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Research article

Clinical research

Create awareness, motivation and counselling on tobacco cessation by clinical pharmacist.

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ABSTRACT

INTRODUCTION: World Health Organization (WHO) estimates in 2004 projected 58.8 million deaths to occur globally, of which 5.4 million are attributed to tobacco use. As of 2002, 70% of the deaths are in developing countries. It is predicted that 1.5–1.9 billion people will be smokers in 2025.

OBJECTIVES: Our objectives are to create Awareness, Motivation and Counselling on Tobacco Cessation by Clinical Pharmacist.

METHODOLOGY: The study was Prospective Observational and Interventional survey based study. This study was approved by the ethical committee. A tobacco cessation survey was conducted at Mahabubnagar.

RESULTS: In this programmed 220 individuals were enrolled and 110 individuals registered for quitting tobacco usage in which 57 individuals participated in counseling session. Out of 57 individual's high number of tobacco users were found to be doing business and more number of individuals are found to be using cigarette compared to other products of tobacco. The starting age of tobacco usage is in the age group between 19-22 yrs according to our survey. Out of 57 tobacco users 18 individuals reduced or quit the tobacco use. The P value was found to be highly significant i.e., <0.0001***.

CONCLUSION: We conclude that the Studies can be conducted in community pharmacies by giving Education, Awareness and Motivation on Tobacco Cessation. Sufficient funds should be provided to conduct Awareness on Tobacco Cessation Programmers.

KEYWORDS: Nicotine Replacement Therapy, world health organization, smoking, tobacco, clinical pharmacist.

INTRODUCTION

Tobacco is a plant within the Genus Nicotiana of the Solonaceae Family. There are more than 70 species of tobacco. It was first introduced in India by the Portugese 400 years ago. Since then tobacco consumption has continued to rise in India. ¹ The Europeans introduced tobacco into South Asia in

the 1600, for pipe smoking and probably also as snuff.²

In India it has been estimated that 26.2% and 3.6% of Indian Males and Females respectively, are smokers (GATS India, 2010; Tobacco Atlas, 2012). Also, there is growing concern over increasing exposure to secondhand smoke (GATS India, 2010; Tobacco Atlas, 2012).³

World Health Organization (WHO) estimates in 2004 projected 58.8 million deaths to occur globally, of which 5.4 million are attributed to tobacco use. As of 2002, 70% of the deaths are in developing countries. It is predicted that 1.5–1.9 billion people will be smokers in 2025.⁵

It has been estimated that, approximately 180 million tobacco related deaths can be avoided, if tobacco consumption among adults can be reduced to 50% by the year 2020 (Mackay and Eriksen, 2002). Lung cancer leads the table of common cancers in the world with an estimated 1.61 million cases representing 12.7% of all new cancers (Ferlay et al., 2010). Smoking accounts for 80% of lung cancer cases in men (Mackay et al., 2006). It is also an established fact that 55% of total lung cancer deaths are reported from developing countries annually (Ferlay et al., 2010).⁴

In the year 2002, WHO in collaboration with the Government of India has identified 13 Tobacco Cessation centers and they were Operationalized on 31st of May, 2002, on the occasion of “World No Tobacco Day,” with a multidisciplinary approach.⁵

Nicotine, which acts as both stimulant and relaxant is the toxic ingredient in tobacco. When smoke gets inhaled nicotine rich blood passes from the lungs to the brain and releases Epinephrine, Serotonin, Dopamine, Acetylcholine which is responsible for Nicotine Psycho Active Effects.

Nicotine binds stereo specifically to select Acetylcholine receptors (Nicotine receptors). In the CNS, the highest concentrations of Nicotine receptors are found in the Limbic system mid brain and brainstem.²²

DIFFERENT TYPES OF CANCERS AND OTHER HEALTH CONSEQUENCES OF TOBACCO USE

Lung cancer

Non-Pulmonary Cancers

Mouth, Larynx, Esophagus, Stomach, Liver, Pancreas, Bladder, Uterine cavity, Breast and Brain

Respiratory disease

Emphysema, Bronchitis, Asthma, Pneumonia

Cardiovascular disease

Coronary heart disease, Hypertension, Arterial-thrombosis and Stroke

Obstetric and Neonatal conditions

Abortion, Abruption placenta, Placenta praevia, Pre-term labor, Pre-eclampsia, Growth retardation,

congenital malformations, Sudden infant death syndrome, Fatal or Neonatal death

Other conditions

Peptic Ulcer, Osteoporosis, Alzheimer’s disease, Mouth ulcers.²²

The “5 A’s” for smoking cessation intervention

Ask about tobacco use

Identify and document tobacco use status of every patient at every visit

Advise to quit

In a clear, strong and personalized manner, urge every tobacco user to quit

Assess willingness to make a cessation attempt

Is the tobacco user willing to make a cessation attempt at this time?

