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IMPACT OF SMOKING CESSATION INTERVENTION© IN REDUCING NICOTINE DEPENDENCE AMONG PATIENTS WITH LIVER CIRRHOSIS, NEW DELHI – A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Smoking cessation is crucial for patients with liver cirrhosis to mitigate disease progression and improve outcomes among this population. **Aims:** The study aimed to evaluate the impact of a structured smoking cessation program on nicotine dependence and smoking behaviors in patients with liver cirrhosis. **Design:** An experimental design with block randomization allocated 120 participants into experimental and control groups. The intervention group received Smoking Cessation Intervention© while the control group received standard care. **Methods:** Standardized tools assessed nicotine dependence and smoking behaviors longitudinally over 90 days. Statistical analyses included repeated measures ANOVA and correlation tests. **Results:** Both groups showed a decrease in nicotine dependence over time, though no significant differences were found between groups post-intervention. Socio-demographic and clinical variables showed no significant association with nicotine dependence. **Discussion:** Findings suggest the intervention's limited impact on nicotine dependence in this cohort, influenced by study duration and population characteristics. Future research could explore alternative interventions or longer-term effects. **Conclusion:** While the Smoking Cessation Intervention© led to reduced nicotine dependence over time, no significant differences were observed between experimental and control groups post-intervention. The study underscores the need for tailored interventions and ongoing support in smoking cessation efforts for liver cirrhosis patients. **Relevance to Clinical Practice:** Integrating evidence-based smoking cessation strategies into nursing education and practice can enhance patient care and outcomes in liver cirrhosis management.

KEYWORDS: Smoking Cessation Intervention, Nicotine Dependence, Liver Cirrhosis Patients, Experimental Study.

1. INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Cigarette smoking is a leading cause of preventable morbidity and premature mortality worldwide, responsible for approximately 100 million deaths in the 20th century alone. With over 1 billion smokers globally, the tobacco epidemic is particularly growing in developing countries. Tobacco dependence, a chronic condition, often requires repeated interventions for successful cessation. Simply informing patients about health risks is usually insufficient; comprehensive counseling and evidence-based smoking cessation therapies, especially those combined with behavioral interventions, are essential.[1]

Recent advancements in smoking cessation strategies have focused on brief interventions, particularly for smokers with chronic diseases. However, these interventions often fall short, especially for individuals who do not intend to quit. Studies indicate that smokers uninterested in quitting may still be willing to change other health behaviors, suggesting that a general health promotion approach could effectively motivate them to adopt healthier habits, ultimately leading to smoking cessation when they are ready.[2]

To combat the tobacco epidemic, national health systems must take the lead in implementing measures to prevent and treat tobacco dependence. Routine inquiries about tobacco use by primary care providers could significantly

impact cessation rates, with brief advice proving to be both feasible and effective. The World Health Organization's brief tobacco intervention toolkit and the 5A model (Ask, Advise, Assess, Assist, Arrange) provide structured guidance for primary care providers to support patients in quitting smoking. Additionally, motivational counseling addressing the 5Rs (relevance, risks, rewards, roadblocks, repetition) can help those not ready to leave.[3]

Smoking cessation is crucial for managing liver diseases, as smoking negatively impacts liver health through toxic, immunologic, and oncogenic mechanisms. Comprehensive LFTs are essential for assessing liver health, but their interpretation must account for various personal and environmental factors. Prioritizing smoking cessation can significantly improve outcomes for patients with liver diseases.[4]

1.2 NEED OF THE STUDY

The detrimental effects of cigarette smoking on pulmonary and cardiovascular health are well-established; however, its impact on liver health remains less defined.[4]

Smoking-related lung impairment may complicate liver transplant eligibility and increase the risks of post-transplant complications. Emerging evidence suggests smoking's potential role in liver fibrosis progression, highlighting the need for further investigation.[4]

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Current research often isolates the effects of smoking from other factors like alcohol and coffee on liver function tests, lacking comprehensive data on their combined impacts.[5]

2. OBJECTIVES

1) To evaluate the impact of Smoking Cessation Intervention© in reducing Nicotine Dependence among patients with liver cirrhosis.
2) To find the association of the level of Nicotine Dependence with selected Socio-Demographic and Clinical variables among liver cirrhosis patients.

