STUDY ON IMPACT OF NICOTINE REPLACEMEMT THERAPY FOR TOBACCO CESSATION IN INDIA

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Submitted by

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Under the Supervision and Guidance of

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled “Study on Impact of Nicotine Replacement Therapy for Tobacco Cessation in India” is the bonafide record of my original research work. I declare that it has not submitted to any other university or institution for the award of any degree or diploma.

Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

This is to certify that Dr. Apoorva Shetty in partial fulfilment of the requirement for the award of the degree of MBA in Hospital and Health Management from the IIHMR University, Jaipur has successfully completed her/his internship at IIHMR University during March 22, 2021 to June 19, 2021.

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Abstract

Objective:

The primary active ingredient of tobacco products is nicotine, and it promotes tobacco addiction in individuals. Tobacco's other components are the ones that cause widespread mortality and illness. Although other components of cigarettes are to blame for almost all of the dangers associated with smoking, nicotine's pharmacological actions are what lead to tobacco addiction.

As a result, pharmaceutical smoking cessation therapies are evolving in term with our growing knowledge of nicotine addiction's neurochemical base. Nicotine is the most common alkaloid in tobacco smoke and the most important moderator of the endocrine system.

Objective: Evaluating the effect of the tobacco cessation nicotine replacement therapy and understanding of consumer willingness to quit tobacco

Methodology: It will be descriptive study. It includes review of literature from previously published articles, government data, press releases and others. Study will include smoking population of India which includes both male and females. The study will be carried out for one month that is May and June of 2021.The sampling technique used is convenient sampling. Secondary data from websites, articles and journals.

Findings: After analysing relevant articles, journals, and reports, the data was analysed. The other types of nicotine substitution therapy (NST) were all found to be much more successful in supporting smokers in achieving sobriety than placebo or no NRT. Local irritation at the site of administration is one of the most dangerous side effects of nicotine inhalers and nasal sprays. According to a study of adverse events depending on Thirty-five trials involving over nine thousand individuals, nicotine patches do not cause an increase in cardiovascular adverse events. The current review includes data from two randomised short-term follow-up studies and a case-study in a single population-driven samples.

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Abbreviations

1. NRT- Nicotine Replacement Therapy
2. GATS- Global Adult Tobacco Survey
3. NAChRs- Neuronal Nicotinic Acetylcholine Receptors
4. NST- Nicotine Substitute Therapy

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Figure 01: Comparison of NRT

Chapter-1 Background

1.1 Introduction:

According to GATS-2, 28.6% of Indian population are current smokers. Tobacco can be chewed or smoked in the forms of beedi-cigarettes. In India, smokeless tobacco is widely used. Tobacco kills more than seven million people each year in India. Over 6 million deaths are a consequence of direct consumption and others due to passive smoking.25.9% adults use smokeless tobacco. Smoking tobacco contains cancer causing chemicals such as Hydrogen cyanide, formaldehyde, lead. Tobacco can cause long list of health hazards including cancer. Tobacco addiction is the leading preventable cause of death in the United Kingdom. Most smokers do not receive the help they require to quit. Smokers who receive support are three times more likely to quit.

Nicotine is the main active component of tobacco products and promotes behaviour in individual's tobacco addiction. Tobacco's other components are those which cause widespread death and disease. While almost all of the risk of smoking is caused by other components of the cigarette, the phenomena of nicotine lead to tobacco dependence.

As a result, pharmaceutical smoke cessation therapies are evolving in conjunction with our growing understanding of the neurochemical base of nicotine addiction. Nicotine is the most common alkaloid in tobacco smoke and the most important modulator of the psychopharmacological consequences of addiction. Nicotine replacement treatment (NRT) seeks to lessen the desire to smoke and the physiological effects of tobacco use.

The evidence that nicotine replacement therapy (NRT) aids in quitting smoking is now widely established, and many healthcare guidelines suggest NRT as a first-line treatment for smokers seeking pharmacological assistance.

1.2 Implication of research:

This review seeks to describe the literature on various nicotine replacement therapy modalities now in use and to understand the impact of Nicotine replacement therapy on tobacco cessation. The study review also seeks to describe the consumer willingness towards quitting tobacco consumption.

1.3 Definition of Nicotine Replacement Therapy

A gum-form, nasal sprays, transdermal patches and sublingual tablets are available to replace the nicotine (NRT). The provision of an alternative nicotine source helps reduce the transition from smoking by reducing cravings and withdrawal symptoms. The rate of withdrawal has been increased by 50 – 70 percent for all types of NRT. This effect is strong and quite independent of the individual's level of additional assistance. A recent methodology has

shown that the use of a quick-acting form together with a patch has increased smokers' chances of quitting successfully in comparison to single NRT therapy.

