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Original article

Quasi Experimental Study to assess effectiveness of tobacco cessation intervention among reproductive age females in Akole Tribal block, Ahmednagar

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Abstract:

Background: *Tobacco use is a critical global health issue, with higher prevalence among women in India's tribal communities. This study evaluates a tobacco cessation intervention for reproductive-aged women in the Akole Tribal Block, Ahmednagar district, Maharashtra, India.*

Materials and Methods: *A quasi-experimental design with 212 participants was employed using multi – stage sampling: cluster random sampling followed by simple random sampling. The study involved pre-test and post-test phases with data collected via a structured questionnaire. The intervention utilized the 5A model for tobacco cessation, with follow-up after 30 days. Data analysis was conducted using R software, with paired t-tests for score comparisons and multiple linear regression to assess socio-demographic influences on post-test scores.*

Results: *Knowledge about tobacco-related diseases improved significantly, with mean scores rising post-intervention. Smokeless tobacco consumption decreased from 5.45 to 5.19 units/day $t_{(167)} = 3.55$, $p < 0.01$), although the duration of tobacco use remained unchanged. The Fagerstrom Nicotine Dependence Scale scores slightly improved from 7.40 to 7.19 with $t_{(167)} = 6.01$, $p < 0.01$). Education was marginally significant, and marital status was the only significant predictor for post-test dependence scores.*

Conclusion: *The intervention demonstrated promise in increasing knowledge and slightly reducing tobacco consumption. However, a more culturally tailored and comprehensive strategy is needed, combining behavioural therapy with pharmacological support, to effectively address the entrenched habit of smokeless tobacco use among these women.*

Keywords: *Reproductive tribal Women, tobacco cessation, brief counselling*

Introduction:

During the 20th century, tobacco use led to deaths of 100 million people globally. In 2011 alone, tobacco use was linked to around 6 million deaths, making it the leading cause of death worldwide, surpassing the combined fatalities from HIV/AIDS, tuberculosis, and malaria. By 2030, tobacco-related deaths are expected to reach approximately 8 million annually. However, every death caused by tobacco is preventable. (1)Tobacco use significantly increases the risk of severe COVID-19. Nicotine, a component of tobacco, can influence the body's response to the virus in multiple ways, including affecting lung cells and the immune system. (2)Tobacco use can cause complications such as low birth weight, intrauterine growth restriction, antepartum haemorrhage, postpartum haemorrhage, stillbirth, and other health issues for the baby. Additionally, there is an elevated risk of sudden infant death syndrome and episodes of apnoea.(3) Tobacco use causes millions of deaths and illnesses each year, with around 8 million deaths attributed to tobacco-related diseases in 2017. Although tobacco consumption rates are declining, the impact of these diseases is expected to increase over time due to their delayed onset. In 2003, nations worldwide united under the World Health Organization (WHO) to combat the tobacco epidemic by adopting the WHO Framework Convention on Tobacco Control (WHO – FCTC). This treaty outlines

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clear, evidence-based measures for all participating countries to reduce tobacco use effectively. (4)

Methodology:

Research Approach

A quantitative experimental approach was used to assess the effectiveness of a tobacco cessation intervention among reproductive-aged women.

Research Design

A quasi-experimental design with a one-group pre-test and post-test was employed to evaluate the intervention's impact.

Variables

- **Independent Variable:** Health education intervention covering tobacco risks and demographic variables.
- **Dependent Variables:** Tobacco consumption patterns and Fagerstrom Nicotine Dependence Scale (FNDS) scores.

Setting

The study was conducted in Akole Taluka, Ahmednagar district, Maharashtra. The primary healthcare facilities include the Primary Health Centre in Akole, Rajur Hospital, and Pravara Medical Trust Hospital, which serves the majority of the tribal population.

Study Population

Women aged 18 to 45 years from 13 selected villages within Akole Taluka participated in the study.

Sample Size

A sample size of 216 with attrition of 15% was calculated using G*Power software, based on an effect size of 0.17 for the intervention's effectiveness.

