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Review Article

Evaluation of pharmacological and non–pharmacological methods of smoking cessation; A Review

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Abstract

Objective: Tor review the pharmacologic and non-pharmacological therapies of smoking cessation.

During recent years, there have been many advances in different types of pharmacological and non-pharmacological tobacco cessation treatments. This paper reviews the established pharmacological methods such as nicotine replacement therapy (NRT) (patches, gum, sublingual tablets, lozenges, inhalers and nasal spray) and drugs such as Bupropion and Varenicline and non–pharmacological methods such as counselling and yoga (Sudarshan kriya, Kapalbhati, Anuloma-viloma and Bhramari pranayama).

Introduction

Smokers try to quit once every 2 to 3 years, and are most likely to fail because they do not use tested quitting strategies. Smoking tobacco is the process of burning tobacco and either tasting or inhaling the vapor. The practice began as early as 5000–3000 BC. Tobacco consumption is the most common smoking form and the most common smoked substance is nicotine [1].

Globally, over the same period, male tobacco use had risen by around 40 million, from 1.050 billion in 2000 to 1.093 billion in 2018 (or 82% of the world's current 1.337 billion tobacco users). Smoking has a serious effect on almost every organ in the body. Smoking tobacco can contribute to many short- and long-term health effects, including lung and other organ cancers, chronic bronchitis, emphysema, stroke, and heart attack. According to the World Health Organization, tobacco smoking accounts for 90% of all lung cancer cases and 90% of all deaths from chronic obstructive pulmonary disease (COPD). Second-hand smoke contains hundreds of substances that are responsible for illnesses such as respiratory disorders, cancer and cardiovascular disease. Combustible chemicals found in tobacco smoke via mechanisms involving DNA damage, inflammation, and oxidative stress are responsible for diseases such as cancer, cardiovascular disease, and pulmonary disease. Second-hand smoke is impacting more women and children than men worldwide [2].

While conventional methods for preventing relapse may

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be somewhat unsuccessful, alternative therapies such as yoga and intensive care therapy are increasingly recognized for their ability to improve addictions rehabilitation, in part through managing cognitions, feelings, and actions related to stress. Tobacco can be smoked (such as cigars, beedies), chewed (such as gutka, khaini, etc.) and snuffed. The presence of nicotine means that cigarettes and other forms of tobacco are addictive [3].

The effect of Tobacco on body

Effects like arousal or relaxation, enhanced concentration, vigilance, appetite suppression are seen on CNS. Hematologically there is increase in platelet adhesiveness, CVS effects include increase in heart rate, cardiac contractility, increased blood pressure, cutaneous vasoconstriction, systemic venous constriction, increased muscle blood flow and release in catecholamine and change in endocrine system include increase in growth hormone and inhibition of prostacyclin synthesis [4].

Nicotine – A Stimulant

Nicotine, the chemical which makes tobacco users addicted, is a stimulant with similar properties to those of cocaine and amphetamines. This gives the feeling of being pick-me-up that tobacco users get. This increases heart rate, blood pressure, and breathing rate, making users feel more alert. Sadly after twenty minutes or so these benefits wear off, and the consumer of nicotine is left with a craving for another pick-me-up. Chronic usage affects the structures of the brain (locus ceruleus); noradrenergic cells become more thrilling. When a person stops firing rates become abnormally high, triggering symptoms of withdrawal such as feeling stressed and irritable, concentration problems, sleep disturbance, headaches, digestive distress, etc. It is now understood that the role of nicotine in the compulsive use of tobacco products exceeds the role of cocaine, ethanol and morphine [4].

Other products

Acetaldehyde & carbon monoxide: Acetaldehyde has some sedative effects as a tobacco smoke by-product. Cigarette carbon monoxide makes people feel sluggish, just as they do not ventilate in a stuffy environment. These chemical compounds tend to wash certain people's feelings of fear, anger or intense emotion [4].

Other psychological effects: Conditioning takes place over many years of exposure to environmental stimuli, which cause the consumer to want a cigarette or other types of tobacco. By consuming tobacco people learn to manage their emotions. For many, the smoking or self-chewing acts as a pause in one's work, light up, exhale a certain way-becoming a soothing ritual in itself. Tobacco use may go hand in hand with other activities such as morning toilet rituals, drinking tea or alcohol or after-meal relaxation [4].

