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Barriers & Facilitators to Nicotine Replacement Therapy in Smoking Cessation during Pregnancy & Post-partum Period

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Review Article

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ABSTRACT

Smoking tobacco during pregnancy is associated with a number of pregnancy complications and a range of poor foetal outcome. This review aims to assess barriers and facilitators to the use of nicotine replacement therapy in smoking cessation during pregnancy and the postpartum period. A number of barriers to achieving smoking cessation are emerged from three issue areas: pregnant women, health providers, and organizations. Pregnancy-specific barriers included lack of support, lack of knowledge and awareness about smoking harms, lack of planning, and understanding of the consequences of smoking during pregnancy. Health Providers (HPs) related barriers are lack of knowledge and awareness about nicotine replacement therapy (NRT) prescription, Credibility of HPs and at an organization level, weak policies and organizational frameworks are some of the barriers. Facilitators to NRT use in pregnancy are relationships with partners, family, friends, and HPs, knowledge, and awareness about NRT, an organizational framework like stop smoking-cessation services (SSSs), Carbon monoxide (CO) monitoring, community support for smoking cessation, and clear policies. Smoking-cessation treatment should consist of three phases: preparation, intervention, and maintenance. Preparation aims to increase the pregnant smoker's motivation to quit and to build confidence that he or she can be successful. Intervention can take any number of forms (or a combination of them) to help pregnant smokers to achieve abstinence. Maintenance, including support, coping strategies, and substitute behaviors, is necessary for permanent abstinence.

Keywords: Counseling, Pregnancy, Smoking Cessation, Social Support, Tobacco Smoking.

Introduction

Tobacco use is a leading cause of preventable deaths all over the world. Tobacco accounts for almost a million deaths every year in India. As per the Global Adult Tobacco Survey (GATS) India (2010), 35% of adults used tobacco in some form or the other. Among them, 21 % of adults used only smokeless tobacco, 9% only smoked, and 5 % smoked as well as used smokeless tobacco. Overall tobacco use is much higher among Indian males at 48 percent compared to 20% in females.[1]

WHO Framework Convention on Tobacco Control (FCTC) by WHO prescribes demand reduction measures concerning tobacco dependence and cessation. India is a signatory to the FCTC. The government of India passed the cigarettes and other tobacco products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act in 2003. National Tobacco Control Programme, was implemented in the XI Five Year Plan and cessation facilities are being made available at the district hospital level.[1]

Smoking in pregnancy is the leading preventable cause of morbidity and death among women and infants. The prevalence of smoking during pregnancy is 13- 25% in high-income countries and is increasing rapidly in low-income and middle-income countries. Cessation of smoking during pregnancy is important for maternal and fetal health. There is, however, considerable uncertainty about whether medications that have been shown to improve cessation rates among non-pregnant women are also effective during pregnancy.[2]

Concerns regarding potential teratogenicity have prevented clinical trials of Varenicline and Bupropion. Such concerns are less pressing with nicotine replacement therapy, because this therapy contains only nicotine, whereas tobacco smoke contains this and many other toxins. There is a general consensus that nicotine replacement therapy is probably less harmful than smoking, and its use in pregnancy is recommended by several sets of guidelines for smoking cessation in pregnancy. Yet good evidence to support these recommendations is lacking. To date, individual clinical trials of nicotine-replacement therapy in pregnancy have been too small to definitively assess whether it is effective or safe. Barriers to the use of NRT during pregnancy have been reported in the literature.[2]

This overview includes a history of tobacco and its cultivation, the impact of tobacco on health, methods, and medications for smoking cessation (NRT), and barriers and facilitators of NRT in pregnancy.[2]

History of Tobacco

Human beings have been using tobacco since 600 A.D. Within 150 years of Columbus's finding "strange leaves" in the New World, tobacco was being used around the globe. Earlier, tobacco was generally smoked using different types of pipes or as cigars or was consumed orally (smokeless tobacco). In 1828 Nicotine was isolated from tobacco leaves. The twentieth century saw the rise of the manufactured cigarette and with it a greatly increased number of smokers. At the beginning of the 21st century about one-third of adults in the world, including increasing numbers of women, used tobacco.[3]