3. METHODS

This randomized control trial was conducted based on Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines.

3.1 TRIAL DESIGN

A quantitative research approach was chosen to assess the impact of Smoking Cessation Intervention© on reducing Nicotine Dependence among liver cirrhosis patients at the Institute of Liver and Biliary Sciences, New Delhi. An open-labeled randomized controlled trial was conducted, with the intervention delivered as a brief intervention to the Experimental Group and compared to the Control Group.

Trial Registration: This RCT was registered with the Clinical Trials Registry of India (CTRI) on 22/09/22, with the trial reference number Trial/REF/2022/07/056541.

3.2 CRITERIA FOR SELECTION

3.2.1 SETTINGS

Conducted at the ILBS OPD, a 234-bed super specialty hospital renowned for Liver and Biliary Sciences. ILBS OPD serves 200 to 300 outpatients daily across five Hepatology sections. Patients visit the OPD regularly, typically two to three times per month on fixed schedules.

3.2.2 PARTICIPANTS

The eligibility criteria for sample selection in the present study are divided into inclusion and exclusion criteria and are mentioned below:

Inclusion Criteria

1. Smokers with Nicotine Dependence scores of 5-10 on the Fagerstrom Test.
2. Patients diagnosed with liver cirrhosis.
3. Have access to a telephone.
4. Available for study participation for 3 months.

Exclusion Criteria

1. Diagnosis of Alcohol Dependence Syndrome (ADS).
2. Significant cognitive impairment.
3. Visual or hearing impairments.
4. Lack of willingness to participate.

3.2.3 SAMPLES

Patients diagnosed with liver cirrhosis and smokers were consecutively sampled during OPD visits. Baseline data from previous studies informed the sample size calculation (power of 80%, 30% attrition), confirming 60 participants per group.[6] Ultimately, 120 eligible patients participated, ensuring robust representation across both groups.[3,6] Figure 1 shows the Cohort diagram of patients from eligibility assessment/enrollment to final data analysis.

3.2.4 VARIABLES

Independent Variable: Smoking Cessation Intervention©

Dependent Variables: Level of Nicotine Dependence and Heaviness of Smoking

Socio-Demographic Variables: Age, Gender, Marital Status, Educational Status, Occupational Status, Monthly Income, Socio-Economic Status, Smoking-related parameters.

Clinical Variables: Height, Weight, BMI, AST, ALT, AKP, GGT, Albumin, Serum Bilirubin, Serum Creatinine, Prothrombin time, INR, Serum Sodium, MELD Scores.

3.2.5 INTERVENTIONS

The Smoking Cessation Intervention©, endorsed by the WHO, utilizes a toolkit for health professionals, delivering effective brief interventions over five sessions within three months for 8 to 10 minutes.

Implemented in phases with the 5A's and 5R's, it guides primary care providers in tailored cessation strategies.

- Phase 1 - Establishes rapport, assesses Nicotine Dependence, and introduces the WHO module.
- Phase 2 - Involves telephonic follow-ups on Days 15, 30, 60, and 90, integrating the interventions.
- Phase 3 - Concludes the intervention positively.

The principal investigator received WHO certification through a six-hour Pan American Health Organization (PAHO) e-learning course.

3.2.6 RANDOMIZATION

Patients were selected by the Consecutive Sampling Technique and randomized into two groups (experimental and control) on an equivalent footing to avoid confounding and selection bias. Sequence generation of both groups was randomized using computer-generated block randomization into a 1:1 ratio to avoid the predictability of the allocation sequence. The sample size is 120, and 12 blocks were computer-generated with a block size of 10 with the help of random allocation software used by the trial coordinator of ILBS.