Stages of development of addiction

1. Forming Attitudes and Beliefs about Tobacco

2. Trying Tobacco

3. Experimenting with Tobacco

4. Regularly Using Tobacco

5. Becoming Addicted to Tobacco

This whole process of tobacco addiction generally takes about 3 years. Attempts to stop may lead to craving, withdrawal symptoms and high rates of relapse [5].

Pharmacological approach

Nicotine replacement therapy: Nicotine Replacement Therapy (NRT) is used in tobacco users to alleviate withdrawal symptoms while trying to stop. It has to be made very clear, though, that NRT alone is not the solution. Modification of behavior is an important aspect of any change in behaviour, in particular cessation of tobacco. Having NRT means individuals may concentrate on the mental aspects of leaving without experiencing severe symptoms of withdrawal. Nicotine replacement therapy is gradually reduced after the acute withdrawal period, so that there should be no withdrawal [4].

In a study done by Shahab et al. in London (2014) which aimed to estimates use of NRT and associated nicotine exposure among smokers, recent and longer-term ex-smokers in England, a country with a permissive regulatory regime for nicotine substitution. Between November 2006 (the survey start) and July 2011 (when follow-up saliva collection was paused), 21,821 current smokers and recent ex-smokers at baseline agreed to be followed up. Of these, 5,539 responded at 6 months follow-up. Seventy-two participants (1.3%) were excluded due to missing information on NRT use or smoking status which resulted in a response rate of 25.1% and a total analytic sample of N=5,467, of whom 29.5% (N=1,614) also provided saliva. The author concluded that mutual use of nicotine replacement during smoking is very uncommon and not associated with higher nicotine intakes. NRT use is popular for ex-smokers in short but not longer periods, and is associated with lower nicotine consumption in long-term customers than in smokers [6].

Further, in a study by Tønnesen et al. (2006) in Denmark, 5,587 patients with mild COPD showed that repeated smoking cessation for a period of 5 years resulted in a quit rate of 37%. After 14.5 years the quitters had a higher lung function and a higher survival rate. A study with a new nicotine formulation, a mouth spray, showed high relative efficacy. As 5–10% of quitters use long-term NRT, we report the results of a study where varenicline compared with placebo increased the quit rate in long-term users of NRT. Smoking cessation is the most effective intervention in stopping the progression of COPD, as well as increasing survival and reducing morbidity. This is why smoking cessation should be the top priority in the treatment of COPD [7].

In a Canadian study by Kasza et al.(2013), it was found that lower expired baseline CO rates and a longer degree of pharmacological treatment remained, important predictors of

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successful smoking cessation A total of 7436 adult smokers (18+ years) were selected via random digit dialling and interviewed as part of the International Tobacco Control Four Country Survey (ITC-4) between 2002 and 2009 [8]. These findings are in agreement with the Ontario study Zhang et al.(2015) which showed that the majority of the people (86%) using NRT to quit smoking. Users of NRT have been smoking extra cigarettes per day and had strained to quit more often in the past compared with persons who did not use NRT [5]. In the research carried out by Savant et al. in Pune, India, tobacco abstinence rate was also found to be very small in the counseling groups alone (individual and group counseling), and the individual counseling group was reduced by 6% compared with 7.5% in the group counseling after 6 months [9].

Pharmacokinetics of nicotine replacement therapies

Due to the large absorption surface of the lungs and the direct delivery of nicotine to the brain through the pulmonary arteries and heart carotid circulation, the bioavailability of nicotine by cigarette smoke inhalation is close to 100 percent.

NRTs 'bioavailability of nicotine is much lower than that of cigarette smoke. The transdermal patch device, depending on the brand, offers continuous nicotine release for 16 to 24 hours. By contrast, oral formulations (i.e. buccal absorption) are short acting, the dose can be self-titrated and, therefore, time-adjusted according to the patient's needs. Therefore, when nicotine cravings arise, oral NRTs provide smokers with a coping strategy.

