that root of *W. somnifera* is a potential source of hypoglycemic, diuretic and hypocholesterolemic agents. Clinical observations revealed no adverse effects.

**10.** Andrade, C., A. Aswath, S. Chaturvedi, M. Srinivasa and R. Raguram (2000). "**A double-blind, placebo-controlled evaluation of the anxiolytic efficacy of an ethanolic extract of *Withania somnifera*.**" Indian Journal of Psychiatry **42**(3): 295-301.

A double-blind, placebo-controlled study was conducted to evaluate the efficacy an ethanolic extract of Aswagandha (***Withania somnifera***), in patients with ICD-10 anxiety disorders. The sample comprised 39 subjects, of whom 20 received the drug and 19 received placebo. The two groups were sociodemographically and clinically similar at baseline. At 2 and 6 weeks follow-up, data from approximately 85% of patients in each group were available for analysis. Statistical trends favouring the drug were observed at both time points. At 6 weeks, significantly more patients met a priori response criteria in the drug group (88.2%) as compared with the placebo group (50%). The drug was well-tolerated and did not occasion more adverse effects than did placebo. It is concluded that this ethanolic extract of *Withania somnifera* has useful anxiolytic potential and merits further investigation.

**11.** Angadi, S. S. and S. T. Gowda (2014). "**Management of Vyanga (facial melanosis) with Arjuna Twak Lepa and Panchanimba Churna.**" AYU **35**(1): 50-53.

Vyanga is one of the Kshudraroga, characterized by the presence of Niruja (painless) and Shavavarna Mandalas (bluish-black patches) on face. It is one of the most common diseases as regards the face is concerned. On the basis of clinical features, it can be compared with facial melanosis, one of the hyper pigmented disorders. Drugs with Rakta Prasadaka, Twak Prasadaka and Varnyakara properties are helpful in the management of Vyanga, that pacifies aggregated Doshas and help in Raktashodhana (blood purification). Aim: To evaluate the efficacy of Arjunatwak Lepa and Panchanimba Churna in Vyanga. Materials and Methods: In this study, the trial drugs used were Arjunatwak Churna for Lepa (tropical application) and Panchanimba Churna for oral administration. Ingredients of Panchanimba Churna are as follows: Nimba (*Azadirachta indica* A. Juss., Pippali (***Piper longum*** Linn.), Maricha (***Piper nigrum*** Linn.), Chitraka (*Plumbago zeylanica* Linn.), Haritaki (***Terminalia chebula*** (Gareth) Roxb.), Amalaki (***Emblica officinalis*** Gaerth.), Bakuchi (*Psoralia corylifolia* Linn.), Gokshura (*Tribulus terristris* Linn.), Vidanga (*Embelia ribes* Burm.), Araghwada (*Cassia fistula* Linn.), Haridra (*Curcuma longa* Linn.), Chakramarda (*Cassia tora* Linn.),

Shunti (***Zingiber officinale*** Roxb.), Bhallataka (*Semicarpus anacardium* Linn.), Louha bhasma, Sharkara (*Saccharum officinarum* Linn.), Bhringaraja (*Eclipta alba* Hassk.), Khadira (*Acacia catechu* Willd.). A total 30 patients of Vyanga were selected from outpatient department and inpatient department of Shalakya Tantra Department and allotted randomly in two groups. In group-A, the patients were treated with external application of Arjunatwak Churna and Madhu for 21 days, while in group-B, patients received Panchanimba Churna orally for 21 days in addition to Arjunatwak Churna for Lepa. Effect of therapy on chief complaint i.e., bluish-black pigmentation in Group A was 60% relief, while in Group B 80% relief was found. The clinical study has shown that combined therapy gives better results than topical treatment.

**12.** Antony, B., M. Benny and T. N. B. Kaimal (2008). "**A pilot clinical study to evaluate the effect of *Emblica officinalis* extract (Amlamax™) on markers of systemic inflammation and dyslipidemia.**" Indian Journal of Clinical Biochemistry **23**(4): 378-381.

***Emblica officinalis*** Gaertn., commonly known as the Indian gooseberry or "Amla", has been used as health food for centuries in India and other Asian countries. The biological effects of amla have been attributed to the antioxidant properties of the low-molecular weight hydrolysable tannins present in the fruit. Amlamax™ is a purified, standardized, dried extract of amla containing about 35% galloellagi tannins along with other hydrolysable tannins. Earlier studies on rabbits showed significant reduction in total cholesterol and triglycerides as well as increase in HDL. The present study extends these results to human volunteers. Two doses of the extract were evaluated - 500 mg and 1000 mg per day for 6 months. Blood samples were collected at the 3 rd and 6 th months showed reduction in total and LDL cholesterols and enhancement of beneficial HDL cholesterol. In addition, blood CRP levels, a marker for inflammation, were also significantly reduced. Since dyslipidemia and inflammation are the two major components of cardiovascular diseases, the present results must be considered encouraging and indicate the potential of AmlamaxTM in the management of heart diseases.

**13.** Arslan, M. and L. Ozdemir (2015). "**Oral Intake of ginger for chemotherapy-induced nausea and vomiting among women with breast cancer.**" Clinical Journal of Oncology Nursing **19**(5): E92-E97.

Chemotherapy-induced nausea and vomiting (CINV) is among the most common and distressing symptoms experienced by patients receiving cancer treatment. Nurses play a substantial role in the prevention and management of CINV. Ginger (***Zingiber officinale*** Roscoe) is often advocated as beneficial for nausea and vomiting. Whether the herb is truly efficacious for this condition is, however, still a matter of debate. This experimental randomized, controlled trial was done to assess the effect of ginger on chemotherapy-related nausea and vomiting. All patients in the study (N = 60) received standard antiemetic drugs. The patients in the study group (n = 30) also received oral ginger for the first three days of the chemotherapy cycle. No intervention was performed in the control group (n = 30) except for the routine antiemetic treatment. Nausea severity and the number of vomiting and retching episodes were measured four times each day for the first five days of the chemotherapy cycle in the patient diary. Nausea severity was evaluated using a numeric scale ranging from 0 (no nausea) to 10 (very severe nausea). Nausea severity

and the number of vomiting episodes were significantly lower in the intervention group than in the control group ($p > 0.05$). However, the change in the number of retching episodes between the intervention and control groups was not statistically significant ($p > 0.05$).

**14.** Aspalli, S., V. S. Shetty, M. V. Devarathnamma, G. Nagappa, D. Archana and P. Parab (2014). "**Evaluation of antiplaque and antigingivitis effect of herbal mouthwash in treatment of plaque induced gingivitis: A randomized, clinical trial.**" Journal of Indian Society of Periodontology **18**(1): 48-52.

Ayurvedic drugs have been used since ancient times to treat diseases including periodontal diseases. Oral rinses made from ayurvedic medicines are used in periodontal therapy to control bleeding and reduce inflammation. The aim of this clinical study is to verify the efficacy of herbal mouthwash containing Pilu, Bibhitaka (***Terminalia bellirica***), Nagavalli, Gandhapura taila, Ela, Peppermint satva, and Yavani satva on reduction of plaque and gingivitis. A total of 100 volunteers with clinical signs of mild to moderate gingivitis were selected and assigned to Group A (only scaling done) and Group B (scaling along with the use of herbal mouthwash). After recording the clinical parameters, the patients were instructed to use herbal mouthwash 15 ml for 30 s twice daily after food in Group B and oral hygiene instructions were given to all patients. Plaque and gingivitis assessment were carried out using the plaque index (Silness nd Loe, 1964), Gingival index (Loe And Silness, 1963), Gingival bleeding index (Ainamo and Bay, 1975) at baseline and at 21 days of the herbal mouthwash use. Statistically analysis was carried out using the student's t-test for normally distributed data and Wilcoxson test or Mann-Whitney U-test for skewed data. These results showed that herbal mouthwash was effective in treatment of plaque induced gingivitis in Group B when compared with the Group A. Herbal mouthwash is effective in treatment of plaque induced gingivitis and can be effectively used as an adjunct to mechanical therapy with lesser side-effects.

**15.** Atashak, S., M. A. Azarbayjani, M. Piri and A. Jafari (2012). "**Effects of combination of long - Term ginger consumption and resistance training on lipid peroxidation and insulin resistance in obese men.**" Journal of Medicinal Plants **11**(42): 179-188.

The present study investigated the effects of long-term ginger (***Zingiber officinale***) consumption and progressive resistance training on lipid per oxidation and insulin resistance in obese men. In a randomized double-blind design, 32 obese men (BMI≥ 30) were assigned in to one of four groups: a Placebo (PL,n=8), Ginger group, that consumed 1 gr ginger/d for 10 wk (GI,n=8), resistance training plus Placebo (PLRT,n=8), and 1gr ginger plus resistance exercise (GIRT, n=8). Progressive resistance training was performed three days per week for 10 weeks and included 8 exercises. At baseline and after 10 weeks venous blood samples were obtained from the antecubital vein, and Malondialdehyde (MDA) as an indicator of lipid peroxidation, pectrophotometrically were assayed by measurement of TBARS assay. Moreover, insulin resistance was determined using a homeostasis model assessment (HOMA-IR). Two-way ANOVA were used in the statistical analysis. Results: After 10 weeks of intervention, authors observed a significant decrease for MDA concentration in all groups exception Placebo group ($P<0.05$). Moreover, significant decreases in the

mean values of insulin resistance were observed in CIRT and PLRT groups (P<0.05). While it remained unchanged in GI and PL groups (p>0.05): Therefore, according to this results it can be said, that, long term ginger consumption and resistance training has been an effective therapeutic devise to favorable changes in lipid peroxidation and insulin resistance in obese men.

**16.** Atashak, S., M. Peeri, M. A. Azarbayjani and S. R. Stannard (2014). "**Effects of ginger (*Zingiber officinale* Roscoe) supplementation and resistance training on some blood oxidative stress markers in obese men.**" Journal of Exercise Science and Fitness **12**(1): 26-30.

Excessive adiposity increases oxidative stress, and thus may play a critical role in the pathogenesis and development of obesity-associated comorbidities, in particular atherosclerosis, diabetes mellitus, and arterial hypertension. Improved body composition, through exercise training and diet, may therefore significantly contribute to a reduction in oxidative stress. Further, some foods high in antioxidants (e.g., ginger) provide additional defense against oxidation. This study was conducted to assess the effects of ginger (***Zingiber officinale*** Roscoe) supplementation and progressive resistance training (PRT) on some nonenzymatic blood [total antioxidant capacity (TAC) and malondialdehyde (MDA)] oxidative stress markers in obese men. Thirty-two obese males (body mass index ≥30, aged 18-30 years) were randomized to one of the following four groups: a placebo (PL; n=8); resistance training plus placebo (RTPL; n=8); resistance training plus ginger supplementation (RTGI; n=8); and ginger supplementation only (GI; n=8). Participants in the RTGI and GI groups consumed 1g ginger/day for 10 weeks. At the same time, PRT was undertaken by the RTPL and RTGI groups three times/week. Resting blood samples were collected at baseline and at 10 weeks, and analyzed for plasma nonenzymatic TAC and MDA concentration. After the 10-week intervention, authors observed significant training×ginger supplementation×resistance training interaction for TAC (p=0.043) and significant interactions for training×resistance training and training×ginger supplementation for MDA levels (p<0.05). The results of this study show that 10 weeks of either ginger supplementation or PRT protects against oxidative stress and therefore both of these interventions can be beneficial for obese individuals; however, when combined, the effects cancel each other out.

**17.** Auddy, B., J. Hazra, A. Mitra, B. Abedon and S. Ghosal (2008). "**A standardized *Withania somnifera* extract significantly reduces stress-related parameters in chronically stressed humans: A double-blind, randomized, placebo-controlled study.**" The Journal of the American Nutraceutical Association **11**(1): 50-56.

***Withania somnifera*** (WS) has historically been used in Asia for treating stress-related health conditions. In this study, authors investigated the effects of standardized WS root and leaf extract (WSE) in chronically stressed humans in a modern clinical trial. Participants were randomly assigned to WSE (125 mg QD, 125 mg BID, or 250 mg BID) or placebo groups. Stress levels were assessed at Days 0, 30, and 60 using a modified Hamilton anxiety (mHAM-A) scale. Biochemical and clinical variables were measured at Days 0 and 60. Of 130 subjects enrolled, 98 completed the study. Between Days 0 and 60, the WSE 125 mg QD group decreased significantly more than placebo for mean mHAM-A score, serum cortisol, serum C-reactive

protein, pulse rate and blood pressure, and increased significantly for mean serum DHEAS and hemoglobin. Other WSE treatment groups had greater dose-dependent responses in these parameters and had significantly greater responses compared to placebo in mean fasting blood glucose, serum lipid profiles and cardiac risk ratios. Participants and dropouts reported no adverse effects. Therefore, this study provides evidence that the consumption of WSE significantly reduces experiential and biochemical indicators of stress without adverse effects.

**18.** Awasthi, H., R. Nath, K. Usman, D. Mani, S. Khattri, A. Nischal, M. Singh and K. K. Sawlani (2015). "**Effects of a standardized Ayurvedic formulation on diabetes control in newly diagnosed Type-2 diabetics; a randomized active controlled clinical study.**" Complementary Therapies in Medicine **23**(4): 555-561.

The purpose of this study was to investigate the efficacy of a standardized polyherbal formulation consists of aqueous extracts from six herbs, in patients with Type-2 diabetes mellitus. Randomized, active control study. Interventions 93 patients, newly diagnosed with Type-2 diabetes mellitus were randomly allocated to group 1 (received polyherbal capsules containing six herbal extracts viz. *Berberis aristata, Cyperus rotundus, Cedrus deodara,* ***Emblica officinalis****,* ***Terminalia chebula*** and ***Terminalia bellirica***, 500 mg/day, up titrated weekly to a maximum of 3 g/day) and group 2 (received Metformin 500 mg/day, up titrated weekly to a maximum of 2 g/day). Main outcome measures were: the primary endpoint was effect on the change from baseline in blood glucose (Fasting blood Glucose and Postprandial blood glucose), and glycosylated hemoglobin (HbA1c). The secondary outcome includes the effect on lipid levels, liver enzymes and renal function test. After 24 weeks, mean laboratory measured fasting and post prandial blood glucose showed a decrease of 25.52% and 24.22% in polyherbal formulation (PHF) treated group, compared to 31.46% and 24% decrease in Metformin treated group (estimated treatment difference −10.8; 95% CI −22.63 to 1.03 and −0.36; −12.1 to 11.38, respectively). Reduction in HbA1c was also similar for PHF and Metformin (estimated treatment difference 0.01; 95% CI −0.51 to 0.53). However, **the decrease in the mean total cholesterol level was more pronounced in PHF treated group (estimated mean difference 61.3; 95% CI 55.32 to 67.28) than Metformin treated group (estimated mean difference 41.12; 95% CI 34.92 to 47.32).** Also, there was statistical significance between the treatment groups in total cholesterol level at the end of six months treatment (estimated treatment difference 20.18; 95% CI 12.34 to 28.02). The study demonstrated that daily intake of this PHF decreased the glycemic level and improved lipid homeostasis, while maintaining the other serum biochemical levels to the normal, and therefore it may be useful for the patients with Type-2 diabetes. This trial is registered in the Clinical Trials Registry – India (CTRI) (CTRI/2014/03/004490).

**19.** Ayaz, A. and V. D. Roshan (2012). "**Effects of 6-weeks water-based intermittent exercise with and without *Zingiber officinale* on pro-inflammatory markers and blood lipids in overweight women with breast cancer.**" Journal of Applied Pharmaceutical Science **2**(5): 218-224.

Overweight and obesity is a risk factor for breast cancer. In contrast, physical regular activity has been suggested to help increase the survival of individuals with breast

cancer. However, few studies have assessed effect of individually and combined ***Zingiber officinale*** (as a anti-inflammatory factor) with water-based exercise on the pro-inflammatory markers and blood lipid levels in overweight women with breast cancer and results have been inconsistent. The aim of this study was to determine the individual and concomitant effect of 6-wks water-based exercise and oral *Zingiber officinale* supplement on the aforesaid markers in overweight women with breast cancer. Forty women diagnosed with breast cancer(48±5.4 years, 76±9 kg, fat mass 41.8±4 %), volunteered to participate in the study. Subjects were randomly assigned into four groups; placebo, water-based exercise, *Zingiber officinale* and water-based exercise + *Zingiber officinale* groups. Subjects in the *Zingiber officinale* group and the exercise training+ *Zingiber officinale* group orally received 4 capsules (each capsule contained 750 mg), 7 days a week and for 6 weeks. The water-based exercise program were collected at a progressive intensity and time, ranged from 50% to 75% of heart rate reserve, in a pool with 15 meters width, 4 times a week for 6 weeks. Fasting blood sampling was collected at the pretest and post-test. The *Zingiber officinale* supplementation and or the water-base exercise resulted in a reduction of hs-CRP, IL-6 and TG, as compared to pretest. However, the combined intervention (water-base exercise and *Zingiber officinale*) group showed significantly a far better effect on the markers of pro-inflammatory and blood lipids, as compared to the water-base exercise or *Zingiber officinale* supplement alone groups and the age-matched placebo group. These findings indicate a protective effect of the nondrug strategies such as water-base exercise and anti-inflammatory herbal factors such as *Zingiber officinale* in the pathogenesis of inflammatory and metabolic responses in overweight women diagnosed with breast cancer.

**20.** Badar, V. A., V. R. Thawani, P. T. Wakode, M. P. Shrivastava, K. J. Gharpure, L. L. Hingorani and R. M. Khiyani (2005). "**Efficacy of *Tinospora cordifolia* in allergic rhinitis.**" Journal of Ethnopharmacology **96**(3): 445-449.

The efficacy of ***Tinospora cordifolia*** (TC) extract in patients of allergic rhinitis was assessed in a randomized double blind placebo controlled trial. Seventy-five patients were randomly given either TC or placebo for 8 weeks. They were clinically examined and Hb %, TLC, DLC and nasal smear was done. At the end of trial baseline investigations were repeated, drug decoded and results analyzed. With TC treatment 100% relief was reported from sneezing in 83% patients, in 69% from nasal discharge, in 61% from nasal obstruction and in 71% from nasal pruritus. In placebo group, there was no relief in 79% from sneezing, in 84.8% from nasal discharge, in 83% from nasal obstruction, and in 88% from nasal pruritus. The difference between TC and placebo groups was highly significant. TLC increased in 69% patients in drug treated group and in only 11% with placebo. After TC, eosinophil and neutrophil count decreased and goblet cells were absent in nasal smear. In the placebo group, decrease in eosinophil and neutrophil count was marginal and goblet cells were present. TC significantly decreased all symptoms of allergic rhinitis. Nasal smear cytology and leukocyte count correlated with clinical findings. TC was well tolerated.

**21.** Bajaj, N. and S. Tandon (2011). "**The effect of *Triphala* and Chlorhexidine mouthwash on dental plaque, gingival inflammation, and microbial growth.**" International Journal of Ayurveda Research **2**(1): 29-36.

The objective of this study was to ascertain the effects of a mouthwash prepared with ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) on dental plaque, gingival inflammation, and microbial growth and compare it with commercially available Chlorhexidine mouthwash. This study was conducted after ethics committee approval and written consent from guardians (and assent from the children) were obtained. A total of 1431 students in the age group 8-12 years, belonging to classes fourth to seventh, were the subjects for this study. The Knowledge, Attitude and Practice (KAP) of the subjects was determined using a questionnaire. The students were divided into three groups namely, Group I (n = 457) using *Triphala* mouthwash (0.6%), Group II (n = 440) using Chlorhexidine mouthwash (0.1%) (positive control), and Group III (n = 412) using distilled water (negative control). The assessment was carried out on the basis of plaque scores, gingival scores, and the microbiological analysis (Streptococcus and lactobacilli counts). Statistical analysis for plaque and gingival scores was conducted using the paired sample t-test (for intragroup) and the Tukey's test (for intergroup conducted along with analysis of variance test). For the Streptococcus mutans and Lactobacillus counts, Wilcoxon and Mann-Whitney test were applied for intragroup and intergroup comparison, respectively. All the tests were carried out using the SPSS software. Both the Group I and Group II showed progressive decrease in plaque scores from baseline to the end of 9 months; however, for Group III increase in plaque scores from the baseline to the end of 9 months was noted. Both Group I and Group II showed similar effect on gingival health. There was inhibitory effect on microbial counts except Lactobacillus where *Triphala* had shown better results than Chlorhexidine. It was concluded that there was no significant difference between the *Triphala* and the Chlorhexidine mouthwash.

**22.** Bandari, S. and P. Murthy (2012). "**Clinical Evaluation of Panchavaktra Ras in the Management of Amavata (Rheumatoid Arthritis).**" International Journal of Ayurvedic Medicine **3**(1): 22-39.

This study was conducted to evaluate the effectiveness of Panchavaktra Ras in the Management of Amavata (Rheumatoid Arthritis). A single blind clinical trial was conducted at Dr. Achanta Lakshmipati Govt. Ayurvedic Hospital, M.G. Road, Vijayawada. 50 patients were selected and trial drug was advocated in a dose of 300 mg. (2 tablets) twice a day with ***Trikatu*** (***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***) and Arka moola twak kashaya as anupana. Treatment was given for 45 days with the result assessment recorded at every 15 days. Subjective and objective parameters were analyzed before and after the treatment. In subjective parameters Sandhi Shula, Jadya, Angamarda, Alasya, Agnimandhya and Vidvibandha are taken, while Sandhi Shotha, Erythrocyte Sedimentation Rate (ESR) and R.A. Factor are considered as objective parameters. It was observed that 48% were in mild relief group, while 50% were of moderate relief and there was Good relief in 2% of patients. Both Subjective and Objective parameters have been analyzed statistically. The relief of Sandhi Shula, Stabdata, Angimandya, Angamarda, Alasya and Vidvibandha found highly significant ($P < 0.001$) and same results in reduction Sandhi Shotha, ESR levels and RA Factor. Panchavaktra Ras prepared as per the textual standards is highly effective in Amavata and showing a way out to the individual suffering from this

chronic disease. The study confirmed the effect of trial drug in Amavata (Rheumatoid arthritis) in improving the quality of life of patients without any untoward effects.

**23.** Banerjee, P., S. Maity, T. Das and S. Mazumder (2011). "**A double-blind randomized placebo-controlled clinical study to evaluate the efficacy and safety of a polyherbal formulation in geriatric age group: A phase IV clinical report.**" Journal of Ethnopharmacology **134**(2): 429-433.

Authors sought to determine the efficacy as antioxidant and safety profile of the polyherbal formulation in geriatric patients of eastern India. The study was double-blind, randomized including placebo controlled and was approved by the ethical committee of SSKM hospital. Geriatric patients attending the OPD (outpatient department) of SSKM hospital formed the study group. The patients were randomized to receive either the polyherbal formulation or the identical-looking placebo at a dose of 2 tablets twice daily for a period of 6 months. Each tablet of polyherbal formulation contained *Capparis spinosa* 13.8 mg, *Terminalia arjuna* 6.4 mg, ***Withania somnifera*** 30mg, *Asparagus racemosus* 20mg, *Glycyrrhiza glabra* 20 mg, *Centella asiatica* 20mg, ***Terminalia chebula*** 15mg and *Curcuma longa* 5 mg. Follow-up of patient status was done monthly. The clinical parameters were assessed before and after 6 months of medication or placebo intake. The results showed that significant rejuvenation of the anti-oxidant property which is determined by the enzymatic and non enzymatic anti oxidants, superoxide dismutase, catalase, glutathione peroxidase, glutathione reductase, reduced glutathione and malondialdehyde in the geriatric patients were seen in patients treated with Geriforte tablets as compared to patients treated with placebo and control group. There were no significant adverse effects experienced by cases in any group. Polyherbal formulation is effective in rejuvenating geriatric age group compared to the placebo. This formulation is safe and compliance to the treatment was good. In ancient Ayurveda the constituents of polyherbal formulation were prescribed for different diseases including cardiological, neurological, sepsis, etc.

**24.** Bansal, P., R. Sannd, N. Srikanth and G. Lavekar (2009). "**Effect of traditionally designed nutraceutical on stress induced immunoglobulin changes at Antarctica.**" African Journal of Biochemistry Research **3**(4): 84-88.

This study was conducted to establish the effect of a traditionally designed nutraceutical on stress related changes in selected immunoglobulin levels in the body. The nutraceutical containing Ashwagandha (***Withania somnifera***), Guduchi (***Tinospora cordifolia***), Safed musli (*Chlorophytum arundinaceum*), Pippali (***Piper longum***), Badam (*Prunus amygdalus*) and some other herbs was prepared from different potent herbs described in Ayurveda using standard operative procedures and were tested for heavy metal and microbial load. Initially, 21 subjects were selected in addition to 7 volunteers for control group who did not consume nutraceutical. Sampling was done at zero days and at fortnightly intervals. The levels of selected immunoglobulin IgG, IgA and IgM were estimated with turbidity metric immunoassay at different time intervals. The concentration of immunoglobulin IgA was 146±15.96 at zero day stage. The levels of these immunoglobulins were lower at all stages as compared to the concentration at zero day in trial group subjects whereas the concentration was significantly higher (t stat.>t critic. at $p<0.05$) in

control group subjects. The concentration of IgG was very high to the tune of 3091±705 at zero day stage. The level of IgG was lower in trial subjects as compared to control subjects at all stages except at the 6th week stage where it was higher in trial subjects. Concentration of immunoglobulin IgM was 80.75±30.39 (t stat.>t critic. at $p<0.05$) at zero day followed by a decrease in both groups at the 2nd week, however **the concentration was almost 1/3 rd in trial drug subjects as compared to the levels in control subjects followed by an abrupt increase at the 4th week**. The levels increased to 106±8.94 at the 4th week stage and 115±9.35 at the 6th week stage in control subjects (even higher than at zero day) whereas the values were 46.15±11.39 and 55.38±15.34 (t stat.>t critic. at $p<0.05$) at respective stages in trial drug subjects. On the whole the pattern of fall and rise in levels of IgM were similar in the control as well as treatment group subjects at all stages. Studies revealed that the components of the nutraceutical tended to exert significant (t stat.>t critic. at $p<0.05$) anti-stress effect against stress related changes in immunoglobulin in the body due to the battery of stresses encountered at Antarctica.

**25.** Bargale, S. S., H. Shashirekha and U. C. Baragi (2014). "**Anti-aging effect of amalaki rasayana in healthy elderly subjects.**" Journal of Ayurveda and Holistic Medicine (JAHM) **2**(1): 10-18.

