Internship Training

At

International Institute of Health Management Research, New Delhi

Effect of smokeless tobacco use during pregnancy on fetal outcomes: A Literature Review

By

Name – Dr. Aanchal Singhal

Enroll No. PG/19/001

Under the guidance of **Dr. Anandhi Ramachandran**

Post Graduate Diploma in Hospital and Health Management 2019-21



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2019-21



International Institute of Health Management Research New Delhi The certificate is awarded to

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10.06.2021

At

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I wish her all success in all her future endeavors.

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The following dissertation titled "Effect of smokeless tobacco use during pregnancy on fetal outcomes: A Literature Review" at "International Institute of Health Management Research, New Delhi" is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of Post Graduate Diploma in Health and Hospital Management (Hospital & Health Management) for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

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Dr. Rajeev Patni

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This is to certify that Dr. Aanchal Singhal, a graduate student of the PGDM (Hospital &

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this dissertation titled "Effect of smokeless tobacco use during pregnancy on fetal

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This dissertation has the requisite standard and to the best of our knowledge no part of it has

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Dr. Preetha GS, Professor and Dean Research, IIHMR- Delhi Dr. Anandhi Ramachandran Associate Professor IIHMR-Delhi

6

CERTIFICATE BY SCHOLAR

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FEEDBACK FORM

| Name of the Student: Dr. Aanchal Singhal |
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| Dissertation Organization : International Institute of Health Management Research, New Delhi |
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Dr. Aanchal Singhal

Amghal

TABLE OF CONTENTS

| | Certificates | ii - viii |
|-----|-----------------------|-----------|
| | Acknowledgements | ix |
| | Table of Content | Х |
| | Organization Profile | 11 - 13 |
| | Abstract | 14 |
| | List of abbreviations | 15 |
| 1 | Introduction | 16 - 17 |
| 1.1 | Aim | 18 |
| 1.2 | Objective | 18 |
| 2 | Methodology | 19 |
| 3 | Results | 20 - 22 |
| 4 | Discussion | 23 |
| 5 | Conclusion | 24 |
| 6 | Recommendations | 25 |
| 8 | Bibliography | 26 - 28 |
| 9 | Plagrism Report | 29 - 30 |

International Institute of Health Management Research New Delhi

INTRODUCTION AND BRIEF ORGANIZATIONAL PROFILE

IIHMR (International Institute of Health Management Research) Delhi, a part of the IIHMR Society, was founded on 18th August 2008, with a mandate to focus on national and international health, catering to the growing needs of the country as well as those of the Asia-Pacific region. The Institute aims to play a major role in promoting and conducting research in policy analysis and formulation, strategy development and effective implementation of policies, training and capacity development in preparing professionals for the healthcare sector. It conducts and designs policy analysis and reviews. It also undertakes intervention research, evaluation studies and operations research studies. The Institute offers a two-year full-time Postgraduate Diploma with specialization in Hospital Management, Health Management and Healthcare Information Technology. The program is approved by the All India Council for Technical Education (AICTE) and has been accredited by the National Board of Accreditation (NBA). To meet the educational challenges of the rapidly growing health sector in India, IIHMR Delhi equips its students with a strong managerial and technical foundation for careers in consulting, hospital management, health care systems, healthcare quality management, health insurance and healthcare information technology, business analysis and transformation.

The aesthetically designed and magnificently built campus of IIHMR is located in Dwarka, New Delhi. The infrastructure as well as the facilities are at par with international standards and meet all academic and administrative requirements. The well-lit spacious air-conditioned classrooms equipped with audio-visual facilities create an atmosphere conducive to learning. The library of the Institute is equipped with the latest books, journals and magazines of national and international standards that are required for academic as well as research activities. The computer center of the Institute is a state-of-the-art facility and uses technologies to provide a competitive advantage to both its faculty as well as the students in core areas of education and research. Three large air-conditioned conference halls provide adequate space to host national and international conferences, seminars and workshops within the Institute. Other facilities include individual rooms for the faculty, gymnasium, tennis court, mini-amphitheater, centralized air-conditioning system and a car-parking lot. The Institute also has a spacious and well-equipped cafeteria and a guesthouse for visiting guests and dignitaries.

