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Clinical Efficacy of *Vishamushtyadi Vati* in Tobacco Addiction- A Randomized Control Trial

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ABSTRACT

Tobacco chewing as well as smoking is a severe problem all over the world including India. There are so many smokeless products like *Gutka, Jarda, and Pan Masala* etc. available in the market that contains nicotine and more than 4000 other toxins which are harmful to human beings and cause incurable disease like cancer. According to Centre for Disease Control report, chewing of tobacco used 7-8 times in a day may be equivalent to smoking 30-40 cigarettes per day. In Ayurveda, certain terms like *Oaksatmya, Vyasana, Mada*, etc were found and those can be correlated with addiction. *Pragyaapradha* is the main causative factor of all kind of Addiction.

In this study, 40 patients with tobacco chewing addiction were registered and they were categorized into two groups viz., Group-A & Group-B, consisting of 20 patients in each group from de-addiction OPD of National Institute of Ayurveda, Jaipur. It was noticed that five patients from each group had discontinued the trial. All 30 patients were randomly divided into two groups. Group-A patients were treated with *Vishamushtyadi Vati* (250 mg BD) along with *Tagaraadi kwath ghan vati* (500mg) and Group-B patients were treated with *Haridra ghan vati* (500 mg BD) along with *Tagaraadi kwath ghan vati* (500 mg BD). The result was prepared on the basis of statistical analysis and it is concluded that study drug is more effective than control drug in Tobacco chewing Addiction.

KEYWORDS

Tobacco, Addiction, Dependence, Tolerance, Panaapkram

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INTRODUCTION

Tobacco use kills nearly six million people worldwide each year. According to NFHS-III, in India, 55.8% male, 10.8% female in the age group of 12 to 6 years have been found to be consuming tobacco. Among males, 32.7% smokers while 36.5% tobacco chewers are reported, while among females; it is reported to be 1.4 and 8.4%, respectively[1].

Tobacco was first discovered by the native people of Mesoamerica and South America and later introduced to Europe and the rest of the world. In India, tobacco was introduced by Portuguese during 1605. Chewing Tobacco is one of the oldest methods of consuming smokeless tobacco product. It was frequently mixed with mineral lime and Coca leaves thus commercially very popular in the late 19th century. It was also consumed by placing a portion of tobacco between the check and gum or upper lip teeth and chewing the same. It must be crushed by teeth to release flavour of nicotine and unwanted juices were then expectorated.

Kasyapa Samhita describes about *Panaapkram* for withdrawal of Alcohol, specifically. Also, it has given detailed description about *Mada*, *Madya*, and *Madatyaya*, but not described much in detailed about De-addiction method of any other addictive substance like tobacco. So there is a need to develop better *Ayurvedic* drugs and methods to elaborate for De-addiction of Tobacco without any side effects.

AIMS AND OBJECTIVES

- To evaluate, elaborate and discussion of *Ayurvedic* aspect of tobacco addiction, withdrawal and management.
- To study the clinical efficacy of *Vishamushtyadi vati* along with *Tagaraadi kwath ghan vati* in tobacco addiction and withdrawal.
- To compare the clinical efficacy of *Vishamushtyadi vati* with *Haridra ghan vati* in tobacco addiction and withdrawal along with *Tagaraadi kwath ghan vati*.

MATERIALS AND METHODS

Ethical Committee Approval No. IEC/ACA/2016/02

I. Pharmaceutical preparation

Preparation of trial drug was done in the Pharmacy of National Institute of Ayurveda, Jaipur. The following drugs are made by pharmacy.

1. *VISHAMUSHTYADI VATI*[2]*:*

It was prepared from the powder of purified *Kuchla* seeds (*Strychnos nuxvomica*) with *Maricha* (*Pipper nigreum*) seeds, then *Bhawana* (Prituration) to be given with

juice of *Indravaruni*, and its *vati* were formed from this mixture.

2. *HARIDRA GHAN VATI:*

It was prepared from decoction of *Yavkuta churna* of *Haridra*. First, its decoction was prepared and kept at low flame till its volume reduced up to 1/10th, cool this mixture for some time to make *vati* from this *ghan.*

3. *TAGARADI KWATH GHAN VATI*[3]*:*

It was composed of 12 drugs, prepared with the same method as *Haridra ghan vati* was made earlier and the same is depicted in the table no- 1 below.