Despite thousands of studies showing that tobacco in all its forms kills its users, and smoking cigarettes kills non-users, people continue to smoke, and deaths from tobacco use continue to increase. However, despite historical attempts to legally ban tobacco, its use has continued to grow in popularity as a non-productive pastime. In modern medicine, its harmful effects have been recognized over the past several decades. Although its use has declined in developed nations in recent years, it continues to be popular in developing countries.[3]

Tobacco cultivation accounts for 10% of the area and 9% of total production. Principal cultivated varieties are Flue-cured, Burley, Rustica, Natu, Kasturi, Malawi Western Sun Cured (MWSC), Dark fire-cured, Oriental, Talmari. It is grown in light soils (Sandy, Red) with pH 7.5-8. Botanical classifications include more than 240 denominations for the various species, subspecies, and varieties of the genus Nicotiana, which belongs to the family Solanaceae, subclass Asteridae, class Magnoliopsida (Dicotyledoneae).[4]

Tobacco is smoked in the forms of beedis and cigarettes or by using devices like hooka, hookli, chhutta, dhumti, or chillum. Cigarette smoking is common in urban areas and more common among the upper and middle socioeconomic classes than among the poor population. Smokeless forms in India include betel quid chewing, mishri, khaini, gutka, snuff, and as an ingredient of pan masala.[1]

Tobacco and Health

Tobacco smoke contains over 4000 chemical compounds including tar, carbon monoxide, nicotine, hydrogen cyanide, acetone, ammonia, arsenic, phenol, naphthalene, cadmium, and polyvinyl chloride. Many of these agents are toxic and at least 43 % cause cancer. Tobacco is a known or probable cause of many diseases like macular degeneration in the eyes, ageing, wrinkles, wound infection in the skin, cancer, emphysema, pneumonia in the lungs, coronary artery disease in the heart, cervical cancer, early menopause, irregular and painful periods in women are very common.[5]

Mechanism and Actions of Nicotine

The systemic actions of nicotine are mediated by nicotinic receptors found in the central nervous system (CNS), peripheral autonomic nodes, supra-renal glands, sensitive nerves and the skeletal striated muscle Nicotine's main acute effects over the cardiovascular system are peripheral vasoconstriction, an increase of the blood pressure and heart rate. Nicotine also interferes in the endocrine system, yielding the release of the anti-diuretic hormone and water retention. In the gastrointestinal system, nicotine acts parasympathetically, stimulating tonus increase, and intestinal motor activity. In nervous endings, nicotine stimulates the release of the following neurotransmitters: acetylcholine, dopamine (DA), glutamate, serotonin, and gamma-aminobutyric acid (GABA). Nicotine is a CNS stimulant, leading to increased alertness and to reduced appetite.[6]

The main sensations may include dizziness, nausea, and vomiting. Nicotine interferes in the reticular formation blood flow, including areas of the pons, mesencephalon, and thalamus, and plays a role in awareness and awakening mechanisms.[6]

Low doses of nicotine have a central stimulating effect, while higher doses have a depressing effect. Nicotine also leads to a dose-dependent increase in blood flow in the left hemisphere amygdala, which may explain the anxiolytic effect of smoking. Nicotine acts as an enzymatic inductor in the liver and reduces the half-life of several medicines such as local anesthetics, morphine, codeine, theophylline, heparin, warfarin, amitriptyline, imipramine, propranolol, chlorpromazine, diazepam, chlordiazepoxide, and indometacin. Thus, smokers may require larger doses of these medicines to have the expected therapeutic effects.[6]

Mechanism of Nicotine Dependency

Nicotine is metabolized to cotinine, an inactive metabolite, principally by CYP2A6.1 which is a wild type allele with normal enzyme activity action. CYP2A6*4 is a whole deletion type of the CYP2A6 gene.2,3 CYP2A6*9 has a single-nucleotide polymorphism in TATA box, T-48G substitution, which impairs the transcriptional activities and, consequently, its enzymatic activity. It has been clearly demonstrated that the pharmacokinetics of nicotine is influenced by CYP2A6 polymorphisms.[7]