Our Mission

IIHMR is an institution dedicated to the improvement in standards of health through better management of health care and related programme. It seeks to accomplish this through management research, training, consultation and institutional networking in a national and global perspective.

Vision

IIHMR is a premier institute in health management education, training, research, program management and consulting in the health sector globally. The institute is known as a learning organization with its core values as quality, accountability, trust, transparency, sharing knowledge and information. The institute aims to contribute to social equity and development thorough commitment to support programs aiming at poor and deprived population.

Core Values

The institute is known as a learning organization with the following core values:

- 1. Quality
- 2. Accountability
- 3. Trust
- 4. Transparency
- 5. Sharing knowledge and information

Thrust Areas

IIHMR is engaged in policy issues, program planning and management and capacity building mainly in the health sector. It undertakes research, training and consulting activities in the following areas:

- Primary Health Care
- Health and Hospital Management
- Health Economics and Finance
- Population and Reproductive Health
- NGO Management and Networking
- HIV / AIDS Program Management and Evaluation

Research Strength at IIHMR

IIHMR has a pulsating research portfolio that primarily focuses on health systems, with a determination to embrace every component of the system into its research and training. The Institute conducts a diverse range of studies that directly or indirectly have a bearing on different levels of the health system, ranging from programme to community to policy level. The Institute conducts evaluation studies, operations research studies and programme evaluations on different dimensions of the health system for a range of different clients including national and state government organizations, national and international nongovernment organizations, as well as UN agencies, such as, WHO, UNICEF etc. The key areas of research include reproductive and child health, functioning of health care organizations, non-communicable diseases, health economics, and population based issues and climate change.

Capabilities

Management Research, Education and Training

- Planning, Designing and Conducting Management Training for Health Professionals
- Institutional Capacity Development and Networking
- Project Planning and Management
- Operations Research and Evaluation
- Economic and Financial Analysis
- Survey Research
- Social Assessment
- Quality Assurance
- Health Sector Reforms
- Programme Evaluation
- Health Information Technology

Effect of smokeless tobacco use during pregnancy on fetal outcomes: A <u>Literature Review</u>

ABSTRACT

Background- India is home to a large number of Smokeless Tobacco (SLT) users and consequently bears a major burnt of its disease burden. Among the non-carcinogenic ill effects adverse pregnancy outcomes are very important in India because of the high fertility rates and the millions of births occurring every year. Adverse pregnancy outcomes contribute to a huge disease burden, part of which can be potentially overcome by reducing Smokeless tobacco use among prospective mothers. The aim of this review was to understand the magnitude and effect of smokeless tobacco use on fetal outcomes. Published literatures were identified by searching electronic databases like Google scholar, pro quest advanced search, PubMed advanced search, Wiley, J Gate. Inclusion criteria applicable to any literature documenting any form of smokeless tobacco use during pregnancy along with the fetal outcomes, documented in English language in any part of the world and within the time frame of 30 years (from 1990 till 2021). Articles of any other language other than English also grey literature like unpublished data, dissertations, and conference proceedings were excluded from the study. Studies that talked about any other form of tobacco than smokeless or studies that do not contain tobacco were excluded. Result – Pertinent data was retrieved from 19 shortlisted articles and all the three outcomes (Low birth weight, preterm and still birth) were found to be positively associated with smokeless tobacco use during pregnancy. Conclusion – Maternal smokeless tobacco use may not be safe for mother or fetus, but subsequent studies are needed in this matter. Barriers to smoking cessation must be identified and steps should be taken to eradicate them to reduce smoking among pregnant women. Information sharing and awareness raising campaigns and activities should be initiated at community level to encourage and create awareness on subject matter.