Sampling Technique

Proportionate cluster random sampling was used. Thirteen villages were selected, and 212 women were sampled proportionally from these villages.

A cluster random sampling approach was utilized to select 13 villages with a total population of 15285 and 2791 households. Based on the statistics from previous studies an effect size of 0.17 was utilized. A detailed list of females in the reproductive age group i.e. 18 – 45 – years old was procured from Anganwadi Workers/Accredited Social Health Activist (ASHA) from which a probability proportional sampling of 212 females was done.

Sample Selection Criteria

- **Inclusion:** Women aged 18-45, fluent in English, Hindi, or Marathi, and willing to attend follow-up visits.
- **Exclusion:** Non-fluent in the specified languages, with psychiatric disorders, learning disabilities, or major systemic issues.

Development of the Tool

The data collection tool included:

1. Demographic Information
2. Tobacco Usage Patterns and FNDS
3. Tobacco Cessation Practices
4. Knowledge regrading harmful effects of tobacco

Content Validity

Validation by experts in Public Health, Community Physiotherapy, and Psychology was done. Experts feedback was incorporated into the final tool design.

Ethical Considerations

Approval was obtained from Institutional Review Committee (Letter No. PIMS/SPHSM/IRC/2023/1004/3) and the CTRI (Registration No. CTRI/2024/05/066834).

Informed consent was secured, and confidentiality was maintained.

Pilot Study was conducted with 10 participants to test the feasibility, refining and validation of the data collection tools and procedures.

Data Collection Procedure

- **Pre-Intervention:** Baseline data collected through structured questionnaires.
- **Intervention:** Delivered using the 5A model, including group teaching and audiovisual aids.
- **Post-Intervention:** Data collected 30 days later using the same tools.

Data Analysis

- **Descriptive Statistics:** Means and standard deviations to summarize data.
- **Inferential Statistics:** Paired t-tests for pre-test and post-test comparisons; Multiple Linear Regression to assess associations with FNDS scores.

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Results:

Basic Demographics and Reproductive Characteristics

Participants: The study included 212 women, with 68.87% from the Mahadev Koli tribe and 31.13% from the Thakar tribe. The average annual income was approximately ₹25,500 (Mahadev Koli) and ₹24,800 (Thakar), *with years of education* in Mahadev Koli was (4.10 ± 4.4 [Mean ± SD]) while in Thakar (1.70 ± 3.2) with significant difference of $p < 0.001$. *Weight:* 63.00% of Mahadev Koli and 52.00% of Thakar women weighed ≤50 kg, with no significant difference. *Marital Status:* 95% of women were married; 8 were divorced/widowed, and 2 were unmarried. *Age at Marriage:* Thakar women married earlier (15.14 ± 1.90 years – old) compared to Mahadev Koli (16.40 ± 2.73 years), with a significant difference ($p < 0.001$). *Pregnancies:* Average pregnancies per woman were 2.53 ± 1.14, with no significant difference between tribes. Mahadev Koli women had more births with low birth weights (<2500 grams) compared to Thakar women (52.05% vs. 21.21%) and significant statistically with $p < 0.001$. *Delivery Locations:* A majority (74.00%) of deliveries were domiciliary, significantly higher among Thakar women (95.00%) compared to Mahadev Koli (65.00%) and also statistically significant with $p < 0.001$.

Tobacco Usage

Desire to Quit: 68.40% of women didn't expressed the desire to quit tobacco, while 31.60% wished to quit tobacco. *Perceived Stress Relief:* 73.58% of women felt tobacco relieved stress. *Mishri Usage:* Roasted mishri was preferred by 98.58% of users. *Quit Attempts:* 26.42% attempted to quit in the last 12 months without any assistance. *Home Acceptance:* Tobacco use was universally accepted at home. *Medical Inquiry:* Only 10.85% of women reported being asked about tobacco use by doctors and advised to quit it. *Tobacco Use Initiation:* Women typically began using tobacco around at the age of 15 ± 5.21 years. *Cessation Support:* None of the participants have received formal cessation counseling or medication, and no telephone support was available.