Withdrawal Symptoms Associated with Smoking Cessation

Both smoked and smokeless forms of tobacco contain nicotine, a highly addictive chemical, making it difficult for habituated tobacco users to quit. Over time, users become dependent on nicotine, and suddenly stopping produces both physical and psychological withdrawal symptoms. As the person stops tobacco use, these chemicals decrease in the body, and withdrawal symptoms start. Commonly experienced withdrawal

symptoms on stopping tobacco use include: Depressed mood, insomnia, irritability, frustration, anger, anxiety, craving and difficulty in concentration, restlessness, decreased heart rate, and increased appetite or weight gain, etc.[1]

Methods of Smoking Cessation

Different methods for smoking cessation include methods without assistance (Cold turkey Gradually reducing the number of cigarettes), medications (Nicotine replacement therapy), antidepressants (Bupropion, Nortriptyline, Varenicline, Clonidine), use of psychedelic mushrooms, interventions delivered via health care providers and health care systems, substitutes for cigarettes (Electronic cigarette, Chewing cinnamon sticks or gum), psychosocial approaches and alternative approaches (acupuncture, aromatherapy, hypnosis, etc). The majority of smokers try to quit without assistance, though only 3–6% of quit attempts are successful. The use of medications and behavioural counseling increases success rates.[8]

Nicotine Replacement Therapy (NRT)

Prevalence of tobacco use can be effectively reduced through two-pronged approach: large scale promotions to educate the people about the harmful effects of tobacco use and benefits of quitting along with providing adequate facilities to those who want to quit.[1]

Strategies for Tobacco Cessation

The Five A's (Ask, Advise, Assess, Assist and Arrange) and Five R's (i.e. Relevance, Risk, Rewards, Roadblocks, and Repetition) are five to fifteen-minute research-based counselling approaches that have proven global success. It is important to tell the tobacco user about the benefits of quitting. Individual users may have other motives to quit, which should be explored and documented for future use.

Step 1: Ask

Systematically identify all tobacco users at every visit. It should be an essential part of the evaluation that for every tobacco user at every consultation, tobacco-use status be queried and documented.

Step 2: Advice "Strongly urge all Tobacco users to quit"

Advice should have a clear message, strong message & personalized message.

Step 3: Assess

Determine willingness to make a quit attempt.

Step 4: Assist

The following actions are suggested to assist tobacco users in the motivational stage, (a) Help in making a quit plan, (b) Provide practical counseling (problem-solving / skills training), (c) Provide intra-treatment social support, (d) Help in obtaining extra-treatment social support and (e) Recommend pharmacotherapy.

Step 5: Arrange

Arrange - Schedule a follow-up contact

The 5 "R"s Approach

For tobacco users who are not ready to make a quit attempt, provide a brief intervention designed to promote the motivation to quit and information about the harmful effect of tobacco. This group may respond to a motivational intervention designed to educate, reassure, and motivate and build around the 5 "R"s, (i.e. Relevance, Risk, Rewards, Roadblocks, and Repetition).

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Relevance: Encourage the tobacco user to consider the personal relevance of cessation.
Risks: Discuss short term, long term and environmental risks of continued tobacco use.
Rewards: Encourage tobacco user to identify benefits of cessation.
Roadblocks: Barriers that the tobacco user may face in his / her quit attempt should be identified.
Repetition: This information should be reviewed regularly with tobacco users who are not yet ready to quit.[1]

Products	Dose	Flavor	Adverse effects
Gum	2 mg, 4 mg	Cinnamon, Fruit, Mint	•Mouth and throat irritation •Jaw muscle soreness
Lozenge	2 mg, 4 mg	Cherry, Mint	• Hiccups •GI complaints (dyspepsia, nausea)
Trans-dermal Patch	7 mg, 14 mg, 21 mg (24-hr release)	----------	• Sleep disturbances (abnormal/vivid dreams, insomnia)
Nasal Spray	10 mg/ml nicotine solution	----------	•Ocular irritation/tearing • Sneezing • Cough
Oral Inhaler	10 mg cartridge delivers 4 mg inhaled vapor	----------	• Cough • Hiccups

Medications used in Smoking Cessation (NRT)[9]