The Sequentially Numbered Opaque Sealed Envelopes (SNOSE) concealment technique was used to ensure participants were randomized into the experimental and control groups. This method helped maintain allocation concealment, thereby minimizing potential biases and ensuring the integrity of RCT. The envelopes containing group assignments were sequentially numbered and opaque, ensuring neither participants nor researchers could predict or influence group allocation before randomization. This approach enhanced the reliability and validity of the study findings by reducing the risk of selection bias and ensuring a rigorous experimental design.

3.3 STATISTICAL METHODS

Normal distribution (except for clinical variables) was assessed using the Shapiro-Wilk test. Descriptive statistics included mean, standard deviation, frequency, and percentage calculations. Inferential statistics employed for analysis comprised the Chi-Square test, Repeated Measures ANOVA (Analysis of Variance), Independent t-test, One-Way ANOVA, and Spearman's Rank correlation coefficient. (Figure 2)

4. RESULTS

4.1 ETHICAL CONSIDERATIONS

The study obtained Institutional Review Board clearance through the Scientific Review Committee (SRC) and the Ethics Committee of the College of Nursing, ILBS, New Delhi. Feedback from the SRC was incorporated into the study proposal before submission to the Ethics Committee, ensuring compliance with ethical standards set by WHO, ICMR, and subsequent amendments.

4.2 PILOT STUDY

A pilot study, conducted in October 2022 with twelve patients, aimed to test and refine methods planned for a larger study. Patients were randomly assigned to experimental and control groups to assess feasibility, refine tools, and plan statistical analysis. The study encountered minor initial venue arrangement issues but overall confirmed the feasibility of the final study, ensuring patient consent and adherence to protocol.

4.3 ORGANIZATION AND PRESENTATION OF DATA

Data from 120 liver cirrhosis patients were managed in Microsoft Excel 2019, ensuring accuracy through sorting, coding, and decoding. Statistical analysis, conducted using SPSS 22.0, included descriptive and inferential methods.

Repeated measures ANOVA was applied with Greenhouse-Geisser correction for lack of sphericity for comparison of mean scores at different time intervals.

Normality tests via Shapiro-Wilk indicated data on Nicotine Dependence and Smoking Heaviness were normal, while not the same for Clinical Variables. Independent t-test were employed accordingly for analysis, aligning with the study's methodological rigor.

4.4 IMPACT OF THE INTERVENTION

The Effectiveness of Smoking Cessation Intervention© on the Level of Nicotine Dependence and Heaviness of Smoking depicted in Table 1 following comparison of the Mean scores among patients with liver cirrhosis within the experimental and control groups.

The mean and standard deviation of the level of Nicotine Dependence among patients of the experimental group on Day 1 (7.04 ± 1.73), Day 15 (5.92 ± 1.27), Day 30 (4.76 ± 1.29), Day 60 (3.90 ± 2.32) and Day 90 (3.76 ± 2.40) along with F value as 142.65 with greenhouse geisser correction value of 0.423. The p-value (0.000) was found to be highly significant as $p<0.001$ when

tested at a 0.05 level of significance for the level of Nicotine Dependence.

In relation among the patients of the control group, the mean and standard deviation of the level of Nicotine Dependence on Day 1 (7.16 ± 1.71), Day 15 (6.08 ± 1.32), Day 30 (4.84 ± 1.66), Day 60 (4.20 ± 2.52) and Day 90 (4.16 ± 2.49) along with F value as 142.65 with greenhouse geisser correction value of 0.423. The p-value (0.000) was found to be highly significant as $p<0.001$ when tested at a 0.05 level of significance for the level of Nicotine Dependence.

Hence, it was inferred to be significant in terms of the level of Nicotine Dependence within both the experimental and the control groups.

