

Pregnancy Outcomes in Smokeless Tobacco Users Cohort Study in a Tertiary Care Hospital

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Received 24 March 2014; revised 20 April 2014; accepted 28 April 2014

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Abstract

There is a dearth of literature regarding the pregnancy outcomes in antenatal women using smokeless tobacco products (STP). Objective: To compare maternal and neonatal pregnancy outcomes in antenatal women using smokeless tobacco products with those not using tobacco products. Method: Pregnant women attending antenatal clinic at Guru Teg Bahadur hospital, Delhi received brief information about smokeless tobacco products. Antenatal women using STP and matched controls, 92 in each group (total 184) were recruited for the study. After obtaining consent, the urinary cotinine level was measured in both groups at first contact. Antenatal, labour and postpartum events were recorded in both groups. Urinary cotinine levels were again measured at 6 months in the user group. Results: Average age of antenatal women under study was 24.8 yrs and 25.21 yrs in user and non-user groups respectively. More women in the user group were illiterate ($P < 0.05$). Mean urinary cotinine in user and non-users was $44.21 \pm 20.39 \mu\text{g/ml}$ and $24.37 \pm 20.14 \mu\text{g/ml}$ respectively ($p < 0.0001$). Women using STPs for more than 5 yrs recorded higher urinary cotinine levels. There was no significant difference in urinary cotinine levels with the type of tobacco product consumed. Pregnancy outcomes of 39 women are known. There was no significant difference in antenatal, intra-natal and postpartum complications in the two groups. Neonatal weight difference was 20 gms. Conclusion: Smokeless tobacco products are the most common forms used by women in low and middle income countries. Larger studies are required to understand their effects on pregnancy outcomes.

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Keywords

Pregnancy, Smokeless Tobacco Product, Urine Pregnancy Outcome

1. Introductions

Global Adult Tobacco Survey (GATS) 2009-2010 [1] reported that 35% of adults and 20% of women in India use tobacco. Smokeless tobacco is used by 21% of (estimated 163.7 million) adults. Amongst women, 18% of them use only the smokeless form.

There are a variety of smokeless tobacco products available in India namely, Khaini, Jarda/Zarda, Gutkha, Creamy snuff, Red tooth powder, Tuiber (Tobacco water), paan masala with tobacco, “Mishri”, gul, mawa, etc. Other than oral malignancy, smokeless tobacco is now found to be associated with pancreatic cancer, cardiovascular diseases [2]-[4] and adverse reproductive outcome.

There is a dearth in literature regarding the use of smokeless tobacco in women and pregnancy outcomes. Today, there is robust evidence regarding the reproductive and pregnancy outcomes in women with use of the smoked forms of tobacco but the evidence regarding the harmful effects of smokeless tobacco product use. Research in this area is especially important for the developing nations where prevalence of smokeless tobacco products use especially amongst women is high, greater socio-cultural acceptance is high. This study aims to address this issue and generate evidence related to the use of smokeless tobacco during antenatal period and pregnancy

2. Objective

It is to compare maternal and fetal outcomes amongst pregnant users versus non-users of smokeless tobacco products.

3. Methodology

This cohort study was conducted at Department of Obstetrics & Gynecology, Guru Teg Bahadur Hospital (GTB Hospital), Delhi and Department of Biochemistry, University College of Medical Sciences (UCMS), Delhi from March to December 2011.

Selection of participants was done from antenatal clinic at GTB hospital.

Informed consent for inclusion in the study was obtained from all participants.

The women were then interviewed as per a set semi-structured questionnaire. Urine samples of the women (both groups) were then collected for estimation of cotinine levels and tested on the same day. Urine cotinine was measured by ELISA technique (Calbiotech Cotinine ELISA Kit) at recruitment and then, again at 6 months at follow-up to confirm continued use or non-use of STP.

All women received antenatal care as per the set institutional guidelines. Antenatal maternal weight gain during pregnancy, complications like pre-eclampsia, antepartum hemorrhage, fetal growth restriction, operative delivery, neonatal weight and perinatal outcome were recorded for both the groups.