Aging is the accumulation of changes in a person over time. Ageing in humans refers to a multidimensional process of physical, psychological, and social change. The increasing number of the aged (≥60 years) in the present scenario signifies a new outlook for our reflection. Populations worldwide are ageing. In present era, medical science deals exclusively with the problem of ageing and the diseases of the elderly. Ayurveda is basically the science of life and longevity. It presents a good concept of ageing, process of delaying the ageing and its management. Amalaki Rasayana (with ***Emblica officinalis***) consist of rich of vitamin C, both ascorbic acid and its oxidized product dehydroascrobic acid are biological active, active vitamin C enhances promotion of non heam absorption. Aims and objectives were to evaluate the effect of amalaki rasayana in healthy elderly person. The clinical study was carried out to evaluate the efficacy of amalaki rasayana in subjects above 60 yr to 75 yrs. These subjects were divided in to two group A and B in 15 each. Person were given placebo capsule 60 days in group A and amalaki rasayana in the dose 10 gm once in a day for 60 days in group B and effect was evaluated on pre-test and post-test design. **Statistically significant ($p<0.01$) results were seen in subjective symptoms like physical disability, insomnia, difficulty in breathing, grasping power, loss of appetite, constipation, flabbiness of joint** etc. The trial drug amalaki rasayana along with milk has shown highly significant result in treating symptoms like insomnia, constipation, digestive weakness and hemoglobin percentage. Hence amalaki rasayana along with milk is very effective in treating ageing ailments.

**26.** Betz, O., P. Kranke, G. Geldner, H. Wulf and L. H. J. Eberhart (2005). "**Is ginger a clinically relevant antiemetic? A systematic review of randomized controlled trials.**" Forschende Komplementarmedizin und Klassische Naturheilkunde **12**(1): 14-23.

The aim of this systematic review was to evaluate the clinical impact of ginger (***Zingiber officinale***) as an antiemetic. A systematic search of the literature was performed using the databases of MEDLINE, EMBASE, and the Cochrane-Library. Of

100 published reports discerned as potentially relevant, 24 randomized controlled trials were evaluated, covering 1073 patients which had received ginger. Of these reports, 16 contained information regarding the antiemetic activity of the phytotherapeutic agent against kinetosis, postoperative nausea and vomiting (PONV), and morning sickness and hyperemesis gravidarum, respectively. Only a few studies were eligible for a quantitative analysis (meta-analysis). Thus, the majority of the reports were analyzed descriptively. To analyze the potential side effects of the drug, 15 reports with 777 patients were eligible. Of these, 3.3% suffered from slight side effects, mainly mild gastrointestinal symptoms and sleepiness, both not requiring specific treatments. One severe adverse event was reported in a study: an abortion occurred in the 12th week of gestation. However, a total of 136 patients were treated with ginger within the first trimenon of pregnancy without complications. There is no clear evidence for the efficacy of ginger in the treatment of PONV and of kinetosis. The results for the treatment of nausea and vomiting in pregnancy are encouraging, however, ginger should be applied for the time being only in controlled clinical studies. Applied in daily doses up to 6 g ginger seems to be a drug with few side effects.

**27.** Bhattacharjee, R., S. Nekkanti, N. G. Kumar, K. Kapuria, S. Acharya and K. C. Pentapati (2015). "**Efficacy of *Triphala* mouth rinse (aqueous extracts) on dental plaque and gingivitis in children.**" Journal of Investigative and Clinical Dentistry **6**(3): 206-210.

The aim of the present study was to evaluate the efficacy of ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) mouth rinse (aqueous) in the reduction of plaque and gingivitis among children. The study was a randomized, double-blinded, controlled trial, with a total of 60 school children (n = 30 in each group; *Triphala* and chlorhexidine groups). Plaque and gingival indices were used to evaluate baseline and follow-up plaque and gingivitis. A total of 57 children completed the study. Both chlorhexidine and *Triphala* groups showed significantly lower mean gingival and plaque index scores at follow up than baseline ($P < 0.001$). There was no significant difference in the percentage change in the mean gingival index between the two groups ($P = 0.826$). The percentage change in the mean plaque index was significantly higher in the chlorhexidine group compared to the *Triphala* group ($P = 0.048$). The effectiveness of *Triphala* in the reduction of plaque and gingivitis was comparable to chlorhexidine, and can be used for short-term purposes without potential side-effects. It is a cost-effective alternative in reducing plaque and gingivitis.

**28.** Bhosale, S. and S. Kapgate (2015). "**Effect of Hingu-Pippali Yoga, a herbal formulation in respiratory disorders caused by air pollution in traffic police - A pilot study.**" Asian Journal of Water, Environment and Pollution **12**(2): 99-106.

Traffic police in metropolitan cities are exposed to higher level of air pollution and are suffering from respiratory symptoms. Conventional symptomatic treatment is effective to give temporary relief but the lung capacity of the subjects reduces progressively. Present study was aimed to evaluate effect of Hingu-Pippali yoga, a herbal formulation in containing ***Piper longum***, respiratory disorders caused due to air pollution in traffic police. With a prior institutional ethical permission an open, randomised clinical study was carried out. Informed consent was taken from every

subject enrolled in trial. An authenticated and standardised test drug was administered twice a day in dose of 250 mg for 28 days with honey and sugar to trial group. Lung function test with spirometer and Haemogram before starting the treatment and at the end of study was done to evaluate the results. The subjective parameters viz. cough, rhinitis and dyspnoea showed significant reduction ($p < 0.001$) in trial group. Pulmonary Function Tests-FVC, FEV1, MVV and FEF ($p < 0.001$)-showed significant results indicating the increase in lung capacity in trial group. There was significant reduction seen in eosinophil count and ESR. Hingu-pippali yoga is effective to reduce the respiratory disorders caused due to air pollution and enhances the lung capacity of subjects.

**29.** Bhuyan, C., S. Gupta and T. Dudhamal (2015). "**Clinical effect of Madhu Amalaki Rasayan (MAR) in the treatment of Amlapitta. WSR to acid peptic disorders.**" Indian Journal of Ancient Medicine & Yoga **8**(3): 129-134.

Amlapitta is a very common disease which can be correlated with Acid peptic disorder (APD) in modern parlance. In Ayurveda the main cause of Amlapitta is due to Agnimandya (Indigestion), different dietetic habits like Adhyashan (Intake of food before digestion), Vishmashana (Irregular food intake) and spiced oily food etc. and the psychic factors like Chinta (anxiety) Udveg (Stress), Krodha (Anger) etc. In modern the causative factors are mainly hurry, worry and curry adding new sherry (Alcohol) and mechanical lifestyle with unsuitable food habits. The disease became chronic due to negligence and western life style adopting in diet and routine activity which is nonconductive regimen in our Indian climate. In this study 80 patients of Amlapitta were selected and divided into two groups. In group-A (Treated group) 50 patients were treated with Ayurveda formulation tablet Madhu Amalaki Rasayan (MAR) containing ***Emblica officinalis***, 250 mg two times a day before meal. In group-B (Control group) 30 patients were treated with modern medicine i.e. tablet famotidine-20 mg two times a day before meal. The treatment was continued for consecutive 30 days in both groups and patients were followed up for further two months by every fortnight. Lastly study concluded that tablet Madhu Amalaki Rasayan (MAR) is better as a remedial measure for Amlapitta having good palatability without any adverse effect.

**30.** Binorkar, S. V., C. M. Sreekrishnan and K. V. Asha (2013). "**Role of bilwadi agada in the management of scorpion sting.**" International Journal of Research in Ayurveda and Pharmacy **4**(1): 59-62.

Scorpion sting is a particularly devastating and an endemic public health problem in some part of the India. 50 species out of 700 in India can cause serious illness. Most of the studies have focused on the clinical and epidemiological aspects of scorpion stings. Ayurveda has explained numerous medicinal preparations for the management of Vrishchika Damsha (Scorpion sting) but so far very little statistical data is available regarding the efficacy of these medicines particularly in the management of pain. This Paper is focused on efficacy of one of such preparations, Bilwadi Agada which was a part of research for internal medications. A clinical study was conducted in 2005 at Pappinissery Visha Chikitsa Kendra, Kannur. Total 10 subjects suffering from Scorpion sting satisfying inclusion criteria were selected and after obtaining consent, treated with Bilwadi Agada for 4 days. Drug contains *Aegle*

*marmelos, Berberis aristata,* ***Piper nigrum****,* ***Piper longum****, Cedrus deodara, Curcuma longa,* ***Emblica officinalis****, Ocimum tenuiflorum, Pongamia pinnata,* ***Terminalia bellirica****,* ***Terminalia chebula****,* and *Valeriana wallichii*. Thorough clinical assessment was done before and after the treatment. The result was analyzed statistically with paired t-test which was found highly significant in reducing the cardinal symptom, pain, erythema and inflammation in scorpion sting (P<0.001). Drug also proved effective in reducing other associated symptoms like burning sensation and itching sensations in Scorpion sting.

**31.** Bisht, D., Y. Sharma and B. Mehra (2009). "**A clinical study to evaluate the efficacy of Pippali Rasayana in certain respiratory disorders.**" AYU **30**(3): 337-341.

Two million people die per year due to pulmonary tuberculosis all over the world. The 15 million new cases are diagnosed every year in India, of which 90% have pulmonary tuberculosis. Chronic bronchitis is the second most common lung disorder after pulmonary tuberculosis equally prevalent in rural and urban areas. Similarly nearly 6% population suffers from Bronchial asthma in India. Respiratory system is one such in human body which gets affected from a variety of infections and condition may become worse when body lacks sufficient immunity. Though drugs like corticosteroids, bronchodilators, anti tubercular therapy offer relief but may have many side effects. In Ayurveda answer to these problems is Rasayana therapy. Role of Rasayana therapy with recent advancement can be adjusted in terms of immuno modulatory, cytoprotective, genoprotective, adaptogenic, stress reliever actions etc. In this study a textual formulation. 'Pippali Rasayana' was given for a period of 45 days after Koshtha shodhana to 15 patients diagnosed with common respiratory diseases. Pippali Rasayana (PR) is an Ayurvedic drug prepared from Palash (*Butea monosperma* (Lamk) Kuntze; Leguminaceae) and Pippali (***Piper longum*** L.; Piperaceae). Control group of 12 patients was observed as such while taking their respective medications. A remarkable improvement was noted in clinical features as well as general conditions of these patients indicating the beneficial role of 'Pippali Rasayana' as adjuvant.

**32.** Biswal, B. M., S. A. Sulaiman, H. C. Ismail, H. Zakaria and K. I. Musa (2013). "**Effect of *Withania somnifera* (Ashwagandha) on the development of chemotherapy-induced fatigue and quality of life in breast cancer patients.**" Integrative Cancer Therapies **12**(4): 312-322.

Hypothesis was that ***Withania somnifera*** is an herb with antioxidant, anti-inflammatory, anticancer, antistress, and adaptogenic properties. Previous studies have shown its antistress effects in animals. Traditional Indian medicine has used it for centuries to alleviate fatigue and improve general well-being. This is an open-label prospective nonrandomized comparative trial on 100 patients with breast cancer in all stages undergoing either a combination of chemotherapy with oral ***Withania somnifera*** or chemotherapy alone. The chemotherapy regimens were either taxotere, adriamycin, and cyclophosphamide or 5-fluorouracil, epirubicin, and cyclophosphamide. *Withania somnifera* root extract was administered to patients in the study group at a dose of 2 g every 8 hours, throughout the course of chemotherapy. The quality-of-life and fatigue scores were evaluated before, during, and on the last cycles of chemotherapy using the EORTC QLQ-C30 (Version 3), Piper

Fatigue Scale (PFS), and Schwartz Cancer Fatigue Scale (SCFS-6). Results. The median age distributions in the study and control arm were 51 years (range = 36-70) and 50.5 years (range = 32-71), respectively. The majority (77%) of patients had stage II and III disease. Patients in the control arm experienced statistically significant higher estimated marginal means of fatigue score compared with the study group (P <.001 PFS, P <.003 SCFS-6). Furthermore, various symptom scales of the EORTC QLQ-C30 were statistically significant in 7 out of 18 symptoms in the intervention group compared with the control group (P <.001). The 24-month overall survival for all stages in study and control group patients were 72% versus 56%, respectively; however, the result was not significant (P =.176), at a median follow-up duration of 26 months. *Withania somnifera* has potential against cancer-related fatigue, in addition to improving the quality of life. However, further study with a larger sample size in a randomized trial is warranted to further validate these findings.

**33.** Biswas, N. R., S. K. Gupta, G. K. Das, N. Kumar, P. K. Mongre, D. Haldar and S. Beri (2001). "**Evaluation of Ophthacare® eye drops - A herbal formulation in the management of various ophthalmic disorders.**" Phytotherapy Research **15**(7): 618-620.

An open prospective multicentre clinical trial was conducted in patients suffering from various ophthalmic disorders namely, conjunctivitis, conjunctival xerosis (dry eye), acute dacryocystitis, degenerative conditions (pterygium or pinguecula) and postoperative cataract patients with a herbal eye drop preparation (Ophthacare®) containing basic principles of different herbs which have been conventionally used in the Ayurvedic system of medicine since time immemorial. These include *Carum copticum*, ***Terminalia bellirica***, ***Emblica officinalis***, *Curcuma longa*, *Ocimum sanctum*, *Cinnamomum camphora*, *Rosa damascena* and meldespumapum. These herbs reportedly posses antiinfective and antiinflammatory properties. The present study was undertaken to elucidate the role of this herbal product in a variety of eye ailments. Side effects, if any, were noted during the study. An improvement was observed with the treatment of the herbal eye drop treatment in most cases. There were no side effects observed during the course of the study and the eye drop was well tolerated by the patients. The herbal eye drop Ophthacare® has a useful role in a variety of infective, inflammatory and degenerative ophthalmic disorders.

**34.** Biswas, P., A. Saha and L. N. Maity (2015). "**Antistress activity of *Tinospora cordifolia* with application of Yoga.**" International Journal of Ayurvedic Medicine **6**(3): 220-224.

Mental stress can lead to various biochemicals, physiological and psychological changes in human body. The present study was designed to evaluate the antistress activities of ***Tinospora cordifolia*** (wild) Miers associated with yoga. Methods: A randomized double blind placebo control 8 weeks study was conducted. The mental stress patients were diagnosed clinically by using different validated psychological rating scales. A total of 63 patients with mental stress were randomized into four groups. The antistress activities of the treatments were measured by different psychological rating scales as well as various biochemical parameters i.e. lipid profile, serum glucose concentration. The serum glucose, lipid like triglyceride, cholesterol, ldl –cholesterol and psychological parameters like anxiety, depression were significantly increases in patients with chronic mental stress. However following treatment with *Tinospora cordifolia* associated with practice of yoga significantly

reduced various stress induced psychological and biochemical parameters (P< 0.001). The findings of the clinical study suggested that *Tinospora cordifolia* and practice of yoga have significant anti stress activities as shown by its mitigating effects on chronic stress induced psychological and biochemical perturbation comparable to that induced by well known adaptogenic agent diazepam.

**35.** Biswas, S. C., R. Dey, G. S. Kamliya, R. Bal, A. Hazra and S. K. Tripathi (2011). "**A single-masked, randomized, controlled trial of ginger extract in the treatment of nausea and vomiting of pregnancy.**" Journal International Medical Sciences Academy **24**(4): 167-169.

In order to evaluate the efficacy and tolerability of an oral ginger (***Zingiber officinale***) extract formulation in comparison to oral fixed dose combination of doxylamine 10 mg plus pyridoxine 10 mg, seventy eight (78) women between 6-16 weeks of pregnancy, complaining of nausea and vomiting (NVP), were randomized to receive either ginger formulation or pyridoxine-doxylamine preparation in a single blind fashion. Efficacy variables were the severity of nausea and vomiting scored by visual analog scale, on the day of each visit, as well as averaged over the past week; the average number of nausea spells or vomiting episodes per day over the past week; and subjective well-being assessed as a binary variable. Study was completed by 63 women (34 on ginger extract). Statistically, no appreciable difference in efficacy parameters was noted between groups. Tolerability of ginger extract was satisfactory with no severe or serious adverse events noted. Ginger extract can provide a safe and effective alternative for management of NVP.

**36.** Biswas, T. K., S. Chakrabarti, S. Pandit, U. Jana and S. K. Dey (2014). "**Pilot study evaluating the use of *Emblica officinalis* standardized fruit extract in cardio-respiratory improvement and antioxidant status of volunteers with smoking history.**" Journal of Herbal Medicine **4**(4): 188-194.

***Emblica officinalis*** (Indian Goosebery, ***Phyllanthus emblica***) was evaluated for cardio-respiratory and anti-oxidant status in human volunteers with a long smoking history, using a randomized, double-blind, placebo controlled pilot study. *Emblica officinalis* fruit extract (EOE) standardized to contain not less than 60% (w/w) of low molecular weight hydrolyzable tannoids (Emblicanin-A, Emblicanin-B, Pedunculagin, Punigluconin) was used in this randomized, double-blind, placebo-controlled clinical study, with Group I consisting of 20 subjects receiving 250 mg of EOE twice a day for 60 days and Group II consisting of 10 subjects receiving 250 mg of placebo twice a day for 60 days. Subjective parameters - mouth hygiene, cough with expectoration, shortness of breath on exertion, loss of appetite, feelings of impending doom, palpitation, sleep deprivation, irritability, heart burn and tiredness were evaluated at 0 (baseline), 30 and 60 days. Objective parameters - hemogram, lipid profile, cardiovascular risk factors, genotoxicity, antioxidant status and pulmonary function were assessed at days 0 (baseline) and 60 of the study. EOE treated group showed a significant improvement compared to the placebo group in all the subjective and objective parameters tested with no reports of adverse events. This pilot study provides some further evidence of the protective effect of *Emblica officinalis* in cardio-respiratory and antioxidant status of volunteers with chronic smoking history.

**37.** Black, C. D., M. P. Herring, D. J. Hurley and P. J. O'Connor (2010). "**Ginger (*Zingiber officinale*) reduces muscle pain caused by eccentric exercise.**" Journal of Pain **11**(9): 894-903.

Ginger (***Zingiber officinale***) has been shown to exert anti-inflammatory effects in rodents, but its effect on human muscle pain is uncertain. Heat treatment of ginger has been suggested to enhance its hypoalgesic effects. The purpose of this study was to examine the effects of 11 days of raw (study 1) and heat-treated (study 2) ginger supplementation on muscle pain. Study 1 and 2 were identical double-blind, placebo controlled, randomized experiments with 34 and 40 volunteers, respectively. Participants consumed 2 grams of either raw (study 1) or heated (study 2) ginger or placebo for 11 consecutive days. Participants performed 18 eccentric actions of the elbow flexors to induce pain and inflammation. Pain intensity, perceived effort, plasma prostaglandin E 2, arm volume, range-of-motion and isometric strength were assessed prior to and for 3 days after exercise. Results Raw (25%, -.78 SD, P = .041) and heat-treated (23%, -.57 SD, P = .049) ginger resulted in similar pain reductions 24 hours after eccentric exercise compared to placebo. Smaller effects were noted between both types of ginger and placebo on other measures. Daily supplementation with ginger reduced muscle pain caused by eccentric exercise, and this effect was not enhanced by heat treating the ginger. This study demonstrates that daily consumption of raw and heat-treated ginger resulted in moderate-to-large reductions in muscle pain following exercise-induced muscle injury. These findings agree with those showing hypoalgesic effects of ginger (*Zingiber officinale*) in osteoarthritis patients and further demonstrate ginger's effectiveness as a pain reliever.

**38.** Bone, M. E., D. J. Wilkinson, J. R. Young, J. McNeil and S. Carlton (1990). "**Ginger root - a new antiemetic. The effect of ginger root on postoperative nausea and vomiting after major gynaecological surgery.**" Anaesthesia **45**(8): 669-671.

The effectiveness of ginger (***Zingiber officinale***) as an antiemetic agent was compared with placebo and metoclopramide in 60 women who had major gynaecological surgery in a double-blind, randomized study. There were statistically significantly fewer recorded incidences of nausea in the group that received ginger root compared with placebo ($p < 0.05$). The number of incidences of nausea in the groups that received either ginger root or metoclopramide were similar. The administration of antiemetic after operation was significantly greater in the placebo group compared to the other two groups ($p < 0.05$).

**39.** Borrelli, F., R. Capasso, G. Aviello, M. H. Pittler and A. A. Izzo (2005). "**Effectiveness and safety of ginger in the treatment of pregnancy-induced nausea and vomiting.**" Obstetrics and Gynecology **105**(4): 849-856.

Conventional antiemetics are burdened with the potential of teratogenic effects during the critical embryogenic period of pregnancy. Thus, a safe and effective medication would be a welcome addition to the therapeutic repertoire. This systematic review was aimed at assessing the evidence for or against the efficacy and safety of ginger (***Zingiber officinale***) therapy for nausea and vomiting during pregnancy. Systematic literature searches were conducted in 3 computerized databases (MEDLBME, EMBASE, and Cochrane Library), and the reference lists of all

papers located were checked for further relevant publications. For the evaluation of efficacy, only double-blind, randomized controlled trials (RCTs) were included. All retrieved clinical data, including uncontrolled trials, case reports, observational studies, and RCTs, were included in the review of safety. Six double-blind RCTs with a total of 675 participants and a prospective observational cohort study (n = 187) met all inclusion criteria. The methodological quality of 4 of 5 RCTs was high. Four of the 6 RCTs (n = 246) showed superiority of ginger over placebo; the other 2 RCTs (n = 429) indicated that ginger was as effective as the reference drug (vitamin B6) in relieving the severity of nausea and vomiting episodes. The observational study retrieved and RCTs (including follow-up periods) showed the absence of significant side effects or adverse effects on pregnancy outcomes. There were no spontaneous or case reports of adverse events during ginger treatment in pregnancy. Ginger may be an effective treatment for nausea and vomiting in pregnancy. However, more observational studies, with a larger sample size, are needed to confirm the encouraging preliminary data on ginger safety.

**40.** Brockwell, C., S. Ampikaipakan, D. W. Sexton, D. Price, D. Freeman, M. Thomas, M. Ali and A. M. Wilson (2014). "**Adjunctive treatment with oral AKL1, a botanical nutraceutical, in chronic obstructive pulmonary disease.**" International Journal of COPD **9**: 715-721.

The objective of this pilot trial was to evaluate the safety and efficacy of AKL1, a patented botanical formulation containing extracts of *Picrorhiza kurroa*, *Ginkgo biloba*, and ***Zingiber officinale***, as add-on therapy for patients with chronic obstructive pulmonary disease (COPD) and chronic cough. Patients and methods: This randomized, double-blind, placebo-controlled trial enrolled male and female patients >18 years old with COPD and Leicester Cough Questionnaire (LCQ) score of <18. The 10-week study period comprised a 2-week single-blind placebo run-in period followed by add-on treatment with AKL1 or placebo twice daily for 8 weeks. The primary study endpoint was the change from week 0 to week 8 in cough-related health status, as assessed by the LCQ. Results: Of 33 patients enrolled, 20 were randomized to AKL1 and 13 to placebo. Patients included 19 (58%) men and 14 (42%) women of mean (standard deviation [SD]) age of 67 (9.4) years; 15 (45%) patients were smokers and 16 (49%) were ex-smokers. The mean (SD) change from baseline in LCQ score at 8 weeks was 2.3 (4.9) in the AKL1 group and 0.6 (3.7) in the placebo group, with mean difference in change of 1.8 (95% confidence interval: -1.5 to 5.1; P=0.28). The St George's Respiratory Questionnaire score improved substantially in the AKL1 treatment group by a mean (SD) of -7.7 (11.7) versus worsening in the placebo group (+1.5 [9.3]), with mean difference in change of -9.2 (95% confidence interval: -19.0 to 0.6; P=0.064). There were no significant differences between treatment groups in change from baseline to week 8 in other patient-reported measures, lung function, or the 6-minute walk distance. Further study is needed with a larger patient population and over a longer duration to better assess the effects of add-on therapy with AKL1 in COPD.

**41.** Cady, R. K., J. Goldstein, R. Nett, R. Mitchell, M. E. Beach and R. Browning (2011). "**A Double-Blind Placebo-Controlled Pilot Study of Sublingual Feverfew and Ginger (LipiGesicTMM) in the Treatment of Migraine.**" Headache: The Journal of Head and Face Pain **51**(7): 1078-1086.

Therapeutic needs of migraineurs vary considerably from patient to patient and even attack to attack. Some attacks require high-end therapy, while other attacks have treatment needs that are less immediate. While triptans are considered the "gold standard" of migraine therapy, they do have limitations and many patients are seeking other therapeutic alternatives. In 2005, an open-label study of feverfew/ginger suggested efficacy for attacks of migraine treated early during the mild headache phase of the attack. In this multi-center pilot study, 60 patients treated 221 attacks of migraine with sublingual feverfew/ginger or placebo. All subjects met International Headache Society criteria for migraine with or without aura, experiencing 2-6 attacks of migraine per month within the previous 3 months. Subjects had <15 headache days per month and were not experiencing medication overuse headache. Inclusion required that subjects were able to identify a period of mild headache in at least 75% of attacks. Subjects were required to be able to distinguish migraine from non-migraine headache. Subjects were randomized 3:1 to receive either sublingual feverfew/ginger or a matching placebo and were instructed but not required to treat with study medication at the earliest recognition of migraine. Sixty subjects treated 208 evaluable attacks of migraine over a 1-month period; 45 subjects treated 163 attacks with sublingual feverfew/ginger and 15 subjects treated 58 attacks with a sublingual placebo preparation. Evaluable diaries were completed for 151 attacks of migraine in the population using feverfew/ginger and 57 attacks for those attacks treated with placebo. At 2 hours, 32% of subjects receiving active medication and 16% of subjects receiving placebo were pain-free (P = .02). At 2 hours, 63% of subjects receiving feverfew/ginger found pain relief (pain-free or mild headache) vs 39% for placebo (P = .002). Pain level differences on a 4-point pain scale for those receiving feverfew/ginger vs placebo were −0.24 vs −0.04 respectively (P = .006). Feverfew/ginger was generally well tolerated with oral numbness and nausea being the most frequently occurring adverse event. Sublingual feverfew/ginger (***Zingiber officinale***) appears safe and effective as a first-line abortive treatment for a population of migraineurs who frequently experience mild headache prior to the onset of moderate to severe headache.

**42.** Carounanidy, U., R. Satyanarayanan and A. Velmurugan (2007). "**Use of an aqueous extract of *Terminalia chebula* as an anticaries agent: A clinical study.**" Indian Journal of Dental Research **18**(4): 152-156.