Assist in cessation attempt

For the patient willing to make a cessation attempt, use counselling and pharmacotherapy to help him or her quit

Arrange follow-up

Schedule follow-up contact, preferably within the first week after the cessation date.¹⁰

The “5 R’s” to enhance motivation to quit tobacco

Relevance

Identify motivational factors that are relevant for the patient: risk factors of heart diseases, cancers, social situations, second hand smoke, personal barriers to cessation, and prior quit attempts.

Risks

Ask the patient about the negative health effects of tobacco use.

Rewards

Ask the patient about the potential benefits of tobacco cessation.

Roadblocks

Ask the patient to identify the barriers that will make a quit attempt difficult.

Repetition

Repeat motivational interventions with each patient.¹⁰

PHARMACOLOGICAL THERAPY

Nicotine replacement therapy

The aim of Nicotine Replacement Therapy (NRT) is to provide some of the Nicotine from Cigarettes minus the harmful constituents contained in Tobacco smoke. NRT reduces withdrawal symptoms associated with Smoking Cessation and makes it easier to avoid smoking by replacing some of the Nicotine obtained from smoking.¹¹

Types of NRT

There are several different forms of Nicotine Replacement Therapy:

- Chewing gum (2 mg and 4 mg doses);
- Transdermal patches (16 hour and 24 hours in varying doses);
- Nasal spray;
- Inhalers; and
- Sublingual Tablets and Lozenges.

Non-pharmacological therapy

Clinical approaches to smoking cessation include self-help programs, telephone counseling, cognitive-behavioral approaches such as individual and group counseling, health care provider interventions, and exercise programs.⁶

OBJECTIVES OF THE STUDY

Primary objective

- To create Awareness, Motivation and Counselling on Tobacco Cessation by Clinical Pharmacist.

Secondary objective

- To assess the effectiveness of Tobacco Cessation Program by Clinical Pharmacists.
- To identify the type of Tobacco use.
- To conduct Awareness program in Schools, Colleges, Villages and Public places
- To prepare and provide Leaflets, Patient Data Collection form, Registration form, Consent forms.
- To assess the severity of Tobacco usage among the individuals.
- To provide Free Nicotine Samples.
- To evaluate the measurement of severity on Tobacco users
- To assess the Clinical Pharmacist intervention on tobacco users after 2 months

MATERIALS AND METHODOLOGY

Study site

The Present study was conducted in and around MAHABUBNAGAR.

Study design

The study is Prospective Observational and Interventional survey based study.

Study approval

This study was approved by the ethical committee constituted by SVS MEDICAL COLLEGE AND HOSPITAL, MAHABUBNAGAR.

Study period

The study was carried out for a period of 6 months.

Inclusion criteria

- Tobacco users of either gender.
- Individuals who are above 15 years of age.
- Tobacco users who are willing to sign and participation in the study by the giving consent form.

Exclusion criteria

- Patients who are not willing to give the Consent.
- Pregnant/Lactating women.
- Bedridden people.

SOURCE OF DATA COLLECTION

Study materials

- Patient Data Collection Form
- Patient Information Leaflet
- Registration Form
- Patient Consent Form
- Fagerstrom severity scale
- Softwares

Tobacco user's data collection forms

It contains the demographic and socio demographic details of the subjects like age, sex, education, occupation and smoking. And it includes knowledge and questionnaires. Questionnaires were designed and prepared based on the parameters to be evaluated and previously available questionnaires in the literatures. Questionnaire contains components to assess the Education and Knowledge towards smokers and non-smokers. During the survey the tobacco user's data collection was used. And it was designed by the project team.

Patient Information Leaflets

It contains the tobacco hazards information and regarding the consequences of the tobacco use and it was designed by the project team and during the survey the patient information leaflets were distributed.

Registration form

It is designed by the project team to call for the public awareness program for public and provide education, motivation. And it contains the total demographic details of the register like age, sex, occupation and address of the individual who are register to quit from tobacco use.

Fagerstrom severity scale

The Fagerstrom Test for Nicotine Dependence (FTND) is a 6-item questionnaire designed to assist the healthcare professional in determining the likelihood of nicotine dependence. A score of 6 or greater (maximum score of 10) on the FTND indicates a high level of nicotine dependence (see below Table1). The FTND, along with a history of prior attempts to quit, is a valuable tool for determining a course of action for smoking cessation. Therapeutic interventions are based on the FTND, previous attempts to quit, and patient preferences.

Table: 4.1 Assessment of severity scale

0-2	Very low dependence
3-4	Low dependence
5	Medium dependence
6-7	High dependence
8-9	Very high dependence

Softwares

Softwares like SAS 9.2 is used for the statistical analysis of data, Ms word and excel sheets are used to generate tables and graphs.