In the period from March to July 2012, a total of 184 pregnant women were recruited for the study. Of these, 92 were using smokeless tobacco, another 92 antenatal women matched for age, BMI, literacy and parity not using any tobacco products, were considered as controls.

Use of tobacco (both smoked and smokeless forms) amongst other family members was also recorded.

Data were entered into SPSS version 18 and analysis included descriptive statistics, independent t-tests and Chi Square. All levels of significance were two-tailed and set at $p < 0.005$.

The study was approved by the Institutional Ethics Committee.

4. Definitions

Smokeless tobacco use was defined as at least once a day use for a minimum of three times a week of any of the following locally available smokeless tobacco products e.g., Gul, Zarda, Khaini, gutka, paan masala, etc.

Quitting Tobacco use was defined as complete non-use of any of the smokeless tobacco product.

5. Exclusion Criteria

- 1) Known smoking habit.
- 2) Medical disease in the mother.
- 3) Other addictions e.g., alcohol, any other substance abuse.
- 4) Pregnancy associated complications at recruitment likely to affect the outcome of the pregnancy e.g., pre-eclampsia, anti-phospholipid antibodies.

6. Results

The mean age of pregnant women recruited for study in both groups was 24.86 \pm 3.91 years while that in the control group was 25.21 \pm 3.6 years. Illiteracy rates amongst STP users were 54% compared to 33.7% in non-users. Mean monthly income in the user group was Rs 4869 \pm 16.73 while that in the non-user group was Rs 4548 \pm 15.47. Average money spent by the smokeless tobacco user group was about Rs 30/day. Percentage wise use of smokeless tobacco products and their composition is given in **Table 1**. Mean urinary cotinine value in the non-users was 24.37 \pm 20.14 μ g/ml, 35% of these women had urinary cotinine values 0 - 10 μ g/ml. Mean urinary cotinine value in the user group was 44.21 \pm 20.39 μ g/ml, 27% of these women had urinary cotinine values 50 - 60 μ g/ml (**Figures 1-3**). Women using tobacco for longer durations in years, recorded higher urinary cotinine levels (**Table 2**). Urinary cotinine levels in daily users were 46.22 \pm 18.09 μ g/ml versus 40.75 \pm 23.75 μ g/ml in women using it twice or thrice per week.

Delivery outcome could be known in 39 out of 92 women since some women returned to maternal homes for delivery and also the harvesting season resulted in many families returning to their village. There was no stastical difference in pregnancy outcomes in terms of maternal complications, miscarriage, antepartum hemorrhage, intrauterine growth restriction, birth weight. The mean birth weight in the user group was 2.411 \pm 0.417 Kg while that in the non-user group was 2.433 \pm 0.620 Kg, *i.e.*, a difference in birth weight of 20 gms (**Table 3**). When neonatal weights were compared at urinary cotinine cut-off levels at 20 μ g/ml, the difference in birth weight was 250 gms (**Tables 4-5**). Though this was not stastically significant, it does have clinical significance since in a country with high incidence of low birth weight; further reduction of 250 gms has an added significance. Comparing two groups with neonatal weight above and below 2.5 kg, there was no significant difference in maternal urinary cotinine values.