Keyword - smokeless tobacco, Low birth weight, Pregnancy, areca nut, snuff, betel quid, gutka, Mishri, pregnant women, fetus.

LIST OF ABBREVIATIONS

| ST | Smokeless Tobacco |
|------|-----------------------------|
| LBW | Low Birth Weight |
| IUD | Intra Uterine Devices |
| GATS | Global Tobacco Adult survey |

INTRODUCTION

Smokeless Tobacco has been popularly known to be widely used in different parts of the world especially In South America and Southeast Asia, and Is Increasingly gaining popularity and acceptance in other parts of the world. (Asma et al., n.d., p. 1) Tobacco can be used alone or in combination with products such as betel quid, ash, lime, etc. Betel quid with tobacco, also known as "gutka," is used primarily on the Indian subcontinent. (Rogers, 2008) India has also gained popularity for other forms such as Khaini, mishri, zarda etc., prepared through different procedures such as drying, roasting or boiling. The habit of nass is common In Central Asia with prevalence rates of up to 20% in some countries. (Abdul Ghani et al., 1987), (Aziz Ali et al., 2020) Nass Is usually made with local tobacco, ash and cotton or sesame oil, but the composition varies in different regions. Nasal snuff is widely used among the Bantu population In South Africa. (Smokeless Tobacco.Pdf, n.d., p. 51)

India is known to be the third largest tobacco producer and second largest consumer of tobacco worldwide. The scenario around tobacco use In India Is even more of a challenge. Mortality due to tobacco use In India Is estimated at upwards of 1.3 million. Though, a downward trend has been observed amongst the prevalence of smokeless tobacco usage In Global adult tobacco survey held in 2009 and 2016. From GATS 1 (2009-10) to GATS 2 (2016-17), the prevalence of tobacco use has reduced by six percentage points. The number of tobacco users has reduced by about 81 lakh. However according to GATS survey (2016) 19.0% of men, 2.0% of women and 10.7% (99.5 million) of all adults observed smoking tobacco whereas prevalence of smokeless tobacco was seen In 29.6% of men, 12.8% of women and 21.4% (199.4 million) of all adults. Also 42.4% of men, 14.2% of women and 28.6% (266.8 million) of all adults currently use tobacco (smoked and/or smokeless tobacco). Every fifth adult is documented using smokeless tobacco and every tenth adult prefer smoking tobacco according to the data recorded. (GATS2 (Global Adult Tobacco Survey) Fact Sheet, India, 2016-17, n.d.) The absorption of nicotine per dose is greater with use of chewing tobacco (average 4.5 mg nicotine) or snuff (average 3.6 mg nicotine) compared with that for smoking cigarettes (average 1.0 mg nicotine).

Smokeless tobacco has a good amount of nicotine similar to what is found in cigarette smokers. The difference lies In Its consumption, as It Is taken orally or consumed nasally but not smoked. The application of oral smokeless tobacco is mainly through placing it in mouth, inside cheek or below lip by sucking or chewing It. Likewise, fine tobacco powder mixtures are usually inhaled and absorbed in the nasal passages and tobacco pastes are placed on gums or teeth. Smokeless tobacco contains high quantity of nicotine which can be related as the main reason for its chronic usage or we say addiction. (Benowitz, 1988, p. 1) It has been seen that substance nicotine is absorbed slowly from smokeless tobacco as compared to cigarette smoke, still the peak venous blood levels are similar. It has also been observed that after smoking blood levels of smoking fall rapidly whereas the concentration plateau during and

after use of smokeless tobacco are consistent with continued absorption, even after the tobacco Is removed from the mouth (Benowitz, 1988, p. 1).