Post Test Sessions

The post – test was conducted 1 month after the initial evaluation. In this study there was a lost – to – follow – up of 44 people in total i.e. 212 – 44 = 168. The attrition rate was 20.75%. Hence after this, N = 168 was used for comparison and assessment of the intervention.

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Fagerström Nicotine Dependence Scale (FTND)
Annexure 1: Fagerstrom Nicotine Dependence Scale - Questionnaire

Table 1: Fagerstrom Nicotine Dependence Scale-Smokeless Tobacco (FTND-ST)				
	Question	Pre - Test Score	Post - Test Score	T - test (Paired)
		Mean ± SD	Mean ± SD	(*p - value*)
Q1	How soon after you wake up do you place first dip?	2.54 ± 0.79	2.49 ± 0.79	2.89 ***
Q2	How often do you intentionally swallow tobacco juice?	1.24 ± 0.69	1.21 ± 0.69	1.64
Q3	Which Chew would you hate to give up most?	0.63 ± 0.49	0.57 ± 0.50	3.07 **
Q4	How many cans /pouches per week do you use?	1.01 ± 0.69	0.92 ± 0.69	3.90 ***
Q5	Do you use chew more frequently during the first hours after awakening than during the rest of the day?	1.33 ± 0.47	1.33 ± 0.47	No Change
Q6	Do you chew if you are so ill that you are in bed most of the day?	0.66 ± 0.47	0.66 ± 0.47	No Change
Total		7.40 ± 1.96	7.19 ± 1.90	6.01 ***
p value: "." < 0.01; "" < 0.05; "**" < 0.01; "***" < 0.001*				

Pre-Test vs. Post-Test: The average pre-test score was 7.40, indicating high nicotine dependence, which slightly decreased to 7.19 post-intervention ($p < 0.001$). Significant reductions were observed in the frequency of tobacco use and preference for specific tobacco types, but overall dependence remained high.

Table 2: Smokeless Tobacco - Mishri Usage and Duration: Pre vs Post Test				
	Test	Mean ± SD	t Stat $_{(df)}$	p - value
Average Mishri Usage Times/Day	*Pre - Test*	5.45 ± 2.70	3.55 $_{(167)}$	*0.00*
	Post - Test	5.19 ± 2.58		
Mishri Hold Duration per setting/Minutes	*Pre - Test*	15.32 ± 13.40	1 $_{(167)}$	*0.32*
	Post - Test	15.29 ± 13.42		

Average Consumption: Average daily consumption decreased from 5.45 to 5.19 units ($p < 0.001$). *Hold Duration:* The average hold duration was nearly the same pre-test (15.32 minutes) and post-test (15.29 minutes), with no significant difference.

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Knowledge of Tobacco's Health Impacts

Serious Illness: Awareness of tobacco causing serious illness increased significantly from 120 to 163 ($p < 0.001$). *Stroke:* Knowledge that tobacco causes stroke rose from 27 to 167 ($p < 0.001$). *Heart Attack:* Awareness of tobacco causing heart attack increased from 33 to 167 ($p < 0.001$). *Lung Cancer:* Knowledge that tobacco causes lung cancer grew from 131 to 167 ($p < 0.001$). *Diabetes Mellitus:* Awareness that tobacco causes diabetes increased from 13 to 159 ($p < 0.001$). *Empyema:* Understanding that tobacco causes empyema improved from 6 to 134 ($p < 0.001$).

Multiple Linear Regression Analysis

In the multiple linear regression model with $R^2 = 0.95$ indicated Pre-test FTND score is a significant predictor of Post-Test FTND scores *($\beta = 0.95$, $p < 0.001$)*. The effects of age, tribe, income, education, weight, occupation, and marital status on nicotine dependence were generally non-significant, except for unmarried status which showed a significant negative impact ($\beta = -1.68$, $p < 0.001$).

Discussion

The results of this study underscore the significance of prevalence and cultural acceptance of tobacco use among reproductive-aged women in the Akole Tribal Block. Despite a modest improvement in knowledge about tobacco-related diseases at post-intervention, the entrenched habit of smokeless tobacco consumption, particularly mishri, remains a formidable challenge.