Side Effects of NRT

Nicotine per se is a unique active ingredient for a consumer product in that the majority of nicotine's effects are mediated by binding and activating nicotinic acetylcholine (nACh) receptors in a wide variety of neuronal (central and peripheral nervous system) and non-neuronal tissue. Consequently, nicotine exposure affects numerous systems, including neurological, neuromuscular, cardiovascular, respiratory, immunological, dermatological, gastrointestinal, and oral. The presence of different types of nACh receptors, receptor up-regulation, and receptor desensitization influence these complex physiological effects. Evidence from experimental animal models clearly demonstrates nicotine's ability to enhance existing tissue injury and diseases such as cancer, cardiovascular disease, stroke, pancreatitis, peptic ulcer, renal injury, and developmental abnormalities (e.g. pulmonary, reproductive, and central nervous system). These reported adverse health effects were observed following short-term exposure to nicotine per se (<12 weeks) and appear to be dependent on nicotine activation of nACh receptors in the affected tissue.[10-22]

Cancer

Based on findings from animal and mechanistic studies, a case for biological plausibility has been proposed for a potential role of nicotine in carcinogenesis. Nicotine at concentrations relevant to NRT uses exhibit genotoxic properties. Similarly, nicotine has been reported to stimulate cell proliferation, inhibit apoptosis, induce angiogenesis, and inhibit immune function. Thus, there is considerable evidence that nicotine exposure (at

levels relevant to NRT users) can affect many of the cellular processes that are considered important for the initiation, promotion, or progression of the carcinogenic process.[10]

Stroke

NRT product warning label statements indicate a potential health risk to NRT users with high blood pressure. Such warnings suggest a potential risk of stroke with NRT or nicotine exposure. Several animal studies support a potential role for nicotine in increasing cerebral micro-vessel thrombosis and inhibiting restoration of brain micro-vascular in experimental models of thromboembolic injury and repair as compared to vehicle controls without nicotine.[10]

An understanding of the nature and likelihood of the most common side effects may help clinicians communicate to patients the benefits and risks associated with their use of NRT. This information may also improve the selection of specific delivery mechanisms based on patient history, which may improve treatment adherence.[23]

Smoking Tobacco during Pregnancy

Risks of Cigarette Smoking During Pregnancy: Cigarette smoking during pregnancy substantially increases the risk of spontaneous abortion, prematurity, low birth weight, and perinatal mortality. Smokers have an increased risk of spontaneously aborting a chromosomally normal foetus, with an odds ratio of 1.2 to 1.8 compared with non-smokers. The incidence of low birth weight (<2500 g) increased with increasing cigarette consumption, and 21% to 39% of low-birthweight births have been attributed to maternal cigarette smoking.[24]

It is estimated that maternal smoking resulted in death. These deaths are related to a higher than usual incidence of premature delivery related to abruptio placentae, placenta previa, and premature rupture of the membranes in smoking mothers, as well as intrauterine growth retardation. A likely cause of growth retardation in foet uses of smoking mothers was an induction of foetal hypoxia and/or ischemia, which could be produced by both carbon monoxide and nicotine. Furthermore, babies born to smoking mothers had a four times greater risk of a low APGAR score if the mother smokes two packs per day compared with babies of non-smoking mothers (with correction for gestational age).[24]

Relative Risks of Cigarette Smoking and Nicotine Replacement during Pregnancy

Cigarette smoking delivers not only nicotine and carbon monoxide but also many other toxic chemicals to smokers. Smoking in general delivers more nicotine at a more rapid rate, resulting in more intense cardiovascular and central stimulation, than does nicotine from nicotine chewing gum or transdermal nicotine delivery systems. Therefore, nicotine replacement therapies are likely to present substantially lesser side effects than cigarette smoking, particularly heavy smoking, during pregnancy.[24]