STUDY PROCEDURE

A Tobacco Cessation Awareness Program was conducted at the study site among College students, School children, Farmers, Tobacco Vendors. These Awareness Programs were conducted in association and consultation with Colleges and Schools in a systematic manner. Smokers and non-smokers are included in this awareness program. Participants were enrolled after providing informed consent form.

Regarding the study there was a community survey of the collection of data. At enrollment, tobacco users were interviewed and completed a series of questionnaires. This form mainly contains the demographic details of the patient, general information of tobacco usage and law related questions.

Tobacco users were asked about their smoking history as well as regular exposure to others who smoke. After assessing the severity of tobacco usage individuals were counseled, educated, and

motivated to stop using tobacco and given the cessation tools like information leaflet as well as the free samples of the Nicotine Replacement Therapy (NRT) which helps the individual to stop tobacco use and assess the Clinical Pharmacist intervention on tobacco users after 2 months. We have assessed severity of tobacco users by using a severity scale (Fagerstrom test scale). Scores of 6 or greater are generally interpreted as high degree of dependence with more severe withdrawal symptoms and greater difficulty in quitting. These individuals, possibly need higher doses of medication. After the collection of Data it was analyzed for statistical significance (p-value). P value was calculated using Paired Student t-test.

RESULTS AND DISCUSSIONS

A tobacco cessation survey was conducted at Mahabubnagar in which 220 tobacco users were enrolled. Out of which 105 members registered for quitting tobacco and 57 of them attended the tobacco cessation program which was conducted on 22/5/2014 in our college i.e., Smt. Sarojini Ramulamma College Of Pharmacy. The Results of the study are as follows.

Table 5.1: Age wise distribution

Age group	Frequency	Percentage (%)
16-20	7	12.28
21-30	30	52.63
31-40	9	15.79
41-50	6	10.53
51-60	4	7.02
61-70	1	1.75
Total	57	100

From the above table it was inferred that more number of people are using tobacco at the age group between 21-30 yrs i.e., 30(52.63%).

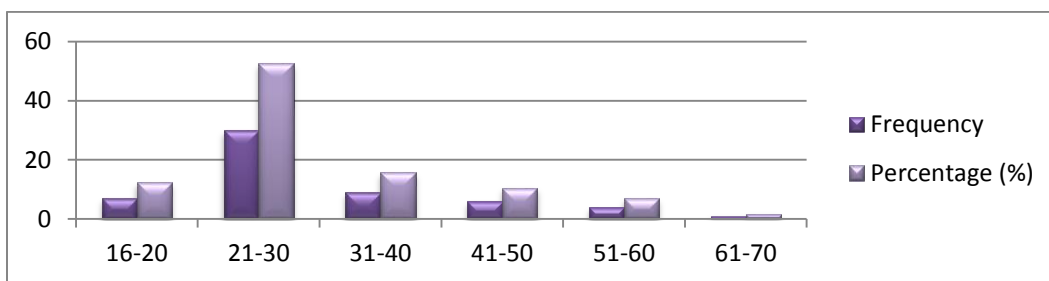


Figure: 5.1: Age wise distribution.

Table 5.2: Comparison of occupation among tobacco users

Occupation	Frequency	Percentage (%)
Businessmens	21	36.85
Farmers	3	5.26
Job Holders	19	33.33
Students	14	24.56
Total	57	100

From the above Table it is inferred that Out of 57 tobacco users, 21(36.86%) are doing business, 3(5.26%) are farmers, 19(33.33%) are doing jobs and 14(24.56) are students.

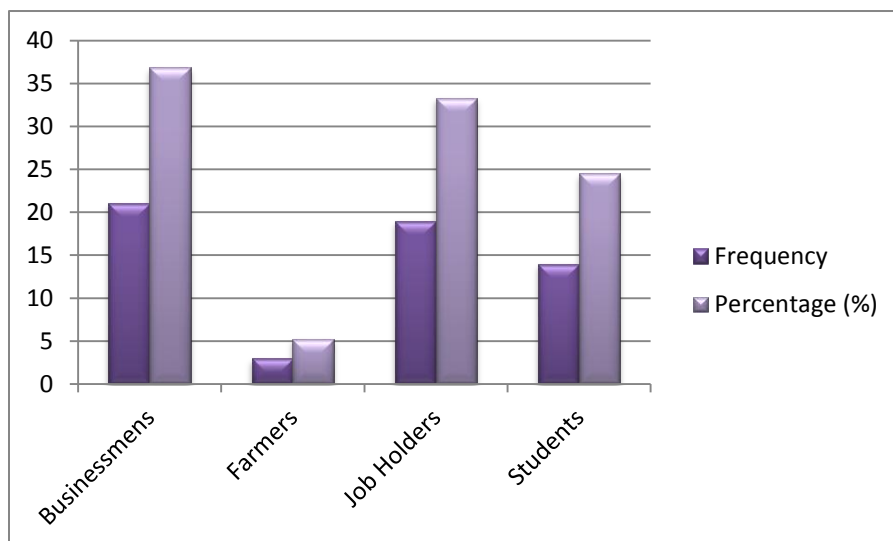


Figure: 5.2 Comparison of occupation among tobacco users

Table 5.3: Comparison of economical status among tobacco users

Annual income	Frequency	Percentage (%)
Less than 1 lakh	1	1.75
1-5 lakhs	55	96.50
Make than 5 lakhs	1	1.75
Total	57	100