Table 1 Ingredients of *Tagaradi Kwath Ghan Vati*

S. no	Drug Name	Latin Name	*Rasa*	*Guna*	*Veerya*	*Vipaka*
1.	*Tagar*	*(Valeriana wallichii)*	*Tikta, Katu, Kashaya*	*Laghu, Snigdha*	*Ushna*	*Katu*
2	*Ashwagandha*	*(Withania somnifera)*	*Tikta kashaya*	*Laghu, Snigdha*	*Ushana*	*Madhura*
3	*Parpat*	*(Fumaria vaillantii)*	*Tikta*	*Laghu*	*Sheeta*	*Katu*
4.	*Shankpushpi*	*(Convolvulus pluricaulis)*	*kshaaya*	*Snigdha*	*Ushna*	*Katu*
5.	*Jyotishmati*	*(Celastrus panniculatus)*	*Katu, Tikta*	*Tikshna*	*Ushna*	*Katu*
6.	*Devadaru*	*(Cedrus deodara)*	*Tikta*	*Laghu, Snigdha*	*Ushna*	*Katu*
7.	*Tikta*	*(Picrorhiza kurroa)*	*Katu, Tikta*	*Laghu, Ruksha*	*Sheeta*	*Katu*
8.	*Brahmi*	*(Centella asiatica)*	*Tikta, kashaya, Madhura*	*Laghu*	*Sheeta*	*Madhura*
9.	*Nagarmotha*	*(Cyperus rotundus)*	*Katu, Tikta, kshaya*	*Laghu, Ruksha*	*Sheeta*	*Katu*
10.	*Aargwadh*	*(Cassia fistula)*	*Madhura*	*Guru, Mradu, Snigdha*	*Sheeta*	*Madhura*
11.	*Haritki*	*(Terminalia chebula)*	*Madhura, Amla,Katu, Tikta, Kashaya*	*Ruksha*	*Ushna*	*Madhura*
12.	*Draksha*	*(Vitis vinifera)*	*Madhura, kashaya*	*Guru*	*Sheeta*	*Madhura*

II. Research Performa: Information of patients regarding their demographic history, personal history, social history, systemic examinations etc. were noted down.

III. Awareness of patients for trial: during starting phase of trials, many camps were organized in villages of Jaipur city. Counselling were given to many tobacco addicted patients with the help of videos, flex, banner and also tried to spread awareness about the ill effects of chronic use of tobacco.

IV. Selection of patients

A list of 30 patients was made, who had desire to withdraw tobacco were selected from OPD of National Institute of Ayurveda, Jaipur and were treated after

proper physical examination in OPD and IPD level. Selected 30 patients were randomly divided in two groups. Randomization was done by the help of lottery drawing method, if odd number was outcome then kept this patient into Group-A, and if even number was came then kept this patient into Group-B.

1. Study group (Group-A) – *Vishamushtyadi vati and Tagraadi kwath ghan vati* were given in 15 patients of tobacco addiction and withdrawal.

2. Control group (Group-B) – *Haridra ghan vati and Tagaraadi Kwath Ghan Vati* were given in 15 patients of tobacco addiction and withdrawal.

Both the groups were given psychological counseling and suggested meditation and normal diet.

Duration of Trial: 35 days in each group.

Diagnostic Criteria's Adopted

1. Patients presented with History of Tobacco chewing at least one year. For this purpose a special research proforma was prepared as per the Modern and *Ayurvedic* view.

2. The diagnosis of the disease was done on the basis of clinical manifestations like craving for nicotine, anxiety, depression, restlessness etc.

Inclusion Criteria

1. Diagnosed patient of tobacco addiction.
2. Clinical manifestation of tobacco chewing withdrawal patients including craving for nicotine, anxiety, depression, restlessness etc. which were presented at that time.
3. Age between 18-60 years.
4. Patient willing to give consent for clinical trial.
5. Both sexes.
6. Patients having history of Tobacco Addiction (chewing) at least one year.

Exclusion Criteria:

1. Tobacco addicted patient suffering from cancer of lung, oral cavity, larynx, and oesophagus.
2. Tobacco addicted patients who suffered from major psychiatric disorders.
3. Tobacco addicted patients suffering from major systemic illness like diabetes, hypertension, myocardial infarction, ischemic heart disease, pulmonary tuberculosis etc.