The intervention, while showing some promise in reducing tobacco consumption and increasing knowledge, fell short of inducing substantial behavioural change. The slight decrease in mishri consumption and the marginal improvement in FNDS scores suggest that a more comprehensive and culturally tailored approach is necessary. The lack of significant change in the duration of tobacco use, highlights the depth of addiction and the need for sustained interventions.

The socio-demographic factors influencing tobacco use are complex. While education demonstrated a marginal association with post-test dependence scores, marital status emerged as a significant predictor. Unmarried women exhibited lower nicotine dependence, suggesting potential protective factors related to marital roles and responsibilities. However, further exploration of this relationship is warranted. Our study identified a mean age of tobacco initiation at 15.21 ± 5.21 years among tribal individuals in Akole block, suggesting a wider range in starting ages compared to the more tightly clustered distribution found by Zahiruddin et al. (2011).(5) The alarmingly high number of females in our sample (38) who initiated SLT use before age ten emphasizes the critical public health issue of early substance use. These results corroborate the findings of Gaikwad (2019) who reported a mean age of onset at 6.07 ± 1.47 years (6).

According to the Fagerström Test for Nicotine Dependence (FTND), a score of 5 or more indicates significant dependence, while a score of 4 or less indicates moderate dependence. In our study, among 212 participants in pretest, 198 showed significant dependence (93.40%), and in the post-test of 168 participants, 155 indicated significant dependence (92.26%). This compares to a study by Mhaske et al. (2021) where, out of 100 patients, 95 (95%) at baseline showed a significant dependance but at follow – up along with multiple intervention most of the were nicotine dependence free.(7) Our study revealed a concerning discrepancy in tobacco cessation intentions among women. A substantial majority (68.4%) indicated no desire to quit smoking, while a significant minority (31.6%) expressed interest in cessation. These findings underscore the critical need for targeted interventions to address the diverse needs of women smokers cconsistent with finding from Persai et al. (2014). (8) Our study found that nearly one-quarter (26.42%) of participants tried to quit tobacco use within the past year without seeking any help. This finding contrasts with the research conducted by Aluckal et al. (2020) which indicated that individuals with higher socioeconomic backgrounds were more likely to attempt quitting tobacco compared to those with lower socioeconomic status. (9) There was a significant increase in level of knowledge in regards to harmful effects of tobacco and disease caused by it which is consistent with other studies. (10)

Even though tobacco is banned in most states, the prevalence of tobacco consumption is still high in Maharashtra, as evidenced by our findings. The Jharkhand Government, in a recent order, has

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banned the consumption of any form of tobacco products for all State Government employees from 01 April 2021. Such initiatives should be taken in all other states for tobacco control.

Conclusion

While a combined approach using the 5A model and the Fagerstrom Nicotine Dependence Scale showed some promise in reducing tobacco use and significantly increasing knowledge among tribal women, especially young women who start tobacco use early, it fell short in addressing the deeply ingrained habit of smokeless tobacco. To effectively combat the high prevalence of daily tobacco consumption among these women of reproductive age, a more comprehensive strategy is needed. This strategy should combine individually tailored behavioural therapy that respects their cultural background with appropriate pharmacological support.

Strength of Study:

This study evaluated the effectiveness of a tobacco cessation intervention among reproductive-aged tribal women in India. While the intervention increased knowledge about tobacco-related risks and modestly reduced smokeless tobacco consumption, it had limited impact on overall tobacco use and dependence. Addressing the deeply ingrained habit of smokeless tobacco requires a more comprehensive approach combining behavioral therapy and pharmacological support.

Limitations and Weaknesses

The study's limitations include its quasi-experimental design, relatively short follow-up period, and focus on a single intervention. Additionally, the lack of significant changes in hold duration and Fagerstrom Nicotine Dependence Scale scores suggests the intervention's limited impact on addiction. The study's focus on smokeless tobacco might have overlooked other tobacco products used by participants. Furthermore, the influence of socio-cultural factors on tobacco use among tribal women was not extensively explored.

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