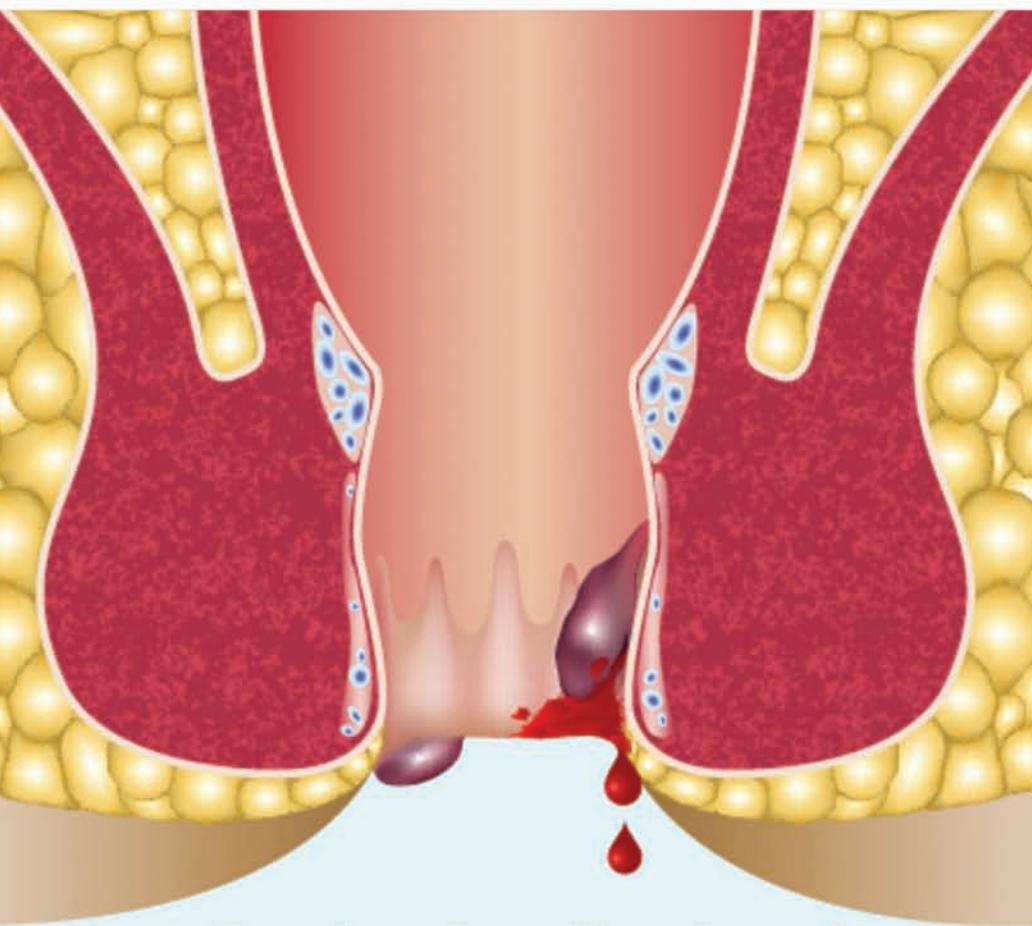


# MEDICINE UPDATE

 Passi HealthCom



**Reviewing the burden  
of haemorrhoids in  
pregnancy: Appraising  
role of Diosmin in  
management**

Volume 31

Number 8

December 2023



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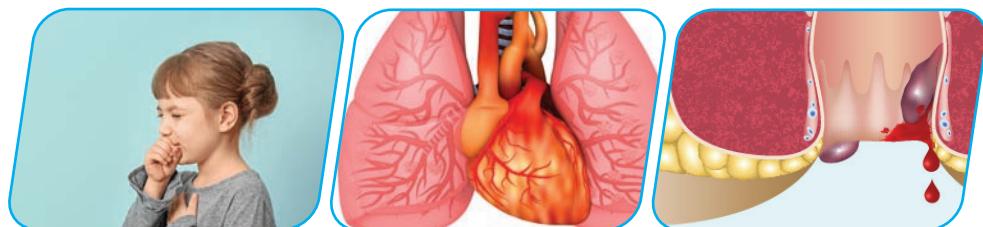
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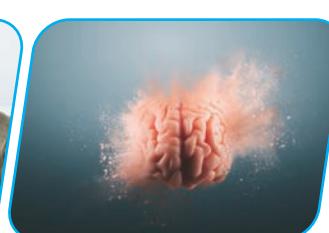
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# EDITORIAL

## Combating psoriatic arthritis with Apremilast

**Dr. Vinay Singh**  
M.D. Dermatology  
Director, Vibrance Skin Laser & Cosmetic Clinic  
President: IADVL DSB 2021

**P**soriatic arthritis (PsA) is characterized by cutaneous manifestation of psoriasis which coexists with arthritis usually in the absence of rheumatoid factor and is known to affect 20 to 30% of such patients. It is known to affect men and women between the ages of 40 and 50 years affecting peripheral and axial joints, entheses, skin, and nails. PsA is associated with comorbidities such as osteoporosis, uveitis, subclinical bowel inflammation, and cardiovascular disease. Though the etiology of PsA is not well understood, it involves the interaction between genetic and environmental factors that leads to immune-mediated inflammation involving the skin and joints and may involve other organs. In patients with psoriasis or PsA wherein patients are already at risk due to genetic risk factors, environmental factors such as infection or mechanical stress initiate a chronic inflammatory process primarily involving the joints and skin, resulting in the production of IL-23 which is a central cytokine in the pathogenesis of PsA and psoriasis.

The conventional therapeutic agents for psoriasis such as methotrexate, acitretin, and cyclosporine are invariably associated with end-organ toxicities and treatment related side effects. High cost and inconvenient modes of administration and along with the possibility



of iatrogenic immunosuppression further degrade their position as a treatment option for psoriasis. Apremilast, a phosphodiesterase-4 (PDE4) inhibitor inhibits PDE4 conversion of cyclic AMP to AMP, thus indirectly downregulating the inflammatory response through decreased inflammatory cytokine expression and increased expression of anti-inflammatory cytokines.

# SECTION 1

## GLOBAL UPDATE

### ASSOCIATION BETWEEN WINTER-TIME AIR POLLUTION AND MORTALITY IN PATIENTS WITH COPD AND THE MODIFYING ROLE OF INDIVIDUAL RISK FACTORS

Air pollution is one of the contributing factor for premature mortality. However, its potential impact differ in populations with existing disease such as COPD including individuals with multiple risk factors. The vulnerability to air pollution is increased in COPD and susceptible to the effect of acute outdoor air pollution. A study was conducted to identify the association between winter-time air pollution and mortality in patients with COPD and the modifying role of individual risk factors. A total of 19,243 veterans with COPD were evaluated. Geocoded addresses were used and individuals were assigned winter-time fine particulate matter (particulate matter [PM] smaller than  $2.5 \times g$  in diameter) and nitrogen dioxide air pollution exposures. Estimations of associations between acute air pollution and mortality were done by using a time-stratified case-crossover design with a conditional logistic model, and assessment of individual risk differences was done according to stratified analysis. Results showed that Estimation of 1.05 as mortality risk for each  $10 \times g/m^3$  increase in daily winter-time PM<sub>2.5</sub>. Additionally, Elevated risk was noted amongst older patients and African-American subjects. Substantial air pollution-related mortality risk factor was obesity. Estimated risk for individuals with obesity plus CAD or obesity plus diabetes was 16% higher.

Winter time PM<sub>2.5</sub> exposure has an association with elevated mortality risk in people with COPD. However, individuals with multiple comorbidities especially obesity, had high vulnerability. This study was also suggestive of obesity, CAD, and diabetes to be understudied modifiers of air pollution-related risks for people with existing COPD.