Discontinuation criteria:

1. Aggravation of symptoms.
2. Patients not willing to continue.

VII. Drugs and its administration:

1. ***VISHAMUSHTYADI VATI:*** **-** 250 mg twice daily with *Koshana jal* for two weeks then one week gap then continue for two weeks.

2. ***HARIDRA GHAN VATI:*** **-** 500mg twice daily with *Koshana jal* for five weeks continuously.

3. *TAGARADI KWATH GHAN VATI:* - 500 mg twice daily with *Koshana jal* for five weeks continuously.

VIII. Counselling

A regular psychological counselling was given with the help of pictures or videos to every patient and their family members. The aim was to create awareness about the harmful effect of long term consumption of smokeless tobacco product.

IX. Clinical Assessment

1. Subjective parameters

Fagerstrom Test For Nicotine Dependence-Smokeless Tobacco (FTND-ST)[4]:

Tobacco dependency was assessed by the Fagerstrom Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST) for smokeless tobacco users. It consists of six questions, which must be asked to the patients before and after treatment as depicted in the table no- 2 below.

Table 2 Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST)

1. How soon after you wake up do you have your first dip?	A. Within 5 minutes (3) B. 6-30 minutes (2) C. 31-60 minutes (1) D. After 60 minutes (0)
2. How often do you intentionally swallow tobacco juice?	A. Always (2) B. Sometimes (1) C. Never (0)
3. Which chew would you hate most to give up?	A. The first one in the morning (1) B. All others (0)
4. How many cans/pouches do you use per week?	A. More than 3 (3) B. 2-3 (1) C. 1 (0)
5. Do you chew more frequently during the first hours after waking than during the rest of the day?	A. Yes (1) B. No (0)
6. Do you chew if you are so ill that you are in bed most of the day?	A. Yes (1) B. No (0)
TOTAL: _____ SCORE	Add together the points for each answer. Use the scale below to determine the level of dependence on nicotine. Your level of dependence on nicotine is: 0-2: Very low dependence , 3-4: Low dependence 6-7: High dependence 8-10: Very high dependence

2. Nicotine withdrawal scale

This scale quantitatively measures nicotine withdrawal symptom severity. All these clinical features of tobacco withdrawal should be scored from 0 to 4 according to the severity (0- None, 1- mildly severe, 2- Moderate severe, 3- severe, 4- extremely severe) as depicted in Table No- 3 below. The baseline score of this scale is established up to 48 points maximum, if the total score comes < 16 out of 48 points or < 25 % then it is moderate severe, if the total score comes < 8 out of 48 points then it is very mild and if the score comes more than

16 out of 48 then the patient's Nicotine withdrawal symptoms are more severe.

Table 3 Assessment of Tobacco withdrawal symptoms with the help of Nicotine Withdrawal Scale[5]

1. Craving/Desire to Smoke a Cigarette	0	1	2	3	4
2. Constipation	0	1	2	3	4
3. Restlessness/Impatience	0	1	2	3	4
4. Increased Appetite (Excessive Hunger) or Weight Gain	0	1	2	3	4
5. Depression/Sadness/Tearfulness/Moodiness	0	1	2	3	4
6. Tension	0	1	2	3	4
7. Bizarre/Vivid Dreams or Nightmares	0	1	2	3	4
8. Frustration	0	1	2	3	4
9. Psychological Need to Smoke a Cigarette	0	1	2	3	4
10. Anger	0	1	2	3	4
11. Difficulty Falling Asleep	0	1	2	3	4
12. Difficulty Remaining Asleep	0	1	2	3	4
13. Irritability	0	1	2	3	4
14. Pimples	0	1	2	3	4
15. Headache	0	1	2	3	4
16. Anxiety	0	1	2	3	4
17. Difficulty Concentrating	0	1	2	3	4
18. Mouth Sores	0	1	2	3	4
19. Other:	0	1	2	3	4
20. Other:	0	1	2	3	4

Investigations Performed

Following investigations were advised- Blood for CBC, ESR, BT, and CT.