1.4 Mechanism of Action of Nicotine

Nicotine affects the brain's ventral tegmental region via stimulating neuronal nicotinic acetylcholine receptors (NAChRs). Dopamine is released in the nucleus accumbens as a result of this. Nicotine withdrawal symptoms in regular smokers who stopped were reduced as a result of this. NRT can also act to copy products, thus reducing cigarette products' desirability. Because no nicotine delivery device can duplicate the rapid and high levels of arterial nicotine achieved when cigarette smoke is inhaled, withdrawal symptoms are not completely eliminated. Because all known therapeutic nicotine preparations rely on systemic venous absorption, they don't deliver nicotine to the bloodstream as quickly. Nicotine from cigarettes reaches the brain in a couple of seconds, whereas therapeutic drugs take several minutes to reach similar amounts.

1.5 **Nicotine Replacement Therapy (NRT) comes in different types.**

The most frequently studied and used pharmacotherapy for controlling nicotine dependency and withdrawal is the therapeutic use of nicotine-containing medicines. NRT products come in a variety of forms.

1. Transdermal patches
2. Lozenges
3. Nasal sprays
4. Oral inhalers
5. Tablets
6. Gums

Nicotine transdermal patches are a long-acting nicotine delivery system. Gum, nasal spray, oral inhaler, and tablet are some more nicotine acute dose options.

Comparison of NRTs

Drug	Dosage Strengths	Dosage	OTC	Evidence	Adolescent ADRs
Nicotine gum (Nicorette)	2 mg (<25 cig/day), 4 mg (>25 cig/day)	1 pc. q1-2h × 6 wk, then decrease to 1 pc. q2-4h × 3 wk, then 1 pc. q4-8h × 3 wk, then discontinue	Yes	RCT	Sore throat, hiccups, pruritus
Nicotine patch (Nicoderm CQ)	7 mg/day, 14 mg/day, 21 mg/day (24 h)	21 mg/day × 4 wk, then 14 mg/day × 2 wk, then 7 mg/day × 2 wk (total 8 wk); start at 14 mg if pt <100 lb or smokes <10 cig/day	Yes	RCT	Shoulder/arm pain, pruritus, erythema
Nasal spray (Nicotrol NS)	10 mg/mL (1 spray = 0.5 mg) 1 dose = 2 sprays (1 spray per nostril)	*Initial dose:* 1-2 sprays q1h; max 10 sprays (5 doses)/h or 80 sprays (40 doses)/day	Rx only	ND	Nasal irritation, sneezing, cough, tearing, headache
Nicotine inhaler (Nicotrol)	4 mg	4 mg nicotine (= 2 cig smoked) released for 20 min active inhaler puffing *Usual dose:* 6-16 cartridges/day × up to 12 wk, then reduce gradually over 12 wk, then discontinue	Rx only	ND	Mouth/throat irritation, cough
Nicotine lozenge (Commit)	2 mg (pt who smokes 1st cig >30 min after waking); 4 mg (pt who smokes 1st cig ≤30 min after waking)	Wk 1-6: 1 lozenge q1-2h Wk 7-9: 1 lozenge q2-4h Wk 10-12: 1 lozenge q4-8h	Yes	ND	Mouth irritation, nausea, hiccups, heartburn

NRT: nicotine-replacement therapy; ADR: adverse drug reaction; cig: cigarette(s); pc.: piece; RCT: randomized, controlled trials; pt: patient; max: maximum; ND: no data.
Source: References 21, 25.