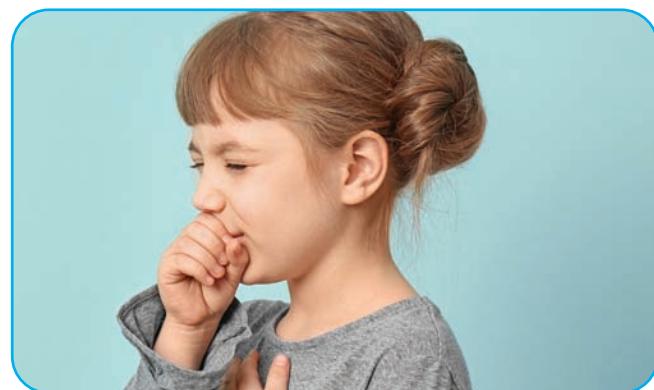
**Source:** Aron J, Baldomero AK, Rau A, Fiecas MB, Wendt CH, Berman JD. Individual Risk Factors of PM<sub>2.5</sub> Associated With Wintertime Mortality in Urban Patients With COPD. Chest. 2023;S0012-3692(23)05642-8.



## EFFECT OF MONTELUKAST COMBINED WITH BUDESONIDE ON INFLAMMATORY RESPONSE AND PULMONARY FUNCTION IN CHILDREN WITH COUGH VARIANT ASTHMA: A META-ANALYSIS

A study was conducted to compare the effectiveness of montelukast (MKST) combined with budesonide (BUD) and BUD alone in the treatment of pulmonary inflammation and pulmonary function in children with cough variant asthma (CVA).

Five electronic databases were searched for 22 studies regarding MKST+BUD therapy and BUD alone therapy on inflammation and pulmonary function in CVA children from inception to November 23, 2021. Results revealed In comparison to BUD alone, the combination treatment could achieve better improvement of pulmonary function and lower levels of inflammation.



Outcome measures	MKST+BUD group (SMD)	BUD alone group (SMD)
FEV1	2.77	1.83
FVC	2.54	1.39
PEF	2.27	1.51
IgE	-7.95	-4.93
TNF-α	-4.67	-2.78
IL-8	-8.18	-4.94

Montelukast and budesonide therapy is more effective in improving pulmonary function and reducing inflammation in CVA children in comparison to budesonide.

**Abbreviations:** FEV1; Forced expiratory volume , FVC; Forced vital capacity , PEF; Peak expiratory flow , IgE; immunoglobulin E , TNF- ; Tumor necrosis factor alpha , IL-8; Interleukin 8

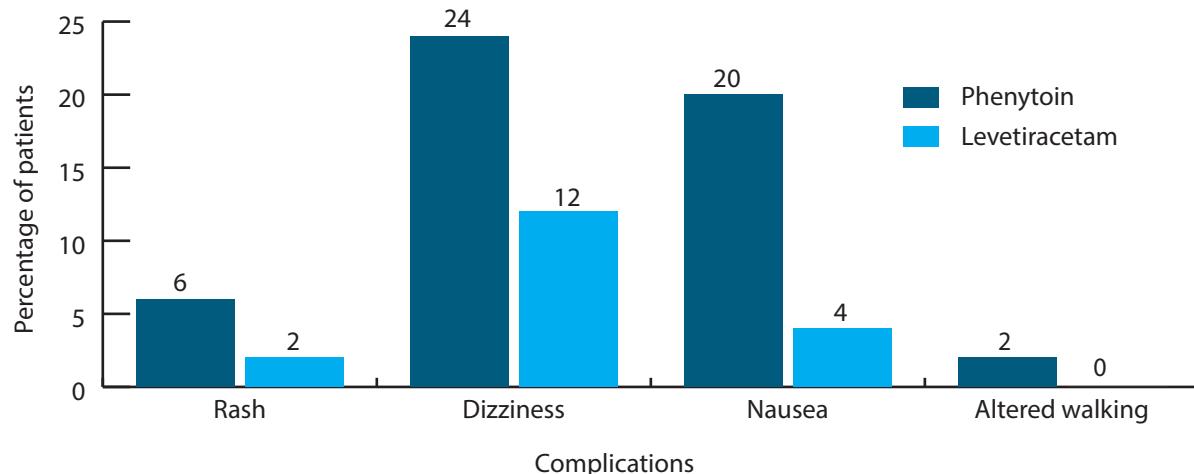
**Source:** Wu Q, Wang L, Wu M, Lin H. Effect of Montelukast Combined with Budesonide on Inflammatory Response and Pulmonary Function in Children with Cough Variant Asthma: A Meta-analysis. J Coll Physicians Surg Pak. 2023;33(9):1040-1049.

## COMPARISON OF PHENYTOIN VERSUS LEVETIRACETAM FOR SEIZURE PREVENTION AFTER TRAUMATIC HEAD INJURY

Levetiracetam and phenytoin are two most commonly used antiepileptic drugs. However, levetiracetam is a unique anticonvulsant because it suppresses inflamed seizures. In addition, it has fewer known side effects and fewer drug-drug interactions than phenytoin, while maintaining good compliance and dosing regimen in terms of cost. Recently, the use of levetiracetam for seizure prevention has increased. This study was conducted to compare the effectiveness of levetiracetam and phenytoin in patients with head injuries and documenting the side effects of both drugs.

A total of 170 patients with acute subdural hematoma [mean age of patient (phenytoin group:  $32.27 \pm 11.31$  years and levetiracetam group:  $33.98 \pm 11.18$  years)] were included in the study and treated with either levetiracetam or phenytoin. Phenytoin was administered as standard at 15–20 mg/kg as a loading dose and 5–8 mg/kg/dose three



**Figure 1: Comparison of safety profile of levetiracetam and phenytoin for seizure prevention after traumatic head injury**

times daily as a maintenance dose. Maximum 400 mg per day. Levetiracetam 10 milligrams/kg/dose was administered in two divided doses with a maximum dose of 3 grams per day and the dose was increased by 10 mg/kg/dose every 2 weeks. The patients were followed up for 2 years. Results showed that both levetiracetam and phenytoin demonstrated comparable efficacy in seizure reduction. Rash was more common in phenytoin-treated patients with 6% vs. 2% in the levetiracetam group. Dizziness was more prevalent in patients treated with phenytoin (24% vs. 12%; Figure 1).

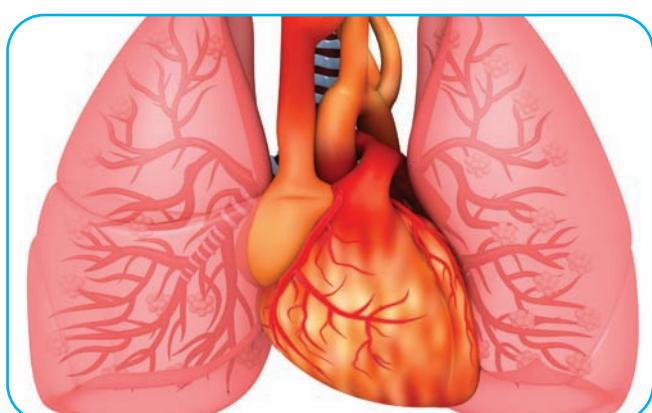
Both drugs are equally effective in preventing seizures after traumatic head injuries, with levetiracetam being better tolerated. Therefore, levetiracetam may be considered as an alternative treatment for seizure prophylaxis.