Potential Risks of Nicotine in Pregnancy

Nicotine and carbon monoxide are suspected to contribute to reproductive disturbances, however, the nature and magnitude of its adverse effects are yet unknown. The evidence for a causal link between cigarette smoking and reproductive disorders is well established, while the pathophysiology is not. Carbon monoxide impairs oxygen availability by binding avidly to foetal haemoglobin, thereby reducing the availability of oxygen to the foetus. A maternal 10% blood carboxyhaemoglobin level, which is present in a two-pack-per-day cigarette smoker, can be associated with a 10% to 15% higher carboxyhaemoglobin level in the foetus than in the mother. This has been related to a 60% reduction in foetal blood flow. Nicotine may contribute to foetal

ischemia by its effects on the placental circulation. Smoking acutely and chronically reduces placental blood flow in pregnant women, presumably due to nicotine.[24]

Cigarette smoking and nicotine chewing gum have been found to increase foetal heart rate during the second trimester, consistent with sympathetic neuroactivation. During the third trimester, cigarette smoking or nicotine gum chewing decreases foetal heart rate and reduces foetal breathing movements (signs of foetal hypoxia). Foetal hypoxemia has also been considered to be a contributory cause of behavioral abnormalities, such as hyperactivity, short attention span, and lower scores on spelling and reading tests, which occur at a higher frequency in children whose mothers have smoked throughout pregnancy than in those born to non-smoking mothers.[24]

Nicotine Replacement Therapies (NRT) In Pregnancy

Certain nicotine-containing and non-nicotine containing drugs, otherwise known as nicotine replacement therapies (NRT), are utilized to assist with smoking cessation by controlling the symptoms associated with nicotine dependency. The Food and Drug Administration (FDA) has classified both nicotine and NRT as category D drugs based on studies conducted in animals. Pregnant or breast-feeding women who make an informed choice to try NRT should probably be advised to use shorter-acting products to minimize foetal exposure to nicotine overnight.[25]

Benefit of Nicotine Replacement Therapies

Pregnant women who smoke are often highly motivated to quit and maybe more responsive than are other patients to advise that they stop smoking. Prenatal smoking cessation programs have resulted in quitting rates of 9% to 43%.[28] Women who quit smoking before or during their pregnancy can substantially reduce and even eliminate adverse health risks to themselves and their foetuses.[26]

A meta-analysis indicated an overall smoking cessation rate (in men and non-pregnant women) at 6 months was 27% for nicotine chewing gum compared with 18% for placebo chewing gum. Another trial has shown a dose-response relationship between nicotine therapy and smoking cessation outcomes. It reported that the effectiveness of treatment with 4-mg nicotine chewing gum was higher than 2-mg nicotine chewing gum among highly dependent smokers. This rate of effectiveness was comparable with that obtained with 2-mg nicotine chewing gum in smokers with a medium or low level of dependence. Thus, nicotine replacement appears to be of particular value in more-dependent smokers. Similar data for smoking cessation rates have been observed with the use of transdermal nicotine delivery systems.[24]

Side Effect of NRT during Pregnancy

The FDA's classification suggests that NRT use in a sensitive group, such as pregnant women, maybe inadvisable due to the uncertainties of its effects. Clinical tests addressing the safety of nicotine in the pregnancy of animals have found the drug to be a neuroteratogen to the developing foetus. In fact, although many physicians consider NRT an effective tool for smoking cessation during pregnancy, most do not prescribe NRT because of the unknown safety concerns.[26] NRT may also have adverse effects on placental function and foetal development, but although the magnitude of these pure nicotine effects in humans is uncertain, the likelihood is that obtaining nicotine from cigarette smoke is far more harmful.[25]

Barriers and Facilitators of NRT

Smoking during pregnancy is a leading cause of adverse prenatal outcomes, including miscarriage, stillbirth, and prematurity. It is also associated with a wide range of childhood health problems. The UK National

Institute for Health and Care Excellence (NICE) guidance recommends that through discussion and carbon monoxide (CO) testing (a non-invasive biochemical method for helping to assess whether or not someone smokes), all pregnant women identified as a smoker should be referred to specialist cessation services unless they decline or 'opt-out'.[27]

Barriers

Barriers include social patterns of tobacco use, family and partners smoking, stressful life events, misconceptions or lack of knowledge, inadequate support and low efficacy for quitting.[28] Association between maternal smoking and social disadvantage was a considerable barrier to addressing and supporting smoking cessation.[29] Workplaces were often barriers to quitting, particularly where smoking was the norm and, in the workplace, too, smoking was regarded as a stress management intervention, for workers and supervisors, exerting pressure to quit could result in increased levels of smoking.[30] Pregnant smokers lacked information on the risks of prenatal smoking and underestimated the difficulty of smoking cessation.[32]