Figure 01: Comparison of NRT

Chapter-2 Literature Review

1. Umesh Wadhgave (2016) reported various modes of nicotine replacement therapy methods currently used to treat nicotine dependence, and to give an overview about future possible approaches to treat tobacco use disorder.
2. R.C. Joloha (2014) defines Pharmacotherapies for smoking cessation should reduce withdrawal symptoms and block the reinforcing effects of nicotine without causing excessive adverse effects. All forms of nicotine replacement therapy (NRT) – gum, patches, and inhaler – and bupropion are safe and effective for increasing smoking cessation rates in the short and long-term use. Combination NRT (more than one therapy) may be indicated in patients who have failed monotherapy.
3. Rajkumari E Devi and Diplina Barman (2020) in their article reflects a way to educate and sensitize the doctors about the various choices of NRT products available in the market which can be prescribed to the tobacco users who are at the will of quitting. The doctors can further educate the society about the quitting protocols and the ease of use of these products and help in making a tobacco free society. Keeping in mind the benefits of NRT, it is essential for the professionals to become familiar with them for achieving successful tobacco cessation. Even incorporating it into an organized teaching of the undergraduate curriculum to improve confidence and knowledge will be beneficial for the patients, the budding dentist, and the nation in the upcoming days ahead.
4. Chandan Kumar and Ravi Mehrotra (2018) in their study mentioned there is limited information available on Smokeless cessation intervention trials, research on which must be encouraged, especially in the low-resource, high Smokeless Tabaco burden countries; behavioural interventions are most suitable for such settings. Appropriate training/sensitization of healthcare professionals, and school-based Smokeless tabaco use prevention and cessation programmes need to be encouraged.
5. KA Kamala and SG Sujith (2019) reported that Nicotine addiction is the major factor impeding smoking cessation and long-term abstinence. The effectiveness of NRT appears to be largely independent of the intensity of additional support, and longer courses of NRT are not demonstrably superior to shorter durations of therapy. NRTs increase the rate of quitting by 50%–70% and appear to be a safe and effective option for current smokers who wish to quit with lack of serious adverse effects. It is essential for health professionals to become familiar with all forms of NRT to be able to address the questions and needs of tobacco users who appear to be increasingly interested in tobacco cessation.
6. Siddharth Sarkar and Nishtha Chawla (2020) in their study expressed that effective treatment strategies are available to assist individuals in quitting smoking or tobacco use. It is especially important in the elderly as their mobility is reduced, and so is their motivation to quit, mainly due to the longer duration of tobacco use and insufficient knowledge about its adverse effects than the younger population. This review intends to present clinically relevant aspects of smoking and tobacco use in the elderly, including epidemiology, predictors and risk factors, adverse impact on physical health, and assessment and management of tobacco use and smoking.
7. Rohini Ruhil (2016) stated that NRT may be the therapy of choice for Government and non-Government employees who use tobacco and are willing to quit. Young and male smokeless tobacco users need special attention in tobacco cessation therapy because they may show lower compliance as compared to their counterparts. We must not forget that choosing a particular mode of treatment for tobacco users also depends

on several other factors, such as severity of addiction, tobacco users' stage of readiness to quit, and the presence of a comorbidity.

8. Rajesh Kumar (2020) in his article suggest that a video-assisted nurse-led nicotine replacement therapy found effective in reducing tobacco use. Developing culturally appropriate material and technology use can be a cost-effective means to curb the problem of tobacco and substance abuse.
9. Ravneet Malhi (2018) in their study expressed that the utilization of the pharmacologic methodologies available for smoking termination substantively mends the likelihood of realizing efficacious abstinence, the best upshots for cessation are accomplished when pharmacologic techniques are combined with behavioural means to treatment as the modus operandi of tobacco dependence counselling.
10. Kornitzer and Puska(1995) In the two trials which compared a combination of patches and gum with gum or patch alone, early increases in abstinence rates in the more intensively treated group were not sustained at one year follow up.
11. Bohadana (2000)-A trial comparing nasal spray and patch with patch alone found a significant increase in sustained abstinence at one year with the combined therapy (Blon-dal 1999). One trial combining patch with inhaler also showed a non-significant increase in cessation compared to inhaler alone

Chapter-3 Methodology

3.1 Research Question:

- What is the Impact of Nicotine Replacement Therapy for Tobacco Cessation in India?

3.2 Objective:

- To assess the impact of nicotine replacement therapy for quitting tobacco
- To understand consumer willingness towards quitting tobacco consumption

3.3 Study design:

- It will be descriptive study. It might include review of literature from previously published articles, government data, press releases and others.

3.4 Study population:

- Study will include smoking population of India which includes both male and females.

3.5 Duration of study:

- The study will be carried out for one month that is May and June of 2021

3.6 Data Collection Type:

- The sampling technique used is convenient sampling. Secondary data from

  websites, articles and journals

3.7 Data collection procedure:

- research conducted on secondary data basis.

3.8 Keywords:

- NRT, Nicotine replacement Therapy, Smokers, Nicotine forms. Tobacco Cessation

Chapter-4 Results

Data was analysed after reviewing relevant articles, journals, and reports.