**Source:** Singh A. A comparison of seizure prophylaxis in traumatic head injury patients: phenytoin versus levetiracetam. *Int J Acad Med Pharm* 2023; 5 (5); 49-53

## ROLE OF SILDENAFIL AMONG ADULT ASIAN PATIENTS WITH PAH

This systematic review and meta-analysis was conducted with the purpose to assess the safety and efficacy of sildenafil [20 mg/three times a day (TID)] for adult Asian PAH patients. This review included 480 adult Asian patients with a diagnosis of PAH and a total of 10 RCTs and non-randomized studies of interventions were included that compared sildenafil (20 mg/TID) versus placebo or symptomatic treatment for adult Asian PAH patients. The results demonstrated that in comparison to symptomatic treatment, patients treated with sildenafil walked 57.68 meters further in 6 MWD, showed an improvement in systemic arterial oxygen saturation, and an increase in the score of the Borg scale for dyspnea. Additionally, in comparison to placebo, sildenafil was associated with a reduction in the mean pulmonary artery pressure and the level of brain natriuretic peptide. Mild adverse effects were noted. This review concluded that sildenafil (20 mg/TID) is effective and well-tolerated in adult Asian PAH patients, and it is associated with statistically significant improvements in exercise capacity, cardio-pulmonary function, and hemodynamic indices.

**Source:** Shi Q, Wang Z, Yang N, Ma Y, Chen Y, Wei H, Yao H. Sildenafil for adult Asian patients with pulmonary arterial hypertension: a systematic review and meta-analysis. *Ann Palliat Med*. 2022;11(1):339-351.



## SECTION 2

### CLINICAL UPDATE

# Reviewing the burden of haemorrhoids in pregnancy: Appraising role of Diosmin in management

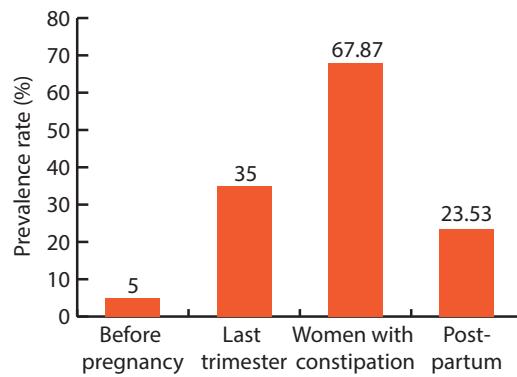
#### HAEMORRHOIDS DURING PREGNANCY: REVIEWING THE EPIDEMIOLOGY

Haemorrhoidal disease is one of the frequently encountered anorectal disorders in clinical practice along with an increased prevalence during pregnancy and postpartum. Clinical data has reported prevalence rates of 5% before pregnancy, 25–35% during the last trimester of pregnancy and around 67.87% in pregnant females with constipation. Prevalence rate has been found to be around 23.53% postpartum (Figure 1).<sup>1,2</sup> In certain populations, upto 85% of pregnancies are affected by haemorrhoids during the second and third trimesters.<sup>3</sup> Likewise, prospective studies have shown one-third of females to suffer from thrombosed external haemorrhoids following delivery with high incidence determined by several risk factors.<sup>4</sup>

#### RISK FACTORS OF HAEMORRHOIDS DURING PREGNANCY

Several risk factors have been thought to contribute to the development of haemorrhoids during pregnancy.

Figure 1: Prevalence rates of haemorrhoids in women during pregnancy and post-partum



Adapted from: Buckshee K, Baxla AP. Emerging trends of Diosmin treatment in haemorrhoids during pregnancy: a review. IOG. 2018;8(1):25-34.

- *Constipation and prolonged straining:* They are widely associated with haemorrhoids as hard stools and increased intra-abdominal pressure have been implicated in causing obstruction of venous return, thus resulting in engorgement of the haemorrhoidal

plexus.<sup>5,6</sup> Multiple factors such as mechanical obstruction due to compression of the lower bowel by the uterus, decreased motility or prolonged transit time in association with smooth muscle relaxation and increase in water absorption from the colon may give rise to constipation during pregnancy.<sup>7</sup>

- **Hormonal factors:** Increased estradiol and progesterone levels may reduce orocecal transit time as well as gastrointestinal motility which in turn can directly promote constipation; moreover, estrogens are associated with enlargement of venous walls. Likewise, progesterone tends to lower the strength of venous wall muscle, decrease circular and longitudinal smooth muscle contractility and slow gastrointestinal transit, thus contributing to constipation and increased predisposition to the development of haemorrhoids. Furthermore, reduced plasma motilin levels, reduced fluid intake, iron supplementation, decrease in physical activity and psychosocial stress may also increase the risk of constipation and hence haemorrhoids.<sup>7</sup>
- **Factors related to labour and delivery:** These include prolonged straining during spontaneous delivery, assisted vaginal births, traumatic delivery, prolongation of second stage of labor, higher birth-weight of neonates and delivery after 40 weeks of pregnancy. Although it remains unclear as to why late delivery is a risk factor for anal disease, it has been suggested that the exposure of perineum to the effects of pregnancy for longer period and prolongation of hormonal effects may be the underlying reasons.<sup>2,7</sup>
- Other risk factors implicated in haemorrhoidal disease include lack of fiber in diet, chronic straining while defecation, spending excess time on the commode, diarrhea, sedentary lifestyle, age, increased BMI, obesity, spicy food, alcohol intake and hereditary factors.<sup>2</sup>

These factors related to pregnancy, delivery, and postpartum period may lead to alterations in normal functioning of the haemorrhoidal cushion, thus resulting in haemorrhoidal symptoms.<sup>5</sup>

## PATOPHYSIOLOGY OF HAEMORRHOIDS DURING PREGNANCY

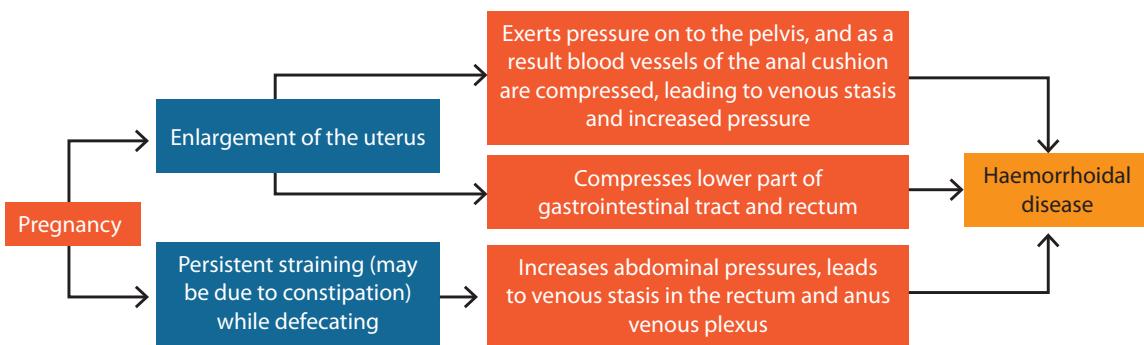
It remains elusive as to what is the exact pathophysiology of haemorrhoids; however, it is thought to be multifactorial. Increased intra-abdominal pressure during pregnancy can result in symptomatic haemorrhoids by causing a

reduction in the venous return from the haemorrhoidal veins which in turn causes an increase in the size of the vascular cushions. Inadequate dietary fiber intake can cause hardening of stools and increased straining, all of which contributes to local tissue trauma and resultant bleeding.<sup>1</sup>

In addition, it has been suggested that previous haemorrhoids recur or exacerbate during pregnancy attributing to the increase in susceptibility of pregnant women to haemorrhoids. Changes in physiological, biochemical and hormonal parameters during pregnancy make mechanical factors, uterus enlargement and diet and lifestyle changes act as facilitating factors for the development of haemorrhoids. Enlargement of the uterus and engagement of head of the fetus in pelvis during the third trimester of pregnancy cause compression of lower part of gastrointestinal tract and rectum, thus preventing the return of blood into larger blood vessels. Furthermore, strained defecation increases intra-abdominal pressure and promotes stasis of blood in the rectum and anal venous plexus, thereby aggravating haemorrhoidal symptoms (Figure 2).<sup>2</sup>