The Data in the line chart (Figure 3) depicts that the Mean score of the level of Nicotine Dependence in the experimental group was 7.16, and the control group was 7.04 on Day 1 was in the category of High Dependence on nicotine as per Fagerstrom Test for Nicotine Dependence (FTND) scoring. Then, on Day 15, in the experimental group mean score was 5.92, which indicated Moderate Dependence on Nicotine, whereas in the control group, the mean was 6.08, which indicated High Dependence on Nicotine. Further, on Day 30 and 60, in the experimental group level of Nicotine Dependence was in the category of Low Dependence as the mean scores was 4.76 and 3.9, respectively, whereas, in control group level of Nicotine Dependence was also in the category of Low Dependence as the mean scores was 4.84 and 4.2, respectively as per FTND scoring. On Day 90, the level of Nicotine Dependence for both the experimental and control groups was 3.76 and 4.16, respectively, which indicated Low Dependence on Nicotine.

Table 1 also depicts the comparison of Mean scores of Heaviness of Smoking among patients with liver cirrhosis within the experimental and the control groups. The mean and standard deviation of Heaviness of Smoking among patients of the experimental group on Day 1 (4.16 ± 1.33), Day 15 (3.84 ± 1.22), Day 30 (3.58 ± 1.21), Day 60 (3.08 ± 1.60) and Day 90 (2.96 ± 1.67) along with F value as 46.85 including greenhouse geisser correction value of 0.394. The p-value (0.000), which was found to be highly significant as $p<0.001$ when tested at 0.05 level of significance for Heaviness of Smoking.

In relation among patients of the control group, the mean and standard deviation of Heaviness of Smoking on Day 1 (4.14 ± 1.33), Day 15 (3.86 ± 1.28), Day 30 (3.62 ± 1.37), Day 60 (3.22 ± 1.67) and Day 90 (3.20 ± 1.65) along with F value as 46.85 including greenhouse geisser correction value of 0.394. The p-value (0.000), which was found to be highly significant as $p<0.001$ when tested at a 0.05 level of significance for Heaviness of Smoking. Hence, it can be inferred that $p\geq0.05$, which was to be significant in terms of the Heaviness of Smoking within both the experimental and the control groups.

The information related to Mean scores within both groups is also depicted in Figure 4, where the mean scores of Heaviness of Smoking among patients with liver cirrhosis. The Data in the line chart depicts that the Mean score of Heaviness of Smoking in the experimental group was 4.16, and the control group 4.14 on Day 1 was in the category of Moderate Addiction as per Heaviness of Smoking Index (HSI) scoring. Then, on Day 15, in the experimental group mean score was 3.84, indicating Moderate Addiction, whereas in the control group, the mean was 3.86, which also indicated Moderate Addiction. Further, on Day 30 and 60, in experimental group Heaviness of Smoking was also in the category of Moderate Addiction as the mean scores was 3.58 and 3.08, respectively, whereas, in the control group level of Heaviness of Smoking was also in the category of Moderate Addiction as the mean scores was 3.62 and 3.22, respectively as per HSI scoring. On Day 90, Heaviness of Smoking for both the experimental and the control groups was 2.96 and 3.2, respectively, which indicated Moderate Addiction as per HSI scoring.

ASSOCIATIONS WITH SELECTED SOCIODEMOGRAPHIC AND CLINICAL VARIABLES

Data shows no significant association of Nicotine Dependence with Age (t=0.03), Marital status (F=0.25), but significant associations with Educational status (F=4.14), Occupational status (F=12.19), and Monthly Income (F=4.33) ($p<0.001$).

Correlations between clinical variables and Nicotine Dependence among experimental group patients on Day 90 using Spearman's rank correlation coefficient. Height showed a moderate positive correlation ($r = 0.25$, $p = 0.12$), while Weight exhibited a stronger positive correlation ($r = 0.36$, $p = 0.04$). BMI displayed a weak positive correlation ($r = 0.18$, $p = 0.39$). Bilirubin showed a moderate positive correlation ($r = 0.28$, $p = 0.03$), while Albumin displayed a negligible correlation ($r = -0.01$, $p = 0.08$). Other clinical variables did not show significant correlations with Nicotine Dependence ($p > 0.05$). (Table 2)

4.5 HARMS

Twenty participants out of the initial 120 voluntarily withdrew due to mortality and other factors, highlighting the severity of end-stage liver disease and the importance of stringent ethical considerations and participant support throughout the study.