Plant-derived medicines have been a part of our traditional health care system, and the antimicrobial properties of plant-derived compounds are well documented. The purpose of this study is to evaluate the effect of an aqueous extract of ***Terminalia chebula*** (a medicinal plant) on salivary samples and its potential for use as an anticaries agent in the form of mouthwash. A concentrated aqueous extract was prepared from the fruit of T. chebula. A mouth rinse of 10% concentration was prepared by diluting the extract in sterile distilled water. The efficacy of the mouth rinse was assessed by testing on 50 salivary samples. Salivary samples were collected from subjects assessed to be at high risk for caries. Salivary pH, buffering capacity, and microbial activity were assessed before rinsing, immediately after, and 10 min, 30 min, and 1 h after rinsing. There was an increase in the pH and buffering capacity and decrease in microbial count. An aqueous extract of T. chebula used as a mouth rinse seems to be an effective anticaries agent.

**43.** Castillo, A., J. Ramos, J. De Francia, P. Quilala and M. Dujunco (2014). "**Immunomodulatory effects of *Tinospora cordifolia* lotion on interleukin-1, interleukin-6 and interleukin-8 levels in scabies-infected pediatric patients: a single blind, randomized trial.**" Intl J Pharma Sci Drug Res **6**: 204-210.

Scabies is a contagious, parasitic skin infestation caused by Sarcoptes scabiei mite, which has the ability to regulate the host's inflammatory and immune responses. It is a serious community health problem in many less-developed countries. A randomized, controlled, parallel, pilot clinical study was performed to investigate the immunomodulatory effect of the formulated Tinospora lotion in clinically diagnosed scabies-infected patients through Enzyme-Linked Immunosorbent Assay (ELISA) for Interleukin-1, Interleukin-6 and Interleukin-8 using blood serum samples. The pediatric patients were treated with ***Tinospora cordifolia*** and Permethrin lotions for three consecutive days for two weeks. Blood extraction was performed before and after the second and fourth week of treatment period. *Tinospora cordifolia* lotion significantly reduced the Interleukin-1 (IL-1) and Interleukin-6 (IL-6) levels from Day 14 to Day 28 ($p=0.0002$) comparable to Permethrin lotion ($p<0.050$). Permethrin efficiently decreased Interleukin-8 (IL-8) levels than Tinospora at Day 14 ($p=0.0155$). Down regulation of Interleukin 1, 6, and 8 levels in scabies infestation inhibits hyperkeratosis and infiltration of inflammatory cells into scabietic lesion. The modulation effect of the Tinospora lotion on interleukin levels reinforces its anti-scabies activity.

**44.** Castillo, A. L., M. O. Osi, J. D. A. Ramos, J. L. De Francia, M. U. Dujunco and P. F. Quilala (2013). "**Efficacy and safety of *Tinospora cordifolia* lotion in Sarcoptes scabiei var hominis-infected pediatric patients: A single blind, randomized controlled trial.**" Journal of Pharmacology and Pharmacotherapeutics **4**(1): 39-46.

Objective was to evaluate the clinical efficacy and safety of ***Tinospora cordifolia*** lotion including its cure rate and clearance time compared with permethrin lotion. Materials and Methods: A single blind, randomized, controlled, pilot clinical study was performed in three government institutions to investigate clinical efficacy of *T.cordifolia* lotion in sixty-six clinically-diagnosed scabies-infected patients. The patients were treated with *T.cordifolia* or permethrin lotions for three consecutive days for two weeks and clinical assessment of each patient was performed for five weeks. *T. cordifolia* lotion and permethrin significantly reduced the mean global evaluation score after four weeks of treatment. The two lotions showed comparable effects as anti-scabies agent. Moreover, the clearance time (days) and cure rate using the two lotions did not differ. Clinical improvement, mean clearance time and cure rate of *T. cordifolia* lotion are comparable with permethrin. *Tinospora cordifolia* lotion exhibits anti-scabies activity comparable with permethrin. Its incorporation as therapeutic reagent in Sarcoptes scabiei infections is highly recommended.

**45.** Chandrasekhar, K., J. Kapoor and S. Anishetty (2012). "**A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of Ashwagandha root in reducing stress and anxiety in adults.**" Indian Journal of Psychological Medicine **34**(3): 255-262.

Stress is a state of mental or emotional strain or tension, which can lead to underperformance and adverse clinical conditions. Adaptogens are herbs that help in combating stress. Ayurvedic classical texts, animal studies and clinical studies describe Ashwagandha (***Withania somnifera***) as a safe and effective adaptogen. The aim of the study was to evaluate the safety and efficacy of a high-concentration full-spectrum extract of Ashwagandha roots in reducing stress and anxiety and in improving the general well-being of adults who were under stress. It was a single center, prospective, double-blind, randomized, placebo-controlled trial. A total of 64 subjects with a history of chronic stress were enrolled into the study after performing relevant clinical examinations and laboratory tests. These included a measurement of serum cortisol, and assessing their scores on standard stress-assessment questionnaires. They were randomized to either the placebo control group or the study drug treatment group, and were asked to take one capsule twice a day for a period of 60 days. In the study drug treatment group, each capsule contained 300 mg of high-concentration full-spectrum extract from the root of the Ashwagandha plant. During the treatment period (on Day 15, Day 30 and Day 45), a follow-up telephone call was made to all subjects to check for treatment compliance and to note any adverse reactions. Final safety and efficacy assessments were done on Day 60. Statistical Analysis: t-test, Mann-Whitney test. The treatment group that was given the high-concentration full-spectrum Ashwagandha root extract exhibited a significant reduction ($P<0.0001$) in scores on all the stress-assessment scales on Day 60, relative to the placebo group. The serum cortisol levels were substantially reduced ($P=0.0006$) in the Ashwagandha group, relative to the placebo group. The adverse effects were mild in nature and were comparable in both the groups. No serious adverse events were reported. The findings of this study suggest that a high-concentration full-spectrum Ashwagandha root extract safely and effectively improves an individual's resistance towards stress and thereby improves self-assessed quality of life.

**46.** Chaudhary, S. A., K. Patel, V. Kori and S. Rajagopala (2012). "**Management of doshika kasa in sub-acute and chronic stage with vyaghri haritaki avaleha in children.**" Trials **21**: 09.

Respiratory Tract Infections (RTI) accounting about more than 50% of patients attending pediatric OPD as cough is the most frequent symptom of respiratory diseases majority of the patients' present recurrent cough as the manifestation of recurrent respiratory disease. From the Ayurvedic point of view, the descriptions about the disease Kasa clearly correlates with cough. Moreover the pathophysiology of Kasa almost exactly correlates the mechanism of cough reflex. It is important to treat any disease in childhood age at the earliest as it may hamper the Growth and development of child. Long standing disease affects the immunity and chronicity of the Kasa leads to Kshaya which has multi-system involvement. Due to disease, school absenteeism and expenditures of medicine are the burden on the society. As Kasa is Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, clinical study was undertaken on Kasa in sub-acute and chronic stage for duration of 4 weeks and also with follow-up of 4 weeks. The drug Vyaghri Haritaki Avaleha was given orally with luke warm water. Vyaghri Haritaki Avaleha includes *Solanum surattense*,

***Terminalia chebula***, ***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***, *Cinnamomum zylanicum, Cinnamomum tamala, Elleteria cardmomum, Mesua ferrea*. All the patients were kept under strict Pathyapalana (dietary & life-style modification) during the treatment. The observation on effect of therapy was encouraging and showed less recurrence. When the individualized overall effect of therapy were considered highest number of patient (82.60%) got Moderate positive response, 8.69% was observed with Mild positive response, and 8.69% of patients were observed Unchanged. 86.96% of the patients had no recurrence of the symptoms during the follow up period while 13.04% of the patients had recurrence but with lesser frequency and intensity may due to Rasayana (rejuvenation) effect of the drug on Pranavaha srotas.

**47.** Chaudhary, S. A., K. Patel, V. Kori and S. Rajagopala (1014). "**Management of doshika kasa in sub-acute and chronic stage with vyaghri haritaki avaleha in children.**" Ayurpharm Int J Ayur Alli Sci **3**(4): 97 - 111.

Respiratory Tract Infections (RTI) accounting about more than 50% of patients attending pediatric OPD as cough is the most frequent symptom of respiratory diseases majority of the patients' present recurrent cough as the manifestation of recurrent respiratory disease. From the Ayurvedic point of view, the descriptions about the disease Kasa clearly correlates with cough. Moreover the pathophysiology of Kasa almost exactly correlates the mechanism of cough reflex. It is important to treat any disease in childhood age at the earliest as it may hamper the Growth and development of child. Long standing disease affects the immunity and chronicity of the Kasa leads to Kshaya which has multi-system involvement. Due to disease, school absenteeism and expenditures of medicine are the burden on the society. As Kasa is Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, clinical study was undertaken on Kasa in sub-acute and chronic stage for duration of 4 weeks and also with follow-up of 4 weeks. The drug Vyaghri Haritaki Avaleha was given orally with luke warm water. Vyaghri Haritaki Avaleha includes *Solanum surattense*, ***Terminalia chebula***, ***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***, *Cinnamomum zylanicum, Cinnamomum tamala, Elleteria cardmomum*, and *Mesua ferrea*. All the patients were kept under strict Pathyapalana (dietary & life-style modification) during the treatment. The observation on effect of therapy was encouraging and showed less recurrence. When the individualized overall effect of therapy were considered highest number of patient (82.60%) got Moderate positive response, 8.69% was observed with Mild positive response, and 8.69% of patients were observed Unchanged. 86.96% of the patients had no recurrence of the symptoms during the follow up period while 13.04% of the patients had recurrence but with lesser frequency and intensity may due to Rasayana (rejuvenation) effect of the drug on Pranavaha srotas.

**48.** Chaudhari, V., M. Rajagopala, S. Mistry and D. Vaghela (2010). "**Role of Pradhamana Nasya and Trayodashanga Kwatha in the management of Dushta Pratishyaya with special reference to chronic sinusitis.**" AYU **31**(3): 325-331.

Dushta Pratishyaya is the chronic stage of Pratishyaya, which occurs due to neglect or improper management of the disease Pratishyaya. In modern science, chronic

sinusitis can be correlated with Dushta Pratishyaya on the basis of the signs, symptoms, complications, and prognosis. Changing lifestyles, rapid urbanization, and the increase in cases of antibiotic resistance are responsible for the rise in the prevalence of sinusitis. In the present clinical study, 37 patients were registered and were randomly divided into three groups: A, B, and C; of the 37 patients, 31 completed the full course of treatment. In group A, Trayodashanga Kwatha with Madhu was given orally; in group B, Pradhamana Nasya with ***Trikatu*** + ***Triphala*** Churna was administered; and in group C (combined group), Pradhamana Nasya was administered initially, followed by oral Trayodashanga Kwatha with Madhu. Acharya Charaka has advised a combination of ***Trikatu*** (***Zingiber officinale***, ***Piper longum***, ***Piper nigrum***) and ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) Churna for Pradhamana Nasya in the context of Pratishyaya Chikitsa. In group A, complete relief was observed in 10% of the patients; in group B, marked improvement was observed in 81.82% of patients; and in group C, marked relief was observed in 60% of patients. In comparison to other groups (Group A and Group B), Group C showed percentage wise better results in most of the symptoms.

**49.** Chengappa, K. N. R., C. R. Bowie, P. J. Schlicht, D. Fleet, J. S. Brar and R. Jindal (2013). "**Randomized placebo-controlled adjunctive study of an extract of *Withania somnifera* for cognitive dysfunction in bipolar disorder.**" Journal of Clinical Psychiatry **74**(11): 1076-1083.

Cognitive impairments contribute significantly to inadequate functional recovery following illness episodes in bipolar disorder, yet data on treatment interventions are sparse. Authors assessed the cognitive effects of a standardized extract of the medicinal herb ***Withania somnifera*** (WSE) in bipolar disorder. Sixty euthymic subjects with DSM-IV bipolar disorder were enrolled in an 8-week, double-blind, placebo-controlled, randomized study of WSE (500 mg/d) as a procognitive agent added adjunctively to the medications being used as maintenance treatment for bipolar disorder. Study enrollment and data analyses were completed between December 2008 and September 2012. Cognitive testing at baseline and 8 weeks assessed primary efficacy outcomes. Psychopathology and adverse events were monitored at scheduled visits. Fifty-three patients completed the study (WSE, n = 24; placebo, n = 29), and the 2 groups were matched in terms of demographic, illness, and treatment characteristics. Compared to placebo, WSE provided significant benefits for 3 cognitive tasks: digit span backward (P = .035), Flanker neutral response time (P = .033), and the social cognition response rating of the Penn Emotional Acuity Test (P = .045). The size of the WSE treatment effect for digit span backward was in the medium range (Cohen d = 0.51; 95% CI, 0.25-0.77). None of the other cognitive tasks showed significant betweengroup differences. Mood and anxiety scale scores remained stable, and adverse events were minor. Although results are preliminary, WSE appears to improve auditory-verbal working memory (digit span backward), a measure of reaction time, and a measure of social cognition in bipolar disorder. Given the paucity of data for improving cognitive capacity in bipolar disorder, WSE offers promise, appears to have a benign side-effects profile, and merits further study.

**50.** Chopra, A., P. Lavin, B. Patwardhan and D. Chitre (2004). "**A 32-week randomized, placebo-controlled clinical evaluation of RA-11, an Ayurvedic drug, on osteoarthritis of the knees.**" Journal of Clinical Rheumatology **10**(5): 236-245.

The ancient Indian (Asian) Ayurvedic medicinal system uses herbomineral drugs to treat arthritis. Despite centuries of use, very few have been tested by drug trials. RA-11 (ARTREX, MENDAR), a standardized multiplant Ayurvedic drug (***Withania somnifera***, *Boswellia serrata*, ***Zingiber officinale***, and *Curcuma longa*) is currently used to treat arthritis. The objective of this study was to evaluate the efficacy and safety of RA-11 in patients with symptomatic osteoarthritis (OA) of the knees. Methods: A total of 358 patients with chronic knee pain were screened free-of-cost in "arthritis camps" in an Indian metropolis. Ninety patients with primary OA of the knees (ACR classification; Arthritis Rheum 1986;29:1039-1049) were found eligible (postanalgesic washout pain visual analog score [VAS] ≥40 mm in either or both knees on body weight-bearing activities) to enroll into a randomized, double-blind, placebo-controlled, parallel efficacy, single-center, 32-week drug trial (80% power to detect 25% difference, P = 0.05, 2-sided). Concurrent analgesics/nonsteroidal antiinflammatory drugs and steroids in any form were not allowed. Lifestyle and/or dietary restrictions, as per routine Ayurveda practices, were not imposed. Pain VAS (maximum pain in each knee recorded by the patient during the preceding 48 hours) and modified WOMAC (Western Ontario McMaster University OA Index, Likert scale, version 3.0) were the primary efficacy variables. The WOMAC section on "physical function difficulty" was modified for Indian use and validated before the trial. Routine laboratory testing was primarily done to monitor drug safety. At baseline, the groups (active = 45, placebo = 45) were well matched for several measures (mean pain VAS: active = 6.17; placebo = 6.5). Results: 1) Efficacy: Compared with placebo, the mean reduction in pain VAS at week 16 (active = 2.7, placebo = 1.3) and week 32 (active = 2.8, placebo = 1.8) in the active group was significantly (P <0.05, analysis of variance [ANOVA]) better. Similarly, the improvement in the WOMAC scores at week 16 and week 32 were also significantly superior (P <0.01, ANOVA) in the active group. 2) Safety: Both the groups reported mild adverse events (AE) without any significant difference. 3) Withdrawals: Twenty-eight patients were discontinued. None reported drug-related toxicity. The majority failed follow up/compliance. No differences were observed between the groups. This controlled drug trial demonstrates the potential efficacy and safety of RA-11 in the symptomatic treatment of OA knees over 32 weeks of therapy.

**51.** Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, G. Narsimulu, S. Sarmukaddam and B. Patwardhan (2012). "**Evaluating higher doses of Shunthi - Guduchi formulations for safety in treatment of osteoarthritis knees: A Government of India NMITLI arthritis project.**" Journal of Ayurveda and Integrative Medicine **3**(1): 38-44.

Results of an exploratory trial suggested activity trends of ***Zingiber officinale***-***Tinospora cordifolia*** (platform combination)-based formulations in the treatment of Osteoarthritis (OA) Knees. These formulations were "platform combination+***Withania somnifera***+*Tribulus terrestris*0" (formulation B) and "platform combination+Emblica officinale" (formulation C). This paper reports safety of these formulations when used in higher doses (1.5-2 times) along with Sallaki Guggul and Bhallataka Parpati (a *Semecarpus anacardium* preparation). Ninety-two

patients with symptomatic OA knees were enrolled in a 6 weeks investigator blind, randomized parallel efficacy 4-arm multicenter drug trial. The 4 arms were (I) formulation B, 2 t.i.d.; (II) formulation B, 2 q.i.d.; (III) platform combination+Sallaki Guggul; (IV) Bhallataka Parpati+formulation C. A detailed enquiry was carried out for adverse events (AE) and drug toxicity as per a priori check list and volunteered information. Laboratory evaluation included detailed hematology and metabolic parameters. Patients were examined at baseline, first and fourth weeks, and on completion. Standard statistical program (SPSS version 12.5) was used for analysis. Results: None of the patients reported serious AE or withdrew due to any drug-related toxicity. Mild gut-related (mostly epigastric burning) AE was reported. A mild increase in liver enzymes [serum glutamic pyruvate transaminase (SGPT), serum glutamic oxaloacetic transaminase (SGOT)] without any other hepatic abnormality was reported in 2 patients (group IV). Other laboratory parameters remained normal. The mean improvement in active pain visual analog scale (1.4, CI 0.5-2.22), WOMAC (functional activity questionnaire) pain score (1.37, CI 0.22-2.5), and urinary C-TAX (cartilage collagen breakdown product) assay was maximum (NS) in group IV. Lower dose group I showed numerically superior improvement compared with higher dose group II. The results suggested that despite higher doses, standardized Ayurvedic formulations demonstrated a good safety profile. An improved efficacy and likely chondroprotective effect was shown by group IV intervention. A confirmatory drug trial with adequate power and sample size was planned based on the learning from this trial.

**52.** Chopra, A., M. Saluja, G. Tillu, S. Sarmukkaddam, A. Venugopalan, G. Narsimulu, R. Handa, V. Sumantran, A. Raut, L. Bichile, K. Joshi and B. Patwardhan (2013). "**Ayurvedic medicine offers a good alternative to glucosamine and celecoxib in the treatment of symptomatic knee osteoarthritis: A randomized, double-blind, controlled equivalence drug trial.**" Rheumatology **52**(8): 1408-1417.

To demonstrate clinical equivalence between two standardized Ayurveda (India) formulations (SGCG and SGC), glucosamine and celecoxib (NSAID). Ayurvedic formulations (extracts of ***Tinospora cordifolia***, ***Zingiber officinale***, ***Emblica officinalis***, *Boswellia serrata*), glucosamine sulphate (2 g daily) and celecoxib (200mg daily) were evaluated in a randomized, double-blind, parallel-efficacy, four-arm, multicentre equivalence drug trial of 24 weeks duration. A total of 440 eligible patients suffering from symptomatic knee OA were enrolled and monitored as per protocol. Primary efficacy variables were active body weight-bearing pain (visual analogue scale) and modified WOMAC pain and functional difficulty Likert score (for knee and hip); the corresponding a priori equivalence ranges were ∓1.5 cm, ∓2.5 and ∓8.5. Results. Differences between the intervention arms for mean changes in primary efficacy variables were within the equivalence range by intent-to-treat and per protocol analysis. Twenty-six patients showed asymptomatic increased serum glutamic pyruvic transaminase (SGPT) with otherwise normal liver function; seven patients (Ayurvedic intervention) were withdrawn and SGPT normalized after stopping the drug. Other adverse events were mild and did not differ by intervention. Overall, 28% of patients withdrew from the study. In this 6-month controlled study of knee OA, Ayurvedic formulations (especially SGCG) significantly reduced knee pain and improved knee function and were equivalent to glucosamine and celecoxib. The

unexpected SGPT rise requires further safety assessment. Trial registration: Clinical Drug Trial Registry - India, www.ctri.nic.in, CTRI/2008/091/000063.

**53.** Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, G. Narsimulu, R. Handa, L. Bichile, A. Raut, S. Sarmukaddam and B. Patwardhan (2012). "**Comparable efficacy of standardized Ayurveda formulation and hydroxychloroquine sulfate (HCQS) in the treatment of rheumatoid arthritis (RA): A randomized investigator-blind controlled study.**" Clinical Rheumatology **31**(2): 259-269.

Hydroxychloroquine sulfate (HCQS) is a popular disease-modifying antirheumatic drug (DMARD) despite modest efficacy and toxicity. Ayurveda (ancient India medicinal system) physicians treat rheumatoid arthritis (RA) with allegedly safer herbal formulations. Authors report a head-to-head comparison in an exploratory drug trial. The objective is to compare standardized Ayurvedic formulations and HCQS in the treatment of RA. One hundred twenty-one patients with active moderately severe RA (ACR 1988 classified) were randomized into a 24-week investigator-blind, parallel efficacy, three-arm (two Ayurvedic and HCQS) multicenter drug trial study; polyherb (***Tinospora cordifolia*** and ***Zingiber officinale*** based) and monoherb (*Semecarpus anacardium*). Study measures included joint counts (pain/tenderness and swelling), pain visual analogue scale, global disease assessments, and health assessment questionnaire. Oral meloxicam (fixed-dosage schedule) was prescribed to all patients during the initial 16 weeks. Patients on prednisolone could continue a fixed stable dose (<7.5 mg daily). Rescue oral use of paracetamol was permitted and monitored. All groups matched well at baseline. An intent-to-treat analysis (ANOVA, significance $P<0.05$) did not show significant differences by treatment groups. In the polyherb, monoherb, and HCQS arms, 44%, 36%, and 51%, respectively, showed ACR 20 index improvement. Several efficacy measures improved significantly in the HCQS and polyherb groups with no difference between the groups (corrected P). However, the latter was individually superior to monoherb. Only mild adverse events (gut and skin, and none withdrew) were reported with no differences between the groups. Forty-two patients dropped out. This preliminary drug trial controlled for HCQS demonstrated a standardized Ayurvedic polyherb drug to be effective and safe in controlling active RA. A better-designed study with a longer evaluation period is recommended.

**54.** Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, S. Sarmukaddam, A. K. Raut, L. Bichile, G. Narsimulu, R. Handa and B. Patwardhan (2011). "**A randomized controlled exploratory evaluation of standardized ayurvedic formulations in symptomatic osteoarthritis knees: A Government of India NMITLI project.**" Evidence-based Complementary and Alternative Medicine **2011:** Article ID 724291.

The multidisciplinary "New Millennium Indian Technology Leadership Initiative" Arthritis Project was undertaken to validate Ayurvedic medicines. Herbal formulations in popular use were selected by expert consensus and standardized using modern tools. Clinical strategy evolved from simple exploratory evaluations to better powered statistically designed drug trials. The results of the first drug trial are presented here. Five oral formulations (coded A, B, C, D and E), with a common base of ***Zingiber officinale*** and ***Tinospora cordifolia*** with a maximum of four plant extracts, were evaluated; with placebo and glucosamine as controls. 245 patients suffering from

symptomatic OA knees were randomized into seven arms (35 patients per arm) of a double blind, parallel efficacy, multicentric trial of sixteen weeks duration. The groups matched well at baseline. There were no differences for patient withdrawals (17.5%) or adverse events (AE) of mild nature. Intention-to-treat efficacy analysis, demonstrated no significant differences (P<.05) for pain (weight bearing) and WOMAC questionnaire (knee function); placebo response was high. Based on better pain relief, significant (P<.05) least analgesic consumption and improved knee status, "C" formulation was selected for further development. Controlled exploratory drug trials with multiple treatment arms may be used to economically evaluate several candidate standardized formulations.

**55.** Choudhary, B., A. Shetty and D. G. Langade (2015). "**Efficacy of Ashwagandha (*Withania somnifera* [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults.**" AYU **36**(1): 63-68.

Ashwagandha (***Withania somnifera*** [L.] Dunal) has been traditionally used for various actions ranging from vitalizer, improve endurance and stamina, promote longevity, improve immunity, and male and female fertility. However, clinical studies are needed to prove the clinical efficacy of this herb, especially in cardiovascular endurance and physical performance. This prospective, double-blind, randomized, and placebo-controlled study evaluated the efficacy of Ashwagandha roots extract in enhancing cardiorespiratory endurance and improving the quality of life (QOL) in 50 healthy male/female athletic adults. Cardiorespiratory endurance was assessed by measuring the oxygen consumption at peak physical exertion (VO2max) levels during a 20 m shuttle run test. The World Health Organization self-reported QOL questionnaire (physical health, psychological health, social relationships, and environmental factors) was used to assess the QOL. Student's t-test was used to compare the differences in a mean and change from baseline VO2max levels, whereas Wilcoxon signed-rank test was used to assess changes in QOL scores from baseline in the two groups. Results: There was a greater increase from baseline (P < 0.0001) in the mean VO2max with KSM-66 Ashwagandha (n = 24) compared to placebo (n = 25) at 8 weeks (4.91 and 1.42, respectively) and at 12 weeks (5.67 and 1.86 respectively). The QOL scores for all subdomains significantly improved to a greater extent in the Ashwagandha group at 12 weeks compared to placebo (P < 0.05). The findings suggest that Ashwagandha root extract enhances the cardiorespiratory endurance and improves QOL in healthy athletic adults.

**56.** Chuangsuwanich, A. and K. Jongjamfa (2014). "**The efficacy of combined herbal extracts gel preparation in the prevention of postsurgical hypertrophic scar formation.**" Dermatology and Therapy **4**(2).

The objective of preventing surgical scar formation is to improve the quality of life for patients. Many medical products have been used in preventing hypertrophic scarring but an optimal treatment method has not been established yet. At the present, there are several studies demonstrating the potential of herbs in scar prevention. The purpose of this study was to evaluate the efficacy of combined herbal extracts gel (CHG) in the prevention of surgical scar formation. Methods: All the patients who underwent bilaterally symmetric surgical procedures were selected using inclusion and exclusion criteria and were then treated with both the CHG (CHG group) and

placebo gel. The combined herbal extract gel (CHG) is a composition of *Allium cepa* (12% w/w), *Centella asiatica* (5% w/w), *Aloe vera* (4% w/w), ***Phyllanthus emblica*** (1.5% w/w), and *Tamarindus indica* (1.5% w/w) extract. Each gel was applied on separate scars twice daily for 12 weeks. The scars were photographed and evaluated using Patient and Observer Scar Assessment Scale (PSAS and OSAS, respectively). The CHG-treated scars showed lower median PSAS scores than the placebo group in color, stiffness, thickness, irregularity, and overall scores, with statistically significant difference at 12 weeks. For OSAS, the scars in the CHG group showed lower median scores than the placebo group in pigmentation, thickness, and overall scores at 12 weeks. The median OSAS scores in vascularity, relief, and pliability differed from placebo group and were statistically significant at 8 weeks. No side effects were observed in either group. The CHG might be effective in the prevention of surgical scarring.