## SYMPTOMS OF HAEMORRHOIDS DURING PREGNANCY

Symptoms of haemorrhoids are suggested to be common during second and third trimesters of pregnancy. Pre-existing asymptomatic haemorrhoids may present with symptoms of bleeding, pain and pruritus for the first time in pregnancy. Clinical manifestations of haemorrhoids in pregnant women are similar to their non-pregnant counterparts and may include painless rectal bleeding; marked prolapse during activity and on increasing intra-abdominal pressure with defecation, sneezing, coughing or walking; mucoid anal canal discharge; chronic irritation from a moist anus with itching; pain in acute thrombosed or irreducible prolapse; feeling of fullness in perineum and anus; tenesmus, and impaired rectal emptying and intestinal function. Symptoms have been reported to be mild and transient in pregnant women; however, these symptoms are associated with impaired quality of life of patients; the associated mild-to-severe pain can make it difficult for patients to carry out daily-life activities. Another common event in pregnancy is dyschezia which is primarily observed in the last 3 months of pregnancy and also in the postpartum period. Patients with dyschezia mostly suffer from thrombosed external haemorrhoids.<sup>7</sup>

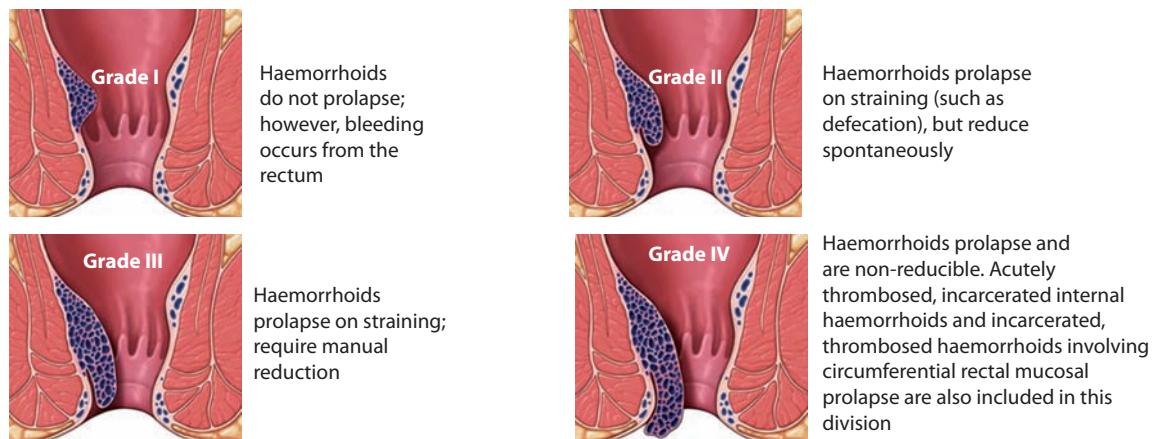
**Figure 2: Pathophysiological mechanisms underlying haemorrhoidal disease during pregnancy**

**Adapted from:** Buckshee K, Baxla AP. Emerging trends of Diosmin treatment in haemorrhoids during pregnancy: a review. *IOG*. 2018;8(1):25-34.

## TYPES OF HAEMORRHOIDS DURING PREGNANCY

Haemorrhoids can be categorized as internal or external depending on their locations; however, mixed types comprising of both internal and external haemorrhoids may also occur together. Internal haemorrhoids are those located above the dentate line and being covered by poorly innervated mucous membrane with columnar epithelium. On the other hand, haemorrhoids found distal to the dentate line, in the zone of the anoderm, and covered by squamous epithelium are referred to as external haemorrhoids.<sup>6</sup>

Internal haemorrhoids do not cause pain although they may be associated with bleeding or they may prolapse. They present with rectal fullness, mucous discharge and dripping of bright red blood. Based on severity, they are categorized into different grades (Figure 3).<sup>2,6-8</sup> On the other hand, external haemorrhoids are characterized by pain, inflammation and tenderness. Prolapsed haemorrhoids may also lead to the development of thrombosis and occasionally gangrene. Hence, careful evaluation and appropriate management of haemorrhoids in pregnancy is essential.<sup>2</sup>

**Figure 3: Grades of internal haemorrhoids**

**Adapted from:** 1) Lohsiriwat V. Hemorrhoids: from basic pathophysiology to clinical management. *World J Gastroenterol*. 2012;18(17):2009–2017. 2) Mott T, Latimer K, Edwards C. Hemorrhoids: Diagnosis and Treatment Options. *Am Fam Physician*. 2018;97(3):172-179.

## CLINICAL EVALUATION OF HAEMORRHOIDS DURING PREGNANCY

Key elements involved in the diagnosis of haemorrhoids during pregnancy include detailed history and physical examination comprising of inspection of anus and anal canal, digital rectal examination and endoscopy. Ruling out other serious causes of rectal bleeding such as inflammatory bowel disease, anal fissure and carcinoma of the colon, rectum, or anus is of paramount importance.<sup>2,7</sup> Extensive investigations for constipation are usually not required during pregnancy. Endoscopy is regarded to be the most definitive diagnostic tool; however, it was earlier thought that endoscopy could lead to complications in the pregnant woman and her fetus either directly from colonic intubation itself or from the use of sedatives. However, the latter can be easily avoided as sedation is not required during assessment of haemorrhoids.<sup>7</sup>

Lower gastrointestinal endoscopy is usually avoided for weak indications in pregnant women and delaying it until after the first trimester or the postpartum period has been supported. However no contraindication for sigmoidoscopy during pregnancy has been reported and it may be particularly useful in pregnant patients with significant lower gastrointestinal bleeding. Performing an unsedated flexible sigmoidoscopy during pregnancy is considered to be quite safe during all three trimesters, provided technologically advanced instruments are used with enhanced monitoring and expertise.<sup>7</sup> Precise history of the pregnancy, presentation and symptoms, prior or current drug use and clinical examination aid in guiding treatment approaches for managing haemorrhoids during pregnancy.<sup>2</sup>

## TREATMENT OF HAEMORRHOIDS DURING PREGNANCY

Management of haemorrhoids during pregnancy is primarily aimed at reducing and relieving symptoms, increasing time duration between attacks as well as preventing complications and relapses without adversely affecting the pregnant woman and her fetus. Individualized approaches should be adopted depending on symptoms, type and severity of haemorrhoids, nature of pregnancy, period of gestation, drug history and patient's preference. Therapeutic approaches comprise of both non-pharmacological and pharmacological strategies.<sup>2</sup>