Patients faced psychological stress from managing both their illness and smoking cessation, while physical stress was exacerbated by participation demands. Confidentiality risks included the

disclosure of personal health data, necessitating stringent privacy safeguards. Ethical considerations guided informed consent and participant support throughout the study to mitigate these challenges effectively.

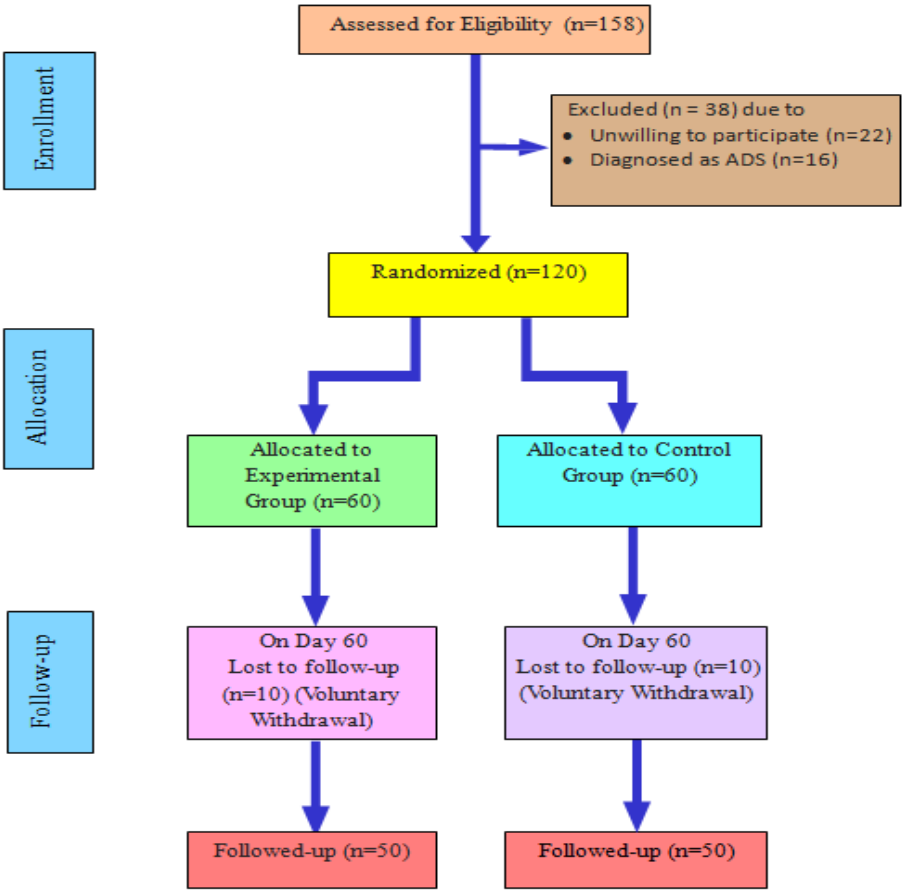

Figure 1: Consort Flow Diagram.