Since the delivery systems available do not recreate the rapid increase and high arterial plasma and brain concentration of nicotine produced by cigarette smoke inhalation, NRTs only partially remove withdrawal symptoms [4].

Nicotine gum

The gum, which is available in India, contains 4 mg of nicotine which can be released by chewing from a resin. Scheduled dosing (e.g., 1/2 piece of 4-mg of gum per hour) and 4-mg of gum for strongly nicotine-dependent smokers is more effective, but 1/2 piece of gum has also been used in response to cravings. The gum produced in India comes in two varieties-a Gutka flavored one for pan paraag and guthka users and a mint flavored one for smokers. Treatment period is 4-6 weeks; weaning starts after 2-3 months [4].

Nicotine patch

The transdermal formulations take advantage of nicotine ready for absorption across the skin. Two of the patches are for use in 24 hours, and one for use in 16 hours (waking). The initial doses are a patch of 21-22 mg/24 hours, and a patch of 15 mg/16 hours. Patches are applied every morning, beginning after smoking has stopped. Nicotine is gradually absorbed by patches, so that the rates of venous nicotine increase 6-10 hours after administration on the first day [4].

Non-nicotine agents: anti-craving medications

Bupropion Hydrochloride Sustained Release tablets

Bupropion (an antidepressant) was used along with NRT as a firstline therapy to treat nicotine dependency. Bupropion's popularity doesn't seem to be because of its antidepressant effects.

The exact mechanism by which bupropion acts is not understood, but it is believed to minimize nicotine-related cravings by affecting noradrenaline and dopamine, two chemicals in the brain that may be key components of the pathway of nicotine addiction [4].

Varenicline

Varenicline has high and selective alpha-4 and beta2 receptor activity. It is an in vivo partial agonist with less reaction than nicotine (30%-60%), but blocks the influence of any nicotine added to the system. It activates the central mesolimbic nerve network, the neural mechanism through which smoking is stimulated and rewarded. Varenicline thus retains a mild dopamine release, reducing symptoms of craving and withdrawal during abstinence. It also prevents enhancing effects of cigarette smoking nicotine in the case of relapse [10-12]. Varenicline is the non-nicotine containing medication developed with the purpose of treating nicotine addiction. Treatment begins 1-2 week in advance of the date of withdrawal. Doses of 0.5 mg per day for the first 3 days and up to 0.5 mg twice a day on the fourth day are administered until the 7th day. Twice daily up to the end of 12 weeks, the dosage is further increased on 8 days up to 1 mg. An additional 12 weeks of therapy with 1 mg twice daily is recommended to avoid relapse [13].

Selegeline hydrochloride

Increases in dopamine levels are believed to play an important role during abstinence in both the smoking incentive and withdrawal symptoms. Medicines that modulate dopamine levels can have beneficial effects on both the rates of withdrawal symptoms and the abstinence reaction to smoking lapses [4].

Nortriptyline

The other antidepressant that tends to improve cessation is nortriptyline, a tricyclic antidepressant that has more noradrenergic effects, and little dopaminergic activity.

Two published studies indicate that nortriptyline improves rate of cessation, an effect apparently unrelated to depressive symptoms. Side effects of nortriptyline include anticholinergic symptoms, nausea and sedation [4].

Cytisine

Cytisine (Cytisus laburnum) is an alkaloid. As per literature available during World War II, the leaves of Cytisus laburnum were used by smokers as a substitute [14]. All parts of this plant contain the alkaloid cytisine, but the largest quantity (up to 3%) is found in seeds [15]. Cytisine has a molecular structure similar to that of nicotine and acetylcholine and is an agonist of nicotinic receptors; in particular, cytisine has a high affinity for nicotinic receptors.

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It is a nicotinic partial agonist that binds to a variety of different sub types of neuronal nicotine receptors, including receptors made up of alpha-4 and beta-2 subunits, which are considered essential to the reward pathway effect of nicotine. Owing to its high receptor affinity, Cytisine prevents other ligands, including nicotine, from being bound to it ,but once bound to the receptor its effect is much less than that of nicotine [16]. The dependence on nicotine can be decreased through this drug interaction and nicotine withdrawal symptoms can be decreased but not be addictive directly or have positive impact [17,18] .