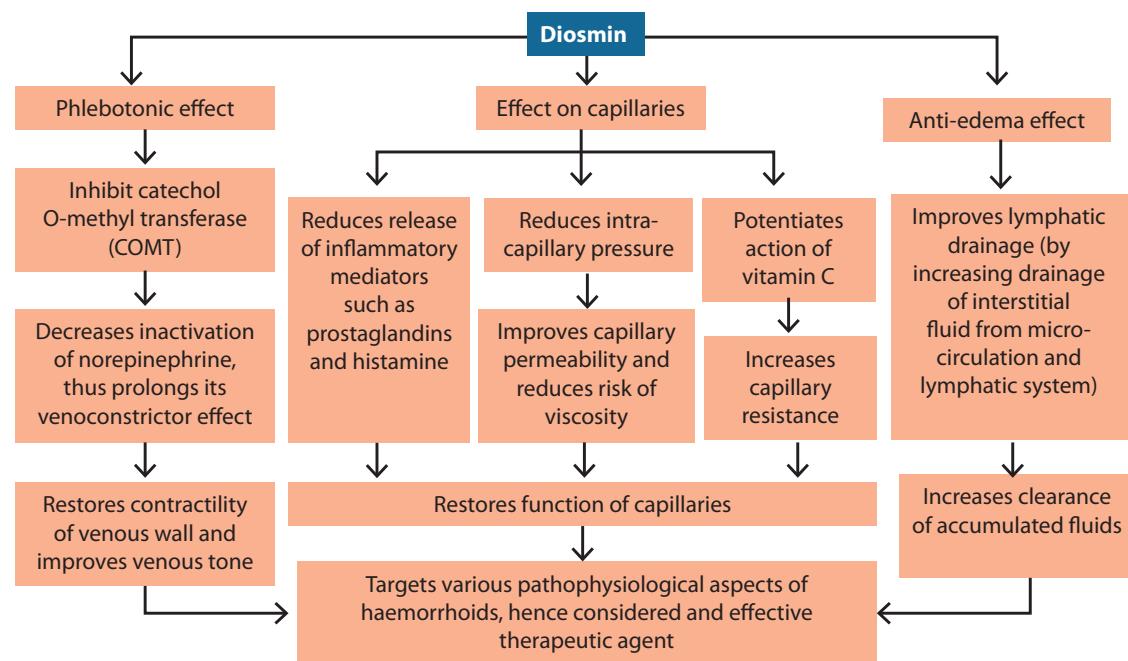
## Pharmacological treatment of haemorrhoids during pregnancy: Role of flavonoid preparations

Pharmacotherapy has been used in the management of anorectal disorders such as haemorrhoids for a long time. Several drugs are being widely utilized in patients with all grades of symptomatic haemorrhoids. They are a major part of the conservative management as well as adjuvant treatment to other invasive procedures. Among pharmacological options, bioflavonoids have gained lot of interest and they are being increasingly used for relief of acute symptoms of bleeding as well as re-bleeding in all grades of haemorrhoids. These agents have been recommended for control of acute bleeding in patients waiting for a definitive outpatient treatment. They are particularly beneficial for haemorrhoid management as they appear to exhibit significant positive effects by enhancing the vascular tone, reducing venous capacity and capillary permeability, facilitating lymphatic drainage and exerting anti-inflammatory effects. Diosmin is one of the bioflavonoids used in the treatment of haemorrhoids.<sup>2,9</sup>

### Diosmin in the management of haemorrhoids: Reviewing its pharmacological properties and mechanism of action

Diosmin is a naturally occurring flavonoid which has been used for more than 30 years as a phlebotonic and vascular-protecting agent. Its utility has been reported in terms of management of several venous diseases such as chronic venous insufficiency and venous ulcers along with haemorrhoids. After oral administration, Diosmin is rapidly transformed by intestinal flora to its aglycone derivative, diosmetin which gets rapidly absorbed and presents with a long plasma half-life of 26-43 hours. Diosmin and diosmetin are then converted to their minor metabolites which are eliminated in the urine as glucuronic acid conjugates. Phlebotonic effect of Diosmin has been shown to be effective in relieving venostasis, reducing capillary permeability and inflammation, reducing capillary fragility, improving its resistance and exerting an anti-edema effect.<sup>2,10</sup>

Clinical rationale for the use of Diosmin in the management of haemorrhoids can be explained by its beneficial role in improving venous tone, venous stasis as well as venous and lymphatic drainage which ultimately results in the reduction of local edema, congestion, inflammation and pain. It has also been shown to

**Figure 4: Mechanism of action of Diosmin in haemorrhoidal disease**

**Adapted from:** Buckshee K, Baxla AP. Emerging trends of Diosmin treatment in haemorrhoids during pregnancy: a review. *IOG*. 2018;8(1):25-34.

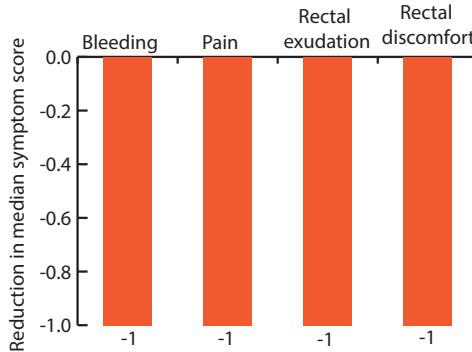
reduce capillary permeability, fragility, and vascular and mucosal erosion. In addition, it acts as a potent inhibitor of prostaglandin E2 (PGE2), thromboxane A2 (TxA2) as well as leukocyte activation, migration and adhesion. Furthermore, a significant reduction in plasma levels of endothelial adhesion molecules and neutrophil activation with Diosmin has also been reported, thus highlighting the molecule's benefits against microcirculatory damage (Figure 4). These effects target different pathophysiological mechanisms of haemorrhoids, thereby proving to be an effective pharmacological agent in the management of haemorrhoids. Diosmin has been subjected to micronization with an objective to enhance absorption, bioavailability, and clinical effectiveness.<sup>2</sup>

### Clinical effectiveness of Diosmin in haemorrhoids during pregnancy

- Clinical evidence suggests that Diosmin can be used as first-line therapy along with diet and lifestyle modifications in normal pregnant women with acute haemorrhoids during the third trimester. Diosmin has been shown to be effective and well-tolerated with clinically relevant benefits in reducing edema and pain along with improving thrombosis<sup>2</sup>

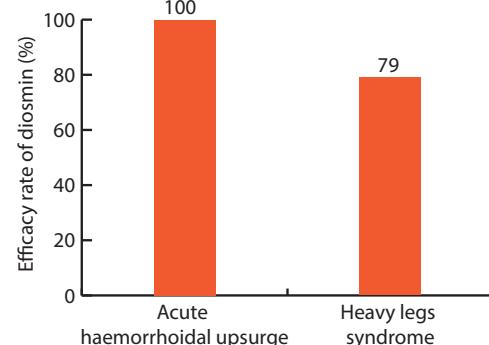
- Data which showed 1.4% of prescriptions of Diosmin to be issued to women subsequently resulted in a normal pregnancy with no reports of adverse effects to either the mother or fetus<sup>11</sup>
- Similar results were obtained in another epidemiological study wherein 24% patients received at least one prescription for venotonic agents during their pregnancy with Diosmin as one of the widely used agents which was found to be safe in late stages of pregnancy<sup>12</sup>
- An open study conducted in pregnant women with haemorrhoids showed micronized Diosmin to be an effective treatment option with 66% patients reporting symptomatic relief by the 4<sup>th</sup> day of treatment as demonstrated by significant reduction in median symptom scores for bleeding ( $p<0.001$ ), pain ( $p<0.001$ ), rectal exudation ( $p<0.05$ ) and rectal discomfort ( $p<0.01$ ) from baseline (Figure 5). Furthermore, relapse occurred in 53.6% fewer patients in the antenatal period and treatment regimen was well-tolerated with no adverse effects on pregnancy, fetal development, birth weight, infant growth and feeding<sup>11</sup>

**Figure 5: Reduction in median symptom score in pregnant women with haemorrhoids receiving Diosmin therapy**



**Adapted from:** Buckshee K, Takkar D, Aggarwal N. Micronized flavonoid therapy in internal hemorrhoids of pregnancy. *Int J Gynaecol Obstet.* 1997;57(2):145-51.

**Figure 6: Efficacy rates of Diosmin in primiparous or multiparous patients in their 2nd and 3rd trimesters of pregnancy**



**Adapted from:** Serment H, Tramier D. Utilisation du Diovenor en obstétrique. *Medit Med.* 1982;273:57-58 (Provided by Walter Bushnell).