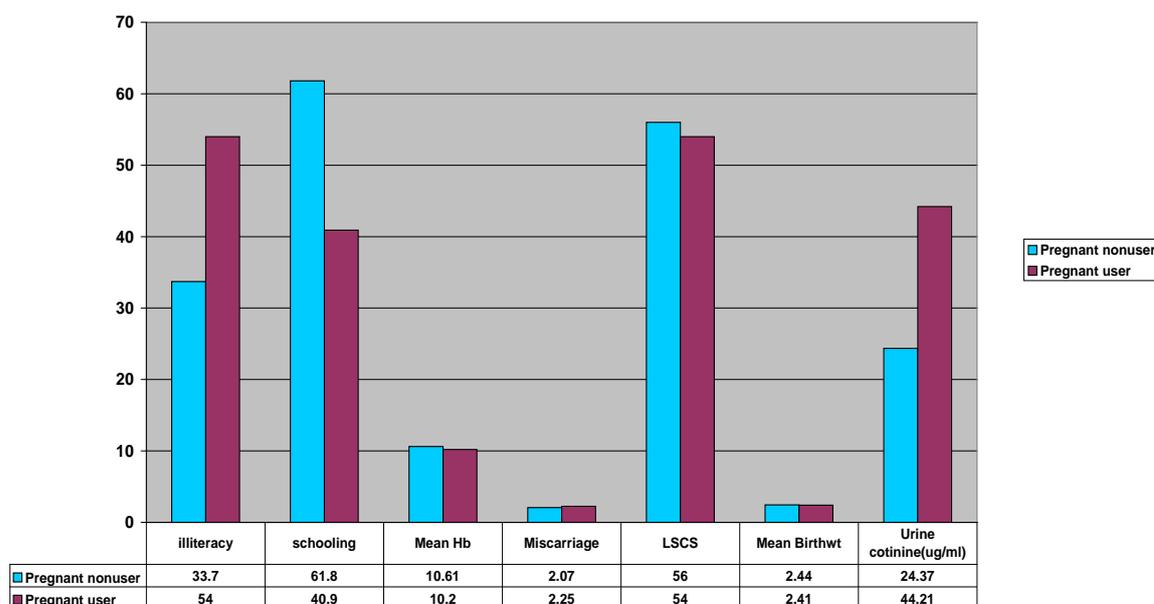


Figure 1. Demographic profile, operative delivery, baby weight and urinary cotinine values in smokeless tobacco user and non-user pregnant women.

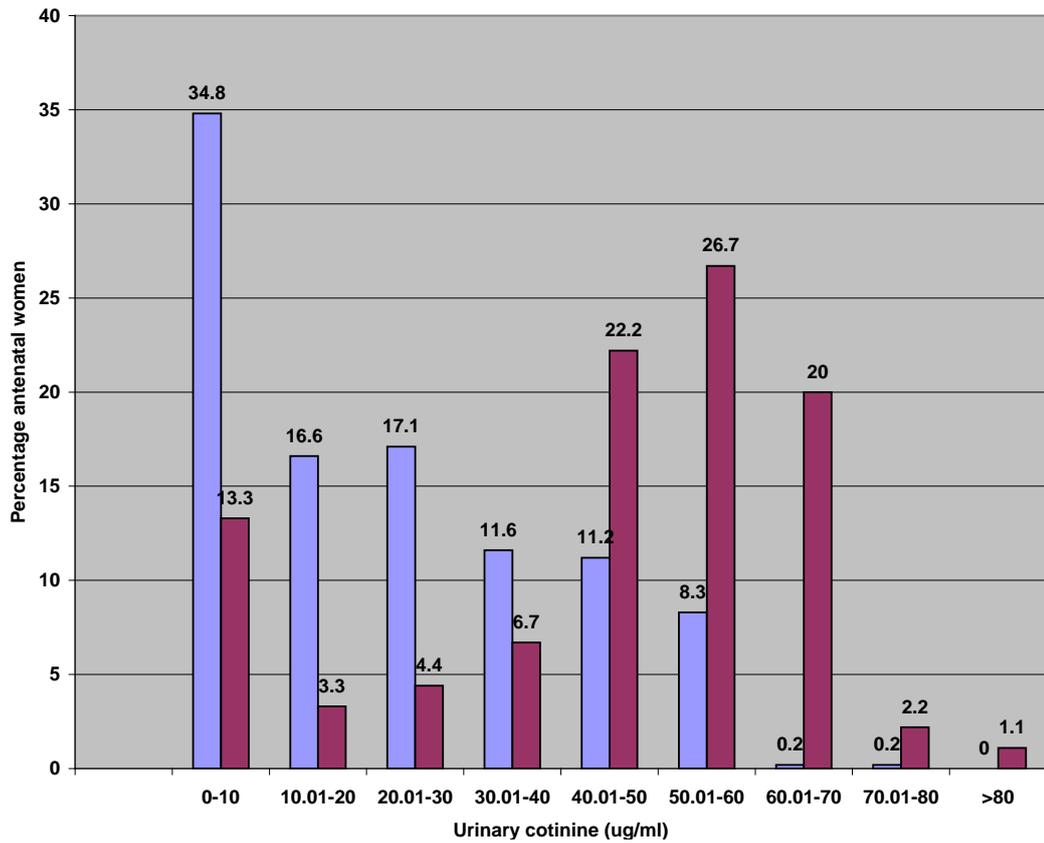


Figure 2. Urinary cotinine values in pregnant user and non-user women.