**57.** Colucci, R., F. Dragoni, R. Conti, L. Pisaneschi, L. Lazzeri and S. Moretti (2015). "**Evaluation of an oral supplement containing *Phyllanthus emblica* fruit extracts, vitamin E, and carotenoids in vitiligo treatment.**" Dermatologic Therapy **28**(1): 17-21.

***Phyllanthus emblica*** (***syn. Emblica officinalis***), vitamin E, and caroteinods are compounds showing antioxidative, anti-inflammatory, and repigmenting effects, whose role in vitiligo treatment has not been evaluated so far. Sixty-five subjects (group A) were treated with one tablet of an oral supplement containing *P. emblica* (100 mg), vitamin E (10 mg), and carotenoids (4.7 mg) three times/day for 6 months and compared with a control group (group B, 65 patients), which instead was not treated with antioxidants. Both groups were simultaneously treated with a comparable topical therapy and/or phototherapy. After a 6 months follow-up, a significantly higher number of patients in group A had a mild repigmentation on the head/neck regions ($p = 0.019$) and on the trunk (trend, $p = 0.051$). The number of patients who presented no repigmentation in head/neck, trunk, upper, and lower limbs was significantly higher in group B (respectively, $p = 0.009$, $p = 0.001$, $p = 0.001$, $p = 0.025$). Moreover, group B patients showed higher signs of inflammation ($p = 0.002$), a more rapid growth of the lesions ($p = 0.039$), a higher percentage of worsening disease ($p = 0.003$), and more erythema ($p = 0.059$), whereas group A patients showed a higher percentage of steady disease ($p = 0.065$). These results suggest that the supplement with antioxidants in patients with vitiligo might represent a valuable instrument to increase the effectiveness of other vitiligo treatments.

**58.** Cooley, K., O. Szczurko, D. Perri, E. J. Mills, B. Bernhardt, Q. Zhou and D. Seely (2009). "**Naturopathic care for anxiety: A randomized controlled trial ISRCTN78958974.**" PLoS ONE **4**(8).

Anxiety is a serious personal health condition and represents a substantial burden to overall quality of life. Additionally anxiety disorders represent a significant cost to the health care system as well as employers through benefits coverage and days missed due to incapacity. This study sought to explore the effectiveness of naturopathic care on anxiety symptoms using a randomized trial. Employees with moderate to severe anxiety of longer than 6 weeks duration were randomized based on age and gender to receive naturopathic care (NC) ($n = 41$) or standardized psychotherapy

intervention (PT) (n = 40) over a period of 12 weeks. Blinding of investigators and participants during randomization and allocation was maintained. Participants in the NC group received dietary counseling, deep breathing relaxation techniques, a standard multi-vitamin, and the herbal medicine, ashwagandha (***Withania somnifera***) (300 mg b.i.d. standardized to 1.5% withanolides, prepared from root). The PT intervention received psychotherapy, and matched deep breathing relaxation techniques, and placebo. The primary outcome measure was the Beck Anxiety Inventory (BAI) and secondary outcome measures included the Short Form 36 (SF-36), Fatigue Symptom Inventory (FSI), and Measure Yourself Medical Outcomes Profile (MY-MOP) to measure anxiety, mental health, and quality of life respectively. Participants were blinded to the placebo-controlled intervention. Seventy-five participants (93%) were followed for 8 or more weeks on the trial. Final BAI scores decreased by 56.5% ($p<0.0001$) in the NC group and 30.5% ($p<0.0001$) in the PT group. BAI group scores were significantly decreased in the NC group compared to PT group ($p=0.003$). Significant differences between groups were also observed in mental health, concentration, fatigue, social functioning, vitality, and overall quality of life with the NC group exhibiting greater clinical benefit. No serious adverse reactions were observed in either group. Many patients seek alternatives and/or complementary care to conventional anxiety treatments. To date, no study has evaluated the potential of a naturopathic treatment protocol to effectively treat anxiety. Knowledge of the efficacy, safety or risk of natural health products, and naturopathic treatments is important for physicians and the public in order to make informed decisions. Interpretation: Both NC and PT led to significant improvements in patients' anxiety. Group comparison demonstrated a significant decrease in anxiety levels in the NC group over the PT group. Significant improvements in secondary quality of life measures were also observed in the NC group as compared to PT. The whole system of naturopathic care for anxiety needs to be investigated further including a closer examination of the individual components within the context of their additive effect.

**59.** Costa, A., M. De Oliveira Pereira, T. Abdalla Moisés, T. Cordero, A. R. Dias Silva, F. T. P. Amazonas, F. Bentivoglio and E. S. Pegas Pereira (2011). "**Evaluation of quality of life improvement in melasma patients, measured by the MELASQoL following the use of a botanical combination based on *Bellis perennis*, *Glycyrrhiza glabra* *Phyllanthus emblica*.**" Surgical and Cosmetic Dermatology **3**(3): 207-212.

Melasma is a common hypermelanosis that mainly affects women and has a negative impact on the quality of life. It is a chronic and recurrent condition, and a number of treatments have already been proposed. Assessment of quality of life for women with melasma before and after treatment with botanical extracts and hydroquinone. A clinical, phase IV, randomized, blinded study was conducted at a clinical research institute. Women (n = 56) aged 18-60, with phototypes I-IV, were randomized into two groups (epidermal or mixed melasma). The Melasma Quality of Life Scale was used to compare the patients' quality of life before and after the use of Bellis perennis, Glycyrrhiza glabra and ***Phyllanthus emblica*** botanical extracts twice a day (Group A), or 2% hydroquinone used at night (Group B). The Melasma Area and Severity Index was used to assess the treatments' efficacy. Results: Appearance, frustration, embarrassment and feeling less attractive were the Melasma Quality of

Life Scale variables that had the greatest negative impact on quality of life at the beginning of the study. After 60 days of treatment, there was improvement in all MELASQoL aspects, with no statistical differences between the two groups. The improvement in melasma patients' self esteem provided by the use of the botanical extracts matched that of 2% hydroquinone.

**60.** Dahanukar, S. A., U. M. Thatte, N. N. Rege and R. D. Bapat (1990). "**Immunotherapeutic activity of *Tinospora cordifolia*.**" European Journal of Pharmacology **183**(2): 608.

In patients of obstructive jaundice who received TC (16 mg/kg) during the course of percutaneous transhepatic biliary drainage and for 15 days following surgery in addition to conventional treatment the neutrophil phagocytic function was 30.71 f 4.03% and intraceliuiar bactericidal capacity was 31.45 + 5.74% (P < 0.05). There was no mortality in this group. (n = 15). The group (n = 15) which received only conventional treatment during intervention exhibited persistent depression of neutriphil function (phagocytic function 21.1 + 3.7% as compared to normal control, 30.7 f 5.1%; intracellular bactericidal capacity was 20.85 + 4.5% as compared to normal control 26.41 f 4.5% P < 0.05). Mortality was 70%. This double blind randomised placebo control trial was conducted in patients with perforative peritonitis and those with local sepsis. After basal immunological and hematological analysis, clinical monitoring was done and patients were graded. The patients received either TC/Placebo as a supplement to antimicrobial therapy. Improvement in neutrophil and montcyte function associated with early wound healing was observed in patients treated with TC. In view of variety of immunosuppressive and infective states that this plant can modify along with its oral efficacy and significant lack of adverse effects, ***Tinospora cordifolia*** shows promise as useful immunotherapeutic agent.

**61.** Daily, J. W., X. Zhang, D. S. Kim and S. Park (2015). "**Efficacy of Ginger for alleviating the symptoms of primary dysmenorrhea: A systematic review and meta-analysis of randomized clinical trials.**" Pain Medicine (DOI: 10.1111/pme.12853 in press).

There has been no attempt to date to synthesize the available evidence for the efficacy of ginger for treating primary dysmenorrhea. This systematic review evaluates the current evidence for the effectiveness of ginger for treating primary dysmenorrhea. Literature searches were conducted using 12 electronic databases including PubMed, EMBASE, Cochrane Library, Korean databases, Chinese medical databases, and Indian scientific database. Search terms used were: "ginger" or "***Zingiber officinale***" and "dysmenorrhea" and "pain." Studies using ginger as a treatment of primary dysmenorrhea were considered for inclusion. The major outcome of primary dysmenorrhea was assessed using a pain visual analogue score (PVAS). Initial searches yielded 29 articles. Of these original results, seven met specific selection criteria. Four of the RCTs compared the therapeutic efficacy of ginger with a placebo during the first 3–4 days of the menstrual cycle and were included in the meta analysis. The meta-analysis of these data showed a significant effect of ginger in reducing PVAS in subjects having primary dysmenorrhea (risk ratio, −1.85; 95% CI of −2.87, −0.84, P = 0.0003). Six RCTs out of 7 exhibited low to moderate risk of bias. Collectively these RCTs provide suggestive evidence for the effectiveness of 750–2000

mg ginger powder during the first 3–4 days of menstrual cycle for primary dysmenorrhea.

**62.** Daily, J. W., M. Yang, D. S. Kim and S. Park (2015). "**Efficacy of ginger for treating Type 2 diabetes: A systematic review and meta-analysis of randomized clinical trials.**" Journal of Ethnic Foods **2**(1): 36-43.

Few clinical trials have investigated the antidiabetic effects of ginger to date. Several recent clinical trials published in 2013 and 2014, although small, have added contradictory but compelling new evidence about the use of ginger in treating diabetes in humans. Therefore, a systematic review and meta-analysis was conducted to clarify the evidence for using ginger to treat diabetes. Five randomized clinical trials (RCTs) were identified and included in the meta-analysis. Four of the RCTs were considered high quality and lasted ≥8 weeks; one lasted only 30 days and was considered low quality. Outcomes measured included fasting blood glucose and insulin, homeostatic model assessment (HOMA)-insulin resistance (IR), and hemoglobin A1c (HbA1c) levels, and were assessed as mean differences in the meta-analysis. Ginger (***Zingiber officinale***) supplementation significantly lowered fasting blood glucose concentrations and HbA1c levels, but did not significantly lower fasting blood insulin or HOMA-IR. In conclusion, Ginger root supplementation significantly lowers blood glucose and HbA1c levels. When combined with dietary and lifestyle interventions it may be an effective intervention for managing Type 2 diabetes mellitus.

**63.** Debnath, P. K., J. Chattopadhyay, A. Mitra, A. Adhikari, M. S. Alam, S. K. Bandopadhyay and J. Hazra (2012). "**Adjunct therapy of Ayurvedic medicine with anti tubercular drugs on the therapeutic management of pulmonary tuberculosis.**" Journal of Ayurveda and Integrative Medicine **3**(3): 141-149.

Pulmonary tuberculosis (PTB) is an age old disease described in Vedic Medicine as 'Yakshma'. Later on, in Ayurveda it earned a prefix and found way into mythology as 'Rajayakshma'. After the discovery of streptomycin, the therapeutic management of PTB received a major breakthrough. The treatment module changed remarkably with the formulation of newer anti-tubercular drugs (ATD) with appreciable success. Recent resurgence of PTB in developed countries like United States posed a threat to the medical community due to resistant strains. Consequently, WHO looked toward traditional medicine. Literature reveals that Ayurvedic treatment of PTB was in vogue in India before the introduction of ATD with limited success. Records show that 2766 patients of PTB were treated with Ayurvedic drugs in a tertiary care hospital in Kolkata in the year 1933-1947. This study evaluated the toxicity reduction and early restoration by adjunct therapy of Ayurvedic drugs by increasing the bio-availability of ATDs. In the present study, treatment response of 99 patients treated with ATD as an adjunct with Aswagandha (***Withania somnifera***) and a multi-herbal formulation described in Chikitsa-sthana of Charaka samhita i.e. Chyawanprash were investigated. Chyawanprash contains ***Emblica officinalis***, ***Piper longum***, ***Withania somnifera***, ***Terminallia chebula***, ***Zingiber officinale***, ***Tinospora cordifolia*** among other ingredients. Hematological profile, sputum bacterial load count, immunoglobulin IgA and IgM, blood sugar, liver function test, serum creatinine were the assessed

parameters besides blood isoniazid and pyrazinamide, repeated after 28 days of treatment. The symptoms abated, body weight showed improvement, ESR values were normal, there was appreciable change in IgA and IgM patterns and significantly increased bioavailability of isoniazid and pyrazinamide were recorded. This innovative clinical study coupled with empowered research may turn out to be promising in finding a solution for the treatment of PTB.

**64.** Deshpande, A., S. Tandon and N. Deshpande (2014). "**Low resource screening method of pre-cancerous lesions and its reversal by *Triphala* in teen-age Indian population.**" AYU **35**(2): 160-167.

Cancer screening is the main weapon for early detection at a pre-invasive or premalignant stage. It has been reported that over 12 million people use some form of tobacco, which is one of the high risk factors and has hence become an alarming world-wide problem. Aim was to evaluate the effective diagnostic screening of disease in its early stage by inexpensive method and also to evaluate the effect of indigenous mouthrinse on reversal of pre-cancerous lesions. The screening for teenagers belonging to low socio-economic status was carried out. Suspected subjects were evaluated for the reversal of the lesions by use of Ayurvedic preparation as a mouthwash. From 13 to19 years working-child population of North India was selected for the study. Screening was performed by new method-visual inspection with acetic acid. The positive subjects were further investigated by pap smear and biopsy was done as a confirmatory histopathological report. In second phase, the subjects showing positive lesions were advised indigenous anti-cancer mouth rinse and its effect was evaluated after 6 month and 9 month of prescribing the rinse. The total 1095 children were screened (831 boys and 264 girls). Out of total 34 teenager boys were diagnosed, as acetowhite positive lesion. All the acetowhite positive lesions were found exclusively in males. Histological findings after 9 month use of ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***) mouth rinse revealed no changes in cells in 23 (85.2%), hyperkeratinization in 2 (7.4%), hyperkeratinization and spongiosis was evident in 1 (3.7%), mild pleomorphism in 1 (3.7%) patient. Comparative evaluation from 0-9 month showed statistically highly significant test ($P < 0.01$). Use of different forms of tobacco and betel nut showed convincing relationship between developments of oral pre-cancerous lesions. ***Triphala*** was found to have great potential for reversal of these lesions.

**65.** Dixit, K. S., S. Saxena, S. Vart, V. S. Narain, A. Mishra, A. Dixit and V. K. Puri (1999). "**CardiPro - A polyherbal preparation in the therapy of angina pectoris.**" Phytomedica **20**(1-2): 7-16.

Coronary Artery Disease (CAD) is one of the commonest causes of male adult morbidity and mortality the world over and its incidence rises with increasing age. Despite a number of modern drugs being available for the treatment of CAD, none of them is able to prevent disease progression or impending myocardial infarction (MI). However, Ancient Indian Medical Science (AIMS) cites several herbal preparations for this purpose. Taking lead from AIMS a polyherbal preparation CardiPro containing standardised extracts of *Terminalia arjuna*, ***Emblica officinalis***, ***Withania somnifera***, *Ocimum sanctum* and *Boerhaavia diffusa* was clinically tried in 29 cases of

chest pain out of which 17 were positive for Inducible Ischaemia on treadmilltest (TMT). The results show that the herbal formulation CardiPro ameliorates Angina symptoms and helps to reduce nitrate use significantly.

**66.** Donata, S., M. Kesavan Sr, K. Austin, K. Rajagopalan and R. Kuttan (1990). "**Clinical trial of certain ayurvedic medicines indicated in vitiligo.**" Ancient science of life **9**(4): 202-206.

An Ayurvedic preparation consisting of dried ginger (***Zingiber officinale***), black pepper (***Piper nigrum***), pippali (***Piper longum***) and leadwort root fermented in cow's urine was given internally and a paste made of several meical herbs including *Psoralea corylifolia* for external application was tried in patients with vitiligo. 4 out of 10 patients had relief within six months of treatment. Three patients had relief with adverse reaction on the skin and other did not respond. The preparations did not have any adverse effect in the body as seen from haematological parameters and biochemical tests.

**67.** Dongre, S., D. Langade and S. Bhattacharyya (2015). "**Efficacy and Safety of Ashwagandha (*Withania somnifera*) Root Extract in Improving Sexual Function in Women: A Pilot Study.**" BioMed Research International **2015**: Article ID 284154.

Many women experience sexual dysfunction where there are orgasm disorders and sexual difficulties. Ashwagandha (***Withania somnifera***) is known to improve the body's physical and psychological condition. The purpose of the study was to determine the efficacy and safety of a high-concentration ashwagandha root extract (HCARE) supplementation for improving sexual function in healthy females. In this pilot study, 50 study subjects were randomized to either (i) HCARE-treated group or (ii) placebo- (starch-) treated group. The subjects consumed either HCARE or placebo capsules of 300 mg twice daily for 8 weeks. Sexual function was assessed using two psychometric scales, the Female Sexual Function Index (FSFI) Questionnaire and the Female Sexual Distress Scale (FSDS), and by the number of total and successful sexual encounters. The analysis indicates that treatment with HCARE leads to significantly higher improvement, relative to placebo, in the FSFI Total score, FSFI domain score for "arousal", "lubrication", "orgasm", and "satisfaction", and also FSDS score and the number of successful sexual encounters at the end of the treatment. This study demonstrated that oral administration of HCARE may improve sexual function in healthy women. The present study is registered in the Clinical Trial Registry, Government of India, with a number CTRI/2015/07/006045.

**68.** Dubey, A. K., S. Rajagopala and K. S. Patel (2014). "**Comparative clinical efficacy of Ashtangavaleha and Vyaghreehareetakee Avaleha on Tamaka Shwasa (bronchial asthma) in children.**" AYU **35**(4): 384-390.

Tamaka Shwasa is a chronic inflammatory condition of the lung airways resulting in episodic airflow obstruction. This disease is more predominant in children and aged population. Apart from being the leading cause of hospitalization for children, it is one of the most important chronic conditions causing elementary school absenteeism. The parallel disease entity in contemporary medical science to this disorder is Bronchial Asthma. Aim: This study was aimed to evaluate the clinical efficacy of Ashtangavaleha and Vyaghreehareetakee Avaleha on Tamaka Shwasa (Bronchial Asthma) in Children. Materials and Methods: The study was therapeutic

interventional randomized clinical trial. Totally 100 patients suffering from Tamaka Shwasa were selected, and 74 patients completed the course of treatment. Patients were divided into two groups. Ashtangavaleha (***Zingiber officinale***, Nigella sativa, Pistacia integerrima, Myrica nagi, Madhu –Honey, ***Piper nigrum***, ***Piper longum***, Inula racemose, Trachyspermum Ammi) was administered in group AG and Vyaghreeharitaki Avaleha (containing ***Trikatu*** and ***Terminalia chebula*** among others) was administerd in group VG (5-15g in divided doses) for 8 weeks duration. Comaprative assesment of both the drugs was done on the signs and symptoms of the disease, pulmonary function test and quality of life parameters. Results: When the individualized overall effect of therapy was considered, more number of patients treated with Ashtangavaleha reached moderate improvement zone than the patients treated with Vyaghreehareetakee Avaleha. The trial showed a marginal better efficacy of Ashtangavaleha (66.66%) in comparison to Vyaghreehareetakee Avaleha (63.15%) on the overall condition of the patients even though the superiority was statistically insignificant (>0.05).

**69.** Dwivedi, R. and S. More (2011). "**A clinical study of Panchakola Siddha Yavagu in the management of Agnimandya.**" AYU **32**(1): 70-75.

This research is carried out with the aim to study Agnidipana effect of Panchakola Siddha Yavagu which comprises Pippali (***Piper longum***), Pippalimula (root of ***Piper longum***), Chavya (*Piper chaba* Hunter), Chitraka (*Plumbago zelynica*) and Nagara (***Zingiber officinale***) which are all in equal proportion processed in six times of water. A randomized open clinical trial on 47 patients of Agnimandya has been screened on the basis of clinical findings and the patients were allocated to two groups. Group A having 29 cases received the trial drug (Panchakola Siddha Yavagu) and 18 cases in Group B received simple Yavagu with roasted rice powder as the control group. Special scoring pattern was done for the assessment of Agnimandya state. Complete cure of the patient was found in 17.24% of the patients, 34.48% patients were improved moderately as well as markedly, whereas mild improvement was observed in 13.80% patients by treatment with Panchakola Yavagu.

**70.** Eberhart, L. H. J., R. Mayer, O. Betz, S. Tsolakidis, W. Hilpert, A. M. Morin, G. Geldner, H. Wulf and W. Seeling (2003). "**Ginger does not prevent postoperative nausea and vomiting after laparoscopic surgery.**" Anesthesia and Analgesia **96**(4): 995-998.

The potential antiemetic effect of two different oral doses of the herbal remedy ginger (***Zingiber officinale***) to prevent postoperative nausea and vomiting in 180 patients undergoing gynecologic laparoscopy was investigated in this randomized, double-blinded trial. Ginger failed to reduce the incidence of postoperative nausea and vomiting after these procedures.

**71.** Ebrahimzadeh Attari, V., M. Asghari Jafarabadi, M. Zemestani and A. Ostadrahimi (2015). "**Effect of *Zingiber officinale* supplementation on obesity management with respect to the uncoupling protein 1 -3826A>G and ß3-adrenergic Receptor Trp64Arg polymorphism.**" Phytotherapy Research **28**(7): 1032–1039.

The present study aimed to investigate the effect of ginger (***Zingiber officinale***) supplementation on some obesity-associated parameters, with nutrigenetics approach. Accordingly, 80 eligible obese women (aged 18-45years) were randomly

assigned to receive either ginger (2-g ginger rhizomes powder as two 1-g tablets per day) or placebo supplements (corn starch with the same amount) for 12weeks. Subjects were tested for changes in body weight, body mass index, waist and hip circumferences, body composition, appetite score, and dietary intake. Moreover, participants were genotyped for the -3826A>G and Trp64Arg polymorphisms of uncoupling protein 1 and ß3-adrenergic receptor genes, respectively. Over 12weeks, ginger supplementation resulted in a slight but statistically significant decrease in all anthropometric measurements and total appetite score as compared with placebo group, which were more pronounced in subjects with the AA genotype for uncoupling protein 1 and Trp64Trp genotype for ß3-adrenergic receptor gene. However, there was no significant difference in changes of body composition and total energy and macronutrients intake between groups. In conclusion, these findings suggest that ginger consumption has potential in managing obesity, accompanying with an intervention-genotype interaction effect. However, further clinical trials need to explore ginger's efficacy as an anti-obesity agent in the form of powder, extract, or its active components.

**72.** Ebrahimzadeh Attari, V., A. Ostadrahimi, M. Asghari Jafarabadi, S. Mehralizadeh and S. Mahluji (2015). "**Changes of serum adipocytokines and body weight following *Zingiber officinale* supplementation in obese women: a RCT.**" European Journal of Nutrition (in press)

The present randomized, double-blind, placebo-controlled study aimed to evaluate the effect of ***Zingiber officinale*** (ginger) consumption on some metabolic and clinical features of obesity. Methods: Eighty eligible obese women (aged 18–45 years) were randomly assigned to either ginger or placebo groups (receiving 2 g/day of ginger powder or corn starch as two 1 g tablets) for 12 weeks. Body mass index (BMI) and body composition were assessed every 4 weeks, and serum levels of leptin, adiponectin, resistin, insulin and glucose were determined before and after intervention. The homeostasis model assessment of insulin resistance (HOMA-IR) and quantitative insulin sensitivity check index (QUICKI) were also calculated. Results: Ginger consumption significantly decreased BMI, serum insulin and HOMA-IR index, along with increasing QUICKIs as compared to the placebo. Moreover, significant reductions in serum leptin, resistin and glucose were observed in both groups, especially in ginger group with nonsignificant differences between groups. The body composition and serum levels of adiponectin were not significantly changed in study groups. In conclusion, these findings demonstrate a minor beneficial effect of 2 g ginger powder supplementation for 12 weeks on weight loss and some metabolic features of obesity. However, given the lack of data in this area, ongoing clinical trials are needed to further explore ginger’s effectiveness.

**73.** Faizal, P., S. Suresh, R. Satheesh Kumar and K. T. Augusti (2009). "**A study on the hypoglycemic and hypolipidemic effects of an ayurvedic drug Rajanyamalakadi in diabetic patients.**" Indian Journal of Clinical Biochemistry **24**(1): 82-87.

A study was undertaken for evaluating the hypoglycemic and hypolipidemic effects of an ayurvedic medicine "Rajanyamalakadi" containing *Curcuma longa*, ***Emblica officinalis*** and *Salacia oblonga* in type II diabetic patients over a period of 3 months. Ethical committee consent for the study was given by the Director, Indian Systems of

Medicine, Kerala. A total of 43 patients with established diabetes mellitus as adjudged from clinical features and FBS values, appeared for the camp (Age group 35-75 yrs). An informed consent for the study was obtained from each patient. The clinical proforma was given to each patient to collect data such as height, weight, diet pattern, previous history of illness etc. The ongoing antidiabetic medications were stopped under medical supervision and the patients were provided with 'Rajanyamalakadi' tablets (dose 1-2 tablets each weighing 500mg). The dosage of the drug was decided by the supervising medical officer on a case to case basis, taking note of the clinical conditions and responsiveness of the patients. The patients were monitored for three months, who were divided into 6 groups based on their age and again into two groups, 5 & 6, based on their mean FBS values. ie; Normal Persons, Diabetics of age groups 35-45yrs, 46-55yrs, >55yrs and those with FBS < 145.9 mg% and > 145.9 mg%. The Ayurvedic medicine "Rajanyamalakadi" has showed significant antidiabetic, hypolipidemic and antioxidant effects. In addition to that significant ameliorating effects on the elevated serum AST and ALT activities were also demonstrated by the treatment. The nutraceuticals present in the drug like Terpenoids, Polyphenols, Curcumin etc are responsible for the medicinal effects.

**74.** Farag, N. H. and P. J. Mills (2003). "**A randomized-controlled trial of the effects of a traditional herbal supplement on sleep onset insomia.**" Complementary Therapies in Medicine **11**(4): 223-225.