OBSERVATION

For the clinical study, 40 clinically diagnosed and confirmed cases of tobacco addiction were registered on the basis of a specially designed proforma prepared for the purpose. They were randomly selected by the help of lottery method. Out of 40 patients, 5 in group A and group B discontinued the treatment. The observations made on 30 patients of Tobacco addiction of this series showed that maximum number of patients were from the age group 25-35 year (43.33%) followed by 35-45 year (33.33%), Male (84.3%), Female (16.6%), Hindu (96.6%), Muslim (3.33%), Graduate (46.6%), Higher Secondary (26.67%), Illiterate (26.67%), Married (73.3%), Unmarried (26.6%), Labor class (23.3%), Private job (23.3%), Middle class family (96.67%), Vegetarian (76.67%), Urban area (93.3%), 43.34% were Habitual of tobacco since less than 10 years, 56.66 % were consuming tobacco from more than 10 years. 43.33% were taken *Jarda* and 33.33% were taken *gutka*. 53.33% patients were consumed tobacco less than 20 times in a day. 70% of patients were used less than 10 pouches, 33.33%

showed friend circle as a causative factor of starting of tobacco use. 75% of patient showed 1 to 2 times past attempt to give up with the help of some medication, 15.38% showed more than three times past attempt to give up without any treatment. 43.33% showed less than 20 days of duration of relapse, 52.63% showed cause of relapse was due to work pressure and 42.11% showed due to friend circle, 10% showed multiple habits of drug addiction like smoking, tobacco chewing and alcohol. 100% showed irregular bowel habits, 96.67 % of patients had *Krura Koshtha*, (3.33%) *Mridu Koshtha*, 66.67% were showed *Alpa Nidra*, 70% of patients were having *Vata pitta Prakruti*, 13.33% showed *Vata kapha Prakruti*, 83.3% showed *Rajsika prakruti* and 16.67% showed *Tamsika prakruti*, 96.67% showed *Madhayam Sahanana*, 3.3% showed *Avara Sahanana*, 63.33% showed *Avara Satva*, 36.67% showed *Madhyama Satva*, 76.67% showed *Madhyama Abhyavarana Shakti*, 76.67 % *Madhyama Jarana Shakti*, 20 % showed *Awara jaran Shakti*, 73.33% showed *Madyama vyayam Shakti*, 26.67% showed *Avara vyayam Shakti*, 100% of patients showed *Manovaha sroto dushti*, 96.6% showed *Anawaha sroto dusti*, 93.33% *Purishvaha sroto dushti*, 76.6% *Rasavaha sroto dusti*, 36.67 % *Medovaha sroto dushti*, 3.33% *Manovaha sroto dusti*, 3.33% *Asthivaha sroto dusti*, 96.67% showed complained of depression, tension and frustration, 86.6% showed headache and anger, 83.35 % showed anxiety, 76.67 % showed restlessness, 56.67% showed increase appetite and 20% were complained of difficulty in remaining asleep, 3.33% were showed mouth sore, 73.35% showed very high dependency, 16.67 % showed high dependency, 6.67 % showed medium dependency, 3.3% showed more dependency, 93.3% showed severe withdrawal symptoms, 6.66 % showed moderate withdrawal symptoms.

RESULTS

The statistical evaluation of therapy was done in two steps. First evaluation was intra-group or within group carried out before treatment and after treatment, in both the groups, separately. Second was evaluation of inter-group or between the two groups to evaluate both the therapies.

1) INTRA GROUP STUDY

a) On subjective parameters

For evaluating the effect of therapy within the group before and after treatment for the subjective parameters **Wilcoxon matched-pairs signed-ranks test** was used. All subjected parameters of group- A and group- B were assessed with the help of FTND scale and Nicotine withdrawal scale.

- **Total FTND score-** The percentage of relief was observed as 50.63% and 42.74% in Group-A and Group- B, respectively. However, the effect of the therapy was found extremely significant at $p < 0.0001$ in Group- A and Group- B.
- **The effect of therapy in Group- A and Group- B were assessed by Nicotine withdrawal scale as depicted in Table No- 4 and Table No- 5 respectively.** Maximum clinical manifestations in Group- A and Group- B were found significant. However Group- A was found more significant and more percentage of relief than Group B i.e. 61.5 %.