Patients asked to take six 1,5 mg tablets, one every 2 hours for their first 3 days, followed by five 4–12 tablets (one every 2.5 hours), 13–16 (each 3 hours), 17–20 day tablets (every 4 hours), and 2 tablets for 21-25 days (each 6 hours) for a total of 100 tablets [19].

Clonidine is an alpha 2-noradrenergic agonist that suppresses emotional activity: used for anxiety, removal of the alcohol and opiates. In eight of nine trials, clonidine improved smoking cessation both as pills and as a patch in low doses (usually 0.2-0.4 mg per day) [4].

Other antidepressants: Imipramine, which has both noradrenergic and serotonergic effects, did not improve the cessation of smoking but a smaller study indicated that doxepine, which has similar neurochemical effects, improved the cessation of smoking in the short term [4].

E Cigarettes

Electronic cigarettes (e-cigarettes) are novel devices that simulate aspects of cigarette smoking and deliver nicotine to users. ECs provide a variety of battery inhalation devices able to deliver nicotine into the cloud of aerosol created by heating a fluid mix of propylene glycol, vegetable glycerol, water, ethanol, nicotine and other additives. The aerosol is produced through a thermal belt that is triggered by the user when the mouthpiece is suctioned, or the user presses a button [20-22]. Inhalation and exhalation of the vapor by the EC user is known as a 'vaper [15].' The aerosol is tobacco smoke, but it is not continuously created and is visible only in the exhalation of the user [16], unlike cigarettes.

ECs have evolved from early devices. The first generation products were small cigarette look alikes (cigalikes) with low capacity batteries and a heating element with a liquid-sowed poly-shake ('carbo-shake') [20]. The majority of cigalikes have an LED at the end that illuminates when suction is applied, but usually has a color that sets them apart from typical cigarettes [21]. More modern, second- and third-generation ECs do not imitate sized or formed cigarettes [20], have higher capacity batteries, larger atomizers and an electronic circuitry refillable (transparent) tank ("clearomizer") to allow the transmission of power to the atomizer [23].

One most common reasons for the patient to use ECs are to stop smoking, cut down the number of cigarettes smoked per day, and use a product that is seen as "healthier" than conventional cigarettes [24]. ECs therefore can have an advantage over existing cessation treatments because they are visually and behaviourally close to smoking. Various sensorial and behavioral aspects of smoking usually missed by cigarettes smokers, for example, non-nicotine rewards and critical sensory motor signals for smoking, visual signals or feelings in the throat are simulated by the use of ECs. Some users have reported mild adverse effects such as headaches, dry mouth or throat, dry cough or nausea [20].

Non – pharmacological approach

Counseling

Counseling is a learning oriented process that usually occurs in an intimate relationship, with the purpose of helping an individual learn more about themselves, and using such understanding to allow the person to become a successful member of society [25].

Various models for counselling the tobacco patient

By 5 A's model - The guideline urges every health care provider to follow a 5 A's protocol with all tobacco users who are willing to quit. The 5A's are the following: ASK, ADVICE, ASSESS, ASSIST & ARRANGE.

By 5 R's model - The guideline recommends a motivational counseling intervention that emphasizes the 5R's, if the patient is unwilling to quit: Relevance, Risks, Rewards, Roadblocks & Repitition [25].

Yoga: The historic outlook

In Indian traditions, yoga (from the Sanskrit word meaning ' yoking ' or ' joining ') is ' the means or strategies for transforming consciousness and attaining liberation (moksha) from karma and rebirth (samsara). It is a practice by which a spiritual seeker seeks to control

nature in order to make the soul ready for union with the Oversoul (the true Self or Atman-Brahman or ' God ') and to achieve uniformity [26].

According to archeological evidence, yoga started in India as early as 3000 B.C. This appeared in the later hymns of the ancient Hindu scriptures (Vedanta or Upanishads) (600–500 B.C.). It is mentioned in the ancient Indian epic Mahabharata (400 B.C.-400 A.D.) and addressed in the Bhagavad Gita, the most famous part of that book. Patanjali systematized meditation in the Sutras of Meditation (300–200 B.C.). Patanjali described yoga's in as awareness of the true "self" (God) and outlined eight steps for the direct "self" experience [26].