- Another study which was conducted in 50 primiparous or multiparous patients receiving Diosmin in their 2<sup>nd</sup> and 3<sup>rd</sup> trimesters of pregnancy showed 100% efficacy rates in terms of acute postpartum haemorrhoidal upsurge and 79% efficacy rate in syndrome of heavy legs of pregnancy (Figure 6)<sup>13</sup>
- In concordance to the above findings, another study showed “good” and “very good” results with 900 mg pure Diosmin among pregnant patients with haemorrhoids and other conditions with chronic venous insufficiency.<sup>14</sup>

These findings helped conclude that micronized pure Diosmin is an effective and well-tolerated pharmacological option in all types of haemorrhoids including haemorrhoids of pregnancy during the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters of pregnancy.

Furthermore, local interventions such as xylocaine-containing topical formulations may be effective for pain relief while surgical interventions may be required in advanced cases.<sup>15</sup>

## CONCLUSION

Haemorrhoids are one of the frequently encountered anorectal disorders in clinical practice along with an increased prevalence during pregnancy and postpartum. Although symptoms have been reported to be mild

and transient with intermittent rectal bleeding and pain, they are associated with impaired quality of life of patients. Treatment goals include reducing and relieving symptoms, increasing time duration between attacks as well as preventing complications and relapses without adversely affecting the pregnant woman and her fetus. Both non-pharmacological and pharmacological strategies have been suggested for management. Drug treatment is considered to be a major part of the conservative management as well as adjuvant treatment to other invasive procedures. Bioflavonoids have gained lot of interest among the pharmacological treatment options due to their clinical benefits in terms of vascular tone improvement, venous capacity and capillary permeability reduction, enhanced lymphatic drainage and anti-inflammatory effects. Diosmin is one of the bioflavonoids with clinical utility in management of haemorrhoids. Micronized pure Diosmin has been considered to be an effective and well-tolerated pharmacological option in all types of haemorrhoids including haemorrhoids of pregnancy during the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters of pregnancy.

For therapy, choosing purest form of Diosmin (100% pure) is must. Diosmin is isolated/extracted from the flavonoid hesperidin. Diosmin containing products are available which may be in combination with hesperidin impurity (Diosmin + Hesperidin and MPFF). Impurities may lead to decreased clinical effects and increased side

effects. As per Pharmacopeia (British Pharmacopeia), only Diosmin is considered as main therapeutic drug/agent. Hesperidin is considered as impurity, whose amount should not exceed beyond 4% and overall impurity of not more than 8.5%.

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# Case report: Successful management of scalp psoriasis with apremilast

## CHIEF COMPLAINT

A 23-year-old man presented to the dermatology department for evaluation of skin lesions which were seen initially on elbows and knees but have now spread to scalp.

## HISTORY

- He has a five year history of skin lesions; he was prescribed topical corticosteroids for 2 weeks but got no improvement
- The lesions were asymptomatic. A review of symptoms including joint pain was largely negative.

## EXAMINATION

### General & dermatological examination

- Physical examination revealed a well-nourished man with red, scaly, indurated papules and plaques involving approximately 0.5% of the body surface area
- A very thin, faintly erythematous, scaly patch associated with relative decrease in hair density of the right frontal and parietal scalp
- Erythematous, scaly plaques with hyperkeratosis without the presence of pustular lesions were present on elbows and knees
- Multiple patches of erythema topped with silvery white scaling were present on the scalp
- His vitals were normal
- He was afebrile and stable hemodynamically
- Systemic examination including cardiovascular, respiratory, gastrointestinal, neurological, lymphatic systems was normal.

## INVESTIGATIONS

- Skin sections reported a heavy neutrophilic crust with both hyperkeratosis and parakeratosis overlying a spongiotic and acanthotic epidermis
- H/E sections reported chronic inflammatory infiltration of lymphocytes and scattered neutrophils in the superficial dermis, typically indicative of psoriasis
- Scalp Physician Global Assessment [ScPGA] score = 5
- PASI score was 22

## DIAGNOSIS

On the basis of findings, he was diagnosed as having psoriasis with scalp involvement

## MANAGEMENT

The patient was put on gradually increasing doses of apremilast starting from 10 mg once a day and building on to 30 mg twice daily.

## RESULTS

- About 1 month after the first hospital visit, apremilast swiftly alleviated his scalp and skin lesions.
- PASI score decreased to 5 post-treatment and ScPGA improved to 1.

## DISCUSSION

### Introduction

Dysregulated immune response leads to a chronic, systemic inflammatory disease known as psoriasis.<sup>1</sup> The most common subtype of psoriasis is plaque



Clinical pictures at baseline



After Apremilast treatment

psoriasis and accounts for about 80–90% of cases. Clinically, scalp psoriasis presents as well demarcated erythematous plaques with silvery white scales. Often, scalp is the most affected region of the body with about 80% of psoriasis cases. Scalp psoriasis requires special consideration because of the difficult-to-treat nature and disproportionate impact on quality of life. In addition to the physical symptoms of dry, cracked skin and pruritus, psoriasis, especially with involvement of the scalp, can lead to significant psychosocial impairment.<sup>2,3</sup> Patients of scalp psoriasis have poor adherence and dissatisfaction with treatment due to the presence of hair, poor accessibility, and unacceptable cosmetic appeal of topical therapy. Thus, treatment regime can be complex and is highly dependent on preference of patients.<sup>2</sup>

## Management

Systemic therapy including oral systemic therapies, phototherapy and/or biologic agents is required to treat moderate to severe psoriasis. Conventional systemic treatments (methotrexate, cyclosporin, acitretin and, in some countries, fumarates) and phototherapy are often the first-line treatments. But the risk of organ toxicity contradicts the long-term use of the classic systemic therapies.<sup>1</sup>

Lately, the advent of biologic agents – humanized monoclonal antibodies with an extracellular mechanism of action that block specific pro-inflammatory cytokines – has revolutionized the management of moderate to severe psoriasis due to their excellent efficacy and tolerability profile. These biologic agents, however, have certain limitations, such as the need for parenteral administration, certain adverse effects, and their high cost.<sup>1</sup>

Above drawbacks have motivated the development and identification of alternative molecules with specific intracellular actions, including apremilast – a specific inhibitor of phosphodiesterase 4 (PDE4). It was approved by the Food and Drug Administration (FDA) in 2014 and by the European Medicine Agency (EMA) in 2015. According to the EMA, apremilast is indicated for the management of :-

- Moderate to severe plaque psoriasis in adult patients who have not responded to, have contraindications to, or cannot tolerate other systemic treatments
- For the treatment of psoriatic arthritis.

## Mechanism of action of apremilast

In presence of group of enzymes called adenylate cyclases, adenosine triphosphate (ATP) converts into cyclic adenosine monophosphate (cAMP) (second messenger). Levels of cAMP are also controlled by the action of PDEs, a family of enzymes that degrade intracellular cAMP. As a second messenger, cAMP regulates multiple signaling pathways, including the activation of protein kinase A (PKA). The increase in cAMP concentration favors the activation of PKA, which on the one hand phosphorylates and activates various transcription factors, such as cAMP-response element binding protein (CREB) and activating transcription factor-1 (ATF-1); and, on the other hand, phosphorylates and indirectly inhibits nuclear factor Kappa B (NF- $\kappa$ B) by blocking tyrosine kinases, such as mitogen activated protein kinase (MAPK). This intracellular signaling by PKA regulates cell maturation processes and promotes the synthesis of anti-inflammatory signals that inhibit the production of inflammatory mediators.<sup>1</sup>

Apremilast is a small-molecule inhibitor of PDE4 with an intracellular mechanism of action that increases levels of cAMP expressed by immune cells. PDE inhibitors, such as apremilast, promote the maintenance of high concentrations of intracellular cAMP.