Smoking is largely a problem among men. However, use of smokeless tobacco is quite widespread among both men and women. Among women the three most commonly used tobacco products are betel quid with tobacco, tobacco for oral application and khaini. (*GATS2* (*Global Adult Tobacco Survey*) Fact Sheet, India, 2016-17, n.d.) Health effects from the use of smokeless tobacco products remain unclear, and the potential for long term harm cannot be ruled out. (*General Smokeless Tobacco.Pdf*, n.d., p. 2)There has been enough evidence stating Its harmful effect present In various parts of the body Including ranging from oral cancers, esophageal cancers, sub mucous fibrosis, effects seen on blood pressure, cardiovascular diseases, Crohn's disease and ulcerative colitis, and many more other health hazards. (Cardenas et al., 2019) (Benowitz, 1988)

There has been dearth of literature showcasing effects of tobacco on women, but researches and survey has witnessed increased usage and dependence on smokeless tobacco pertaining towards negative consequences on fetal outcomes and reproductive health resulting in low birth weight, preterm birth, abortion or still births. (Krisshna, 1978), (Kumar, 2013) Some literature study have also linked the effects with the dose Intake but there are still lacking evidences In exploring factors driving SLT use during the reproductive years and especially during pregnancy. (Nair et al., 2015, p. 2) Effects of smoke exposure on the placenta are probably critical and are not adequately understood as they have found to have an Impact on reproductive organs causing Uterine Ischemia and carboxy-hemoglobin formation contributing to fetal hypoxia. Research is needed to better understand the impact and etiology of tobacco related effects on the maternal fetal interface throughout pregnancy. (Inamdar et al., 2015)

In Spite of Its widespread use in various parts of the world, very little attention or legal action has been put into smokeless tobacco usage and Its Impact on health. Especially when there can be Increased demand of smokeless tobacco usage depending on the current emphasis seen on adverse health consequences of tobacco smoking, Including exposure to environmental tobacco smoke. (Pereira et al., 2017)

In 2018, 4.0 million (75% of all under-five deaths) occurred within the first year of life (WHO). Low Birth Weight and Still birth weight amongst the top 5 leading causes of Infant Mortality (CDC). Every year, an estimated 15 million babies are born preterm (before 37 completed weeks of gestation), and this number is rising (WHO).

The aim of this paper is to review and summarize the latest literature related to tobacco use in pregnancy including the effects of smokeless tobacco on mother and baby and the effects of other tobacco products. This study also attempts to study the magnitude of smokeless tobacco

on reproductive outcomes for mothers having habit of taking tobacco (smokeless) while they are pregnant.

OBJECTIVE

- 1. To assess the magnitude of use of smokeless tobacco during pregnancy on fetus based on literature data.
- 2. To understand the effect of smokeless tobacco usage during pregnancy on fetal outcomes

RESEARCH QUESTIONS

The Research question include the following elements: Population (P) to be Pregnant Women; Exposure (E) would be smokeless tobacco with Control (C) as those who were not using or not exposed to smokeless tobacco affecting fetal Outcome (O).

This review endeavored to answer two broad questions:

- 1. What are the maternal and child health outcomes of being exposed to smokeless tobacco products during pregnancy?
- 2. What are the impacts of tobacco or other nicotine products during pregnancy on the fetus? For this review, we systematically synthesized research from existing literature to answer the research questions. This included identifying and summarizing key concepts and evidence related to health outcomes.

METHODOLOGY

Literature search

Studies were identified by searching electronic databases like Google scholar, pro quest advanced search, PubMed advanced search, Wiley, JGate. The search strategy used for PUBMED was: ("Pregnancy" AND "Smokeless tobacco") AND ("Betel Quid" OR "Areca Nut" OR "Mishri") AND ("Tobacco" OR "smokeless tobacco") AND ("Pregnancy" OR "Low Birth weight" OR "Preterm weight" OR "stillbirth") AND ("Reproductive outcomes" OR "Fetal outcomes"). This search strategy was considered the pattern strategy for this review and was adapted to other electronic databases.