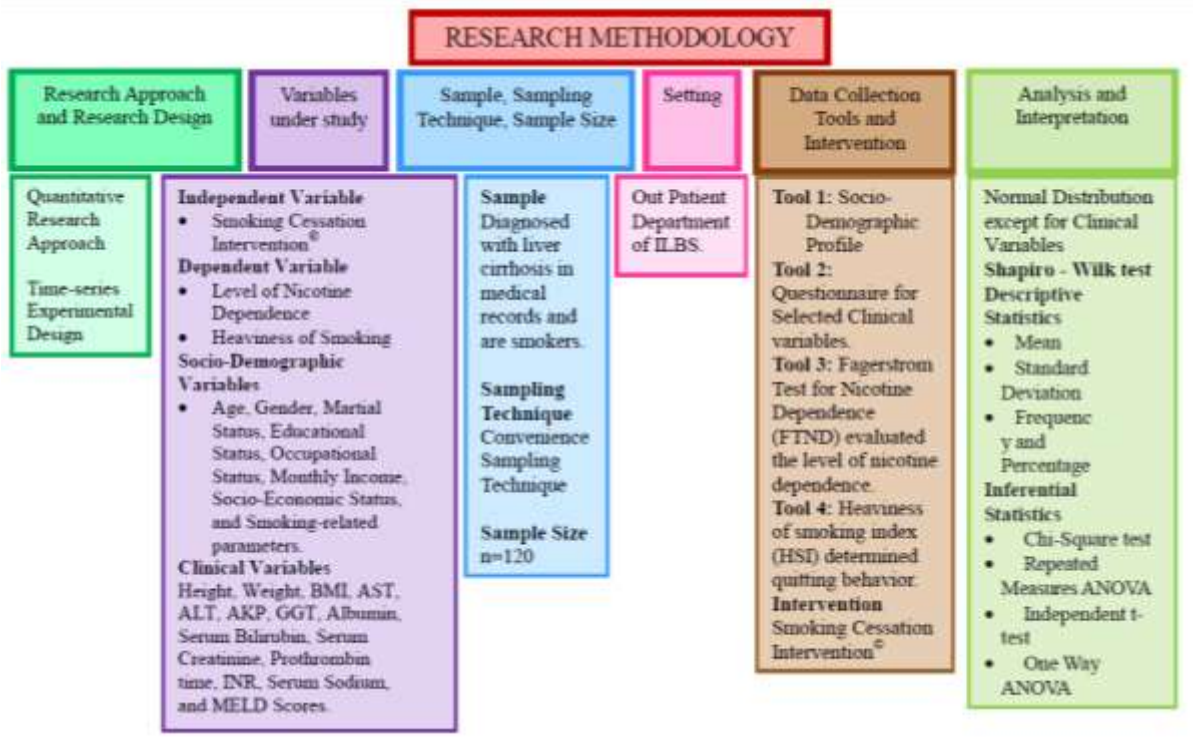

Figure 2: Systemic Representation of Research Methodology.

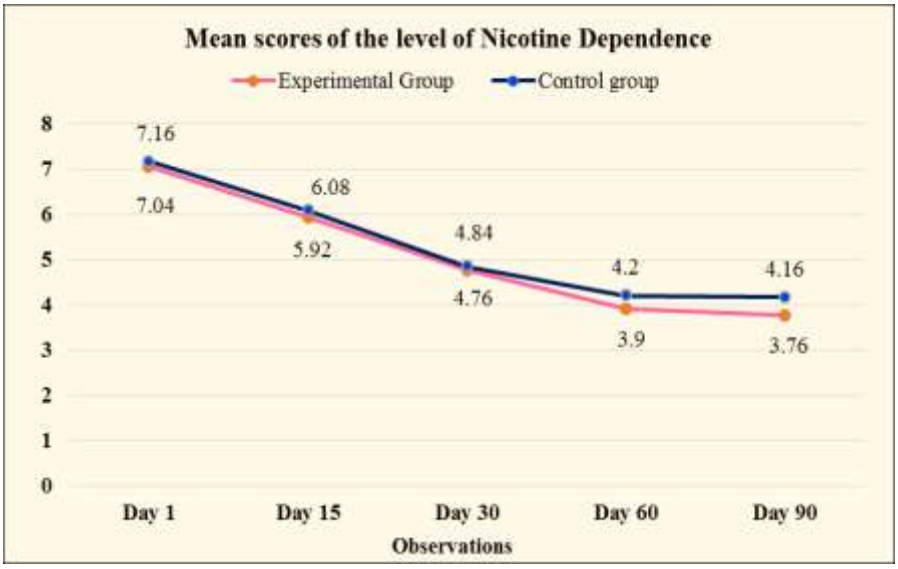

Figure 3: Line Chart showing Mean Scores of the level of Nicotine Dependence of the Experimental and the Control Group following Smoking Cessation Intervention©