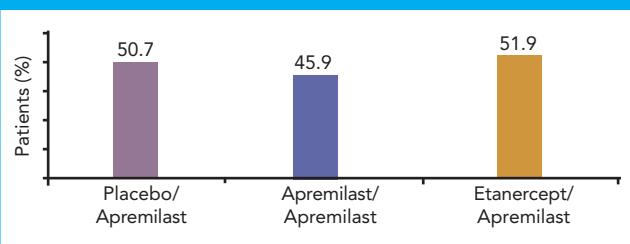
In dendritic cells, the PDE4 inhibitors suppress the release of pro-inflammatory cytokines and increase the production of anti-inflammatory mediators, which regulate the T-cell response by suppressing Th1-type responses.

In T cells, high levels of cAMP favor the differentiation of Th2 lymphocytes and suppress the differentiation and cytotoxic activity of T-CD8+ lymphocytes.<sup>1</sup>

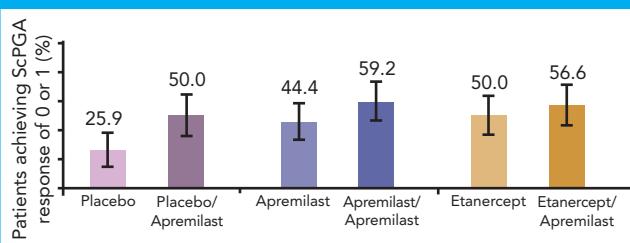
## Clinical evidence

- K Reich and colleagues conducted a study<sup>4</sup> to evaluate long-term efficacy and tolerability of apremilast in biologic-naïve patients with moderate to severe plaque psoriasis and safety of switching from etanercept to apremilast in the phase 3b LIBERATE trial.
- In this study, 250 patients were randomized to placebo, apremilast 30 mg BID or etanercept 50 mg QW through Week 16; thereafter, all patients continued or switched to apremilast through Week 104 (extension phase). The findings were as follows:
- The apremilast-extension phase (Weeks 16-104) included 226 patients divided into the placebo/apremilast ( $n = 73$ ), apremilast/apremilast ( $n = 74$ ) and etanercept/apremilast ( $n = 79$ ) groups, and at Week 104, 50.7%, 45.9% and 51.9% of these patients, respectively, maintained  $\geq 75\%$  reduction from baseline in PASI score (based on last-observation-carried-forward analysis) (Figure 1)
- Across treatment groups, ScPGA 0 (clear) or 1 (minimal) was achieved by up to 59.2% of patients (Figure 2)
- Also, NAPSI mean change from baseline was -48.1% to -51.1%
- DLQI score  $\leq 5$  was achieved by 66.0%-72.5% of patients; and pruritus VAS mean change from baseline was -24.4 to -32.3. AEs in  $\geq 5\%$  of patients (diarrhoea,

**Figure 1: Patients showing improvement in PASI score at week 104**



**Figure 2: ScPGA Response**



nausea, nasopharyngitis, upper respiratory tract infection and headache) did not increase with prolonged apremilast exposure.

## CONCLUSION

In light of available evidence, it is demonstrated that prolonged apremilast treatment is effective and shows sustained improvements in skin, scalp, nails and pruritus and quality of life in patients with moderate to severe plaque psoriasis. Moreover, safety is consistent with the known safety profile of apremilast.

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# Role of radiography in foreign body aspiration

## OVERVIEW

- Foreign body (FB) ingestion is a common presenting complaint in pediatric patients<sup>1</sup>
- Infants and young children between the ages of 6 months and 3 years lack molar teeth, have uncoordinated swallowing mechanisms, and, most importantly, engage with their surroundings by placing objects in their mouths, thus they are vulnerable to foreign body aspiration<sup>2</sup>
- FBs such as coins, toy parts, jewellery pieces, and button-type batteries are commonly ingested by children<sup>1</sup>
- Fortunately, 80–90% of ingested foreign objects that reach the stomach pass through without incident
- The remainder may become obstructed in the esophagus or another region of the alimentary tract, putting the pediatric patient at risk of serious complications such as aspiration, obstruction, bleeding, perforation, fistulisation, sepsis, and death
- The initial pediatric patient assessment aims to determine the type of object ingested, its location in the body, and the presence of any associated complications.<sup>1</sup>

## RADIOGRAPHY IN FOREIGN BODY ASPIRATION

### Chest X-rays

- Chest X-rays are among the most common radiological investigations performed on children in both inpatient and outpatient settings, and accurate interpretation is required to guide management<sup>3</sup>
- Plain radiographs play an important role in assessing

ingested FBs in pediatric patients. They are very useful in confirming the diagnosis of FB ingestion because most ingested FBs are radiopaque<sup>1</sup>

- When an FB has been swallowed, anteroposterior and lateral neck, anteroposterior and lateral chest, and abdominal radiographs should be obtained to perform a thorough examination and rule out the presence of an ingested FB
- Because some FBs, particularly those of discoid shape, cannot be identified in a single projection, lateral and anteroposterior radiographs are important<sup>1</sup>
- Because most aspirated FBs are radiolucent, radiographs are normal. The radiopacity of an FB affects its radiologic visualisation
- Many objects, including meat, tiny bones, aluminium, glass, plastic, and wood, may be radiolucent and thus not visible on plain radiographs<sup>1</sup>
- Despite the fact that only 10% of aspirated foreign bodies are radiopaque, indirect signs of aspiration such as air trapping, focal airspace disease, pleural effusion, mediastinal shift, pneumothorax, or subcutaneous emphysema are important imaging surrogates
- The most common indirect sign of aspiration is unilateral hyperinflation. This finding should be followed up with bilateral decubitus radiographs to rule out air trapping with the side of foreign body aspiration failing to deflate in the dependent position
- However, lateral decubitus radiography has only 68–74% sensitivity and 45–67% specificity. As such, negative chest radiography in the setting of high clinical suspicion should prompt further evaluation with computed tomography.<sup>2</sup>

## TRACHEAL VERSUS ESOPHAGEAL FOREIGN COINS: DIAGNOSTIC DILEMMA

Anteroposterior (AP) and lateral chest X-rays can help to confirm the diagnosis of a coin lodged in the esophagus. Esophageal coins align so as to appear as a circular disc (en face) on the AP view and as a thick line (on edge) on the lateral view. On the other hand, coins lodged in the trachea align to appear on edge on the AP view and en face on the lateral view.<sup>4</sup>

### Esophagus

A radiopaque foreign body (coin) lodged at the proximal portion of the thoracic esophagus



Anteroposterior view



Lateral view

### Trachea

A radiopaque foreign body (coin) lodged in the trachea



Anteroposterior view



Lateral view

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# SECTION 3

## MEDICAL QUIZ



**Q1. Which of the above describes how patients who have features of both asthma and COPD compare with those who have asthma or COPD alone?**

- A. Slower decline in lung function
- B. More frequent exacerbations
- C. Fewer comorbidities
- D. Better quality of life

**Q2. According to GOLD/GINA descriptions, by what is asthma-COPD overlap best identified in clinical practice?**

- A. Chronic airway inflammation
- B. A history of respiratory symptoms that vary over time and in intensity, together with expiratory airflow limitation
- C. The features it shares with both asthma and COPD
- D. Persistent respiratory symptoms

**Q3. A 63-year-old man visits your office because he has dyspnea. He says that for the past 2 months he has had some shortness of breath when walking upstairs. He has an extensive smoking history of 45 pack-years. What medication could you start for this patient to help alleviate his symptoms?**

- A. A SABA as needed
- B. An ICS
- C. A LABA/LAMA combination
- D. Triple therapy with ICS/LABA/LAMA

**Q4. A patient with COPD currently on triple therapy (ICS/LABA/LAMA) has done well for the past year and has had no COPD exacerbations. She visits your clinic for a check-up. What recommendation could be considered for this patient?**

- A. Stop triple therapy and switch to a SABA
- B. Step down to dual therapy (LABA/LAMA) by stopping the ICS
- C. Stop triple therapy and switch to oral steroids for any exacerbations
- D. Add an antibiotic to the regimen