Various combinations of the keywords were used for each condition to search Google Scholar, and its first 50 pages were screened for relevant and non-duplicate articles. Similarly, various combinations of the keywords were used in each of the databases and the same process repeated. Special efforts were taken to retrieve articles where smokeless tobacco use was also one of the factors, but not the main factor for which association was examined. Cross-references of all selected articles were scanned for additional studies. The last date of literature search was 31 May 2021.

Data Inclusion and Exclusion Criteria

The study was designed with an objective to conduct a narrative review to establish evidence regarding the effect of smokeless tobacco on fetal outcomes. The eligibility criteria for inclusion of a study were designed in such a manner so as to include published cohort, case-control and cross-sectional studies focusing on reproductive fetal outcome, adverse pregnancy outcomes related to the mothers were not considered. Inclusion criteria applicable to any literature documenting any form of smokeless tobacco use during pregnancy along with the fetal outcomes, documented in English language in any part of the world and within the time frame of 30 years (from 1990 till 2021). ST of at least one form such as snuff, plug, quid, snus and gutka, with or without additives, used in any amount or frequency, during pregnancy, or at some time during pregnancy, was considered.

Articles of any other language other than English also grey literature like unpublished data, dissertations, and conference proceedings were excluded from the study. Studies that talked about any other form of tobacco than smokeless or studies that do not contain tobacco were excluded.

RESULT

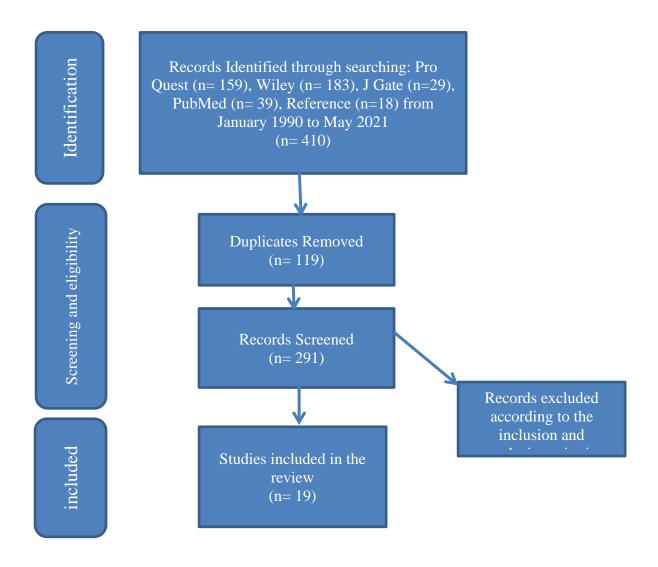


Fig 1: PRISMA flow diagram

Study Selection

The search of database with selected keywords on above stated databases yielded 410 studies (159 from ProQuest, 183 from Wiley, 29 from J Gate, 39 from PubMed) and 18 were obtained by the reference of the selected studies. Of these studies, 119 were duplicates that were excluded from the analysis. After independent assessment of titles and abstracts 59 studies were selected for full text reading, resulting in 19 studies included in the review were considered potentially eligible for inclusion and assessed as full-texts based on the predetermined inclusion and exclusion criteria.

Study Characteristics

The oldest study was published in 1993 in Bombay (India). Three studies were published in the 1990s ten studies between the year 2000 - 2010 and rest six studies were published after 2011. From the selected articles four were retrospective cohort study, six were prospective cohort study, three identified as case control studies and six were secondary literature.

Eight studies were conducted within states of India (Nagpur, Nasik, and Maharashtra); two from Bangladesh; one each from Alaska, UK, USA, Sweden and Palau; three were secondary literature from various parts of world. From 19 studies, 9 took place in hospitals or maternity wards, four in primary health care or community settings and six collected data from secondary sources. There were 16 studies reporting on Low Birth weight, 5 reporting on still birth and 6 studies reporting on preterm birth.

Information on ascertainment on ST use was mainly from self-reports through questionnaires and personal interviews, from public and hospital records and socio demographic data. There was a high risk of recall bias and performance bias (misclassification of exposure) in all studies where information on ST use was obtained mainly from self-reports (none of the studies reported ascertaining the levels of nicotine/cotinine by any biochemical measurements).