Out of 57 tobacco users we found that people having annual income between 1-5 lakhs are using more

tobacco compared to others i.e., 1(1.75%) are poor and 1(1.75%) are rich people using tobacco.

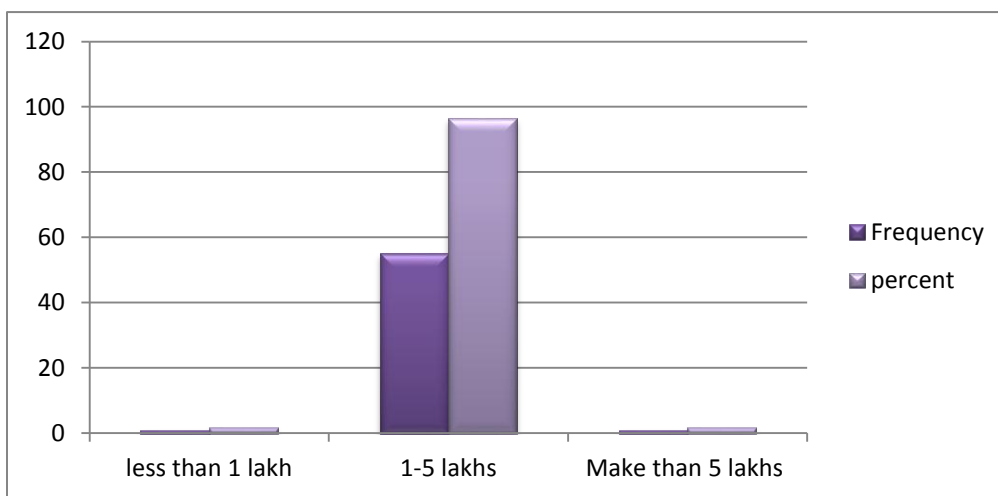


Figure: 5.3 Comparison of economical status among tobacco users

Table 5.4: Comparison of different forms of tobacco products used

Tobacco product	Frequency	Percentage (%)
Beedi	1	1.75
Cigarette	52	91.23
Beedi+gutkha	2	3.51
Cigarette+gutkha	2	3.51
Total	57	100

From the above table it is inferred that Out of 57 tobacco users 1(1.75%) using beedi, 52(91.23%) using cigarettes, 2(3.51%) using beedi+gutkha and

2(3.51%) using cigarette+gutkha. We find more number of cigarette users in our survey compare to beedi, beedi+gutkha and cigarette+gutkha.

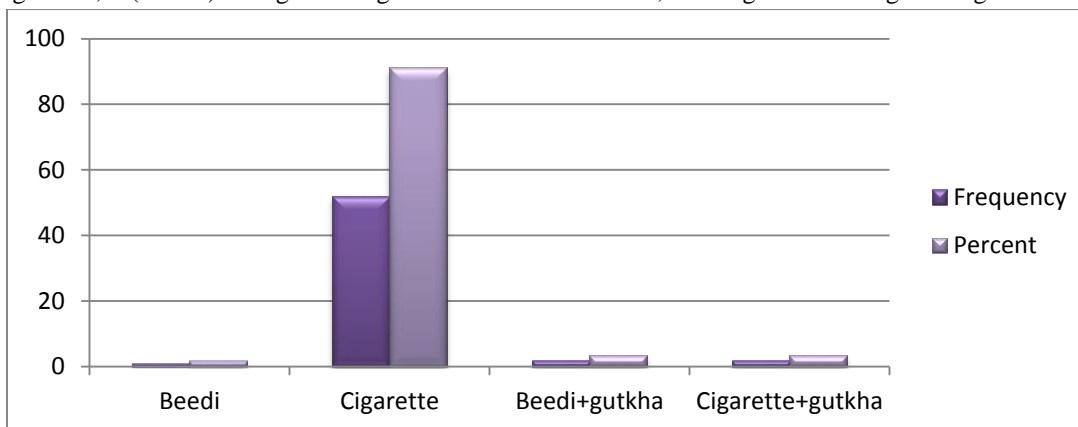


Figure: 5.4 Comparison of different forms of tobacco products use.