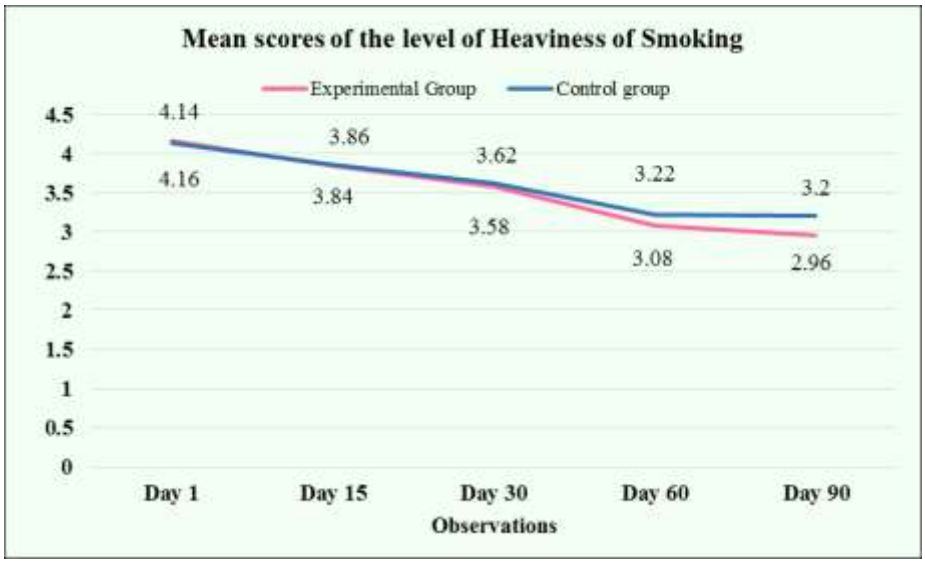

Figure 4: Line Chart showing Mean Scores of Heaviness of Smoking of Experimental and Control Group following Smoking Cessation Intervention©.

Table 1: Comparison of Mean scores of the level of Nicotine Dependence and Heaviness of Smoking among patients within Experimental and Control groups using Repeated measures ANOVA.

Group	Day 1 Mean ± SD (n=60)	Day 15 Mean ± SD (n=60)	Day 30 Mean ± SD (n=60)	Day 60 Mean ± SD (n=50)	Day 90 Mean ± SD (n=50)	F value	ε	p-value
Nicotine Dependence								
Experimental group	7.04 ± 1.73	5.92 ± 1.27	4.76 ± 1.29	3.90 ± 2.32	3.76 ± 2.40	142.65	0.4	**<0.001****
Control group	7.16 ± 1.71	6.08 ± 1.32	4.84 ± 1.66	4.20 ± 2.52	4.16 ± 2.49			**<0.001****
Heaviness of Smoking								
Experimental group	4.16 ± 1.33	3.84 ± 1.22	3.58 ± 1.21	3.08 ± 1.60	2.96 ± 1.67	46.85	0.3	**<0.001****
Control group	4.14 ± 1.33	3.86 ± 1.28	3.62 ± 1.37	3.22 ± 1.67	3.20 ± 1.65			**<0.001****

**p<0.001: Highly Significant
F = Repeated Measures ANOVA; ε = *Greenhouse Geisser*

Table 2: Correlation of mean scores of the level of Nicotine Dependence with selected clinical variables among patients in the Experimental group using Dependent t-test.