**Q5. What is the best diagnostic tool for asthma-COPD overlap?**

- A. Spirometry
- B. Nitric oxide
- C. Taking detailed history
- D. A & B

# SECTION 4



## EVENTS UPDATE

### AMERICAN UROLOGICAL ASSOCIATION'S 2024

3<sup>rd</sup>-6<sup>th</sup> May, 2024  
San Antonio, Texas

### USICON 2024, ANNUAL CONFERENCE OF THE UROLOGICAL SOCIETY OF INDIA

1<sup>st</sup>-4<sup>th</sup> February, 2024  
Patna, Bihar (India)



### 2024 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING

31<sup>st</sup> May-4<sup>th</sup> June, 2024  
Chicago, Illinois

### 39<sup>th</sup> ANNUAL EAU CONGRESS (EAU24)

5<sup>th</sup>-8<sup>th</sup> April, 2024  
Paris, France

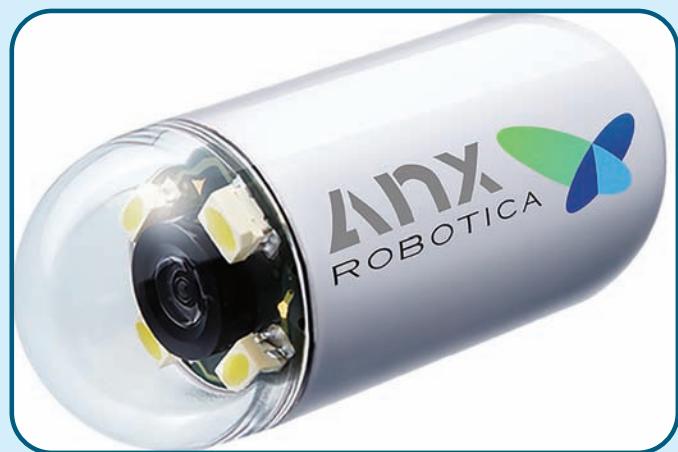
# SECTION 5

## TECH UPDATE

### RESEARCHERS HAVE CREATED A SWALLOWABLE VIDEO CAPSULE TO ASSIST IN IDENTIFYING LESIONS IN THE STOMACH SURGICAL PATCH TO DETECT INTESTINAL LEAK POST GASTROINTESTINAL SURGERY

Though endoscopy is an important diagnostic tool for wide variety of health issues, ranging from gastrointestinal ulcers and bleeding to cancer, it is an invasive procedure for patients and poses a significant financial burden due to the need for anaesthesia and time off work. One of the researchers at George Washington University stated that it therefore became imperative to opt for less invasive ways to visualize the upper gastrointestinal tract for patients with suspected internal bleeding so as to overcome the hurdles faced by traditional endoscopy. Researchers thus created a swallowable capsule containing a video camera that can record video feed of the stomach lining and thus could assist in identifying lesions in the stomach. It is different from other similar devices that have been developed previously, as this capsule can drive around the stomach under the control of a clinician. This allows it to thoroughly navigate and screen the entire area to identify any health issues in the stomach mucosa, such as ulcers or bleeding. The technology requires an external magnet to be placed near the stomach, and the clinician can use a joystick, just like with a video game, to control the movement of the capsule. It is being a ray of hope that the technique will provide a replacement for more invasive approaches, such as conventional endoscopies. If larger studies can prove this method is sufficiently sensitive to detect high-risk lesions, magnetically controlled capsules could be used as a quick and easy way to screen for health problems in the upper GI tract such as ulcers or stomach cancer.

**Source:** Video Capsule Navigates the Stomach. Available at: <https://www.medgadget.com/2023/06/video-capsule-navigates-the-stomach.html>. Accessed on: 20.12.2023



# SECTION 6

## LEGAL UPDATE

### Medicolegal aspects of burn injuries

#### OVERVIEW

Burn injuries constitute a serious medical, psychological and public health problem. Burn injuries are the fourth common type of trauma in the world; the incidence is estimated to be around 265000 deaths per year. In India, approximately 70 lakh people sustain moderate-to-severe burns annually; with more than 7 lakh burn injuries requiring admission.<sup>1-3</sup> A major concern in the Indian context is the increasing incident of burn injuries amongst married women since it has become persistent throughout all social geographical strata. It is said that burn accidents usually take place due to failure to prevent them. Intriguingly, this trauma has an element of suspicion of a crime added to it in many incidences. A treating physician has the responsibility of informing such accidents to legal authority. The medicolegal investigation in deaths due to burns helps in the determination of manner and cause of death, and the nature of burn injuries.<sup>14</sup>

#### BURN INJURIES IN A MARRIED FEMALE

Burns constitute an extreme form of violence against women. Growing evidence has suggested the highest incidence of homicidal and suicidal burns in developing countries. The incidence of death or extensive injuries of young unmarried and married woman by burns is more common in subcontinent, which is usually associated with dowry disputes, unless proved otherwise with circumstantial evidences. If the married life at the time of

mishap is less than 10 years, then the police investigation becomes stringent and is under a senior officer of rank not less than a deputy commissioner. Death in such cases would be governed by section 304B of Indian Penal Code which specifies dowry deaths and can lead to imprisonment ranging from 7 years to life.<sup>4,5</sup>

#### SOCIAL, MORAL, AND LEGAL RESPONSIBILITY

Code of Criminal Procedures in section 39 asks every citizen to inform the police of any incidence which has harmed any human being. Except as required in section 39 of the Criminal Procedure Code, the need of informing the police in case of a suspicious burn injury is a social as well as a moral responsibility. Therefore, for treating physicians, informing the police is an extension of their duty as a citizen. The following situations are required to be informed to the police:<sup>4,6</sup>

- All major burns when received
- Unexplained severity, not corresponding to the history or circumstances
- Patients received after several days of burns
- Patients received without proper treatment
- Patients likely to succumb to the injury
- Patients received dead
- Mass casualties.

Usually, when a patient succumbs to the injuries, a certificate of death is needed to be issued. This certificate has to specifically mention a cause of death.

**Box 1: Compensations for burn victims<sup>4</sup>**

- Payment for treatment (past and future)
  - Hospitalisation
  - Surgical procedures
  - Ongoing medical cares
  - Counselling
  - Scar revisions – cosmetic surgery
  - Physical therapy
  - Occupational therapy
- Compensation for loss of income – past and future
- Vocational rehabilitation (job retraining)
- Compensation for pain and suffering that they have endured and may continue to endure as a result of their injury
- Loss of consortium
  - A novel concept for Indian Judiciary
  - The spouses of a burn survivor may be entitled to compensation when an injury is so severe that it interferes with the injured party's spousal relations.
  - Many courts recognise the right of the injured party's spouse to recover in an appropriate case for a loss of support, services, love, companionship, society, affections, sexual relations and solace in the form of a loss of consortium action.

This underscores the need for a medicolegal post-mortem, particularly when the treating doctor is not certain about the cause of death. Therefore, doctors engaged in management of burn patients in India need to keep themselves abreast with the legal requirements. Of late, concept of the legal rights of burn survivor

and the family are emerging in India. Doctors can help their patients by imparting important information such as demarcation between physical impairment status and disability with pertinent details about Workmen's compensation act, Persons with disabilities act and guidelines for calculation of physical impairments.<sup>4,6</sup>

## **LEGAL RIGHTS OF BURN SURVIVORS TO COMPENSATION**

A burn victim is entitled to various forms of compensation depending upon the existing legal and social support, and based on the cause of the burn injury. The compensatory damages compensate the injured person for various kinds of losses or damages, such as current medical expenses, lost wages, likely future medical expenses, likely future loss of wages, mental or emotional pain and suffering, disfigurement, and any physical or mental impairment or disability (Box 1).<sup>4</sup>

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