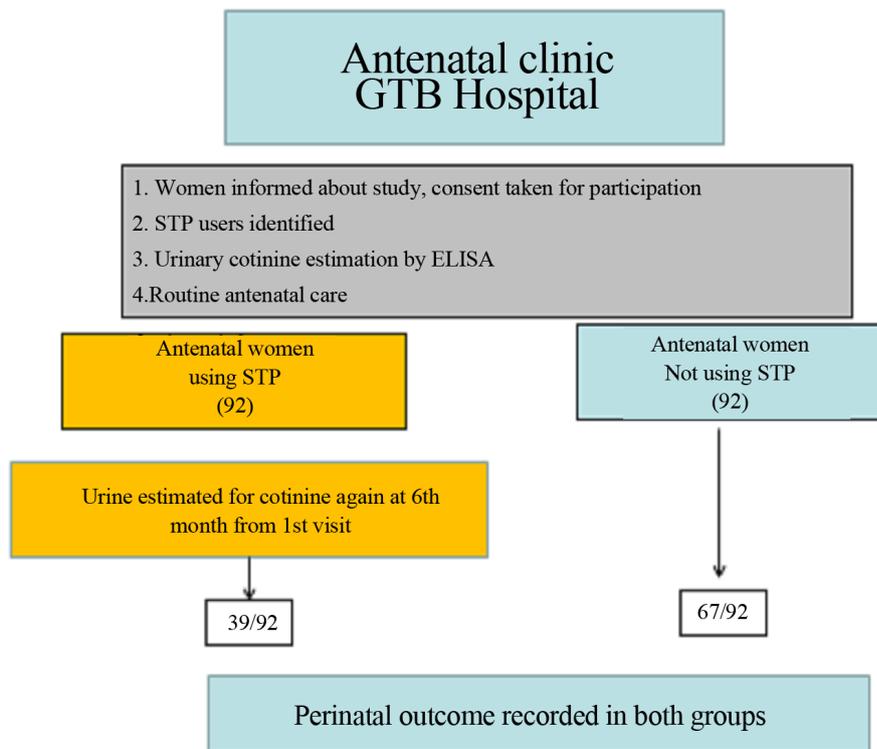


Figure 3. Methodology flow chart.

Table 1. Forms of smokeless tobacco products used, percentage of use and description of tobacco products.

Smokeless tobacco product	Description	Women using (%)
Gul	Made of tobacco powder molasses and other ingredients Used to clean teeth, applied to gums.	66
Gutkha	Areca nut, catechu, tobacco, lime, saffron and flavouring.	16
Pan masala	Made from tobacco, areca nuts, slaked lime and betel nut condiments.	9.5
Tobacco/Khaini/surti	Dried or fermented tobacco, slaked lime paste, sometimes areca nut.	8.4

Table 2. Urinary cotinine levels in relation to duration of use of STP.

Addiction habit	Number of women	Mean cotinine ($\mu\text{g/ml}$)
<1 yr	30	39.08
1-5 yrs	50	50.33
>5 yrs	13	68.90

Table 3. Mean neonatal birth weight in smokeless tobacco user versus non-user pregnant women.

	Pregnant user	Pregnant nonuser
Mean Birth wt (kg)	2.41 +/- 0.417	2.43 +/- 0.620
Urine cotinine ($\mu\text{g/ml}$)	44.21 +/- 20.39	24.37 +/- 20.14

Table 4. Mean birth weight in smokeless tobacco user pregnant women using urinary cotinine value cut-off at 20 ng/ml.

	Mean birth weight (kg)
Urinary cotinine < 20 ng/ml	2.63 +/- 0.345
Urinary cotinine > 20 ng/ml	2.38 +/- 0.421

7. Discussion

Today, the challenge is to contain women's tobacco use in low and middle income countries as women's improving social and economic status has started eroding the traditional barriers to quitting tobacco use.