Objectives were to study the effectiveness and safety of a traditional herbal supplement used for sleep onset insomnia. Design: A double-blind, randomized, placebo-controlled, cross-over study. Setting: A total of 25 healthy volunteers (20-65 years of age) suffering from sleep onset insomnia were recruited from the general population. Intervention: A traditional Ayurvedic supplement formulated to reduce sleep onset insomnia containing species such as *Convolvulus pluricalis* extract, ginger extract (***Zingiber officinale***), Glycyrrhiza extract, musk, ***Piper nigrum*** extract, Rosa centifolia extract, ***Tinospora cordifolia*** extract, and ***Withania somnifera*** extract. Main Outcome Measure: Sleep latency. Results: The supplement led to a statistically significant decrease in reported sleep latency of 16.72 min (S.D. = 44.8) as compared to placebo (P = 0.003). There were no self-reported side effects. The findings suggest that traditional herbal supplements may be of significant benefit to patients suffering from sleep onset insomnia while avoiding the negative side effects of commonly prescribed hypnotics.

**75.** Fatima, N., U. Pingali and R. Pilli (2014). "**Evaluation of *Phyllanthus emblica* extract on cold pressor induced cardiovascular changes in healthy human subjects.**" Pharmacognosy Research **6**(1): 29-35.

Acute and chronic stress is a risk factor for the development and progression of coronary artery disease. Increased arterial stiffness is an independent marker for cardiovascular disease. Cold pressor test (CPT) is known to be associated with substantial activation of the autonomic nervous system. The aim of this study was to evaluate the effect of ***Phyllanthus emblica*** extract on cold pressor stress test induced changes on cardiovascular parameters and aortic wave reflections in healthy human subjects. This was a double-blind, placebo-controlled, crossover study. Participants were randomized to receive either two capsules of *P. emblica* extract 250

mg (containing aqueous extract of *P. emblica*, highly standardized by high-performance liquid chromatography to contain low molecular weight hydrolysable tannins emblicanin-A, emblicanin-B, pedunculagin and punigluconin) or two capsules of placebo twice daily for 14 days. Pharmacodynamic parameters such as heart rate, augmentation pressure, augmentation index (AIx), subendocardial viability ratio (SEVR), radial and aortic blood pressure (BP) were recorded before and after CPT at baseline and end of treatment. After washout period of 14 days, subjects crossed over to the other treatment and the same test procedure was repeated again. Safety assessments were done at baseline and at the end of treatment. Results: A total of 12volunteers completed the study. Compared with baseline and placebo, P. emblica extract produced a significant decrease of mean percent change in the indices of arterial stiffness (AIx, radial and aortic BP) and increase in SEVR, an index of myocardial perfusion with CPT. Both treatments were well-tolerated and no serious adverse events were reported. Proprietary *P. emblica* extract, showed a significant decrease in cold pressor stress test induced changes on aortic wave reflections.

**76.** Fatima, N., U. Pingali and N. Muralidhar (2014). "**Study of pharmacodynamic interaction of *Phyllanthus emblica* extract with clopidogrel and ecosprin in patients with type II diabetes mellitus.**" Phytomedicine **21**(5): 579-585.

Diabetes mellitus is associated with oxidative stress which impairs the platelet function. ***Phyllanthus emblica*** extract a rich source of vitamin C plays an important role in scavenging free radicals. The effect of vitamin C on platelet aggregation in healthy and coronary artery disease patients has been demonstrated. The present study attempts to study the pharmacodynamic interactions of *P. emblica* extract with clopidogrel and ecosprin. This was a randomized open label crossover study of 10 type II diabetic patients. The dosage schedules were either single dose of 500 mg *P. emblica* extract or 75 mg clopidogrel or 75 mg ecosprin or 500 mg P. emblica + 75 mg clopidogrel or 500 mg *P. emblica* + 75 mg ecosprin. After single dose study and washout period, patients received either 500 mg *P. emblica* extract twice daily or 75 mg clopidogrel or 75 mg ecosprin once daily or combinations for 10 days. Platelet aggregation was measured at baseline and at 4 h of treatment after single and multiple dose study along with recording of bleeding and clotting time. After single and multiple dose administration of the three treatments and with combinations there was statistically significant decrease of platelet aggregation compared to baseline. Further, the mean percent inhibition of platelet aggregation was significant, when compared between single and multiple doses of *P. emblica*. The bleeding and clotting time was prolonged with single and multiple dose administration of all treatments compared to baseline. All treatments were well tolerated. *P. emblica* extract demonstrated significant antiplatelet activity with both single and multiple dose administration.

**77.** Fischer-Rasmussen, W., S. K. Kjær, C. Dahl and U. Asping (1991). "**Ginger treatment of hyperemesis gravidarum.**" European Journal of Obstetrics and Gynecology and Reproductive Biology **38**(1): 19-24.

Thirty women participated in a double-blind randomized cross-over trial of the efficacy of a natural product, the powdered root of ginger (***Zingiber officinale***), and placebo in hyperemesis gravidarum. Three patients had to be withdrawn. Each

woman swallowed capsules containing either 250 mg ginger or lactose q.i.d. during the first 4 days of the treatment period. Interrupted by a 2 days wash-out period the alternative medication was given in the second 4-day period. The severity and relief of symptoms before and after each period were evaluated by two scoring systems. The scores were used for statistical analyses of possible differences. Subjectively assessed, 19 women (70.4%) stated preference to the period in which ginger, as was later disclosed, had been given (P = 0.003). More objectively assessed by relief scores a significantly greater relief of the symptoms was found after ginger treatment compared to placebo (P = 0.035). No side effects were observed. The possible mutagenic and antimutagenic characters of ginger reported in a study of E. coli have not been evaluated with respect to any significance in humans. Powdered root of ginger in daily doses of 1 g during 4 days was better than placebo in diminishing or eliminating the symptoms of hyperemesis gravidarum.

**78.** Fulzele, A. V., N. Ingle, M. N. Huda and D. S. Mishra (2014). "**Comparative study to evaluate the effect of a herbal preparation & shirodhara in the management of major depressive disorder.**" International Journal of PharmTech Research **6**(2): 506-511.

Depression is one of the most global public-health issues. In Ayurvedic Psychiatry, it is a complex disorder under the general category of Manas Roga. Patients usually show compliance with pharmacological antidepressant treatment which has many unpleasant side effects & it is quite expensive. With this issue, authors have undertaken this study to assess comparative effect of Herbal preparation & Shirodhara in management of major depressive disorder (MDD).Total 30 patients with mild and moderate type of major depressive disorder were included in a non-blind randomized controlled, open clinical study.The study population was collected from the OPD and IPD of Kayachikitsa at National Institute of Ayurveda and Hospital, Jaipur. Patients were divided into two groups named as Group A was given 5 gm herbal preparation t.d.s. p.o. for 42 consecutive days & Group B was given 5 gm herbal preparation t.d.s. p.o. for 42 consecutive days with Shirodhara therapy (oil dripping therapy) by medicated plain Ashwagandha oil for 14 consecutive days. Herbal preparation was made by the combination two indigenous medicinal plants, *Nardostachys jatamansi* and *Lavandula stoechas*. For the measurements of efficacy, the subjective parameters like clinical symptoms and objective parameters included HDRS-item 17, CGI-S were administered at baseline and the day of 42 and Clinical Global Improvement scales (CGI-I) was evaluated only the day of 42. End of treatment, the clinical symptoms and the HDRS 17, CGI-S and CGI-I score was found highly significant ($p<0.001$) improvement in both groups. So this study claimed that selected herbal preparation & Shirodhara both are effective and safe in mild and moderate condition of major depressive disorder.

**79.** Gajarmal, A. A. and M. B. Shende (2015). "**A clinical evaluation of antistress activity of Ashwagandha (*Withania somnifera* Dunal) on employees experiencing mental stress at work place.**" International Journal of Ayurveda and Pharma Research **3**(1): 37-45.

According to various surveys, the stress is the major problem for many diseases ranging from psychiatric disorders to endocrine disorders. In national capital regions like Mumbai, Chennai, Kolkata and Pune, as per the survey over 76% of senior and middle level executives working endure the highest levels of stress resulting into

mental and physical fatigue. Pertaining to the stress, modern medicine can provide some curable results but they are complicated and unsatisfactory. So the answer is hidden in Ayurveda i.e. Rasayana Chikitsa (Rejuvenation therapy). As similar to the modern concept of adaptogenic agents which gives the protection to the human physiological system against diverse stressor, recent studies shows that the Rasayana Dravyas having adaptogens which could induce a state of non-specific increase of resistance to affect internal homeostasis. The adaptogens improve the response to stress and help the body to adapt by normal physiological processes in times of increased stress. Therefore, Ashwagandha which is the best in Rasayana Karma, identified as ***Withania somnifera*** Dunal, is selected for the study. The present research work has been undertaken with the main objective as the clinical evaluation of antistress effect of Ashwagandha (*Withania somnifera* Dunal) on employees at different work places by various scientific parameters. In conclusion, Ashwagandha possesses potent anti-stress activity as it improves the mental faculties due to its psychotropic and tranquillizing effects over mind. Therefore, it can be used effectively in the management of stress.

**80.** Gannon, J. M., P. E. Forrest and K. N. R. Chengappa (2014). "**Subtle changes in thyroid indices during a placebo-controlled study of an extract of *Withania somnifera* in persons with bipolar disorder.**" Journal of Ayurveda and Integrative Medicine (J-AIM) **5**(4): 241-245.

Laboratory indices of thyroid function (TSH, Free T4, and T3) were measured in a randomized clinical trial in which Ashwagandha ***Withania somnifera*** (ASW) was used to improve cognitive function in patients with bipolar disorder. This was done in light of a case-report of ASW-associated thyrotoxicosis, and data from mice administered ASW that showed significant increases in thyroxine levels. Ten (of the original 60) patients showed abnormal results in one of the thyroid measures either at the beginning or end of the 8-week study. One ASW- treated patient had subclinical hypothyroidism (TSH - 5.7 mIU/L) at baseline that normalized, and all three ASW treated patients experienced T4 increases from baseline (7%, 12%, and 24%). Six of 7 placebo-assigned patients showed decreases in T4 from baseline (4% to 23%), and one patient's TSH moved from the normal to subclinical hypothyroid range (6.96 mIU/L). As thyroid indices were done for safety, and not the primary goal of the original study, only 16.7% had abnormal thyroid indices, and as there was no sub-stratification for treatment assignment by thyroid status, unequal numbers of subjects received ASW (n=3) or placebo (n=7). In spite of these limitations, the subtle laboratory changes noted in thyroid indices in an 8-week study suggest that ASW may increase thyroxine levels, and therefore vigilance regarding hyperthyroidism may be warranted. Nonetheless, the thyroid enhancing properties of ASW may also represent a clinical opportunity for the treatment of subclinical hypothyroidism, and these results suggest the need for further study of the effects of ASW on thyroid indices, especially in those with bipolar and unipolar mood disorders.

**81.** Garai, A. K., M. Rai and A. Kumar (2009). "**Role of an Ayurvedic compound (Panduhara Yoga) in the management of iron deficiency anaemia in children.**" AYU **30**(4): 469-474.

Pandu Roga (Anaemia) is one of the common problem in the developing countries like India specially in women and children. Iron deficiency anaemia (IDA) is the

commonest form of anaemia in children. Allopathic iron preparations are gastric irritant and having common side effects of oral iron including nausea, abdominal pain and either constipation or diarrhoea. To find out a satisfactory answer for the problem an Ayurvedic herbo-mineral compound (Mandura Bhasma one part +Amalaki Churna ten parts) was formulated and named as Panduhara Yoga. According to Ayurveda, Mandura Bhasma (ferrosoferic oxide) and Amalaki (***Emblica officinalis***) are very good drugs to prevent and manage the cases of Pandu Roga in children. Amalaki is Rasayana and it contains Vitamin-C that helps in the absorption of iron. Amalaki can increase bioavailability of Mandura Bhasma and can prevent the common hazards of oral iron therapy. A single blind clinical study was conducted in children of IDA. Panduhara Yoga has been administered in the dose of 110mg/kg body weight in two divided doses with honey after food for a period of 6 weeks. Hemoglobin level was improved with mean increase of 1.19gm/dl in three weeks (8.12g/dl to 9.31g/dl, $p<0.001$), and 2.64gm/dl in six weeks (8.12g/dl to 10.76/dl, $p<0.001$). After 6 weeks treatment with Panduhara Yoga overall 93.33% children showed very good improvement on clinical features, whereas 50% children showed very good improvement on blood hemoglobin level. The results suggest that Panduhara Yoga is significantly effective in the management of iron deficiency amaemia in children. No adverse effect has been noticed during the therapy.

**82.** Geeta, S., S. M. Kamath and R. P. Shenoy (2014). **Evaluating the usefulness and efficacy of the ayurvedic drug-*Tinospora cordifolia* in human.** In, South Regional Conference of the Association of Clinical Biochemists of India", 22-23 May 2014, Kasturba Medical College, Mangalore. Available at: http://eprints.manipal.edu/140092/.

***Tinospora cordifolia*** (TC), known as "Guduchi"- an herbaceousvine of the family Menispermaceae indigenous to the tropical areas of India. The active principles of TC are found to possess immunomodulatory activities. There are a number of scientific and pre-clinical studies which have been done to evaluate the usefulness of this drug. The present study evaluates the multi-potent effect of TC as an effective drug for common acute conditions. 25 patients symptomatic with acute conditions like fever, cold, allergy & rhinitis reported at the Ayurveda Clinic of Kasturba Hospital, Manipal, Karnataka for the months July & August of 2011. These patients were administered TC extract in capsule form (from the Himalaya Drug Company) as 250 mg/ TD for 15 days. Before and after the administration of TC hematological testsand renal function tests were performed. No patient complained of any adverse/side effects during and after the period of the drug intake at the given dose and duration. A significant change was observed in Neutrophil, Eosinophil counts and ESR ($p$ value $< 0.05$) after administration of TC. No changes observedin renal function tests.TC can be considered as an immunomodulatoryagent in cases of common acute conditions.In this study it was also observed that TC was effective in relieving the clinical symptoms that the patients reported prior to the administering of TC in cases of Allergic Rhinitis, Cold and fever and thereby boosting their immunity.

**83.** Geiger, J. L. (2005). "**The essential oil of ginger, *Zingiber officinale*, and anaesthesia.**" International Journal of Aromatherapy **15**(1): 7-14.

It is proposed that a 5% solution of essential oil of ginger, ***Zingiber officinale***, is an effective post-operative nausea and vomiting (PONV) prevention when administered

preoperatively, naso-cutaneously concurrently with conventional therapies to general anaesthesia patients at high risk for PONV. This is a summary of six months clinical experience and impressions of a single anaesthesia practitioner using best practice multimodal management plus 5% oil of ginger, *Zingiber officinale*, in the prevention of PONV in high risk group adult patients. The results of the clinical experience show improvement gained in patient response as measured by lower incidence of nausea and vomiting in the post-anaesthesia recovery unit (PACU). The group treated with the essential oil of ginger experienced approximately less than 20% nausea in the PACU. This low percentage of high risk PONV patients that experienced nausea in the ginger group mostly required only one single intravenous supplemental medication to control nausea. Approximately, 80% of high risk patients had no complaint of PONV and therefore did not require any further intravenous therapy during recovery from anaesthesia through discharge from PACU. The non-ginger oil treated patients in this clinical experience had a roughly 50/50 chance of PONV. A 5% solution of the essential oil of *Zingiber officinale* in grape seed carrier oil, when applied naso-cutaneously, can be administered safely for the effective prevention and therapeutic management of nausea in general anaesthesia patients at high risk for post-operative nausea and vomiting, with increased patient satisfaction and less expense to patients and hospital. Guidelines and regulations established for the safe use of integrative therapy with an essential oil are critical to observe.

**84.** Ghiware, N., T. Nesari and N. Gond (2007). "**Clinical validation of *Piper nigrum* and *Nyctanthes arbor-tristis* formulation for antimalarial activity.**" J Res Educ Indian Med **13**: 33-38.

An uncontrolled, open label clinical study was done on twenty-one smear positive patients of Plasmodium vivax malaria. High solid content deflocculated suspension of ***Piper nigrum*** and Nyctanthes arbortristis was given to patients after their enrollment in study. Vital signs and symptoms of malaria as body temperature, chilly felling/rigors, headache, body ache, nausea/vomiting and anemia were recorded before treatment, after first and second week of treatment. Improvement in condition was recorded as shifting of gradation in signs of malaria. Decrease in increased body temperature was recorded at the end of first week of treatment ($P<0.001$). Global assessment suggests improvement within first week of treatment from chilly felling/rigors, headache and body ache. Recovery from nausea/vomiting and anemic signs was observed only after second week of treatment. Negative smear test for Plasmodium vivax was observed at the end of treatment schedule in all patients.

**85.** Giacosa, A., D. Guido, M. Grassi, A. Riva, P. Morazzoni, E. Bombardelli, S. Perna, M. A. Faliva and M. Rondanelli (2015). "**The effect of ginger (*Zingiber officinalis*) and artichoke (*Cynara cardunculus*) extract supplementation on functional dyspepsia: A randomised, double-blind, and placebo-controlled clinical trial.**" Evidence-based Complementary and Alternative Medicine **2015**. Article number 915087.

Functional dyspepsia (FD) is a frequent clinical finding in western world. The aim of this study is to compare the efficacy of a ginger (***Zingiber officinale***) and artichoke supplementation versus placebo in the treatment of FD. A prospective multicentre, double blind, randomized, placebo controlled, parallel-group comparison of the supplement and placebo over a period of 4 weeks was performed. Two capsules/day

were supplied (before lunch and dinner) to 126 FD patients (supplementation/placebo: 65/61). After 14 days of treatment, only supplementation group (SG) showed a significant amelioration (SG: αS=+1.195 MCA score units (u), P=0.017; placebo: αP=+0.347 u, P=0.513). The intercept (α) resulted to be significantly higher in SG than in placebo (αS-αP=+0.848 u, P<0.001). At the end of the study, the advantage of SG versus placebo persists without variation (βS-βP=+0.077 u, P=0.542). In SG, a significant advantage is observed for nausea (βS-βP=-0.398 u, P<0.001), epigastric fullness (βS-βP=-0.241, P<0.001), epigastric pain (βS-βP=-0.173 u, P=0.002), and bloating (βS-βP=-0.167 u, P=0.017). The association between ginger and artichoke leaf extracts appears safe and efficacious in the treatment of FD and could represent a promising treatment for this disease.

**86.** Gohel, S. D., I. Anand and K. Patel (2011). "**A comparative study on efficacy of Bharangyadi Avaleha and Vasa Avaleha in the management of Tamaka Shwasa with reference to childhood asthma.**" AYU **32**(1): 82-89.

Ayurvedic concept is of the opinion that Tamaka Shwasa (Bronchial Asthma) is a Yapya Vyadhi. The etiopathogenesis, signs, and symptoms of Tamaka Shwasa may be correlated with Bronchial Asthma. Each child reacts differently to the factors that trigger asthma and treated symptomatically. Asthma is the most common chronic allergic disorder in childhood and third leading cause of hospitalization under the age of 15 years. As it is a Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, a clinical study was undertaken on two groups for duration of 6 weeks. The drugs Bharangyadi Avaleha and Vasa Avaleha were given orally, separately in both the groups. Bharangyadi Avaleha contains Bharangi (*Clerodendrum serratum* Linn), Kasamarda (*Cassia occidentalis* Linn.), Vasa (*Adhatoda vasica* Nees.), Maricha (***Piper nigrum*** Linn.), Pippali (***Piper longum*** Linn.), Haridra (*Curcuma longa* Linn.), Guduchi (***Tinospora cordifolia*** Miers.), Sunthi (***Zingiber officinale*** Roscoe.), Dhanyaka (*Coriandrum sativum* Linn.), Madhu, Mishri and Ghrita. Contents of Vasa Avaleha are Vasa (*Adhatoda vasica* Nees.), Pippali (*Piper longum* Linn) and Madhu, Mishri and Ghrita. All the patients were kept under strict dietary control during the treatment. The observation on effect of therapy was encouraging and showed less recurrence.

**87.** Gopa, B., J. Bhatt and K. G. Hemavathi (2012). "**A comparative clinical study of hypolipidemic efficacy of Amla (*Emblica officinalis*) with 3-hydroxy-3-methylglutaryl-coenzyme-A reductase inhibitor simvastatin.**" Indian Journal of Pharmacology **44**(2): 238-242.

To evaluate the efficacy of Amla (***Emblica officinalis***) in patients with type II hyperlipidemia and compare its hypolipidemic effects with those of simvastatin. Sixty type II hyperlipidemic patients of both sexes with plasma total cholesterol and low density lipoprotein level more than 240 mg% and 130 mg%, respectively, were selected for the trial. Out of total 60 selected patients, 40 were treated with Amla capsule (500 mg) daily for 42 days and 20 patients were given simvastatin capsule (20 mg) daily for 42 days. After the day of enrolment, all patients were followed up twice during the 42-day period. Blood samples were analyzed for various biochemical parameters and the values of Total Cholesterol (TC), Low Density Lipoprotein (LDL),

High Density Lipoprotein (HDL), and Very Low Density Lipoprotein (VLDL) were measured before and after completion of the treatment with Amla and simvastatin. Cardiovascular parameters were recorded before and after completion of treatment. Results: Treatment with Amla produced significant reduction of TC ($P<0.0001$), LDL ($P<0.0001$), triglyceride (TG) and VLDL ($P<0.0002$), and a significant increase in HDL levels ($P<0.0002$). Similarly, treatment with simvastatin produced significant reduction of TC ($P<0.0001$), LDL ($P<0.0009$), TG and VLDL ($P<0.017$), and a significant increase in HDL levels ($P<0.0001$). Both treatments produced significant reduction in blood pressure; however, this beneficial effect was more marked in patients receiving Amla. In view of the above findings, it is suggested that Amla produced significant hypolipidemic effect along with a reduction in blood pressure. Addition of Amla to the currently available hypolipidemic therapy would offer significant protection against atherosclerosis and coronary artery disease, with reduction in the dose and adverse effects of the hypolipidemic agents.

**88.** Grøntved, A. and E. Hentzer (1986). "**Vertigo-reducing effect of ginger root: A controlled clinical study.**" ORL **48**(5): 282-286.

The effect of powdered ginger root (***Zingiber officinale***) upon vertigo and nystagmus following caloric stimulation of the vestibular system was studied in 8 healthy volunteers in a double-blind crossover placebo trial. The results reported are based upon 48 vertigo scores and 48 electronystagmograms. Ginger root reduced the induced vertigo significantly better than did placebo. There was no statistically significant action upon the duration or the maximum slow phase velocity of nystagmus.

**89.** Grøntved, A., T. Brask, J. Kambskard and E. Hentzer (1988). "**Ginger root against seasickness: A conctrolled trial on the open sea.**" Acta Oto-Laryngologica **105**(1-2): 45-49.

In a double-blind randomized placebo trial, the effect of the powdered rhizome of ginger (***Zingiber officinale***) was tested on seasickness. Eighty naval cadets, unaccustomed to sailing in heavy seas reported during voyages on the high seas, symptoms of seasickness every hour for 4 consecutive hours after ingestion of 1 g of the drug or placebo. Ginger root reduced the tendency to vomiting and cold sweating significantly better than placebo did ($p<0.05$). With regard to vomiting, a modified Protection Index (PI)=72% was calculated. Remarkably fewer symptoms of nausea and vertigo were reported after ginger root ingestion, but the difference was not statistically significant. For all symptom categories, PI=38% was calculated.

**90.** Guo, R., M. H. Pittler and E. Ernst (2007). "**Herbal medicines for the treatment of allergic rhinitis: A systematic review.**" Annals of Allergy, Asthma and Immunology **99**(6): 483-495.

Study evaluated the efficacy of herbal medicines for the treatment of allergic rhinitis (AR) using five electronic databases until November 8, 2005; bibliographies of located articles; manufacturers of commercially available preparations; and experts in the field. Authors only included double-blind randomized clinical trials (RCTs), which tested a herbal medicine against placebo or active comparator, in patients with AR, and evaluated clinically relevant outcomes. Study selection, data extraction, and evaluation of methodological quality were performed independently by 2 reviewers.

Discrepancies were resolved by discussion and by seeking the opinion of the third reviewer. Meta-analysis was only performed if data were considered suitable for pooling. Sixteen eligible RCTs, testing 10 different herbal products against placebo or active comparator, were included. Six RCTs studied Petasites hybridus (butterbur) extract for AR and suggest that P hybridus is superior to placebo or similarly effective compared with nonsedative antihistamines for intermittent AR. Two RCTs studied an Indian herbal combination, Aller-7, in patients with AR and reported positive results. Single RCTs were identified for 8 other herbal products as treatments for AR, reporting positive outcomes, except for grape seed extract. The median methodological quality score was 4 of a possible maximum of 5. There is encouraging evidence suggesting that P hybridus may be an effective herbal treatment for seasonal (intermittent) AR. However, independent replication is required before a firm conclusion can be drawn because of the financial support from the manufacturer of P hybridus extract to the 3 large trials. There are also promising results generated for other herbal products, particularly Aller-7, ***Tinospora cordifolia***, *Perilla frutescens*, and several Chinese herbal medicines. Although these results are confined to the paucity of data and the small sample size, confirmation in larger and more rigorously designed clinical trials is warranted.

**91.** Gupta, A., A. A. Mahdi, K. K. Shukla, M. K. Ahmad, N. Bansal, P. Sankhwar and S. N. Sankhwar (2013). "**Efficacy of *Withania somnifera* on seminal plasma metabolites of infertile males: A proton NMR study at 800 MHz.**" Journal of Ethnopharmacology **149**(1): 208-214.

Ethnopharmacological relevance Traditional Indian systems of medicine use roots of ***Withania somnifera*** for impotence, infertility treatment, stress, and the aging process. Although *Withania somnifera* improves semen quality by regulating reproductive hormone levels and oxidative stress, the molecular mechanism is not clear. Aim of the study This study uses high-resolution Nuclear Magnetic Resonance (NMR) spectroscopy to explore the scientific basis to reveal the pre- and post-treatment efficacy of *Withania somnifera* on seminal plasma of infertile men - which remains unexplored to date. Materials and methods A total of 180 infertile male patients were administered *Withania somnifera* root powder at the rate of 5 g/d for a 3-month period. The study included age-matched, healthy men as a control (n=50) group. Proton NMR spectroscopy was used to measure lactate, alanine, glutamate, glutamine, citrate, lysine, choline, glycerophosphocholine (GPC), glycine, tyrosine, histidine, phenylalanine, and uridine in all seminal plasma samples. To appraise infertility levels, authors also measured sperm concentration, motility, lipid peroxide, and hormonal perturbation. Results *Withania somnifera* therapy repairs the disturbed concentrations of lactate, alanine, citrate, GPC, histidine, and phenylalanine in seminal plasma and recovers the quality of semen of post-treated compared to pre-treated infertile men. Serum biochemistry was also improved over post-therapy in infertile men. Findings reveal that *Withania somnifera* not only reboots enzymatic activity of metabolic pathways and energy metabolism but also invigorates the harmonic balance of seminal plasma metabolites and reproductive hormones in infertile men. The results suggest that *Withania somnifera* may be used as an empirical therapy for clinical management and treatment of infertility.