Yoga perspective

Yoga, as propounded by sage Patanjali, has eight limbs: a set of things to avoid (yama), a set of things to follow (niyama), postures (äsana), breathing practices (pränäyäma), detachment of the senses (pratyähära), concentration (dhäranä), meditation (dhyäna), and deep immersion (samädhi). The ultimate purpose of yoga is to attain salvation

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or liberation (kaivalya) by complete cessation of all mental alterations (våttis) and being rooted in one's real nature [24]. The behavioral changes are said to be five, encompassing all the mind's behaviors in waking, dreaming, and deep sleep state. All five different types of mental changes can be modulated and regulated independently from all worldly desires by regular practice and dispassion. The eight limbs suggested by the sage Patanjali comprehensively cover anything required for progress towards the ultimate goal. The ultimate goal of completely subjugating the behavioral alteration (cittavåtti) has been suggested. There are five types of mental alterations (cittavåtti)–correct awareness (pramäëa), wrong knowledge (viparyaya), imaginary / fancy knowledge (vikalpa), deep sleep (nidrä), and memory (småti). According to Yoga Vasishta, one of the major vedantic scriptures, there are two ways to achieve liberation or freedom from the bondages of mind–yoga and information [27].

In a study conducted by Zgierska A et al. in 2009, the effectiveness of preliminary efficacy of meditation on alcohol, cigarettes, cocaine, amphetamines, marijuana and opiates in the treatment of several forms of addiction has been shown to be effective [28-30].

In a study conducted by Janakiramaiah et al., dysthymic patients were treated as out-patients with Sudarshan Kriya as their sole treatment. During the very first sudarshan kriya (SKY) session, blood analysis showed the elevation of plasma prolactin and stable cortisol. This is important, as high plasma prolactin can be essential for an effective antidepressant response. Stable levels of cortisol suggest the SKY does not undergo any stress [31]. Further study found the stress hormone levels decreased cortisol and adrenocorticotropic hormone (ACTH) [32].

Kochupillai et al. also studied cancer patients with conventional therapy. At 12 and 24 weeks, SKY substantially increased the number of natural killer (NK) cells compared with baseline. No effect was observed in the study community or between controls on T-cell sub-sets after SKY [33]. Warne AS investigated the case of women with breast cancer where, after completing SKY preparation, there has been a significant change in quality of life, mental wellbeing and perceived tension and consistent follow-up of five weeks [34].

In a research conducted by Bullen et al. e-cigarettes for tobacco withdrawal symptoms were more successful than nicotine replacement therapy and scores were higher [35]. In U.S. based studies the majority of e-cigarette users were non-Hispanic White (83%) [36,37]. There are few studies on vaping cessation attempts among e-cigarette users. However, there is no agreement between these studies [38]. The proportion of e-cigarettes users who reported an intention to quit e-cigarette using in the near future varied from 3% in a study by Skerry, et al. [38], 8% in study by Etter and Eissenberg [39], 65% in study by Wong, et al. [40] and up to 73% in study by Ma, et al. [39]. In a study by Etter JF, 10% of long-term vapers had already tried to quit vaping, and 34% declared an intention to quit vaping in the future. In a study by Canzan, et al. e-cigarette use was not associated with smoking cessation in nursing students in Italy [40].

How do mind-body practices complement smoking cessation?

Drug dependency is associated with increased reactivity to stimuli related to the drug by triggering mesolimbic reward circuits that bypass more complex cognitive processes (bottom-up neural activity). Therefore, drug-related signs produce a clear attention-related bias that may suggest retaining addictive behaviors and leading to relapse. Neuroimaging results recently showed that current smokers have less neural activity in the cortical regions associated with concentration and cognitive function, and more activity in the limbic system subcortical areas than non-smokers and ex-smokers. In addition, ex-smokers displayed increased pre-frontal activity relative to smokers or controls, indicating that successful cessation may require improvements in cognitive control to curb cigarette smoking and avoid relapse (top-down neural activity). Mind-body strategies are known to increase top-down cognitive control, automatic memory, cognitive resilience, emotional regulation, and the ability to reorient focus, in addition to reducing cue-reactivity and conditioned responses. Hence, if proven effective, mental-body therapies can promote smoking cessation by enhancing cognitive control, decreasing reactivity to smoking signs and removal of nicotine, providing a mechanism for coping with stress and cigarette cravings, and improving mood and quality of life. Such activities will strengthen the lifelong value of non-smoking once the treatment ends [41].