Table 4 Effect of therapy on the basis of each withdrawal symptoms of Nicotine Withdrawal Scale of Group- A

Variable	n	Mean		Mean Diff	% Relief	SD±	SE±	P	Results
		BT	AT						
Craving	15	3.067	1.533	1.534	50.01	0.5164	0.133	<0.0001	**E.S**
Constipation	**15**	2.400	0.2667	2.133	88.87	0.8338	0.2153	<0.0001	**E.S**
Restlessness	**15**	1.733	0.8000	0.9333	53.85	0.7037	0.1817	0.0010	**E.S**
Increase Appetite	**15**	0.5333	1.333	-0.8000	61.5	0.5606	0.1447	0.0023	**V.S**
Depression	**15**	2.133	0.5333	1.600	75	0.6325	0.1633	0.0001	**E.S**
Tension	**15**	1.667	0.6667	1.000	59.9	0.5345	0.1380	0.0002	**E.S**
Frustration	**15**	1.533	0.4667	1.067	69.6	0.7037	0.1817	0.0005	**E.S**
Psychological need	**15**	2.933	1.600	1.333	45.4	0.7237	0.1869	0.0002	**E.S**
Anger	**15**	1.333	0.4667	0.8667	65.01	0.5164	0.1333	0.0005	**E.S**
Difficult falling asleep	**15**	1.600	0.2667	1.333	83.31	0.8997	0.2323	0.0005	**E.S**
Difficulty remaining asleep	**15**	0.2667	0.0666 7	0.2000	74.9	0.5606	0.1447	0.5000	N.S
Irritation	**15**	1.867	0.6000	1.267	67.86	0.4577	0.1182	<0.0001	**E.S**
Pimple	**15**	0	0	0	0	0	0		
Headache	**15**	1.067	0.1333	0.933	87.44	0.4577	0.1182	0.0002	**E.S**
Anxiety	**15**	1.40	0.133	1.267	90.5	0.7037	0.1817	0.0002	**E.S**
Difficulty in concentration	**15**	2.33	1.20	1.133	48.6	0.639	0.1652	0.0002	**E.S**
Mouth sore	**15**	0.1333	0.0666	0.0666	49.96	0.2582	0.06667	< 0.999	N.S
Others	**15**	-	-	-	-	-	-	-	-
Total NWS Score	**15**	26.267	10.267	16	61.5	4.309	1.113	<0.0001	**E.S**

Table 5 Effect of therapy on the basis of Nicotine Withdrawal Scale of Group- B

Variable	n	Mean		Mean Diff	% Relief	SD±	SE±	P	Results
		BT	AT						
Craving	**15**	3.067	2.200	0.8667	28.25	0.5164	0.1333	0.0005	**E.S**
Constipation	**15**	2.600	1.333	1.267	48.73	0.7988	0.2063	0.0002	**E.S**
Restlessness	**15**	1.733	1.067	0.6667	38.4	0.6172	0.1594	0.0039	**V.S**
Increase Appetite	**15**	00.1333	0.8000	-0.6667	83	0.6172	0.1594	0.0068	**V.S**
Depression	**15**	1.667	0.8667	0.8000	47.90	0.5606	0.144	0.0010	**E.S**
Tension	**15**	1.933	1.333	0.6000	31	0.6325	0.1633	0.0137	**S**
Frustration	**15**	1.667	0.8000	0.8667	51.9	0.5164	0.1333	0.0005	**E.S**
Psychological need	**15**	3.067	2.267	0.8000	26	0.5606	0.1447	0.001	**E.S**
Anger	**15**	1.533	1.133	0.4000	26	0.5071	0.1309	0.0313	**S**

Difficult falling asleep	**15**	1.533	0.7333	0.8000	52.18	0.6761	0.1746	0.0020	**S**
Difficulty remaining asleep	**15**	0.333	0.0667	0.2667	80	0.5936	0.1533	0.2500	N.S
Irritation	**15**	1.600	0.8000	0.8000	50	0.6761	0.1746	<0.0020	**V.S**
Pimple	**15**	0	0	0	0				
Headache	**15**	1.600	1	0.6000	37.5	0.5071	0.1309	0.0039	**S**
Anxiety	**15**	1.333	0.6667	0.6667	50	0.4880	0.1260	0.0020	**S**
Difficulty in concentration	**15**	2.533	1.600	0.9333	36.8	0.5936	0.1533	0.0005	**E.S**
Mouth Sore	**15**	0	0	0	0	-	-	-	-
Total NWS Score	**15**	26.133	16.600	9.533	36.5	4.121	1.064	< 0.0001	**E.S**

b). Intragroup comparison of objective parameters

For evaluating the effect of therapy within the group before and after treatment for the objective parameters **Paired t test** was used separately on both A and B group. In group A and group B, the overall effects of the therapy on above investigations were statistically not significant at $p > 0.0001$.