**92.** Gupta, A. K., K. Acharya, P. S. Sancheti and R. S. Joshi (2011). "**A double-blind, randomized, multicentric, placebo-controlled clinical trial of antarth, a phytomedicine, in the treatment of osteoarthritis.**" Indian Journal of Pharmacology **43**(1): 69-72.

Objective was to test Antarth, (a polyherbal phytomedicine containing *Boswellia serrata, Commiphora mukul, Curcuma longa, Vitex negundo, Alpinia galangal,* ***Withania somnifera****, Tribulus terrestris, and* ***Tinospora cordifolia***), for its efficacy and safety in patients with osteoarthritis (OA) and compared with placebo. A total of 90 male or female adult patients who were diagnosed clinically and radiologically with OA were recruited in the study. Antarth or placebo was given 2 capsules b.i.d. for 3 months and the patients were assessed every month for its efficacy. Diclofenac sodium was allowed to be taken as rescue medication. After 3 months of treatment, the reduction in severity of pain on Visual Analog Scale (VAS) was more in Antarth group compared to placebo but the difference between the two groups was not significant. However, pain during functioning of disabled joints while walking distance, squatting, sitting cross-legged and climbing steps were significantly reduced in Antarth group compared to placebo ($P < 0.05$). Reduction in consumption of rescue medication, diclofenac sodium, was more in Antarth than in placebo group. In Patients' Global Assessment, patients treated with Antarth were more satisfied than the ones treated with placebo. Observations were similar in Physicians' Global Assessment too. There were no adverse events in both the groups.

**93.** Gupta, D., D. J. Bhaskar, R. K. Gupta, B. Karim, V. Gupta, H. Punia, M. Batra, A. Jain, A. Agarwal and P. Singh (2014). "**Effect of *Terminalia chebula* extract and chlorhexidine on salivary pH and periodontal health: 2 weeks randomized control trial.**" Phytotherapy Research **28**(7): 992-998.

A double blind, randomized, controlled study with three parallel treatment groups was done to evaluate the efficacy of a ***Terminalia chebula*** 10% mouth rinse compared with chlorhexidine 0.12% mouth rinse, applied two times daily for 2 weeks, in the treatment of dental plaque and gingivitis. Seventy-eight patients were included in the study. The efficacy variables were periodontal indices on days 0, 7 and 14 after commencement of therapy. Twenty six patients received chlorhexidine mouth rinse, twenty six *Terminalia chebula* mouth rinse and twenty six received saline solution. The clinical parameters were significantly reduced by both chlorhexidine and *Terminalia chebula* mouth rinse although no significant difference was seen between the two groups ($P>0.05$). This study demonstrated that *Terminalia chebula* mouth rinse is effective in reducing microbial plaque, gingival inflammation and neutralizing salivary pH.

**94.** Gupta, D., R. K. Gupta, D. J. Bhaskar and V. Gupta (2015). "**Comparative evaluation of *Terminalia chebula* extract mouthwash and chlorhexidine mouthwash on plaque and gingival inflammation - 4-week randomised control trial.**" Oral health & preventive dentistry **13**(1): 5-12.

The present study was conducted to assess the effectiveness of ***Terminalia chebula*** on plaque and gingival inflammation and compare it with the gold standard chlorhexidine (CHX 0.2%) and distilled water as control (placebo). A double-blind randomised control trial was conducted among undergraduate students who volunteered. They were randomly allocated into three study groups: 1) *Terminalia*

*chebula* mouthwash (n = 30); 2) chlorhexidine (active control) (n = 30); 3) distilled water (placebo) (n = 30). Assessment was carried out according to plaque score and gingival score. Statistical analysis was carried out to compare the effect of both mouthwashes. ANOVA and post-hoc LSD tests were performed using SPSS version 17 with $p \leq 0.05$ considered statistically significant. These result showed that *Terminalia chebula* mouthrinse is as effective as chlorhexidine in reducing dental plaque and gingival inflammation. The results demonstrated a significant reduction of gingival bleeding and plaque indices in both groups over a period of 15 and 30 days as compared to the placebo. *Terminalia chebula* extract mouthrinse can be used as an alternative to chlorhexidine mouthrinse as it has similar properties without the side-effects of the latter.

**95.** Gupta, K., P. Mamidi and A. B. Thakar (2014). "**Randomised placebo controlled study on Sarasvata choorna in generalised anxiety disorder.**" International Journal of Green Pharmacy **8**(4): 231-236.

Generalised anxiety disorder (GAD) is characterised by a pattern of frequent, persistent worry and anxiety, which is out of proportion to the impact of the event or circumstance that is the focus of the worry. GAD is associated with muscle tension, trembling, twitching, feeling shaky and muscle aches or soreness. Many individuals with GAD also experience somatic symptoms like sweating, nausea and diarrhoea. Epidemiological studies reveal that the prevalence rate of GAD in India is 5.8%. The main objective of the present study was to evaluate the efficacy of Sarasvata choorna in the management of GAD. Sarasvata choorna contains various ingredients that have different properties such as anxiolytic (vacha, brahmi, shankhapushpi, ashwagandha), anti-depressant (shankhapushpi, ashwagandha (***Withania somnifera***), vacha, brahmi, sunthi [***Zingiber officinale*** Roscoe]), muscle relaxant (patha [Cissampelos pareira L], brahmi), tranquiliser or sedative (vacha, ashwagandha) anti-stress and adaptogen (ashwagandha, shankhapushpi, brahmi, etc.) deepana and paachana (sunthi, pippali [***Piper longum*** L], maricha [***Piper nigrum*** L], ajamoda [*Apium graveolens* S], saindhava lavana [Rock salt], krishna jeeraka [*Carum carvi* L], sweta jeeraka [*Cuminum cyminum* L], etc.), analgesic (ajamoda, ashwagandha, sunthi, maricha, etc.), rasayana and medhya rasayana (brahmi, shankhapushpi, vacha, ashwagandha, kushta, etc.), unmadahara (vacha, brahmi, kushta, shankhapushpi, etc.). In this study, a total of 114 patients with GAD satisfying the Diagnostic and Statistical Manual of Mental Disorders - Text Revision (DSM IV - TR) diagnostic criteria were selected and randomly divided; of these, 102 patients completed the course of treatment. In trial group, Sarasvata choorna and in control group, placebo (wheat powder) was given with the dose of 1 g thrice a day (i.e. 3 g/day) along with madhu (honey) and ghrita (cow's ghee) orally for 60 days. Fifteen days of follow up period was kept after treatment. Two assessments were done before and after treatment. Criterion of assessment was based on the scoring of Hamilton Anxiety Rating Scale (HAM-A). Paired and unpaired 't'- test was used for statistical analysis. In trial group (n = 51), 51.1% improvement and in control group (n = 51), 47.67% of improvement was observed with the significance of ($P < 0.001$). No statistically significant difference ($P > 0.05$) was found in between the two groups. Sarasvata choorna did not provide better relief compared with placebo. [Note from the editors: This research did not clearly note if the drug quality was tested before trial].

**96.** Gupta, M., B. P. Shaw and A. Mukherjee (2008). "**Evaluation of antipyretic effect of a traditional polyherbal preparation: A double-blind, randomized clinical trial.**" International Journal of Pharmacology **4**(3): 190-195.

The ancient Ayurvedic text Charak samhita of Indian medicine prescribes a specific group of ten plants having antipyretic properties with minimal side-effects. The aqueous extract of polyherbal ayurvedic preparation PD-10 (from the roots of *Hemidesmus indicus* R. Br. (Asclepiadaceae), *Rubia cordifolia* L. (Rubiaceac), *Cissampelos pareira* L. (Menispermaceae), fruits of ***Terminalia chebula*** Retz. (Combretaceae), ***Emblica officinalis*** Gaertn. (Euphorbiaceae), ***Terminalia bellirica*** Roxb. (Combretaceae), *Vitis vinifera* L. (Vitaceae), *Grewia asiatica* L. (Tillaceae), *Salvadora persica* L. (Salvadoraceae) and granules of *Saccharum officinarum* L. (Poaceae)) exhibited significant antipyretic-analgesic properties during rodent experiments while exhibiting low toxicity and ulcerogenicity. The presence of flavonoids, tannins and polyphenols in this extract prompted this double-blind, randomized clinical trial on 60 patients using Aspirinv (60 mg kg-1 body weight per day) as the standard drug for comparison. The primary outcome measured was reduction in body temperature, while the secondary outcomes measured were prevalence of associated symptoms of fever and routine blood and urine parameters. A representative sample of patients was also studied for reduction in the level of Prostaglandin (PGE2). The clinical trial showed that fever was rapidly and substantially reduced after oral administration of PD-10 and this antipyretic effect was more sustained and highly significant when compared to Aspirin. Many associated symptoms of fever also exhibited significant reductions when PD-10 was administered as compared to Aspirin. Prostaglandin levels also registered a substantial decrease during treatment with the test drug.

**97.** Haghighi, M., A. Khalvat, T. Toliat and S. Jallaei (2005). "**Comparing the effects of ginger (*Zingiber officinale*) extract and ibuprofen on patients with osteoarthritis.**" Archives of Iranian Medicine **8**(4): 267-271.

Ginger (***Zingiber officinale***) extract supplementation has been shown to improve the severity of symptoms and decrease the nonsteroidal antiinflammatory drug (NSAID) requirements in patients with osteoarthritis (OA). To assess the effects of ginger extract as an alternative to NSAIDs and as a supplement drug in the symptomatic treatment of OA. Methods: Between April and October 2002, 120 outpatients with OA of moderate to severe pain, requiring only the use of NSAIDs, were enrolled into a double-blind, randomized, placebo-controlled clinical trial. These patients were randomized into three groups of 40, including the placebo (PL), ginger extract (GE), and ibuprofen (IBP) groups. After a washout period of one week (week 0), patients received either 30 mg ginger extract in two 500 mg capsules, placebo, or three 400 mg ibuprofen tablets daily for one month. Acetaminophen tablet was prescribed as a rescue analgesic during the study. The clinical assessments included a visual analog scale (VAS) for pain, gelling pain, joint swelling measurement, and joint motion slope measurement. Joint motion slope was measured by goniometry (normal = 130°, limited = 120°, and very limited = 110°). Results: The improvement of symptoms (defined as reduction in the mean change) was superior in the ginger extract and ibuprofen groups than the placebo group. VAS scores and gelling or regressive pain

after rising the scores were significantly higher in the PL group than both the GE and IBP groups, a month after the treatment ($P < 0.0001$). However, there was no significant difference in VAS and gelling pain scores between the ginger extract and the ibuprofen groups. Ginger extract and ibuprofen were significantly more effective than the placebo in the symptomatic treatment of OA, while there was no significant difference between the ginger extract and ibuprofen groups in a test for multiple comparison.

**98.** Hasani-Ranjbar, S., N. Nayebi, L. Moradi, A. Mehri, B. Larijani and M. Abdollahi (2010). "**The efficacy and safety of herbal medicines used in the treatment of hyperlipidemia; a systematic review.**" Current Pharmaceutical Design **16**(26): 2935-2947.

This review focuses on the efficacy and safety of effective herbal medicines in the management of hyperlipidemia in human. PubMed, Scopus, Google Scholar, Web of Science, and IranMedex databases were searched up to 11th May 2010. The search terms were "hyperlipidemia" and ("herbal medicine" or "medicine traditional", "extract plant") without narrowing or limiting search elements. All of the human studies on the effects of herbs with the key outcome of change in lipid profiles were included. Fifty three relevant clinical trials were reviewed for efficacy of plants. This study showed significant decrease in total cholesterol and LDL cholesterol after treatment with Daming capsule (DMC), chunghyul-dan, Glycyrrhiza glabra, garlic powder (Allicor), black tea, green tea, soy drink enriched with plant sterols, licorice, Satureja khuzestanica, Monascus purpureus Went rice, Fenugreek, Commiphora mukul (guggul), Achillea wilhelmsii C. Koch, Ningzhi capsule (NZC), cherry, compositie salviae dropping pill (CSDP), shanzha xiaozhi capsule, Ba-wei-wan (hachimijiogan), rhubarb stalk, Silybum marianum, Rheum Ribes and Jingmingdan granule (primrose oil). Conflicting data exist for red yeast rice, garlic and guggul. No significant adverse effect or mortality were observed except in studies with DMC, guggul, and ***Terminalia bellirica***, ***Terminalia chebula***, ***Emblica officinalis***, ginger (***Zinziber officinale***), and garlic powder (Allium sativum). Amongst reviewed studies, 22 natural products were found effective in the treatment of hyperlipidemia that deserve further works to isolate and characterization of their constituents to reach novel therapeutic and more effective agents.

**99.** Hickok, J. T., J. A. Roscoe, G. R. Morrow and J. L. Ryan (2007). "**A phase II/III randomized, placebo-controlled, double-blind clinical trial of ginger (*Zingiber officinale*) for nausea caused by chemotherapy for cancer: A currently accruing URCC CCOP Cancer Control study.**" Supportive Cancer Therapy **4**(4): 247-250.

Despite the widespread use of 5-HT3 receptor antagonist antiemetics such as ondansetron and granistron, up to 70% of patients with cancer receiving highly emetogenic chemotherapy agents experience postchemotherapy nausea and vomiting. Delayed postchemotherapy nausea (nausea that occurs ≥ 24 hours after chemotherapy administration) and anticipatory nausea (nausea that develops before chemotherapy administration, in anticipation of it) are poorly controlled by currently available antiemetic agents. Scientific studies suggest that ginger (***Zingiber officinale***) might have beneficial effects on nausea and vomiting associated with motion sickness, surgery, and pregnancy. In 2 small studies of patients with cancer receiving chemotherapy, addition of ginger to standard antiemetic medication further

reduced the severity of postchemotherapy nausea. This article describes a phase II/III randomized, dose-finding, placebo-controlled, double-blind clinical trial to assess the efficacy of ginger for nausea associated with chemotherapy for cancer. The study is currently being conducted by private practice oncology groups that are funded by the National Cancer Institute's Community Clinical Oncology Program and affiliated with the University of Rochester Cancer Center Community Clinical Oncology Program Research Base.

**100.** Hsia, S. H., M. Bazargan and M. B. Davidson (2004). "**Effect of pancreas tonic (an Ayurvedic herbal supplement) in type 2 diabetes mellitus.**" Metabolism: Clinical and Experimental **53**(9): 1166-1173.

Although there is widespread use of herbal dietary supplements that are believed to benefit type 2 diabetes mellitus, few have been proven to do so in properly designed randomized trials; their efficacy for intermediate-term glucose control remains unclear. Pancreas Tonic is a botanical mixture of traditional Indian Ayurvedic herbs currently available as a dietary supplement. Authors report the results of a single-center, randomized, double-blind, placebo-controlled 3-month trial of Pancreas Tonic in type 2 diabetic patients inadequately treated with diet/lifestyle or stable doses of sulfonylureas and/or metformin for at least 3 months. Patients with type 2 diabetes for ≥ 1 year were entered into 2 strata of hemoglobin A 1c (HbA 1c) levels (stratum 1: 8.0% to 9.9%; stratum 2: 10.0% to 12.0%). Composition of toin includes *Aegle marmelose, Pterocarpus marsupium, Syzigium cumini, Momordica charantia, Gymnema sylvestre, Trigonella foenum graecum, Azadirachta indica, Ficus racemosa,* ***Tinospora cordifolia****, Cinnamomum tamala*. All subjects began a 1-month single-blind placebo run-in phase, followed by randomization in a 2:1 ratio of active treatment: placebo, to 3 months of double-blind treatment with either Pancreas Tonic or matching placebo (2 capsules 3 times a day). Concurrent oral agents were continued unchanged throughout the study. The primary outcome was the change in HbA 1c from randomization; results of each stratum were analyzed independently. The baseline characteristics of 36 subjects who completed the study were comparable between treatment groups. Nineteen subjects entered stratum 1 and 17 entered stratum 2. A statistically significant reduction of HbA 1c from randomization to end-of-study was seen in the stratum 2 subjects (Pancreas Tonic: 10.1% ± 1.0% to 8.8% ± 1.9%, P = .004; placebo: 10.8% ± 1.4% to 11.2% ± 1.8%, not significant [NS]). No significant HbA 1c reductions were seen in the stratum 1 subjects. There were no significant treatment-related differences in the fasting plasma glucose (FPG), lipids, body mass index (BMI), body composition, blood pressure, insulin sensitivity estimates using the minimal model, glucose and insulin responses to a meal challenge, quality of life, adverse events, or other safety indices between treatment groups. Pancreas Tonic was well tolerated. Treatment with Pancreas Tonic (2 capsules 3 times per day) for 3 months significantly improved glucose control in type 2 diabetic patients with HbA 1c levels between 10.0% to 12.0%. This study represents the first properly designed, prospective intervention trial of therapy with an Ayurvedic herbal supplement for intermediate-term glucose control in type 2 diabetes.

**101.** Huda, N. M., D. S. Mishra and J. Singh (2015). "**Clinical evaluation of an Ayurvedic preparation or the treatment of iron deficiency anemia in patients.**" Journal of Homeopathy & Ayurvedic Medicine **3**: doi: 10.4172/2167-1206.1000162.

Iron deficiency anemia is the most widespread nutritional disorder in the world. Prevalence of anaemia in Indian subcontinent is high because of low dietary intake, poor availability of iron and chronic blood loss due to hook worm infestation and malaria. Numbers of preparations are available in Ayurveda for correction of Iron deficiency anemia. So this study was conducted to investigate the efficacy of two Ayurvedic formulations Dhatri louha and Novayas louha in anaemic patients. It was a randomized, non-blinded, and placebo controlled pre-posttest design. Total thirty patients were divided into three groups. Each group contained 10 numbers of patients. Group 1 (control group) was given one starch capsule daily for 30 days and Group 2 and Group 3 were given two Ayurvedic formulations Dhatri louha and Novayas louha respectively in a dose of 250 mg twice a day for 30 days. Hematological parameters like hemoglobin concentration, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration were determined before and after completion of treatment. After the 30 days of treatment it was found significant ($p<0.05$) response in Group 2 and Group 3 when compared with Group 1. Therefore, it claimed that Dhatri louha and Novayas louha have haemopoetic function although it was a preliminary work. Dhatri Lauha contains ***Emblica officinalis***, ***Terminalia chebula***, ***Terminalia bellirica***, ***Zingiber officinale***, ***Piper longum***, ***Piper nigrum***, *Plumbago zeylanica*, *Cyperus rotundus*, *Emblica ribes* and Louha bashma.

**102.** Huded, S., S. V. Gummadi, K. Sankh, H. N. Asha, H. S. Ashwini and K. Lingadore (2013). "**Evaluation of guduchi yoga in the management of vatarakta (gouty arthritis): A clinical study.**" International Journal of Research in Ayurveda and Pharmacy **4**(5): 688-692.

Vatarakta is one of the main articular diseases, which is characterized by severe pain, tenderness, inflammation and burning sensation in the affected joints. It is a tridoshaja vyadhi, with vata pradhanyata and rakta as main dushya. Sedentary lifestyle is one of the etiological factors of Vatarakta. The etiology and symptomatology of Gout is very much similar to that of Vatarakta. Gout is a pathological reaction of joint or periarticular tissues which results from deposition of monosodium urate monohydrate crystals in joints and tissues. In Ayurvedic classics, although there are many dravyas for joint disorders, the area of joint diseases management still remains to be elusive. Hence the present clinical study aims to evaluate the efficacy of combined effect of 'Guduchi extract (***Tinospora cordifolia***) and cucumber juice extract' in the management of Vatarakta (Gouty arthritis). In the present study, 20 patients fulfilling the diagnostic criteria of Vatarakta and who met the American College of Rheumatology (ACR) criteria for acute Gouty arthritis were selected. Detailed profile which incorporated relevant data like symptomatology, physical signs and investigation reports were considered for assessment criteria. The 'Guduchi Yoga' (Aqueous extract of Guduchi and Trapusha) was administered to patients of either sex in the dosage of 1 g BID with lukewarm water after food for 12 weeks (3 months). After the course of therapy for 12 weeks, symptomatic improvement was observed with statistically significant results ($P < 0.001$) along with attainment of normal serum uric acid levels followed by feeling of general wellbeing. From the present study it can

be concluded that the combined effect of Guduchi and Trapusha extracts showed promising results in the management of vatarakta.

**103.** Imani, H., H. Tabibi, I. Najafi, S. Atabak, M. Hedayati and L. Rahmani (2015). "**Effects of ginger on serum glucose, advanced glycation end products, and inflammation in peritoneal dialysis patients.**" Nutrition **31**(5): 703-707.

The aim of this study was to investigate the effects of ginger (***Zingiber officinale***) supplementation on serum glucose, advanced glycation end products, oxidative stress, and systemic and vascular inflammatory markers in patients on peritoneal dialysis (PD). In this randomized, double-blind, placebo-controlled trial, 36 patients on PD were randomly assigned to either the ginger or the placebo group. The patients in the ginger group received 1000mg/d ginger for 10wk, whereas the placebo group received corresponding placebos. At baseline and the end of week 10, serum concentrations of glucose, carboxymethyl lysine, pentosidine, malondialdehyde (MDA), high-sensitivity C-reactive protein (hs-CRP), soluble intercellular adhesion molecule type 1 (sICAM-1), soluble vascular cell adhesion molecule type 1 (sVCAM-1), and sE-selectin were measured after a 12- to 14-h fast. Results: Serum fasting glucose decreased significantly up to 20% in the ginger group at the end of week 10 compared with baseline ($P<0.05$), and the reduction was significant in comparison with the placebo group ($P<0.05$). There were no significant differences between the two groups in mean changes of serum carboxymethyl lysine, pentosidine, MDA, hs-CRP, sICAM-1, sVCAM-1, and sE-selectin. This study indicated that daily administration of 1000mg ginger reduces serum fasting glucose, which is a risk factor for hyperinsulinemia, dyslipidemia, peritoneal membrane fibrosis, and cardiovascular disease, in patients on PD.

**104.** Jacob, A., M. Pandey, S. Kapoor and R. Saroja (1988). "**Effect of the Indian gooseberry (amla) on serum cholesterol levels in men aged 35-55 years.**" European Journal of Clinical Nutrition **42**(11): 939-944.

The effect on total serum cholesterol and its lipoprotein fractions of supplementation of the diet with amla (***Emblica officinalis***, Gaertn., the Indian gooseberry) was studied in normal and hypercholesterolaemic men aged 35-55 years. The supplement was given for a period of 28 d in the raw form. Both normal and hypercholesterolaemic subjects showed a decrease in cholesterol levels. **Two weeks after withdrawing the supplement, the total serum cholesterol levels of the hypercholesterolaemic subjects rose significantly almost to initial levels**.

**105.** Jain, C. (2008). "**Clinical Study of Immunomodulatory Effect of an Ayurvedic Compound (Vayasthadi Yoga) in Children.**" AYU (An international quarterly journal of research in Ayurveda) **29**(3): 123-127.

The immune system plays a vital role in maintaining the body's overall health and resistance to disease. In children, the immune system is in immature state and thus, they are unable to protect the body from invaders. They are suffered from recurrent infections. These infections are suggestive of a deficiency in the local or systemic host defence. In this clinical study, an Ayurvedic compound "Vayasthadi Yoga" containing Haritaki (***Terminalia chebula***), Pippali (***Piper longum***), Kustha, Haridra, Sariva, Vacha, Jatamansi, Kaidarya Brahmihas, shown statistically significant improvement in

morbidity features - Running nose, Sore throat, Nasal obstruction, Enlarged tonsils, Cough, Dyspnoea, Fever and Diarrhoea.

**106.** Janssen, P. L. T. M. K., S. Meyboom, W. A. Van Staveren, F. De Vegt and M. B. Katan (1996). "**Consumption of ginger (*Zingiber officinale* Roscoe) does not affect ex vivo platelet thromboxane production in humans.**" European Journal of Clinical Nutrition **50**(11): 772-774.

Ginger (***Zingiber officinale*** Roscoe) has been claimed to exert an anti-thrombotic effect in humans as ginger extracts inhibit cyclo-oxygenase activity of platelets in vitro. Effects of ginger consumption on ex vivo platelet function, however, are contradictory. Authors therefore investigated whether daily consumption of raw or cooked ginger decreases platelet cyclo-oxygenase activity all assessed by ex vivo maximally stimulated platelet thromboxane B2 production. Design: Authors carried out a randomized placebo-controlled cross-over study of 3 x 2 weeks. Subjects: Eighteen healthy volunteers aged 22 ± 3 y (mean ± s.d.) participated in the study; there were no dropouts. Interventions: Subjects consumed 15 g of raw ginger root, 40 g of cooked stem ginger, or placebo daily for two weeks. Authors took fasted venous blood samples and measured thromboxane B2 production in maximally stimulated platelet-rich plasma at days 12 and 14 of each treatment period. Results: Mean decrease in thromboxane production relative to placebo was 1 ± 9% for ginger root, and -1 ± 8% for stem ginger, with no effect of treatment order (P = 0.984). Study did not confirm the putative anti-thrombotic activity of ginger in humans.

**107.** Jayashankar, S., G. J. Panagoda, E. A. Amaratunga, K. Perera and P. S. Rajapakse (2011). "**A randomised double-blind placebo-controlled study on the effects of a herbal toothpaste on gingival bleeding, oral hygiene and microbial variables.**" The Ceylon medical journal **56**(1): 5-9.