The *OR*s greater than one suggest that there is a greater risk of having a LBW, preterm, SGA, or a stillbirth with ST use in pregnancy.

Exposure Outcome

Still Birth

There are 5 studies {(Hoque et al., 2012), (Suliankatchi & Sinha, 2016), (Gupta & Subramoney, 2006), (Inamdar et al., 2015), (Ratsch & Bogossian, 2014)} addressing stillbirth and all of them confirmed a positive correlation of stillbirth with ST. The Studies reported unadjusted OR ranging between 1.60 to 4.57 in three reports and two studies reporting adjusted OR excluding previous stillbirth and caesarean delivery as 2.6 (1.4-4.8) which was found to be statically significant. In fact one of the studies highlighted upon dose response relationship with Mishri (ST) intake with OR 2.1 when intake was 1-4 times a day whereas OR increased to 3.8 with 5 times a day intake.

Preterm

There are 6 studies addressing preterm and all of them showed significant association with ST users. Three studies {(Hoque et al., 2012), (Munmun et al., 2017), (England et al., 2012) } suggested 3.1 times, 2.69 times and 2 times increased risk of preterm with ST users respectively and found to be statically significant. One of the study (Gupta & Subramoney, 2006) highlighted 26.7% users of ST having preterm as compared to 18.5% non ST Users. The result was highlighted even strong after adjustments with 3.7 (1.9-7.4) OR with fetal outcomes occurring before 32 weeks and 7.2 (2.3 to 22.3) OR with fetal outcomes occurring

before 28 weeks. Another study (Suliankatchi & Sinha, 2016) highlighted that heavy ST users found to be delivering 8.9 days earlier as compared to non-users or light users. All the studies were found to be statically significant (p<0.01 to P<0.002).

Low Birth Weight

Out of the 16 studies {(Hoque et al., 2012), (Suliankatchi & Sinha, 2016), (Gupta & Subramoney, 2006), (Deshmukh et al., 1998), (Mumbare et al., 2012), (England et al., 2012), (Ward et al., 2007), (Rogers, 2008), (Inamdar et al., 2015), (England et al., 2012), (Berger et al., 2016), (Pratinidhi et al., 2010), (Monawar Hosain, 2005), (Rahman, 2018), (Krishnamurthy & Joshi, 1993)} on low birth weight only one study suggested result non-significant after full adjustments of factor with P factor as 0.18 (England et al., 2012) whereas rest 15 studies have shown statically significance of LBW with ST users. Several studies have confirmed positive association of LBW with ST users with Crude OR ranging from 1.6 to 4.1 and adjusted OR ranging from 2.4 (95% CI, 1.2-5.0) to 3.2 (95% CI, 1.5-6.9) with studies showing statically significance. Amongst these there was one study (Gupta & Subramoney, 2006) highlighting lower birth weight among boys (118 gm., p = 0.04) in comparison to girls (86 gm., P= 0.08), though we have lesser evidence on this subject matter, it needs more literature study. Another study (Pratinidhi et al., 2010) found LBW as 169.9 gm. lesser in ST users and was found to be statically significant whereas another study (England et al., 2003) found it to be 40 gm. (95% CI, 6-72 gm.) lesser amongst ST users.