2. INTERGROUP STUDY

a). Intergroup comparison of Subjective Parameters

To access the efficacy of two therapies intergroup comparison was done. As the variables were nonparametric we used **Mann-Whitney Test** for statistical analysis. The results were as follow.

i). Comparison of therapy by FTND scale

Table 6 Intergroup comparison of therapy's Effect on FTND Score

Variable	**Mean Diff.**		**SD±**		**SE±**		**P**	**S**
	Grp-A	**GrpB**	**GrpA**	**GrpB**	**Grp- A**	**GrpB**		
1. How soon after you wake up do you have your first dip?	2.00	1.667	1.000	0.8997	0.2582	0.2323	0.2380	N.S
2. How often do you intentionally swallow tobacco juice?	0.4	0.5333	0.5071	0.6399	0.1309	0.1652	0.6331	N.S
3. Which chew would you hate most to give up?	0.1333	-0.3333	0.7432	0.6172	0.19190	0.1594	0.0817	N.Q.S
4. How many cans/pouches do you use per week?	0.4000	0.4667	0.8281	0.833	0.2138	0.2153	0.7567	N.S
5. Do you chew more frequently during the first hours after waking than during the rest of the day?	0.7333	0.9333	0.4577	0.2582	0.1182	0.06667	0.1578	N.S

6. Do you chew if you are so ill that you are in bed most of the day?	0.4	0.2667	0.5071	0.4577	0.1309	0.1182	0.4616	N.S
Total FTND Score	4.067	3.533	1.907	1.407	0.4925	0.3634	0.5585	N.S

Table 7 Intergroup comparison of therapy's Effect on total average FTND Score

Variable	**Mean Diff.**		**SD±**		**SE±**		**P**	**S**
	Grp-A	**GrpB**	**GrpA**	**GrpB**	**Grp- A**	**GrpB**		
Total Average FTND Score	0.6755	0.5879	0.3177	0.2347	0.08203	0.06061	0.9834	N.S

ii). Comparison of therapy by Nicotine Withdrawal scale

Table 8 Inter group comparison of Effect of therapy on the basis of Nicotine Withdrawal scale

S.No	**Symptoms**	**Mean Diff**		**SD**		**SE**		**P**	**Result**
		Grp-A	**Grp- B**	**Grp-A**	**Grp- B**	**Grp-A**	**Grp- B**		
1.	**Craving**	1.533	0.8667	0.5164	0.5164	0.1333	0.1333	0.0029	**V.S**
2.	**Constipation**	2.133	1.267	0.8338	0.7988	0.2153	0.2063	0.0111	**S**
3.	**Restlessness**	0.9333	0.6000	0.7037	0.6325	0.1817	0.1633	0.1930	NS
4.	**Increase Appetite**	0.8000	0.7333	0.5606	0.5936	0.1447	0.1533	0.6776	N.S
5.	**Depression**	1.600	0.8000	0.6325	0.5606	0.1633	0.1447	0.0020	**V.S**
6.	**Tension**	1.000	0.6000	0.5345	0.6325	0.1380	0.1633	0.0895	N.S
7.	**Frustration**	1.067	0.8667	0.7037	0.5164	0.1817	0.1333	0.3969	N.S
8.	**Psychological need**	1.333	0.8000	0.7237	0.5606	0.1869	0.1447	0.0335	**S**
10.	**Anger**	0.8667	0.4000	0.5164	0.5071	0.1333	0.1309	0.0234	**S**
11.	**Difficult falling asleep**	1.333	0.8000	0.8997	0.6761	0.2323	0.1746	0.0891	N.S
12.	**Difficulty remaining asleep**	0.200	0.2667	0.5606	0.593	0.1447	0.1533	0.6776	N.S
13.	**Irritation**	1.267	0.8000	0.4577	0.6761	0.1182	0.1746	0.0421	**S**
14.	**Pimple**	-	-	-	-	-	-	-	-
15.	**Headache**	0.9333	0.6000	0.4577	0.5071	0.1182	0.1309	0.0777	N.S
16.	**Anxiety**	1.267	0.6667	0.7037	0.4880	0.1817	0.1260	0.0158	**S**
17.	**Difficulty in concentration**	1.133	0.933	0.6399	0.5936	0.1652	0.1533	0.3836	N.S
18.	**Mouth sore**	0.0666	0	0.2582	0	0.066	0	-	-
19.	**Others**	-	-	-		-	-	-	-
20.	**Total**	16	9.533	4.309	4.121	1.113	1.064	0.0007	E.S

b). Intergroup comparison of Objective parameters

The intergroup comparison of **Objective parameters** of both group A and B, evaluated by the **Unpaired T-test** and we found that, there was no statistical difference in the efficacy of both treatments.