Different systems of traditional medicine of the Indian subcontinent, have used *Acacia chundra* Willd, *Adhatoda vasica* Nees., *Mimusops elengi* L., ***Piper nigrum*** L., *Pongamia pinnata* L. Pirerre, *Quercus infectoria* Olivier., *Syzygium aromaticum* L., ***Terminalia chebula*** Retz., ***Zingiber officinale*** Roscoe., individually or in combinations, to cure oral diseases. To investigate the oral hygiene and gingival health benefits of toothpaste formulated with a mixture of the above herbs (15% w/w). Sixty participants (test n = 30, control n = 30, mean age 23.6 +/- 2.25 vs 23.9 +/- 3.2 years) who fulfilled the selection criteria and had similar plaque (1.734 +/- 0.29 vs 1.771 +/- 0.33) and percentage of sites with gingival bleeding (19.6 +/- 7 vs 20.7 +/- 8) were studied in a double blind randomised clinical trial. Brushing instructions to all and a scaling for those with calculus were provided two weeks before baseline examination. One ml of resting saliva was collected to ascertain anaerobic (SAnB) and aerobic (SAB) bacterial counts, plaque index (PI), percentage sites with bleeding on probing (BOP) and pocket depth (PD) (at 6 sites/tooth) were recorded at baseline, followed by home use of the allocated toothpaste (test or placebo) twice a day for 12 weeks. Measurements were repeated at 4, 8, and 12 weeks. PI, BOP and SAnB decreased significantly in the test group at 4, 8, and 12 weeks compared to baseline measurements (Wilcoxon-Signed Rank Test, $p < 0.01$). There was no statistically significant improvement in PI, BOP, and SAnB in the placebo group. The study indicates the beneficial effects of this herbal toothpaste (Sudantha)

on oral hygiene and gingival health variables when compared with the placebo. Further clinical trials using patients with gingivitis are necessary to confirm the therapeutic benefits of this herbal toothpaste.

**108.** Jeeth, A., D. D. Aloknatha, S. V.S and Shreevathsa (2014). "**Utility of bheshaja sevana kala–Open end comparative randomized clinical trial.**" Journal of Ayurveda and Holistic Medicine (JAHM) **2**(7): 4-7.

Bheshaja sevana kala is the principle of time of administration of the medicine. Drug exhibits different actions when administered in different bheshaja sevana kala (time of administration of medicine). Actual aim of bheshaja sevana kala is to provide the fulfillment towards desired action of drug administration in patient in order to pacify the disease. Considering these factors the present study was intended to evaluate the efficacy of bheshaja sevana kala in the disease prameha (diabetes mellitus). Guduchi (***Tinospora cordifolia***) is said to mitigate all types of prameha (diabetes mellitus). According to Sushrutasamhitha, the disease pramehais vyana and apanavata (types of vata- a bodily humour) involved disease. The cardinal symptoms of prameha simulate with the symptoms of diabetes mellitus. Hence the disease diabetes mellitus type II was selected to assess the role of pragbhaktha (before food), pratahaadhobhakta (morning after food) bheshaja sevana kala which are the time of administration of medicine for vyana and panavata involvement respectively. A randomized clinical study was outlined with a pre, mid and post test assessment of 30 patients satisfying the inclusion criteria who were randomly selected. In the present study 15 patients were asked to consume 4gm of guduchichurna (powder of *Tinospora cordifolia*) in pragbhakta (before food) and pratahadhobhaktakala (morning after food) with lukewarm water and another 15 patients were asked to take 4gm of guduchi churna three times a day after food with lukewarm water for the duration of 30 days. After intervention, results were analyzed statistically using descriptive statistics, chi square test, paired samples't' test, repeated measure ANOVA, using SPSS for windows software. Fairly good results were observed in all the parameters of the study. There was no much difference in the result between the groups with regards to subjective parameters i.e. prabhootamootrata (polyurea), pipasa (polydypsia), kshuda (polyphagia), swedapravrutti (excessive sweating), karapadadaha (burning sensation in palms and soles), supti (numbness) and klama (fatigue). With regards to FBS and PPBS patients of group A showed better result than group B, but it was statistically insignificant (P value > 0.05) between the groups. In case of avilamootrata (urine turbidity), also group A showed better result than group B and the result was statistically significant (P value 0.002). Conclusion is that Guduchi churna (powder of *Tinospora cordifolia*) administered during appropriate time showed statistically significant result in subsiding the cardinal symptomof pramehai.e. avilamootrata (urine turbidity).

**109.** Jin, C. Q., Y. X. Jia, H. X. Dong, J. W. Zhou, G. F. Sun, Y. Y. Zhang, Q. Zhao and B. Y. Zheng (2013). "**Stir-fried white pepper can treat diarrhea in infants and children efficiently: A randomized controlled trial.**" American Journal of Chinese Medicine **41**(4): 765-772.

Authors evaluated the efficacy and safety of stir-fried white pepper (***Piper nigrum***) in the treatment of infant and children diarrhea. This was a randomized trial conducted in the pediatric emergency department of the hospital affiliated to Jining Medical

College. One hundred seventy four patients were selected from outpatients from 2011 to 2012. Participants were randomly assigned to treatment with stir-fried white pepper (n = 88) or montmorillonite powder (n = 86). The proportions of chronic diarrhea patients (n = 52) showing success of treatment were similar for both groups. There were great differences between the two groups in acute diarrhea (n = 62) and persistent diarrhea (n = 60), and the cure rate of stir-fried white pepper was higher than montmorillonite powder in both groups. The prescription of stir-fried white pepper significantly decreased the frequency of diarrhea in infants and children under 2.5 years with diarrhea compared to treatment with montmorillonite powder, especially for the patients with acute diarrhea or persistent diarrhea.

**110.** Kalikar, M., V. Thawani, U. Varadpande, S. Sontakke, R. Singh and R. Khiyani (2008). "**Immunomodulatory effect of *Tinospora cordifolia* extract in human immuno-deficiency virus positive patients.**" Indian Journal of Pharmacology **40**(3): 107-110.

To assess the safety and efficacy of TCE in human immuno-deficiency virus positive patients. Efficacy of ***Tinospora cordifolia*** extract (TCE) in HIV positive patients was assessed in randomized double blind placebo controlled trial. 68 HIV positive participants were randomly assigned to two groups to receive either TCE or placebo for six months. After clinical examination TLC, DLC, ESR, platelet count, hemoglobin and CD4 count were done. The hematological investigations were repeated at bimonthly intervals and CD4 count was repeated at the end of the study. Patients were clinically reviewed at monthly intervals for compliance, refill and ADR monitoring. The drugs were decoded at the end of the trial. TCE treatment caused significant reduction in eosinophil count and hemoglobin percentage. 60% patients receiving TCE and 20% on placebo reported decrease in the incidence of various symptoms associated with disease. Some of the common complaints reported by patients on TCE were anorexia, nausea, vomiting and weakness. *Tinospora cordifolia* extract, a plant derived immunostimulant, significantly affected the symptoms of HIV. This was validated by clinical evaluation. However not all of the objective parameters studied by us, back this up. *Tinospora cordifolia* could be used as an adjunct to HIV/AIDS management.

**111.** Kalra, V., H. Zamir, R. Pandey and K. S. Kulkarni (2002). "**A randomized double blind placebo-controlled drug trial with Mentat in children with attention deficit hyperactivity disorder.**" Neurosciences Today **6**(4): 223-227.

A randomized double blind placebo-controlled trial was conducted to evaluate the efficacy of Mentat, an herbal formulation, in school going children with Attention Deficit Hyperactivity Disorder (ADHD). A total of 195 children were screened, out of which 60 satisfied the DSM-IV criteria for ADHD. Among those enrolled in the study, 30 received Mentat and 30 received placebo. An assessment of academic functioning along with psychological tests was done before and after the treatment. Malin's Intelligence Scale for Indian Children (MISIC), Conner's 10 point rating scale, Kaufman Assessment Battery for Children (KABC) and brain SPECT (Simple Photon Emission Computed Tomography) scans and subtests were assessed. Six children were dropped from the study, as they were lost to follow-up and another 4 children showed variable results. Thus, statistical analysis was carried out in only 50 children. The Conner's test and Gestalt closure subtest of KABC showed a statistically

significant improvement in the Mentat group as compared to the placebo group. Pre- and post-SPECT scan observations showed improvement in three children in the Mentat group as compared to one child in the placebo group. For all other tests, no significant difference was found between the Mentat and placebo groups. Composition of each Mentat tablet (Botanical names): Extracts: *Bacopa monnieri* (136 mg), *Centella asiatica* (70 mg), ***Withania somnifera*** (52 mg), *Evovulus alsinodes* (52 mg), *Nardostachys jatamansi* (52 mg), *Valeriana wallichii* (50 mg), *Embelia ribes* (50mg), *Prunus amygdalus* (50 mg), ***Tinospora cordifolia*** (36 mg), ***Terminalia chebula*** (36 mg), ***Emblica officinalis*** (36 mg), *Oroxylum indicum* (32 mg) and *Celastrus paniculatus* (32 mg). Powders: *Bacopa monnieri* (80mg), *Orchis mascula* (18mg), *Mucuna pruriens* (18 mg), *Elettaria cardamomum* (18 mg), *Terminalia arjuna* (18 mg), *Foeniculum vulgare* (18mg), *Ipomoea digitata* (18 mg), ***Zingiber officinale*** (14 mg), ***Terminalia bellirica*** (14 mg), *Myristica fragrans* (14 mg), *Syzygium aromaticum* (10 mg) and Mukta pishti (3 mg).

**112.** Kamal, R. and S. Aleem (2009). "**Clinical evaluation of the efficacy of a combination of zanjabeel (*Zingiber officinale*) and amla (*Emblica officinalis*) in hyperlipidaemia.**" Indian Journal of Traditional Knowledge **8**(3): 413-416.

In Unani System of Medicine, many drugs (single drugs as well compound formulations) are used for the purpose of reducing body weight and treating the obesity (Muhazzil). Indian gooseberry (amla ***Emblica officinalis***) & ginger (Zanjabeel ***Zingiber officinale***) are among these medicines. Since these drugs are useful in obesity, these can also be proved beneficial in lowering increased concentration of plasma lipids or treating hyperlipidaemia. Their efficacy has also been proved pharmacologically and these are documented as good hypolipidaemic as well as antioxidant natural agents. The combination of drugs was found to be significant in lowering the level of serum total cholesterol, serum tryglycerides, serum LDL-cholesterol, serum VLDL-cholesterol and in increasing the level of serum HDL-cholesterol in patients of primary hyperlipidaemia.

**113.** Kamali, S. H., A. R. Khalaj, S. Hasani-Ranjbar, M. M. Esfehani, M. Kamalinejad, O. Soheil and S. A. Kamali (2012). "**Efficacy of 'Itrifal Saghir', a combination of three medicinal plants in the treatment of obesity; A randomized controlled trial.**" DARU, Journal of Pharmaceutical Sciences **20**(1).

Herbal combination of Itrifal Saghir or ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***) has been widely used in traditional medicine. And brings health benefits such as antioxidant effect and scavenger of hydroxyl radicals and nitric oxide radicals activity and substantiated in traditional medicine a anti-obesity. In this study authors aimed to assess the efficacy of this herbal medicinal on reduction of weight and body mass index (BMI) of simple obese subjects in comparison with placebo. Obese subjects aged between 16 and 60 years were selected for 12-week, double-blind, randomized, placebo-controlled trial using a parallel design. Subjects were randomly assigned to take 5 grams of either the Itrifal Saghir (n = 31) or placebo (n = 31), 2 times daily for 12 weeks. Measures of body weight, BMI, waist circumference (WC), hip circumference (HC), were assessed at baseline and once every four weeks during the 12 week treatment period. The safety was evaluated by means of measuring the liver and kidney function. Homeostasis

model of insulin resistance (HOMA-IR) was calculated as [fasting insulin (µU/mL) × fasting glucose (mmol/L)/22.5]. Compared to placebo group, in treatment group the mean difference of effective weight loss was 4.82Kg (CI95% 3.52 - 6.11, ρ < 0.001), the mean of decrease in waist circumference was 4.01 cm (CI 95% 2.13 - 5.90, ρ < 0.001), and the mean decrease in hip circumference was 3. 21 cm (CI 95% 1.96 - 4.45, ρ < 0.001) in treated subjects. No adverse effects or significant changes in liver and kidney function tests were observed in both placebo and treated groups. Itrifal Saghir appears to produce a positive effect on weight loss in obese subjects.

**114.** Karkal, Y. R. and L. K. Bairy (2007). "**Safety of aqueous extract of *Tinospora cordifolia* (Tc) in healthy volunteers: A double blind randomised placebo controlled study.**" Iranian Journal of Pharmacology and Therapeutics **6**(1): 59-61.

It is a common misconception that ayurvedic medicines (traditional Indian system of medicine) are always safe. In fact, they also pose serious health risks either in the form of adverse reactions or in the form of drug interactions. Over 80% of our population takes ayurvedic medicines. The study was aimed to evaluate the safety profile of ***Tinospora cordifolia*** in healthy volunteers using a battery of haematological, and biochemical tests and open questionnaire method. Thirty healthy volunteers (males - 22 and females - 8) aged 18 - 30 years (mean 22.5 ± 0.28) who volunteered to participate were studied in a randomized, double - blind, placebo controlled design. The volunteers were provided with 21 days of medication (coded box) containing *Tinospora cordifolia* 500 mg or matching placebo. One tablet of *Tinospora cordifolia* of 500 mg strength or placebo was taken once daily orally in the morning along with breakfast for 21 days. The safety assessment was done with the help of haematological and biochemical investigations which were assessed before and after the medication by unpaired t test. 'Unpaired t test' using SPSS computer software package. Analysis of the various lab values between the control and the test group before and after taking the drug/placebo by unpaired 't' test shows no significant difference between the groups (p = > 0.05). Hence it can be concluded that *Tinospora cordifolia* is safe at a dose of 500 mg per day for a period 21 days in healthy volunteers for the parameters studied.

**115.** Kashefi, F., M. Khajehei, M. Alavinia, E. Golmakani and J. Asili (2014). "**Effect of ginger (*Zingiber officinale*) on heavy menstrual bleeding: A placebo-controlled, randomized clinical trial.**" Phytotherapy Research **29**(1): 114-119.

A wide range of herbal plants have been reported to treat various gynecological problems of women. This study was set out to investigate the effect of ginger (***Zingiber officinale***) on heavy menstrual bleeding (HMB) in high school girls. Ninety-two young women who experienced HMB and met the inclusion criteria were recruited in this study. Participants were evaluated for six consecutive menstrual cycles. During 3 assessment cycles, their HMB was confirmed by Pictorial Blood Assessment Chart. They were then randomly allocated to two study groups to receive either ginger or placebo capsules. The participants filled in the same chart during three intervention cycles. Results: The level of menstrual blood loss dramatically declined during the three intervention cycles in ginger-receiving group. The decrease of blood loss in ginger-receiving group was significantly more remarkable than that of participants receiving placebo (p < 0.001). Minimum number of participants

reported adverse effects. HMB is highly prevalent among young women. Considering the significance of appropriate and timely treatment and also the importance of prevention of unwanted consequences, ginger may be considered as an effective therapeutic option for HMB.

**116.** Katakdound, S. D. (2015). "**A randomised controlled clinical trial to evaluate effect of Ayurvedic formulation in postnatal care.**" Journal of Ayurveda and Holistic Medicine (JAHM) **3**(1).

Aim was to evaluate postnatal care with Ayurvedic medicine as the basic concept behind this clinical trial. In the present study 20 uncomplicated vaginally delivered patients with episiotomy were taken from the study centre and divided into two groups. In Group A (n=10) patients were treated with Gandhak Rasayanavati, Sookshma ***Triphalavati*** & ***Triphala*** **Kwath** containing ***Emblica officinalis*****,** ***Terminalia chebula*****,** ***Terminalia bellirica*** & in Group B (n=10) Tab. Ciprofloxacin + Tinidazole (500+200) mg, Tab Serratiopeptidase 10mg, Betadine ointment & liquid Dettol for 7 days and results were observed. In observation clinical findings were noted on 0th,3rd, 6th & 9th day. Statistical analysis used: The improvement in the cardinal symptoms were compared and analyzed statistically between the end of the treatment and baseline by using student's paired 't' test. The investigations also analyzed using student's unpaired 't' test. Results: In the GroupA no generalized or localized sepsis observed in any patient. Quality of wound healing, involution of uterus, nature of lochia and local tenderness shows statistically equal 't' value i.e. 0, 0.710, 0.534 and 0.599 respectively when compared with GroupB. It can be concluded that the Ayurvedic drugs are significantly effective in postnatal care when compared with modern drugs to combat infections. Hence Gandhak Rasayanavati, Sookshma *Triphala*vati & *Triphala* Kwath is reliable to use in postnatal care.

**117.** Keating, A. and R. A. Chez (2002). "**Ginger syrup as an antiemetic in early pregnancy.**" Alternative Therapies in Health and Medicine **8**(5): 89-91.

Ginger (***Zingiber officinale***) has been used to ameliorate symptoms of nausea. A beverage containing ginger in a syrup may be easier to consume than a capsule or solid food. Objective was to determine if ginger syrup mixed in water is an effective remedy for the relief of nausea and vomiting in the first trimester of pregnancy. Design was double-blind, placebo-controlled, randomized clinical trial. Subjects were enrolled from the University of South Florida department of obstetrics and gynecology private practice office. Patients were 26 subjects in the first trimester of pregnancy. Intervention: Subjects ingested 1 tablespoon of commercially prepared study syrup (or placebo) in 4 to 8 ounces of hot or cold water 4 times daily. Main Outcome Measures were taken as duration and severity of nausea and vomiting over a 2-week period measured on a 10-point scale. Results suggest that after 9 days, 10 of the 13 (77%) subjects receiving ginger had at least a 4-point improvement on the nausea scale. Only 2 of the 10 (20%) remaining subjects in the placebo group had the same improvement. Conversely, no woman in the ginger group, but 7 (70%) of the women in the placebo group, had a 2-point or less improvement on the nausea scale. Eight of the 12 (67%) women in the ginger group who were vomiting daily at the beginning of the treatment stopped vomiting by day 6. Only 2 of the 10 (20%) women in the placebo group who were vomiting stopped by day 6. Thus, the

ingestion of 1 g of ginger in syrup in a divided dose daily may be useful in some patients experiencing nausea and vomiting in the first trimester of pregnancy.

**118.** Keche, Y., V. Badar and M. Hardas (2010). "**Efficacy and safety of Livwin (polyherbal formulation) in patients with acute viral hepatitis: A randomized double-blind placebo-controlled clinical trial.**" International Journal of Ayurveda Research **1**(4): 216.

The study was planned to evaluate the efficacy and safety of Livwin (polyherbal formulation) in acute viral hepatitis. In this study, there were 29 patients in each group, receiving either Livwin or placebo capsules containing lactose powder (500 mg). Livwin is polyherbal formulation that contains extracts of seven medicinal plants as follows: Arjuna (*Terminalia arjuna* W and A) - 100 mg, Ashwagandha (***Withania somnifera*** Dunal) - 100 mg, Bhumyamalaki (*Phyllanthus niruri* Linn) - 100 mg, Daruharidra (*Berberis aristata* DC) - 50 mg, Guduchi (***Tinospora cordifolia*** (Willd.) Miers) - 75 mg, Kutki (*Picrorhiza kurroa* Royle ex Benn.) - 50 mg, Punarnava (*Boerhaavia diffusa* Linn) - 50 mg. Placebo capsule was containing lactose powder 500 mg. Both drugs were given orally two capsules two times a day for eight weeks followed by treatment free period of four weeks. Recovery of patients was assessed by noting symptomatic recovery and by measuring levels of serum bilirubin, serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT), alkaline phosphatase at baseline, 2, 4, 8 and 12 weeks. Significant earlier recovery of weakness was observed with Livwin as compared to placebo at 2, 4 and 8 weeks. Serum bilirubin and ALT was observed in normal range in significantly more number of patients with Livwin treatment as compared to placebo at 2, 4 and 8 weeks. AST was observed in normal range in significantly more number of patients with Livwin treatment as compared to placebo at 2 and 4 weeks. Livwin is found effective in uncomplicated patients of acute viral hepatitis. Epigastric pain and diarrhea were reported with Livwin treatment.

**119.** Kessler, C., L. Pinders, A. Michalsen and H. Cramer (2015). "**Ayurvedic interventions for osteoarthritis: a systematic review and meta-analysis.**" Rheumatology International **35**(2): 211-232.

Ayurveda is one of the fastest growing systems within complementary and alternative medicine. However, the evidence for its effectiveness is unsatisfactory. The aim of this work was to review and meta-analyze the effectiveness and safety of different Ayurvedic interventions in patients with osteoarthritis (OA). 138 electronic databases were searched through August 2013. Randomized controlled trials, randomized crossover studies, cluster-randomized trials, and non-randomized controlled clinical trials were eligible. Adults with pre-diagnosed OA were included as participants. Interventions were included as Ayurvedic if they were explicitly labeled as such. Main outcome measures were pain, physical function, and global improvement. Risk of bias was assessed using the Cochrane risk of bias tool. 19 randomized and 14 non-randomized controlled trials on 12 different drugs and 3 non-pharmaceutical interventions with a total of 2,952 patients were included. For the compound preparation, Rumalaya, large and apparently unbiased effects beyond placebo were found for pain (standardized mean difference [SMD] −3.73; 95 % confidence interval [CI] −4.97, −2.50; $P < 0.01$) and global improvement (risk ratio 12.20; 95 % CI 5.83, 25.54; $P < 0.01$). There is also some evidence that effects of the herbal compound

preparation Shunti-Guduchi are comparable to those of glucosamine for pain (SMD 0.08; 95 % CI −0.20, 0.36; P = 0.56) and function (SMD 0.15; 95 % CI −0.12, 0.36; P = 0.41). Based on single trials, positive effects were found for the compound preparations RA-11, Reosto, and Siriraj Wattana. For *Boswellia serrata*, *Lepidium sativum*, a *Boswellia serrata* containing multicomponent formulation and the compounds Nirgundi Taila, Panchatikta Ghrita Guggulu, and Rhumayog, and for non-pharmacological interventions like Ayurvedic massage, steam therapy, and enema, no evidence for significant effects against potential methodological bias was found. No severe adverse events were observed in all trials. The drugs Rumalaya and Shunti-Guduchi (***Zingiber officinale*** & ***Tinospora cordifolia***) seem to be safe and effective drugs for treatment of OA-patients, based on these data. However, several limitations relate to clinical research on Ayurveda. Well-planned, well-conducted and well-published trials are warranted to improve the evidence for Ayurvedic interventions.

**120.** Khan, M. S. and A. N. Ansari (2015). "**Effect of leech therapy (Irsal-e Alaq) and Unani formulation (Itrifal Sagheer with Zanjabeel) in the management of varicose veins (Dawali): An open, randomized, standard controlled, three groups clinical trial.**" Spatula DD-Peer Reviewed Journal on Complementary Medicine and Drug Discovery **5**(1): 41-50.

Varicose veins affect up to 5% or more of the adult population of western countries and 15 to 20% of general population. The inability to perform heavy and prolonged standing works affects the quality of life, and earning capacity of patients as well. Unani physicians have described this disease as Dawali and have been treating the disease since ancient times effectively on the principle of evacuation (Tanqiya), restoration (Ta'deel) and potentiation (Taqwiyat). The limitation of conventional treatment in the management of varicose veins paved the way to evaluate the efficacy and safety of leech therapy and a pharmacopoeial Unani poly herbal formulation in the management of varicose veins on scientific parameters. The study was conducted as open, randomized, standard controlled, three groups clinical trial on 30 eligible patients. Leech therapy was selected as a treatment procedure in the test group 'A'. The combination of Unani formulation Itrifal Sagheer with Zanjabeel and leech therapy was selected as a treatment strategy in the test group 'B'. Compression stocking was selected as a standard treatment procedure in the control group 'C'. Significant statistical difference was observed in subjective and objective parameters. Almost all patients reported improvement in pain and heaviness. The more promising result was observed in group 'A' in pain (82%), where group 'B' showed more marked response (64%) in heaviness among all the groups. In intra group comparisons, statistically highly significant difference was observed from baseline to 14th day to 28th day (P<0.001) on Revised VCSS in both groups 'A' and 'B', But the mean difference was more in group 'B' (5.36) than in 'A' (4.53). In group 'C', the mean difference was (-1.60). Highly significant change was also observed in vein diameter below knee and above ankle in group 'A' and group 'B', while no significant change was demonstrable in group 'C'. No significant change was found in safety parameter. The trial regimen of leech therapy and Unani formulation Itrifal Sagheer (including ***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) with Zanjabeel (***Zingiber officinalis***) was found safe and effective in the treatment of varicose veins, predominantly in pain, heaviness, swelling, skin changes and vein diameter.

**121.** Khan, S. and M. J. Balick (2001). "**Therapeutic plants of Ayurveda: A review of selected clinical and other studies for 166 species.**" Journal of Alternative and Complementary Medicine **7**(5): 405-515.

This paper reports on the results of a literature survey involving 166 different species of plants used in the Ayurvedic pharmacopoeia, based on a sampling of the literature available to us. Auyjors found a wide range of clinical and other in vivo studies for many of the plant-based therapies utilized in the Ayurvedic system. Of the 166 plants investigated, 72 (43%) had at least one or more human studies and 103 (62%) had one or more animal studies. These results appear to contradict the generally held notion that herbal remedies used in non-Western systems of botanical medicine have not been evaluated in human or in vivo trials. Some of these studies are not always as large or methodologically rigorous as clinical studies reported in major medical journals. Indeed, a critical assessment of the research according to the standards of evidence-based medicine would eliminate many of these studies for lack of rigor according to criteria of randomization, sample size, adequacy of controls, etc. However, the studies do suggest which species might be appropriate for larger and better-controlled trials in the future. Accordingly, a synopsis of the plants, their therapeutic applications, and their clinical or experimental evaluations is presented. [**Note by the editors**: In this 15 years old study, from the relevance of JVN-8, the species investigated are ***Emblica officinalis*** (Gastrointestinal disease, Serum cholesterol levels, Viral hepatitis), ***Piper longum*** (increase in the bioavailability of drugs, disappearance of Giardia lamblia), ***Piper nigrum*** (no damage to human gastric mucosa), ***Terminalia bellirica*** and ***Terminalia chebula*** (achne vulgaris, congestive cardiac failure), ***Tinospora cordifolia*** (calculi on kidney or urinary bladder, management of obstructive jaundice), ***Withania somnifera*** (Calculi on kidney and urinary bladder, osteoarthritis, psychomotor performance, rheumatoid arthritis), ***Zingiber officinale*** (many studies)].

**122.** Khandouzi, N., F. Shidfar, A. Rajab, T. Rahideh, P. Hosseini and M. M. Taheri (2015). "**The effects of ginger on fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein A-I and malondialdehyde in type 2 diabetic patients.**" Iranian Journal of Pharmaceutical Research **14**(1): 131-140.