Table 5.5: Comparison of duration of tobacco use

Duration of tobacco use	Frequency	Percentage (%)
one year or less	10	17.54
more than 1 yr	14	24.56
more than 5 yrs	13	22.81
more than 10 yrs	20	35.09
Total	57	100

From the above table it is inferred that out of 57 tobacco users more number of individuals are using tobacco products more than 10yrs i.e.,20(35.09%) and

followed by more than 1 yr 14(24.56%), more than 5 yrs 13(22.81%) and one year or less 10(17.54%).

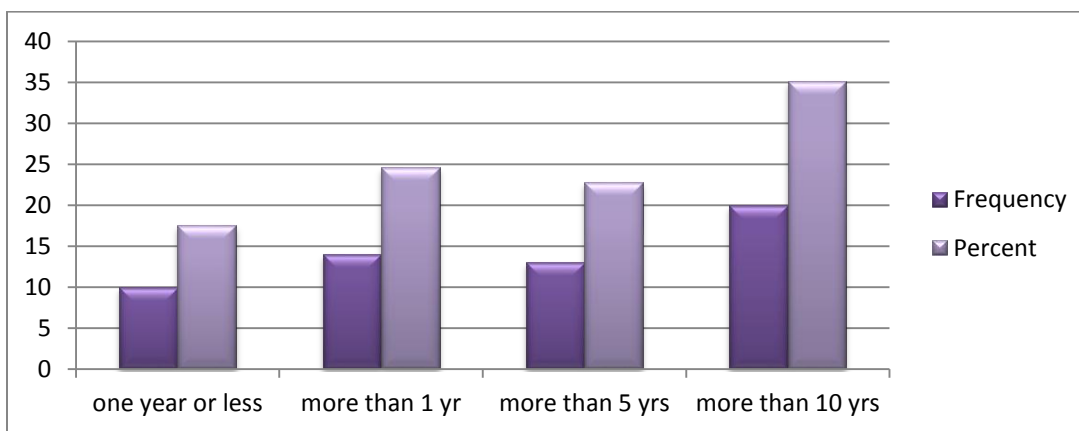


Figure: 5.5 Comparison of duration of tobacco use

Table 5.6: Comparison of the age when they first started using tobacco.

Starting age(yrs) of tobacco use	Frequency	Percentage (%)
0-12	1	1.75
13-14	2	3.51
15-18	19	33.33
19-22	21	36.84
23-30	11	19.30
more than 40 and above	3	5.27
Total	57	100

From the above table it is inferred that out of 57 tobacco users we find more number of people who started using tobacco are in the age group between 19-22 years i.e., 21(36.84%) followed by 15-18 yrs age

group people 19(33.33%), 23-30 yrs 11(19.30%), more than 40 years 3(5.27%), 13-14 yrs 2(3.51%) and 0-12 yrs 1(1.75%).

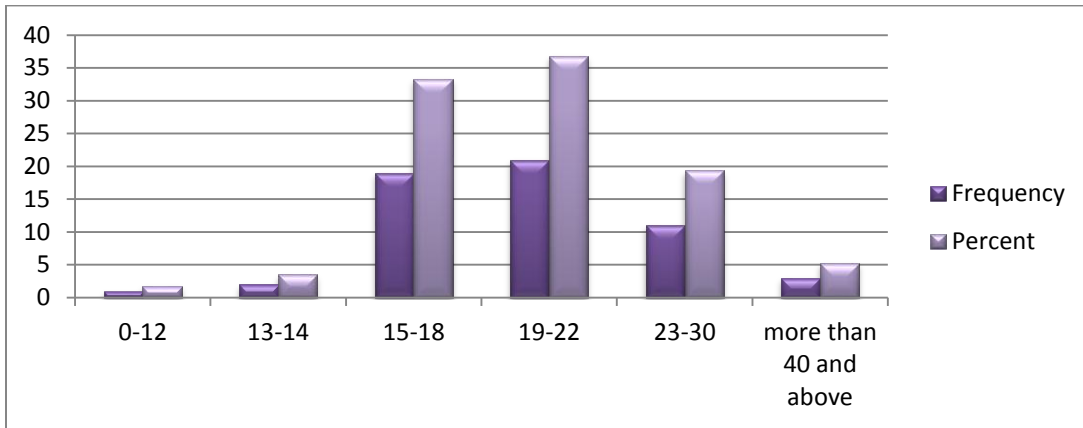


Figure: 5.6 Comparison of the age when they first started using tobacco

Table 5.7: Comparison of diseases among the tobacco users

Disease	Frequency	Percentage (%)
DM	1	1.75
HTN	2	3.51
COPD	1	1.75
No diseases	53	92.99
Total	57	100

From the above table it is inferred that out of 57 tobacco users only 2(3.51%) people found with HTN and 1(1.75%) found with DM and COPD each.