Patient Wise Assessment in Percentage Relief

The Effect of the therapy in Percentage relief was assessed on every patient for nicotine dependency and withdrawal symptoms by **FTND score** and **Nicotine Withdrawal Scale** score respectively as depicted in Table No- 9 and Table No- 10.

Table 9 Distribution of patient according to Relief in FTND score

Relief	FTND Score for Grp- A		FTND Score Grp- B		Total	
	Patient	%	Patient	%	Patient	%
No Relief	0	0	0	0	0	0
Mild	2	13.3	2	13.3	4	13.3
Moderate	7	46.6	10	66.6	17	56.6
Marked	2	13.3	2	13.3	4	13.3
Excellent	4	26.6	1	6.6	5	16.67

Table 10 Distribution of patient according to Relief in Nicotine Withdrawal Symptoms

Relief	Nicotine withdrawal Grp- A		Nicotine withdrawal Grp- B		Total	
	Patient	%	Patient	%	Patient	%
No Relief	0	0	0	0	0	0
Mild	0	0	4	26.66	4	13.33
Moderate	2	13.33	8	53.33	10	33.33
Marked	7	46.67	3	20	10	33.33
Excellent	6	40	0	0	6	20

Total Effect of Therapy (Symptomatic)

1. According to total average score by Fagerstrom Test for Nicotine Dependence

Table 11 Total average score by Fagerstrom Test for Nicotine Dependence

Groups	N	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	P	Result
Group- A	15	1.3330	0.6549	0.6755	50.63	0.3177	0.08203	< 0.0001	E. S
Group- B	15	1.375	0.7876	0.5877	42.74	0.2347	0.0606	<0.0001	E.S

2. According to Nicotine withdrawal Scale

Table 12 Total average score by Nicotine Withdrawal Scale

Groups	N	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	P	Result
Group- A	15	26.26	10.267	16	61.5	4.309	1.113	<0.0001	E.S
Group- B	15	26.133	16.600	9.533	36.5	4.121	1.064	<0.0001	E.S

Note:- Percentage of relief in dependency and withdrawal of Tobacco of Group – A and Group- B as depicted in figure- 1 below

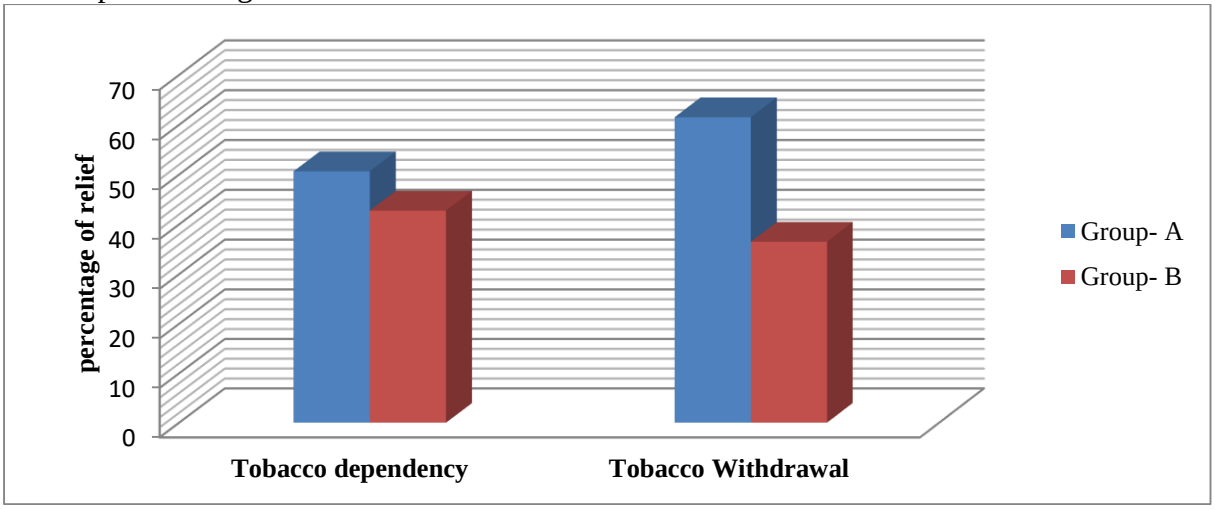

Fig 1 Percentage of relief in dependency and withdrawal of Tobacco of Group – A and Group- B