Diabetes mellitus is the most common endocrine disorder, causes many complications such as micro- and macro-vascular diseases. Anti-diabetic, hypolipidemic and anti-oxidative properties of *ginger* (***Zingiber officinale***) have been noticed in several researches. The present study was conducted to investigate the effects of ginger on fasting blood sugar, Hemoglobin A1c, apolipoprotein B, apolipoprotein A-I, and malondialdehyde in type 2 diabetic patients. In a randomized, double-blind, placebo-controlled, clinical trial, a total of 41 type 2 diabetic patients randomly were assigned to ginger or placebo groups (22 in ginger group and 19 in control group), received 2 g/day of ginger powder supplement or lactose as placebo for 12 weeks. The serum concentrations of fasting blood sugar, Hemoglobin A1c, apolipoprotein B, apolipoprotein A-I and malondialdehyde were analyzed before and after the intervention. Ginger supplementation significantly reduced the levels of fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein B/apolipoprotein A-I and malondialdehyde in ginger group in comparison to

baseline, as well as control group, while it increased the level of apolipoprotein A-I ($p<0.05$). It seems that oral administration of ginger powder supplement can improves fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein A-I, apolipoprotein B/apolipoprotein A-I and malondialdehyde in type 2 diabetic patients. So it may have a role in alleviating the risk of some chronic complications of diabetes.

**123.** Khanna, S., A. Das, J. Spieldenner, C. Rink and S. Roy (2015). "**Supplementation of a standardized extract from *Phyllanthus emblica* improves cardiovascular risk factors and platelet aggregation in overweight/class-1 obese adults.**" Journal of Medicinal Food **18**(4): 415-420.

The objective of this study (clinicaltrials.gov NCT01858376) was to determine the effect of oral supplementation of a standardized extract of ***Phyllanthus emblica*** (CAPROS®) on cardiovascular disease (CVD) risk factors in overweight adult human subjects from the US population. Overweight/Class-1 obese (body-mass index: 25-35) adult subjects received 500 mg of CAPROS supplement b.i.d for 12 weeks. The study design included two baseline visits followed by 12 weeks of supplementation and then 2 weeks of washout. At all visits, peripheral venous blood was collected in sodium citrate tubes. Lipid profile measurements demonstrated a significant decrease in calculated low-density lipoprotein cholesterol and total cholesterol/high-density lipoprotein following 12 weeks of CAPROS supplementation when compared to averaged baseline visits. Circulatory high-sensitivity C reactive protein (hs-CRP) levels were significantly decreased after 12 weeks of supplementation. In addition, both ADP-and collagen-induced platelet aggregation was significantly downregulated following 12 weeks of supplementation. Overall, the study suggests that oral CAPROS supplementation may provide beneficial effects in overweight/Class-1 obese adults by lowering multiple global CVD risk factors.

**124.** Kishore, R. K., H. A. Abhishekh, K. Udupa, J. Thirthalli, G. S. Lavekar, B. N. Gangadhar, T. R. Raju and T. N. Sathyaprabha (2014). "**Evaluation of the influence of ayurvedic formulation (Ayushman-15) on psychopathology, heart rate variability and stress hormonal level in major depression (Vishada).**" Asian Journal of Psychiatry **12**(1): 100-107.

Ayurveda (Indian-complimentary and alternative medicine) is still most sought after in India and has promising potential in management of Vishada [major depressive disorder (MDD)]. But, systematic research is lacking. In this study authors evaluated of influence of ayurvedic treatment (Panchakarma and Ayushman-15) on psychopathology, heart rate variability (HRV) and endocrinal parameters in patients with major depression. Method: 81 drug naive patients diagnosed as Vishada by ayurvedic physician and MDD according to DSM IV-TR were given ayurvedic Virechana module (therapeutic purgation) and were randomized into two groups. Patients in group A (n= 41) received Ayushman-15A while group B (n= 40) received Ayushman-15B for two months and Shirodhara (forehead-oil pouring therapy). Patients were assessed with Hamilton Depression Rating Scale (HDRS), Montgomery Asberg Depression Rating Scale (MADRS), Heart Rate Variability (HRV). Cortisol and adrenocorticotropic hormone (ACTH) were estimated at baseline and after ayurvedic therapy. HRV and endocrinal parameters were compared with age and gender matched healthy volunteers. Results: HRV parameters showed significant sympathetic dominance in patients compared to healthy volunteers. Two months of ayurvedic

treatment significantly decreased psychopathology, showed increase in vagal tone, decrease in sympathetic tone and reduced cortisol levels. However, there was no significant difference between groups receiving Ayushman A and B. Conclusion is that there is evidence for antidepressant, cardiac (HRV) and beneficial neuroendocrine modulatory influence of Ayurveda therapy in patients of Vishada (MDD). Further studies are needed to confirm these findings. Greater insight into the neurobiology behind this therapy might provide valuable information about newer drug target.

**125.** Kizhakkeveettil, A., P. S. Jayagopal and K. Rose (2011). "**Hypercholesterolemia and Ayurvedic Medicine: A Case Report.**" Topics in Integrative Health Care **2**(2): ID: 2.2006.

Over the last two decades there has been an increasing emphasis placed on screening for high cholesterol and adopting interventions to reduce cholesterol levels in order to reduce the risk of heart disease. The high costs and side effects of hypercholesterolemia medications have led many people to search for alternate treatments. Only a few studies have been conducted to evaluate the effect of Ayurvedic herbal medicine formulae on hypercholesterolemia. The objective of this article is to describe a case where Ayurvedic herbs appeared to have been helpful in the management of hypercholesterolemia. Clinical Features: This patient was a 46-year-old woman who had been diagnosed with hypercholesterolemia two years prior to presentation. She had not responded to conventional treatment. She was treated for eight months with the Ayurvedic formulae Kaishora Guggulu, ***Triphala*** and a custom made herbal tea mix. Ayurvedic treatment for this patient consisted solely of the use of herbal formulae over an eight-month period. Three preparations were prescribed for the first 4 months. 1.Kaishora Guggulu: This formula consists of the following ingredients: Haritaki Fruit (***Terminalia chebula***), Vibhitaki Fruit (***Terminalia bellirica***), Amalaki Fruit (***Emblica officinalis***), Guduchi Stem (***Tinospora cordifolia***), Ginger Root (***Zingiber officinale***), Pippali Fruit (***Piper longum***), Black Pepper Fruit (***Piper nigrum***), Vidanga (*Embelia ribes*), Danti Root (*Baliospermum montanum*), Trivruth Root (*Operculina turpethum*), Guggulu Resin (*Commiphora mukul*), The patient was prescribed four 300 mg tablets per day. Two tablets were taken after breakfast and two tablets after dinner. 2. *Triphala* : This formula consists of the following ingredients: Haritaki Fruit (*Terminalia chebula*), Vibhitaki Fruit (*Terminalia bellirica*), Amalaki Fruit (*Emblica officinalis).* The patient was prescribed three 300 mg tablets per day to be taken after dinner. 3. Custom prepared Herbal Tea blend: This formula consists of the following ingredients: *Coriandrum sativuam* -1TBS, *Cuminum cyminum* -1TBS, *Foeniculum vulgare*- 1 TBS, *Curcuma longa* -1/2 TBS, *Elettaria cardamomum* -1/2TBS. Her total cholesterol dropped from 270 to 208 mg/dl, her LDL dropped from 191 to 146 mg/dl, and her HDL rose from 57 to 63 mg/dl. There were no side effects reported. This case demonstrates the use of Ayurvedic herbs in the management of hypercholesterolemia. Further high quality studies with randomized clinical trials should be conducted to better understand the effectiveness of Ayurvedic treatment for hypercholesterolemia.

**126.** Klassen, T. P., B. Pham, M. L. Lawson and D. Moher (2005). "**For randomized controlled trials, the quality of reports of complementary and alternative medicine was as good as reports of conventional medicine.**" Journal of Clinical Epidemiology **58**(8): 763-768.

Objective was to compare the quality of reporting of reports randomized controlled trials (RCTs) published in English and in languages other than English (LOE), and to determine whether there were differences between conventional medicine (CM) and complementary and alternative medicine (CAM) reports. Study Design and Setting: Authors examined more than 600 RCTs associated with 125 systematic reviews. They extracted characteristics of each RCT using a standardized data collection form. Quality was assessed using the Jadad scale and the adequacy of allocation concealment. Results: There were only minor differences in the quality of reports of RCTs published in English compared with other languages (median quality score of 3 vs. 2, P = .10), and the quality of reports of CAM RCTs was similar to the CM reports (median score of 3 vs. 2, P = .14). There was no effect of language of publication on quality of reporting for CM trials (median score of 2 vs. 2, P = .12). Among CAM trials, however, overall quality scores were higher for reports in English than for reports in other languages (median score of 3 vs. 2, P = .04). The overall quality of reports published in languages other than English is similar to that of English-language reports. Moreover, the overall quality of reporting of RCTs of CAM interventions is as good as that for CM interventions.

**127.** Krishnamurthy, M. N. and S. Telles (2007). "**Assessing depression following two ancient Indian interventions: Effects of Yoga and Ayurveda on older adults in a residential home.**" Journal of Gerontological Nursing **33**(2): 17-23.

The effects of yoga and ayurveda on geriatric depression were evaluated in 69 persons older than 60 who were living in a residential home. Participants were stratified by age and gender and randomly allocated to three groups: Yoga, Ayurveda, or Wait-list Control. The 15-item Geriatric Depression Scale was used to assess depressive symptoms prior to the intervention, and after 3 months and 6 months post-intervention. Participation in one of the three groups lasted 24 weeks. The yoga program (7 hours 30 minutes per week) included physical postures, relaxation techniques, regulated breathing, devotional songs, and lectures. The Ayurveda Group received an herbal preparation with ***Emblica officinalis***, ***Withania somnifera*** and ***Piper*** etc. twice daily for the whole period. The depression symptom scores of the Yoga Group at both 3 and 6 months decreased significantly, from a group average baseline of 10.6 to 8.1 and 6.7, respectively ($p < .001$, paired t-test). The other groups showed no change. Hence, an integrated approach of yoga including the mental and philosophical aspects in addition to the physical practices was useful for institutionalized older persons.

**128.** Kuchewar, V. V., M. A. Borkar and M. A. Nisargandha (2014). "**Evaluation of antioxidant potential of Rasayana drugs in healthy human volunteers.**" AYU **35**(1): 46–49.

It is increasingly being realized that many of today's diseases are due to "oxidative stress" that results from an imbalance between formation and neutralization of free radicals. Rasayana Chikitsa is a unique branch of Ayurveda. The word Rasayana means the way for attaining excellent Rasadi Dhatus. Several medicinal plants have been described as Rasayanas in Ayurveda. Ashwagandha and Guduchi are the best among the Rasayanas described by Charaka. Ashwagandha (***Withania somnifera*** (L.) Dunal.), is also known as Indian ginseng, or winter cherry. It has been an important herb in the Ayurvedic and indigenous medical systems for over 3000 years. Guduchi

(***Tinospora cordifolia*** (Thunb.) Miers.) has been used in Ayurvedic preparations for the treatment of various ailments throughout the centuries.The aim was to study the efficacy of Ashwagandha and Guduchi in oxidative stress in healthy volunteers. The study was carried out on 30 healthy volunteers after obtaining written informed consent. They were randomly distributed in three groups. Each group was treated with three different colored capsules containing *Ashwagandha*, *Guduchi* and placebo in the dose of 1 capsule (500 mg) twice a day for 6 months. The parameters such as hemoglobin%, Erythorcyte Sedimentation Rate (ESR), Malondialdehyde (MDA), Super-Oxide Dismutase (SOD) level, etc., were assessed before and after treatment. The Student's t-test was applied to assess significant variations in all of the studied parameters. In this study, there was a significant increase in SOD level and decrease in MDA level in Ashwagandha and Guduchi groups. In conclusion, Ashwagandha and Guduchi may be helpful in preventing the oxidative stress and premature aging.

**129.** Kulatunga, R., A. R. Dave and M. S. Baghel (2012). "**Clinical efficacy of Guduchyadi Medhya Rasayana on senile memory impairment.**" AYU **33**(2): 202.

Aging has become one of the distinctive demographic phenomena in the 21st century and its social, economic and health implications are the most challenging issues. Senile Memory Impairment is a common condition characterized by mild symptoms of cognitive decline and occurs as a part of the normal aging process. It can be correlated to "Jarajanya Smrtibhramsha" according to Ayurveda. The present study deals with the efficacy of Guduchyadi Medhya Rasayana on Senile Memory Impairment. Granules of Guduchyadi Medhya Rasayana (GMR), which contains Guduchi (***Tinospora cordifolia*** Wild.), Apamarga (*Achyranthes aspera* Linn.), Vidanga (*Embelia ribes* Burm. f.), Shankhapushpi (*Convolvulus pluricaulis* Chois.), Vaca (*Acorus calamus* Linn.), Haritaki (***Terminalia chebula*** Zetz.), Kushtha (*Saussurea lappa* C.B. Clarke), Shatavari (*Asparagus racemosus* Wild.), Cow's ghee and sugar. A total of 138 patients aged in between 55–75 years were registered and randomly divided into two groups as the trial and control groups. The drugs were administered for 3. The trial drug showed memory enhancement, anti-stress, anti-depressant and anxiolytic properties. The trial group showed better results in the management compared to the control group.

**130.** Kulkarni, R. R., P. S. Patki, V. P. Jog, S. G. Gandage and B. Patwardhan (1991). "**Treatment of osteoarthritis with a herbomineral formulation: A double-blind, placebo-controlled, cross-over study.**" Journal of Ethnopharmacology **33**(1-2): 91-95.

The clinical efficacy of a herbomineral formulation containing roots of ***Withania somnifera***, the stem of *Boswellia serrata*, rhizomes of *Curcuma longa* and a zinc complex (Articulin-F), was evaluated in a randomized, double-blind, placebo controlled, cross-over study in patients with osteoarthritis. After a one-month single blind run-in period, 42 patients with osteoarthritis were randomly allocated to receive either a drug treatment or a matching placebo for a period of three months. After a 15-day wash-out period the patients were transferred to the other treatment for a further period of three months. Clinical efficacy was evaluated every fortnight on the basis of severity of pain, morning stiffness, Ritchie articular index, joint score, disability score and grip strength. Other parameters like erythrocyte sedimentation rate and radiological examination were carried out on a monthly hasis. Treatment

with the herbomineral formulation produced a significant drop in severity of pain (P < 0.001) and disabilitys core (P < 0.05). Radiological assessment, however, did not show any significant changes in both the groups. Side effects observed with this formulation did not necessitate withdrawal of treatment.

**131.** Kulkarni, R. and A. Kumar (2013). "**A randomized controlled trial on the efficacy of medhya rasayana tablet on academic stress and performance in school children.**" Journal of Ayurveda and Holistic Medicine (JAHM) **1**(3): 1-16.

School children and academics are not exempted from stress. In Indian context, especially for high school children, the demands to be placed high, parental pressures, the future career option and time bound targets along with inherent biological variations of adolescence create paramount stress. Such stress can be detrimental if not well managed. Despite of loss of lives consequent upon stress and poor performance, academic stress is less researched. Psychotherapy is the current gold standard. Hence this trial aims to evolve the risk factors, common manifestations and adaptations with the academic stress, remedial measures with herbal medicine. Objective was the ealuation of efficacy and safety of oral administration of Medhya Rasayana (MR) on manifestations of academic stress and to improve the academic performance. Setting and design: Study was carried out in Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital (SDMCA&H), Hassan, Karnataka, South India, from December, 2010- December, 2012. Interventional, single blinded, randomized psychotherapy-placebo controlled efficacy trial. Materials and methods: 164 children of either sex, studying in tenth standard with normal intelligent quotient (IQ), average and above average stress as indicated from the scores on academic anxiety scale (AASC) and Sarason's Test anxiety scale (TASC), consciously willing to participate in the trial were randomized in to three groups (GP)–medhya (M) and medhya with psychotherapy (MP) and control – Placebo with psychotherapy (PP) group. Ingredients of study drug MR tablet are mandooka parni (*Centella asiatica* Linn), guduchi (***Tinospora cordifolia*** (Wild) Miers), yastimadhu (*Glycirrhiza glabra* Linn) and shankhapushpi (*Evolvulus alsinoides* Linn.). M-group received MR, MP-group with MR and psychotherapy while PP-group given placebo with psychotherapy over 3 months. Stress identified by test anxiety and academic anxiety scores, clinical manifestations and performances were evaluated before, after therapy and after exams. Children suffering from chronic systemic illnesses, developmental disorders, psychiatric illness, post traumatic stress disorder and not willing to participate in the trial were excluded. Results: On statistical analysis using paired and unpaired t test, cross tabs and repeated measures ANOVA, study reveals at par efficacy of trial drug with psychotherapy on clinical manifestations (P=0.000), reducing the stress (P=0.000) for both academic and test anxiety) and hence improving the performance (P=0.000). No adverse reactions documented. MR is effective in management of academic stress and improving academic performance in children.

**132.** Kumar, A. and A. K. Garai (2012). "**A clinical study on Pandu Roga, iron deficiency anemia, with Trikatrayadi Lauha suspension in children.**" Journal of Ayurveda and Integrative Medicine **3**(4): 215-222.

Nutritional iron deficiency is the most common cause of anemia in India. The nearest correlation of iron deficiency anemia (IDA) can be made with Pandu Roga in Ayurveda. As the IDA is a very common prevalent disease in the society and the side effects of oral allopathic iron preparations are very common, therefore to get a better alternative, an Ayurvedic herbomineral medicine, the Trikatrayadi Lauha, was subjected to a clinical trial in children suffering from IDA. Trikatrayadi Lauha suspension is an Ayurvedic herbomineral drug. The trial drug contains herbal drugs like ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***), which is rejuvenative; ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***), which is an appetizer; and Trimada, which is digestive. Herbal ingredients in the trial drug may increase the bioavailability of Mandura bhasma and lauha bhasma which are important contents of the formulation. Aim was evaluation of safety and efficacy of the compound Trikatrayadi Lauha (that also contains *Triphala* and *Trikatu* amon other herbs) suspension in children with IDA. Settings and Design: Randomized, double-blind placebo-controlled clinical study. The study was conducted on 123 children of IDA for a period of 10 weeks. Clinical features and hematological parameters were documented before, during and after treatment. Observations of the study were analyzed and findings were evaluated by using statistical methods (Student's t test).The present study shows that the trial drug Trikatrayadi Lauha suspension is effective to improve clinical features and hematological parameters significantly. The medicine is effective to increase the hemoglobin level 1.94 g/dL (8.52 -10.46 g/dL, P < 0.001) in 5 weeks and 3.33g/dL (8.52 -11.85g/dL, P < 0.001) in 10 weeks. No adverse effect of the trial drug was observed during the study. In conclusions, the results suggest that Trikatrayadi Lauha is significantly effective in the management of IDA in children.

**133.** Kumar, C. U., V. K. Pokuri and U. Pingali (2015). "**Evaluation of the analgesic activity of standardized aqueous extract of *Terminalia chebula* in healthy human participants using hot air pain model.**" Journal of Clinical and Diagnostic Research **9**(5): FC01-FC04.

Pain affects millions of people worldwide, opioid analgesics have been used for chronic painful conditions. Due to their adverse effects, safer alternatives would be beneficial. ***Terminalia chebula***, with proven analgesic action has been evaluated in the hot air pain model for its analgesic activity. To evaluate analgesic activity and safety of single oral dose of *Terminalia chebula* using hot air pain model in healthy human participants. Setting and Design: Randomized, Double blind, Placebo controlled, Cross over study.Materials and Methods: After taking written informed consent to IEC approved protocol, 12 healthy human participants were randomized to receive either single oral dose of two capsules of *Terminalia chebula* 500 mg each or identical placebo capsules in a double blinded manner. Thermal pain was assessed using hot air analgesiometer, to deliver thermal pain stimulus. Mean Pain Threshold time and Mean Pain Tolerance time measured in seconds at baseline and 180 minutes post drug. A washout period of two weeks was given for cross-over between the two treatments. Results: *Terminalia chebula* significantly increased mean pain threshold and tolerance time compared to baseline and placebo. Mean pain threshold time increased from 34.06±2.63 seconds to 41.00±2.99 seconds ($p<0.001$) and mean pain tolerance time increased from 49.67± 3.72 seconds to 57.30±3.07 seconds ($p<0.001$). The increase in mean percentage change for pain threshold time

is 20.42% (p<0.001) and for pain tolerance time is 17.50% (p<0.001). In the present study, *Terminalia chebula* significantly increased Pain Threshold time and Pain Tolerance time compared to Placebo. Study medications were well tolerated.

**134.** Kumar, G., A. Srivastava, S. K. Sharma and Y. K. Gupta (2012). "**Safety and efficacy evaluation of Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) in dyslipidemia patients: A pilot prospective cohort clinical study.**" AYU **33**(2): 197.

Cardiovascular disease has multifaceted in which dyslipidemia, inflammation, and immunity play an important role. Arjuna powder and Arogyavardhini Vati used for centuries has potential for combating these factors. Therefore, the objective of this study was to evaluate the safety and efficacy of Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) for dyslipidemia patients. Total of 108 patients were screened at CGHS Ayurvedic Hospital, New Delhi. It has been used for centuries with claimed efficacy and safety in treatment of jaundice, liver disorders, and various skin disorders. Arogyavardhini Vati consists of ***Terminalia chebula*** (Haritaki), ***Terminalia bellirica*** (Bibhitaka), ***Emblica officinalis*** (Amalaki), Asphaltum (Silajatu-Suddha), *Commiphora wightii* (Guggulu Shuddha), *Ricinus communis* (Eranda), *Picrorrhiza kurroa* (Katuka), leaf juice of *Azadirachta indica* (Nimba) and metals including Shuddha Rasa (purified mercury), Shuddha Gandhaka (purified sulfur), Lauha Bhasma (iron compound in ash form), Abhraka Bhasma (mica in ash form), and Tamra Bhasma (copper compounds in ash form). Ninety-six patients satisfied inclusion criteria, and signed informed consent and detailed medical history was recorded. Arjuna powder (5 g, BD) for 3 weeks and then Arogyavardhini Vati (500 mg, BD) for 4 weeks were prescribed to the patients. The primary efficacy endpoint was reduction in serum total cholesterol, LDL, triglycerides, and increased HDL levels. Secondary endpoints included reduction in serum C-Reactive Protein (CRP) and blood glucose levels. Safety assessments included hepatic function (aminotransferase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), bilirubin, and β2 microglobulin), renal function (urea and creatinine and NGAL) tests, and urine mercury level. The study was completed by 87 patients. The male and female patients were 65.5% (57/87) and 34.5% (30/87), respectively. There was a significant reduction in total cholesterol, LDL, triglycerides, CRP, and blood glucose. However, raised HDL level was also observed. Safety assessment results showed no significant change in serum ALT, AST, ALP and bilirubin, urea, creatinine β2 microglobulin, and NGAL levels at the end of study as compared to the baseline levels. In conclusion, the results of the present prospective cohort study showed that Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) is safe and effective for dyslipidemia.

**135.** Kumar, G., A. Srivastava, S. K. Sharma, T. D. Rao and Y. K. Gupta (2015). "**Efficacy & safety evaluation of Ayurvedic treatment (Ashwagandha powder & Sidh Makardhwaj) in rheumatoid arthritis patients: A pilot prospective study.**" Indian Journal of Medical Research, Supplement **141**(JAN 2015): 100-106.

In the traditional system of medicine in India Ashwagandha powder (***Withania somnifera***) and Sidh Makardhwaj (sublimed product made from pure mercury, sulphur and gold) have been used for the treatment of rheumatoid arthritis. However, safety and efficacy of this treatment have not been evaluated. Therefore, the present study was carried out to evaluate the efficacy and safety of Ayurvedic treatment

respective interventions. The Yoga group showed a significant decrease in the time taken to fall asleep (approximate group average decrease: 10 min, P<0.05), an increase in the total number of hours slept (approximate group average increase: 60 min, P< 0.05) and in the feeling of being rested in the morning based on a rating scale (P<0.05) after six months. The other groups showed no significant change. Yoga practice improved different aspects of sleep in a geriatric population.

**165.** Manohar, P. R. (2012). "**Clinical evidence in the tradition of Ayurveda", In, S. Rastogi (ed.),** ***Evidence-Based Practice in Complementary and Alternative Medicine: Perspectives, Protocols, Problems and Potential in Ayurveda*****.** Springer-Verlag Berlin Heidelberg, pp. 67-78.

A careful study of the classical literature of Ayurveda provides compelling indications to believe that the practice of building clinical evidence was nurtured in the tradition of Ayurveda. Ayurveda exhibits the characteristics of a knowledge system and requires that observations are validated to be accepted as knowledge. The celebrated textbook on general medicine known as the *Charaka Samhita* remarks that the outcome of a clinical intervention is to be dismissed as accidental or due to chance if it cannot be substantiated with proper evidence and reasoning. Classical texts of Ayurveda also discuss about self-limiting diseases and the need to distinguish between the true effect and chance effect of a medical intervention. Classical treatments of Ayurveda are multimodal in nature and cannot be studied using conventional methods of clinical research. Appropriate research designs for both observational studies as well as randomized clinical trials need to be developed for meaningful evaluation of clinical interventions in Ayurveda. This chapter reviews the gaps in the current approaches to clinical research in Ayurveda and highlights the attempts that have been made to develop methodologies that are appropriate not only for Ayurveda but also such other systems of traditional, complementary, or alternative medicine. An elaborate discussion of the classical approach in building clinical evidence in the tradition of Ayurveda will also be attempted in the process.

**166.** Marx, W. M., L. Teleni, A. L. McCarthy, L. Vitetta, D. McKavanagh, D. Thomson and E. Isenring (2013). "**Ginger (*Zingiber officinale*) and chemotherapy-induced nausea and vomiting: A systematic literature review.**" Nutrition Reviews **71**(4): 245-254.

Chemotherapy-induced nausea and vomiting (CINV) is a common side-effect of cytotoxic treatment. It continues to affect a significant proportion of patients despite the widespread use of antiemetic medication. In traditional medicine, ginger (***Zingiber officinale***) has been used to prevent and treat nausea in many cultures for thousands of years. However, its use has not been confirmed in the chemotherapy context. To determine the potential use of ginger as a prophylactic or treatment for CINV, a systematic literature review was conducted. Reviewed studies comprised randomized controlled trials or crossover trials that investigated the anti-CINV effect of ginger as the sole independent variable in chemotherapy patients. Seven studies met the inclusion criteria. All studies were assessed on methodological quality and their limitations were identified. Studies were mixed in their support of ginger as an anti-CINV treatment in patients receiving chemotherapy, with three demonstrating a positive effect, two in favor but with caveats, and two showing no effect on measures