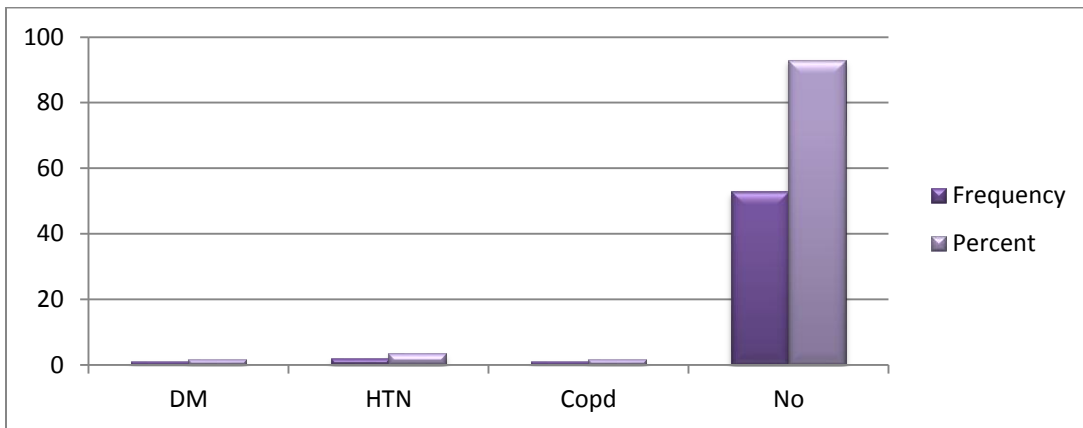


Figure: 5.7 Comparison of diseases among the tobacco users

Table 5.8: Reasons for tobacco use

Reasons	Frequency	Percentage (%)
Single reason	23	40.36
Two reasons	32	56.14
More than two reasons	2	3.50
Total	57	100

From the above table it is inferred that out of 57 tobacco users there are 23(40.36%) with single reason like passion or stress or work load etc., for tobacco use, 32(56.14%) with two reasons like

passion+tension or passion+work load etc., and only 2(3.50%) with multiple reasons passion, tension, work load, and many other problems.

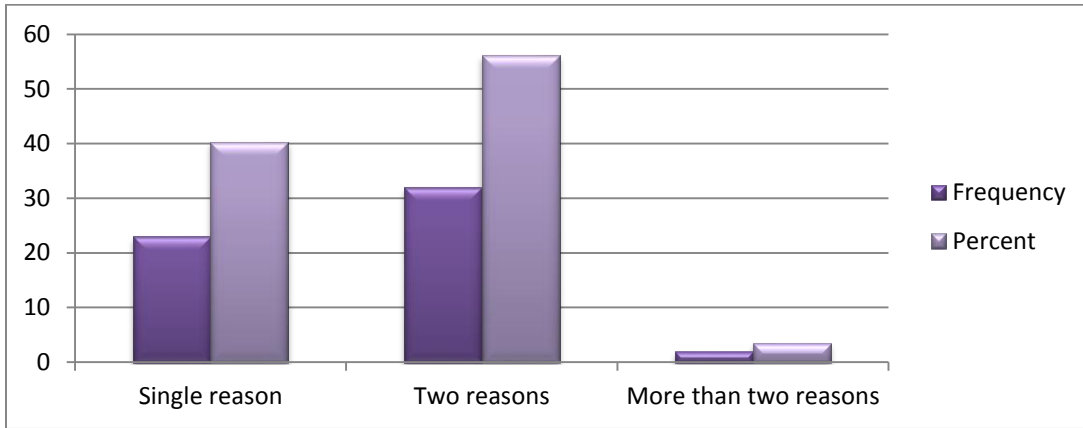


Figure: 5.8 Reasons for tobacco use

Table 5.9: Comparison of main reasons for quitting tobacco

Quitting reasons	Frequency	Percentage (%)
Single reason	36	63.16
Two reasons	16	28.07
More than two reasons	5	8.77
Total	57	100

From the above table it is inferred that out of 57 tobacco users 36(63.16%) want to quit tobacco usage because of single reason like health or family or smells bad or money etc, 16(28.07%) because of two

reasons like health+family, smells bad+money etc, and 5(8.77%) want to quit because of multiple reasons like health, family, smells bad, money etc.