DISCUSSION

- The study has found that maximum i.e. 76.66 % patients were having **very high dependency** of Tobacco, **16.67%** were having **high dependency** of tobacco, **6.67%** were having **medium dependency** of tobacco while **3.33** % were having very **low dependency** of Tobacco.
- During the study period, it was shown that in all 30 registered patients, **93.3%** patients were noticed **severe withdrawal symptoms** while **6.66 %** were noticed **moderate withdrawal symptoms** and there were no any mild and extremely severe withdrawal symptoms noticed.
- The effect of therapy on FTND score in study as well as control group has found variable result from extreme significant to not significant but average effect of therapy in view of FTND score has found extremely significant in both study group as well as control group.
- Though the effect of therapy on NWS scale has found near about significant in maximum clinical manifestation in study group as well as control group but the study group has found more significant than control group.
- The overall therapy has found the significant effect to the Tobacco addiction.
- ***Vishamushtyadi Vati***- The ingredient of this formulation of study drug are *Kuchla*, *Indravaruni* and *Maricha*, Maximum ingredients are having ***Tikta, Kshaya Rasa*** and ***Tikshna*** Property. Due to its ***Tikta Rasa***, its own taste is not good but it alleviating loss of digestive power. It also maintain oral hygiene since in tobacco chewing oral route is involved and tobacco also shows some harmful effect to oral cavity, this can be reduce by ***Kanthasodhana*** and ***Dahahara*** properties of ***Vishamushtyadi vati*** due its ***Tikta Rasa***. ***Kuchla*** is one of the main ingredients of ***Vishmushtyadi Vati***, in this study a **purified *Kuchla*** has used, so **pacify *Vata Dosha***. According to a **National Institute of Drug Abuse**, it has well proved that any types of Addiction is Brain disease and disbalanced of CNS system causes Addiction. In *Ayurveda* it is controlled by ***Vata Dosha***. **The *Buddhi*** is affected in any Addiction. The ***Karma*** of *Buddhi* is carried out smoothly by ***Vata Dosha*** hence this *Dosha* is vitiated in Tobacco Addiction.

  All the drugs of this formulation are having ***Ushna*** property, due to this property it **Pacify *Vata Dosha***. Tobacco is Poisonous drug; it has ***Katu, Tikta Rasa*** and ***Ushna Virya*** which has quite

similar to the properties of ***Vishamushtyadi Vati*.** But *Kuchla i*n its purified form are having ***Vishghna* Property** so it counter the effect of Tobacco and also minimize the **craving effects**. ***Indravaruni*** has a **laxative action** due to its ***Tikshna* property**. In Tobacco Addiction **constipation** is the one of the major withdrawal symptoms, so it is minimized by ***Invaruni*,** which is an ingredient of *Vishamushtyadi Vati.*

- ***Haridra Ghan Vati***- It has selected for control group on basis of a **pilot study** conducted by **Culcutta Medical College** on deaddiction of tobacco chewers and chronic smokers. The ingredient of this formulation is only *Haridra*. *Haridra* has ***Vishghna*, *Vranaropaka***, and ***Amapachaka*** Property. It is used in my dental gum problem due its anti-inflammatory and healing action.
- ***Tagaradikwath ghan vati*** -The drug *Tagaradikwath ghan vati* involves in this trial to calm down the clinical manifestation like **insomnia, anxiety** and **agitation, depression, anger** etc, since the maximum ingredients are having ***Tikta Rasa*** and ***Sheeta Virya***. ***Brahmi*** *and* ***Shankhapushpi*** have act as **Brain tonic.**

CONCLUSION

❖ It is concluded that *Vishamushtyadi Vati along with Tagaradikwath ghan vati is more effective than Haridraghan vati along with Tagaraadikwath ghan vati.* The effect of therapy on FTND score in study as well as control group has found variable result from extreme significant to not significant but average effect of therapy in view of FTND score has found extremely significant in both study group as well as control group.

❖ Though the effect of therapy on NWS scale has found near about significant in maximum clinical manifestation in study group as well as control group but the study group has found more significant than control group.

❖ There were no any adverse effect was found during the entire clinical trial. Thus the entire clinical trial was safe clinically and pathologically.

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