Sudarshan kriya

The Sudarshan Kriya is an important part of the Art of Living services, a powerful rhythmic breathing technique that promotes physical, mental, emotional, and social well-being. Today it is universally acknowledged for its efficacy in eliminating stress and bringing one into the present moment completely. As H.H Sri Sri Ravi Shankar put it, the Kriya of Sudarshan came to him as an inspiration to bridge the gap between the worlds of inner silence and outer expression of life [42].

Su' means proper,' darshan' means vision and' Kriya' is a practice of purification. Therefore the Sudarshan Kriya is a purifying practice, by which one receives a proper vision of one's true self. This particular method of breathing is supposed to be a powerful energy suppressant. According to the propogator each cell becomes completely oxygenated and flooded with new life, bringing in the moment a sense of joy. It flushes our anger, anxiety, and worry; leaving the mind completely relaxed, and energized. It is believed to be powerful technique which energies the body and oxygenate each and every cell of the body and eliminate the negative emotions. The mind is supposed to be free from stress and instills positive thoughts and self-confidence so that he or she does not feel the need to smoking [1].

This art of breathing is practiced before breakfast in a closed and clean building free from dust and in sitting posture with eyes closed [42].

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The SKY procedure consisted of three sequential breathing components, interspersed with normal respiration, as described below.

1) Ujjayi Pranayama consists of slow deep breathing using throat. Each cycle includes breathing in, holding, breathing out and holding. There are three different stages of Ujjayi Pranayama viz.

• Diaphragmatic breathing

• Thoracic breathing

• Clavicular breathing

Bhastrika pranayama

2) Consists of 20-fold forced inhalation & exhalation, performed with one minute relaxation in between for three such rounds. Ujjayi & bhastrika pranayama total length will be about 12-15 minutes.

3) Cyclical respiration consists of slow cycles, medium cycles and fast breathing cycles performed for a total duration of 30 Minutes.

4) Patients were asked to remain in yoga nidra (tranquil state) for approximately 20 minutes at the end of these components [1].

Bhramari pranayama

Bhramari Pranayam training was provided according to standard procedure by trained yoga doctors. Accordingly, the subjects were made to sit with their eyes closed in any relaxed position with an upright spine. At this point, both nostrils (5 secs approx.) were asked to take slow and deep inhalation, followed by deep and slow exhalation in the same manner (15 secs approx.) with their thumbs on two external auditory canals. We are told to recite the "A U Mmm" refrain while exhaling, along with a buzzing nasal sound similar to the one of a wasp. This causes the laryngeal walls and inner walls of the nostrils to vibrate slightly. This full procedure takes 3-4/ min followed with one minute rest forming one Bhramari Pranayam loop [43].

Kapalbhati pranayam

Kapalbhati involves contractions of the abdominal muscles with aggressive forceful exhalation and normal passive inhalation. Together, exhalation and inhalation make up one stroke. Body should be steady when performing Kapalbhati. The head, shoulders, facial muscles, back and legs should not be moving. It is important to avoid excess force and jerk. The pranayama session should be performed before mealtime [44].

Anulom-viloma pranayama

Anulom-viloma Pranayama/ alternate nostril breathing (ANB)/ Nadi-suddhi pranayama is one of the common yogic breathing techniques and involves breathing through one nostril at a time while closing the other nostril manually. The traditional nasal cycle is based upon the predominance of parasympathetic or sympathetic sound, alternating phases of nasal tissue swelling and decongestion [45,46].

Conclusion

The evidence shows that both pharmacological and non-pharmacological methods are effective in cessation in smoking. Dependence on nicotine is a chronic condition but the evidence suggests that there are safe and effective medications available to help patients stop their attempts. When setting up a brief clinical experience, whether as an inpatient or as an outpatient, each patient who uses tobacco should be given at least one of those treatments.

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