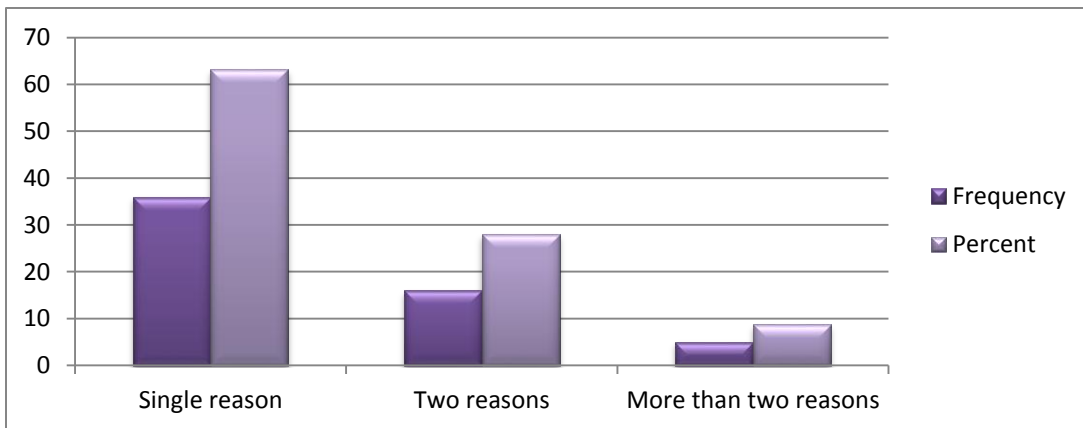


Figure: 6.9 Comparison of main reasons for quitting tobacco

Table 5.10: Intervention survey response

Patient ID	Remarks	Outcomes	Percentage (%)
1	Reduced	Reduced from 6 to 3 cigarette	50
2	Reduced	Reduced from 7 to 4 cigarette	57.14
3	Reduced	Reduced from 8 to 3 cigarette	37.5
4	Reduced	Reduced from 10 to 5 cigarette	50
5	Reduced	Reduced from 40 to 20 beedi	50
6	Reduced	Reduced from 5 to 2 cigarette	40
7	Reduced	Reduced from 6 to 4 cigarette	66.66

8	Reduced	Reduced from 100 to 30 beedi	30
9	Reduced	Reduced from 11 to 5 cigarette	45.45
10	Reduced	Reduced from 4 to 3 cigarette	75
11	Reduced	Reduced from 5 to 4 cigarette	80
12	Reduced	Reduced from 6 to 4 cigarette	66.66
13	Reduced	Reduced from 7 to 6 cigarette	85.71
14	Reduced	Reduced from 8 to 5 cigarette	62.5
15	Reduced	Reduced from 7 to 4 cigarette	57.14
16	Reduced	Reduced from 4 to 3 cigarette	75
17	Reduced	Reduced from 5 to 2 cigarette	40
18	Reduced	Reduced from 4 to 3 cigarette	75

From the above table because of Awareness, Motivation and Counseling 18 tobacco users reduced the usage of tobacco successfully during our study. In which 16 (88.88%) are Cigarette Smokers and 2 (11.11%) are Beedi users.

From this observation, it was noted that many participants had a high interest in quitting tobacco users. A drawback of a group-style is that some people are not always comfortable in this setting,

do not participate, and may feel ashamed in front of the other members if they are not successful.

A major limitation of this study was that smoking status during follow-up was self-reported and attained via telephone.

From the follow up majority of tobacco users informed that the counseling and free Nicotine samples was very helpful in reducing or quitting the tobacco use.

Table: 5.11 Severity scale

Question Wise Severity Score	Before Counselling		After Counselling	
	Score	Mean±SD	Score	Mean±SD
1. How soon after you wake up do you smoke your first cigarette?	112	1.96±0.93	99	1.74±0.95
2. Do you find it difficult to refrain from smoking in places where it is forbidden?	31	0.54±0.5	17	0.3±0.46
3. What cigarette would you hate most to give up?	40	0.7±0.46	23	0.4±0.49
4. How many cigarettes per day do you smoke?	18	0.32±0.6	6	0.11±0.37
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?	28	0.49±0.5	17	0.3±0.46
6. Do you smoke when you are so ill that you are in bed most of the day?	10	0.18±0.38	5	0.09±0.29