Nicotine replacement treatment (NRT) was proven to be far more effective than placebo or no NRT supporting people consuming tobacco in obtaining sobriety. Regardless of the fact that each type of preparation had a high relapse rate, the effect of using nicotine replacement treatment was proven throughout the period of 6-to-12-month follow-up period. Despite the vast range of trial characteristics included in this investigation, statistically proven evidence of important heterogeneity was not detected in any of the studies analysed.

According to this notion, higher doses may have a modest benefit. One study among heavy smokers with a history of alcohol dependence was removed because the follow-up time was only 12 weeks. The lower dose group outperformed the higher dose group with no noticeable difference. The evidence of a benefit would be weakened by including this study.

Nicotine Replacement Therapy in combination:

Kornitzer and Puska in 1995 said that "Early increases in abstinence levels in the more intensively processed group were not maintained in one year's follow up in the two studies which compared patches plus gum to gum or patch alone".

Bohadana in 2000 stated that "The combo medicine resulted in a substantial rise of long-term abstinence, according to a one-year trial comparing nasal spray and patch to patch alone . When compared to the inhaler alone, combining the patch and the inhaler resulted in a non-significant increase in smoking cessation in one trial".

Blondal in his research stated that "the combination of patch and inhaler resulted in non-significantly lower quit rates than either type alone. According to a research that compared nasal spray and patch to either one alone, the combination had no discernible benefit".

Smokers who have relapsed:

Gourley in 1995 said that "Despite the fact that many of the trials listed here did not specifically exclude patients who had previously tried and failed to quit smoking with NRT, only one experiment looked at the effectiveness of NRT (patch) in smokers who had relapsed after previous patch use, only one experiment looked at the effectiveness of NRT (patch) in smokers who had relapsed after previous patch use . Despite the fact that there

was no difference in continuous abstinence between active treatment and placebo in this study, the patch group had a small increase in quitters using their selected abstinence endpoint in the 28 days previous to evaluation. The rates of quitting were low in absolute terms

Despite the fact that many of the trials included here did not specify exclude patients who had previously attempted and failed to quit smoking with NRT, only one investigation looked at the effectiveness of NRT (patch) in smokers who had relapsed after previous patch use. Despite the fact that the patch group had a modest increase in quitters using their chosen abstinence goal in the 28 days prior to evaluation, there was no difference in continuous abstinence between active treatment and placebo in this trial. In absolute terms, the rates of quitting were modest".

Pre-treatment with NRT before to quit attempt:

Schuurmans(2004)stated in his study that "People who used a nicotine patch for two weeks before attempting to stop had a greater probability of succeeding, but the difference was not significant, according to one study".

Adverse events:

The incidence of the various side effects observed with the various NRT formulations was not quantified in this summary.

Fiore and Palmer in their study demonstrated that "This was the case due to the wide range of symptoms mentioned in terms of origin, chronology, and duration. The transdermal patch does not have the same side effects as nicotine gum, such as hiccups, gastrointestinal disturbances, jaw pain, and orodental disorders. The only negative effect that appears to interfere with patch use appears to be skin sensitivity and irritation; this may affect up to 54 percent of patch users, but it is usually mild and seldom leads to patch withdrawal".

Schneider in 1996 said that "Local irritation at the administration site is one of the most typical side effects of the nicotine inhaler and nasal spray (mouth and nose respectively). Symptoms such as throat discomfort, coughing, and oral burning were reported substantially more frequently by nicotine inhaler users than by placebo users; placebo users reported none of the feelings".

Wallstrom in 1999 quoted that “They were, nevertheless, described as grave. Nasal pain and a runny nose are the most common nasal spray adverse effects. Nicotine sublingual pills have been linked to coughs, burning and smarting sensations in the mouth, sore throats, coughing, dry lips, and mouth ulcers”.

Greenland in 1998 stated in his study that “When nicotine patches were used, there was no evidence of an increase in adverse cardiovascular events, and the total number of such events was small, according to a review of 35 trials involving over 9,000 people . Concerns concerning the safety of NRT in smokers with heart disease have been raised . A nicotine patch experiment enrolled smokers over 45 with at least one diagnosis of cardiovascular disease, and found no evidence that the nicotine patch group had a higher risk of serious adverse events”.

Joseph in 2003 stated in research that “Even though there was no difference in whether or not they were using NRT, events linked with cardiovascular disease, such as an increase in the severity of angina, occurred in roughly 16 percent of patients. According to a study, there was no evidence of an increased risk of cardiac events in patients with cardiovascular disease”.