Clinical Variables	Nicotine Dependence	r value	p-value
	Mean ± SD		
Height	166.65 ± 8.08	0.25	0.12
Weight	69.52 ± 9.80	0.36	0.04
BMI	25.07 ± 3.69	0.18	0.39
ALT	80.28 ± 58.57	0.05	0.19
AST	102.05 ± 44.86	0.12	0.30
AKP	143.43 ± 131.90	0.08	0.34
GGT	132.88 ± 177.21	0.20	0.12
Bilirubin	3.90 ± 4.67	0.28	0.03
Albumin	4.27 ± 9.21	0.01	0.08
PT	17.97 ± 4.73	0.16	0.22
INR	1.62 ± 0.55	0.07	0.71
Creatinine	0.87 ± 0.41	0.14	0.10
Sodium	130.72 ± 7.91	0.09	0.11
MELD Scores	18.15 ± 7.68	0.02	0.92

$p \geq 0.05$; Not Significant, df = 49
r = Spearman's rank correlation coefficient

5. DISCUSSION

Underscores the importance of integrating Smoking Cessation Intervention© into nursing education, administration, practice, and research for patients with liver cirrhosis. Further research should explore long-term intervention effectiveness and patient-specific factors. Overall, integrating evidence-based smoking cessation strategies in nursing can enhance care quality and support healthier outcomes for patients with liver cirrhosis.

5.1 STRENGTH OF THE STUDY

This study exhibits several strengths: it employed an experimental design to evaluate Smoking Cessation Intervention©, used validated tools for assessing Nicotine Dependence and Smoking Heaviness, and was conducted by a certified researcher. Block randomization minimized bias, enhancing internal validity. Conducted at ILBS, New Delhi, in outpatient settings, findings may generalize broadly. Therapy and control separation prevented data contamination. Longitudinal data collection over three months captured behavioral changes. Comprehensive data on Socio-Demographic and Clinical Variables bolstered validity. Rigorous statistical tests like chi-square and ANOVA validated findings. Telephonic intervention for controls post-data collection ensured thoroughness and applicability.

5.2 LIMITATIONS OF THE STUDY

It includes a small sample size of 100 participants, potentially limiting statistical power and generalizability. The three-month data collection period might be too short to fully assess long-term effects. The focus on patients with liver cirrhosis restricts the findings' applicability to other populations. Conducting the study in a single healthcare facility may affect external validity. Reliance on self-reported tools for nicotine dependence and smoking behavior could introduce response bias; supplementing with objective measures may improve data validity.

5.3 RECOMMENDATIONS OF THE STUDY

Future studies should consider: increasing sample size, extending study duration, replicating across diverse settings, validating self-reported data, comparing intervention effectiveness, and exploring long-term impacts on disease progression and quality of life.

6. CONCLUSION

This study highlights the complexity of addressing nicotine dependence in liver cirrhosis patients, revealing that Smoking Cessation Intervention did not significantly outperform routine care. Further research is needed to refine tailored interventions and mitigate smoking-related risks in this vulnerable population.

7. RELEVANCE TO CLINICAL PRACTICE

Nursing Education

- It should prioritize smoking cessation in liver cirrhosis by enhancing student awareness, developing supportive educational materials, and integrating cessation strategies into nursing curricula.

Nursing Administration

- Healthcare organizations should develop and implement policies supporting smoking cessation interventions, allocate resources for staff training, and systematically integrate these interventions to reduce nicotine dependence among liver cirrhosis patients.

Nursing Practice

- Healthcare providers should educate and counsel liver cirrhosis patients on smoking cessation benefits, assess and address nicotine dependence, and collaborate with interdisciplinary teams to tailor interventions and support smoking cessation efforts.

Nursing Research

- Researchers should evaluate the effectiveness of smoking cessation interventions in liver cirrhosis patients, explore long-term outcomes, and investigate factors influencing nicotine dependence to develop targeted and evidence-based interventions.

Overall Impact

- Emphasizes the role of evidence-based practices in nursing to enhance patient outcomes and lifestyle improvements in liver cirrhosis patients.

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