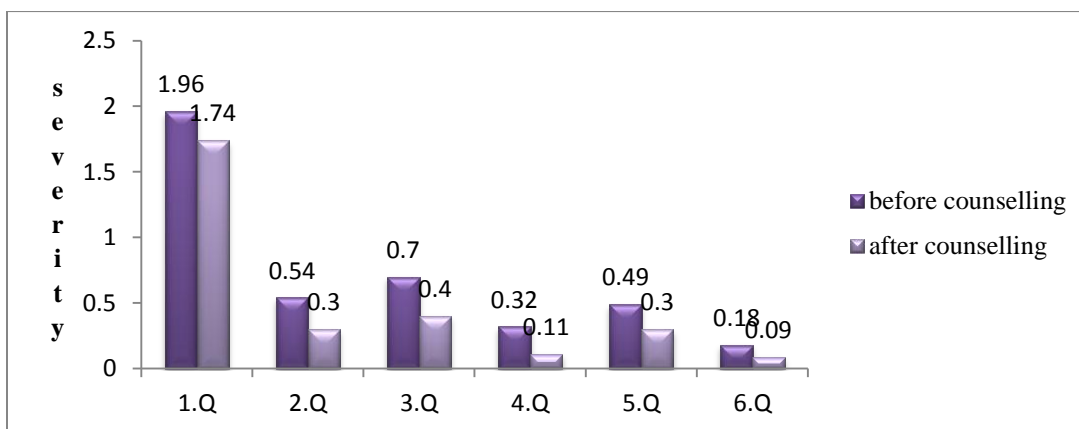


Figure: 5.11 Question Wise Severity Score

Table 5.12: Comparison between base line and first follow up

severity scale	Total score	Mean	SD	P value
Baseline	239	4.19	1.87	
1st follow up	167	2.93	1.73	P<0.0001***

According to paired student-t test we find the P value as <0.0001 (highly significant).

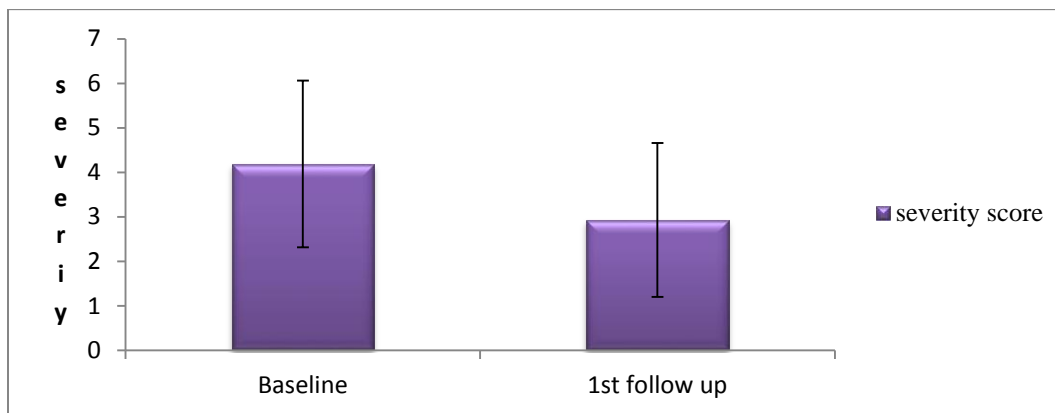


Figure: 5.12 .SD for total score

SUMMARY

Usage of tobacco has been growing widely in India. It also became a major risk factor for many of the diseases. This is mainly due to lack of knowledge and awareness on tobacco. The Institutional Ethical Committee of SVS MEDICAL COLLEGE AND HOSPITAL, approved the study for conducting Tobacco Cessation programs in various places (i.e., In and around Mahabubnagar). In order to assess the knowledge on tobacco a questionnaire was developed and used. Tobacco users were enrolled by clinical pharmacist directly on the study site. By conducting the survey, we come to know that people are having a poor Knowledge on tobacco. Most of the people are ready for quitting tobacco, but they are addicted and realized to eradicate, but in vein. So by creating awareness and also conducting counseling sessions on tobacco usage people may get an idea to quit tobacco.

In counseling session information about the consequences of tobacco use, Pharmacological (NRT therapy) and non-pharmacological (Behavioral therapy, etc.,) treatment and cessation tips was provided to the individuals and supplied free Nicotine gums with information leaflet and severity of nicotine dependence was measured using Fagerstrome severity scale.

Family and friends play a crucial role in tobacco cessation by building confidence in the individuals saying that they can able to quit tobacco. By providing effective counseling and developing strong will power in the individuals achieved a successful outcome of the tobacco cessation program.

CONCLUSIONS

The Clinical pharmacy department established a Clinical Pharmacist-Managed program on Creating Awareness, Motivation and Counseling on Tobacco Cessation at Mahabubnagar. In this program 220 individuals were enrolled and 110 individuals registered for quitting tobacco usage in which 57 individuals participated in the counseling session. Out of 57 individuals high numbers of tobacco users were found to be doing business and a number of individuals are found to be using cigarette compared to other products of tobacco. The starting age of tobacco usage is in the age group between 19-22 yrs according to our survey. Out of 57 tobacco users 18 individuals reduced or quit the tobacco use. The severity of tobacco use was estimated using Fagerstome Severity Scale. Using this scale the severity of the individuals before counseling and after counseling was assessed and P value was calculated. The P value was found to be highly significant, i.e., <0.0001***. By providing effective counseling and developing

strong will power in the individuals achieved a successful outcome of the tobacco cessation program.

FUTURE DIRECTIONS

- Interventional studies can be carried out for the benefit of tobacco cessation.

- Studies can be conducted in community pharmacies by giving Education, Awareness and Motivation on Tobacco Cessation.
- Sufficient funds should be provided to conduct Awareness on Tobacco Cessation Programs.
- Laws related to tobacco should be followed strictly.

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