DISCUSSION

As per findings of Global Adult tobacco survey (GATS) India report 2016-2017, there are about 4.7 percent pregnant women of age group 15 to 24 years and 9.9% pregnant women of aged group 25 to 49 years who are currently consuming smokeless tobacco. 5.5% urban women and 8.2% rural women according to the report belonged to the pregnant women category that was found using smokeless tobacco. Percentage of pregnant women using ST in India is reported for about 21.7% of which Tripura (48.5%), Manipur (36.5%) and Odisha (42.9%) were amongst the highest. Two states, Uttar Pradesh and Maharashtra, together account for one-third (33%) of smokeless tobacco users in the country. Amongst Women betel quid with tobacco, tobacco for oral application and khaini were found to be most populous. (Global-Adult-Tobacco-Survey-Second-Round-India-2016-2017.Pdf, n.d., pp. 58–70). In Other studies Sharda, Jorda, Gul was amongst the most popular forms. (A1, A8, A22, A2, A20) {(Hoque et al., 2012), (Gupta & Subramoney, 2006), (Ratsch & Bogossian, 2014), (Munmun et al., 2017),(Monawar Hosain, 2005)}

Out of 19 studies 3 studies talked about association of ST consumption in pregnant women with still birth, low birth weight and Preterm weight. It reported approximately two to three fold increases in perinatal outcomes in all these studies. The studies included in our report found following confounders consistent with studies under consideration including age of mother, Education, Antenatal care, Socioeconomic status, parity or previous history of cesarean and Marital status which were taken into consideration. {(Suliankatchi & Sinha, 2016), (Gupta & Subramoney, 2006), (Berger et al., 2016)}

The results we got in the analysis were consistent and showed statical significance pointing towards a positive association between maternal ST use and its subsequent fetal outcomes in newborn. This review has reviewed extensively searching the online databases without limiting the search for studies by language or geographical location. Although majority of the studies reported on low birth weight outcomes of ST consumption only few reported on still birth (five) and preterm weight (six).

Though we have enough evidence on fetal outcomes on three areas but there is lack of evidence on other perinatal outcomes apart from the three under study, the same was suggested in other study (Inamdar et al., 2015). It is suggestive to focus on other adverse newborn outcomes as well apart from these which can be further explored. Also there is another important thing observed while doing analysis was differentiation in the type of ST usage and their content clarity as they vary widely in content.

LIMITATION

- The Result of some studies was based upon small sample size and hence cannot be stated as conclusive it required further study and correlation. (Hoque et al., 2012), (Deshmukh et al., 1998), (England et al., 2003), (Berger et al., 2016), (Ratsch & Bogossian, 2014)}
- In a study Confounding due to weight gain and over-reporting of gestational hypertension could not be eliminated, which limits the conclusions of the study. (Gupta & Subramoney, 2006)
- Very few studies have analyzed or talked about Dose Response relationship there can be a possible correlation in that aspect but we could not gather enough evidence on that subject in this study. Only one study has talked about dose response relationship and found it to statically significant with increased dosage and its consequences on still birth. (Ratsch & Bogossian, 2014)
- There was a high risk of recall bias and performance bias (misclassification of exposure) in all studies where information on ST use was obtained mainly from self-reports (none of the studies reported ascertaining the levels of nicotine/cotinine by any biochemical measurements). (Pratinidhi et al., 2010)

CONCLUSION

Tobacco in pregnancy contributes towards many adverse outcomes for both the mother and fetus, not only at birth but through the entire life course. There has been evidence that usage of smokeless tobacco has proven to have adverse impact on pregnancy and fetus. Consumption of smokeless tobacco during pregnancy decreases birth weight, increases chances of still birth and preterm delivery. It should receive specific attention as a part of routine prenatal care. Complete cessation is the only certain way for tobacco users to reduce their risk of adverse pregnancy outcomes. There is a positive dose response relationship with smokeless tobacco use on still birth and preterm. There was a suggestive evidence of SLT use associated with adverse pregnancy outcomes among women. Further studies in this field are required to generate more conclusive evidence.

RECOMMENDATION

- 1. It is advisable to identify facilitators of smokeless tobacco and necessary steps should be taken with strict guidelines to eradicate them.
- 2. More studies are required in this field with robust study designs.
- 3. There is urgent need of concentrated efforts in health as well as non-health sectors for initiating improvement in health and social status of women.

Conflict of interest – The writer has no conflict of interest **Funding** - Not required **Ethical approval** – Not required

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