Tzivoni in 1994 stated that “Data from two randomised trials with short-term follow-ups, as well as a case-control study in a population-based sample, were excluded from the current review”.

Chapter-5 Conclusion

The majority of NRT users stop taking it too soon. Low compliance is frequently caused by misinformation about NRT. Poor NRT compliance has been linked to concerns about safety, addictiveness of NRT, lack of faith in efficacy, adverse effects, cost, and relapse. The effectiveness of NRT has been identified as one of the most common reasons for poor compliance. Patients may incorrectly feel that treatment is no longer necessary when cravings and withdrawal are well handled with medication. NRT's effectiveness is harmed by these assumptions.

The greatest major impediment to smoking cessation and long-term sobriety is nicotine addiction. Nicotine treatments come in a variety of forms, doses, and flavours, and they are advised for all tobacco users who do not have any medical contraindications. Choosing a NRT product should usually be guided by the patient's preferences.

All commercially available types of NRT (gum, transdermal patch, nasal spray, inhaler, and sublingual tablets/lozenges) boost their odds of effectively quitting smoking, according to current studies. NRTs boost the likelihood of quitting by 50 to 70%.

Another meta-analysis discovered that NRT boosted the likelihood of reducing habit size in smokers who are unable to entirely quit smoking. To improve the efficacy of NRT, recent research has focused on fast administration strategies and immunological procedures. To get these new modalities from the bench to the bedside, more high-quality research is required. Given the potential of NRT, it is vital for health practitioners to get familiar with all types of NRT in order to respond to the queries and requirements of tobacco users who appear to be more interested in quitting.

Nicotine dependence:

Nicotine gum has previously been shown to be beneficial to smokers who have a high level of nicotine dependence (Gourlay 1990; Lam 1987; Tang 1994). The 4 mg gum is substantially more helpful in these people than the lesser dose.

5.5 Non Dependence On Nicotine:

In a direct comparison to non-nicotine pharmacotherapies, one big study (Jorenby 1999) found that bupropion is more successful than the nicotine patch. The use of both NRT and bupropion was not found to be any more effective than bupropion alone.

Chapter-6 Recommendations

1. As part of a tobacco quitting approach, all commercially available forms of NRT (gum, transdermal patch, nasal spray, inhaler, and sublingual pill) are successful. Regardless of setting, they increase the chances of long-term quitting by 1.5 to 2 times.

2.NRT should be addressed primarily to smokers who are motivated to quit (as evidenced by their willingness to seek help) and who have a high level of nicotine dependence.

3.There is limited evidence that NRT is effective for people who smoke less than 10 to 15 cigarettes per day.

4.Patient needs, tolerance, and economic considerations should all be taken into account when deciding which type to utilise. Patches are anticipated to be easier to employ in primary care settings than gum or nasal spray.

Eight weeks of patch therapy is just as effective as lengthier courses, and tapering therapy isn't any better than sudden cessation. Only wearing the patch during waking hours (16 hours per day) has the same effect as wearing it for 24 hours a day.

If gum is used, it might be given in a fixed dose or on an as-needed basis. 4 mg gum should be administered to extremely dependent smokers or those who have failed with 2 mg gum.

There is some evidence of a modest benefit from combining the nicotine patch with a form that allows ad lib dosage when compared to using a single form. Combination therapy may help patients who have been unable to cease taking a single type of NRT.

When compared to the usual dose patch, there is some evidence that using the nicotine patch at doses higher than 22 mg (24 hours) or 15 mg (16 hours) provides a slight benefit. These may be used by heavy smokers (those who smoke 30 or more cigarettes per day) or those who are relapsing due to persistent cravings and withdrawal symptoms despite regular dosage therapy.

The intensity of additional support provided to the smoker appears to have little effect on the effectiveness of NRT. Although providing more intensive amounts of support is good in increasing the likelihood of quitting, it is not required for NRT to be successful.

There is only a limited amount of evidence suggesting a second course of NRT in patients who have relapsed after using nicotine patches recently will result in a slight increase in the likelihood of stopping.

In smokers with a history of cardiovascular disease, NRT does not enhance the risk of adverse cardiovascular events.

In one study, the nicotine patch was found to be less effective than bupropion. However, when deciding which pharmacotherapies to utilise, it's important to consider both the risks and the benefits.

Finally, producers of NRT products should make marketing statements that reflect these considerations to avoid health professionals and the general public believing that any of these treatments alone delivers a miracle 'cure' for the smoking habit.

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