Lack of time, nicotine replacement therapy cost and safety concerns, and being unfamiliar with the Quit-line (particularly for Aboriginal and Torres Strait Islander pregnant smokers) were perceived as challenges.[32] Scepticism about smoking harms, stress and societal attitudes, reliance on smoking for stress relief, smoking behaviour of others, lack of willpower, and fear of weight gain were also considered as barriers to NRT among pregnant women.[33] Lack of skills, knowledge, and training opportunities, and changing service priorities and policies were all barriers to managing women's smoking.[34] Insufficient knowledge of smoking harms, inadequate saliency of antismoking messages, and lack of awareness and use of pharmacotherapy were the barriers to quit smoking.[35] Delay in the use of nicotine replacement therapy (NRT) and the absence of subsidized intermittent NRT are some of the barriers reported in the literature.[36]

Barriers to providing referrals to Quit-line were lack of client access to a phone, cost of a phone call, preference for face-to-face interventions, and low client motivation to quit.[37] Health professional barriers to cessation counselling included inadequate knowledge and motivation, perceived low self-efficacy, and concerns about inadequate time and large workload. Health system barriers included low prioritization of smoking cessation and a lack of clinic protocols to implement interventions.

Facilitators

Facilitators identified were the perception of risk to baby and self-efficacy.[38] Women's desire to protect their baby from the harms of smoke was perceived to be an important facilitator to smoking cessation in pregnancy.[39] Better advice on the overall use of NRT and other nicotine delivery devices, including the safety of use in pregnancy and about products available could also be beneficial. Routine CO monitoring and opt-out referrals to specialist cessation advisors were also considered effective.[32]

Facilitators to women's ability to quit smoking in pregnancy and postpartum: psychological well-being, relationships with significant others, changing connections with her baby through and after pregnancy; appraisal of the risk of smoking.[40] The most frequently endorsed benefits were advice about cigarette cravings and praise and encouragement with quitting.[41]

Today tobacco use is the single greatest preventable cause of death in the world. Nicotine addiction is the major factor impeding smoking cessation and long-term abstinence.[42] Pregnancy is a time when women are generally highly motivated to try and stop smoking, however, they may experience certain barriers, which can impinge on cessation attempts, or facilitators which can make quit attempts easier. This literature review aims

to summarize various barriers to nicotine replacement therapy and gives an idea about the facilitators of NRT used to treat nicotine dependence among pregnant women.

Examples of barriers include partner's continued smoking and social norms that encourage and normalize smoking whereas the desire to protect the baby from unnecessary harm can help facilitate a successful quit attempt. Nicotine replacement therapy (NRT) temporarily replaces much of the nicotine from tobacco to reduce motivation to consume tobacco and nicotine withdrawal symptoms, thus easing the transition from cigarette smoking to complete abstinence.

Various alternative nicotine sources (Gum, trans-dermal patch, nasal spray, inhaler, and sublingual tablets/lozenges) have been incorporated into tobacco cessation programs. Recent research is focusing on the rapid delivery of nicotine (Nicotine preloading, true pulmonary inhaler) to tackle nicotine dependence among pregnant women. These NRTs are in general well tolerated and have minimal adverse effects.

Conclusion

Women's perceptions and experiences were mixed, demonstrating that individual factors could act as barriers to or facilitators of smoking cessation depending on the context of women's lives. However, there appeared a predominance of barriers at the individual level. These are issues related to support, lack of knowledge, and awareness about smoking harms, lack of planning, and understanding of the consequences of smoking during pregnancy. On the other hand, there were facilitators such as relationships with partners, family, friends and HP, health perception, and being parents. Hence physicians, dentists, and other health professionals can provide important assistance to their patients who smoke. Clinicians also play an important role in providing nicotine replacement products such as nicotine gum or transdermal patches. By increasing their knowledge about smoking-cessation methods, health professionals can support and encourage the large majority of pregnant smokers who want to quit.

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