Studying health effects of the various tobacco products is challenging since different products could have varying levels of nicotine, bioavailability, nicotine delivery, presence of additives, toxin levels, portion size. Moreover, stigma around tobacco use during pregnancy may discourage women from disclosing their tobacco use.

It is well documented that smoking during pregnancy is associated with higher incidence of low birth weight, abruptio placentae, placenta previa and premature rupture of membranes. Studies for the smokeless tobacco use in antenatal mothers and measuring the outcome are few. Assessment of the tobacco use can variously be done by measuring cotinine level, which is a metabolite of nicotine. Cotinine is metabolized in the liver. About 70% of the nicotine is converted to cotinine in the body. Cotinine has a half life of 15-20 hrs in the body. This is better than nicotine and hence considered a reliable estimate of tobacco use in any form [5]-[6].

In another study of 70 antenatal tobacco users in Jabalpur, birth weight and height of the neonate in the users were significantly reduced (390 gms & 0.5 cm respectively) [7]. In a study on the effects of maternal smoking on birth outcomes, multiple linear regression analysis showed exposure of the fetus to nicotine for the entire duration of pregnancy at urinary cotinine levels more than 5 $\mu\text{g/ml}$ resulted in a decrease in birth weight by about 100 gms. For every further increase in cotinine, there was a decrease in the birth weight by 12 +/- 0.02 gms [8]. In cohort study of 1217 pregnant women in Mumbai, smokeless tobacco users delivered earlier by 6.2 days ($p < 0.001$), the cumulative stillbirth in the smokeless tobacco users was significantly higher than in the non-users (8.9% vs. 3.1%) [9]. A statistically significant difference in intrauterine demise rates is also seen in our study—

Table 5. Socio-demographic profile and pregnancy outcomes.

Variable	Non user (%)	User (%)
Age (yrs)		
15 - 19	nil	3.2
20 - 25	63.44	59.13%
26 - 30	29.03	31.18
31 - 35	6.45	6.45
Education		
<i>Wife</i>		
Illiterate	29.03	56.98
Primary	16.13	15.05
Middle	3.22	5.37
Secondary	29.03	18.27
Higher	13.98	2.15
Graduate	8.6	2.14
<i>Husband</i>		
Illiterate	18.28	35.48
Primary	7.57	13.97
Middle	5.37	5.37
Secondary	46.24	36.55
Higher	17.2	5.37
Graduate	5.37	3.22
Income (Rs)		0
1000 - 3099	26.88	9.67
3100 - 5099	53.76	69.89
5100 - 7099	16.12	15.05
>7100	3.22	5.36
Gravida		
G1	35.48	30.10
G2	33.33	41.93
G3	20.43	20.43
G4	6.45	9.67
>= G5	1.075	2.15
Hb > 11 gm%	39.13	21.74
Complications		
Abortion	1.07	2.12
Pre-eclampsia	19.35	2
Intrauterine demise	1.07	6
Delivery		
NVD	31.11	76
LSCS	56.99	18
Baby weight (kg)		
<1.5	5.37	2.08
1.5 - 2.49	41.93	35.41
>2.5	43	52.6

being higher in the user category (1.07% vs. 6%, $p < 0.05$). A Cochrane review of 72 studies found that while the smoking cessation interventions had modest effect on quit rates, the impact on infant outcomes were significant [10]-[18].

Expenditure on tobacco products competes with the household expenses on food, health care and other basic needs. The results of the present study highlight the urgent need to implement evidence based interventions to prevent and control tobacco use among pregnant women.

This was an attempt by us to address an important health issue. The limitations of this study include a small sample size, a sizeable numbers were lost to follow-up largely. Traditionally, in India, women go back to their maternal home for delivery.

Conflict of Interest

The study was funded by World Health Organization; no other financial relationships such as patent or stock ownership, consultancies, speaker's fees, personal, political, intellectual or religious interests with any organization exist. There are no other potential conflicts of interests.

Endorsed by all authors.

Funding

The study was funded by World Health Organization.

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