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Research Article

A COMPARATIVE CLINICAL STUDY ON THE EFFECT OF TAGAR (*VALLERIANA WALLICHII* DC.) AND ASWAGANDHA (*WITHANIA SOMNIFERA*) IN THE MANAGEMENT OF PREOPERATIVE ANXIETY

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ABSTRACT

Preoperative anxiety is a clinical condition which requires medical management apart from reassurance. Surgical patients have the high incidence of anxiety. Relief from anxiety is accomplished by pharmacological and non-pharmacological measures, often there is no need of a therapeutic agents for control of preoperative anxiety. Various drugs are used for control of preoperative anxiety in the ward. Ayurveda has an age proved natural ways for the management of disease. Many Acharya have prescribed *Rasayana* and *Aushadha* for treatment of mental illness which is safe and effective under optimal doses. **Method:** Here is a study has been planned for *Rogi Sambandhit Purva Karma* in which administration of pre–operative medication and other measures are done to relieve the anxiety and other conditions. So, the present study is conducted to evolve an effective Ayurvedic drugs for management of preoperative anxiety. Here in this study *Tagar Churna* has been taken for study. Various ancient texts and online journals related to the topic have been reviewed. **Result:** Results were obtained by analysing the data using student's t-test. **Discussion:** Discussions were done regarding entire clinical study and the results obtained with relative opinions and arguments.

INTRODUCTION

Preoperative anxiety is a challenging concept in the preoperative care of the patients. Most patient awaiting elective surgery experience anxiety and it is widely accepted as an expected response. Preoperative anxiety can be defined as an unpleasant state of uneasiness or tension that is secondary to a patient being concerned about a disease, hospitalization, anaesthesia and surgery, or the unknown.

In Ayurveda various psychological disorders are mentioned which shows some similarity with the anxiety disorders. There is no separate and wide description of anxiety in Ayurvedic texts. Various texts described many terms related to *Mansika Vyadhis* which are *Chittavibhransha*, *Chittavibhrama*, *Chittaviparyaya*, *Anvasthita Chitta* etc., but *Chittodvega* seems to be the nearest term for anxiety, which is one of the psychological disorders described by Charaka. The etiology of *Chittodvega* shows similarity with the anxious state of mind. On the basis of these consideration, it can be postulated that *Chittodvega* is a minor mental disorder.

Chittodvega **–** It can be defined as *Chitta* (mind) + *Udevga* (anxiety) = *Chittodvega* (anxious state of mind). Acharya Charaka states that single clinical features can be considered as a common symptom in many diseases, or as a single disease entity.[1] Causes can be stated as *Pragyapradha* (intellectual error) can be defined as the karma done due to *Dhibhransha* (derangement of intellect), *Dhritibhransha* (derangement of restrain/ will) and *Smritibhransha* (derangement of memory)[2]. *Chittodvega* has been stated as one of the *Purvarupa* of *Unmada* by Charaka and Sushruta[3]. On studying the disease entity *Unmada* from the classics, it can be understood that the disease indicates and includes all the *Mansika Vyadhi*.

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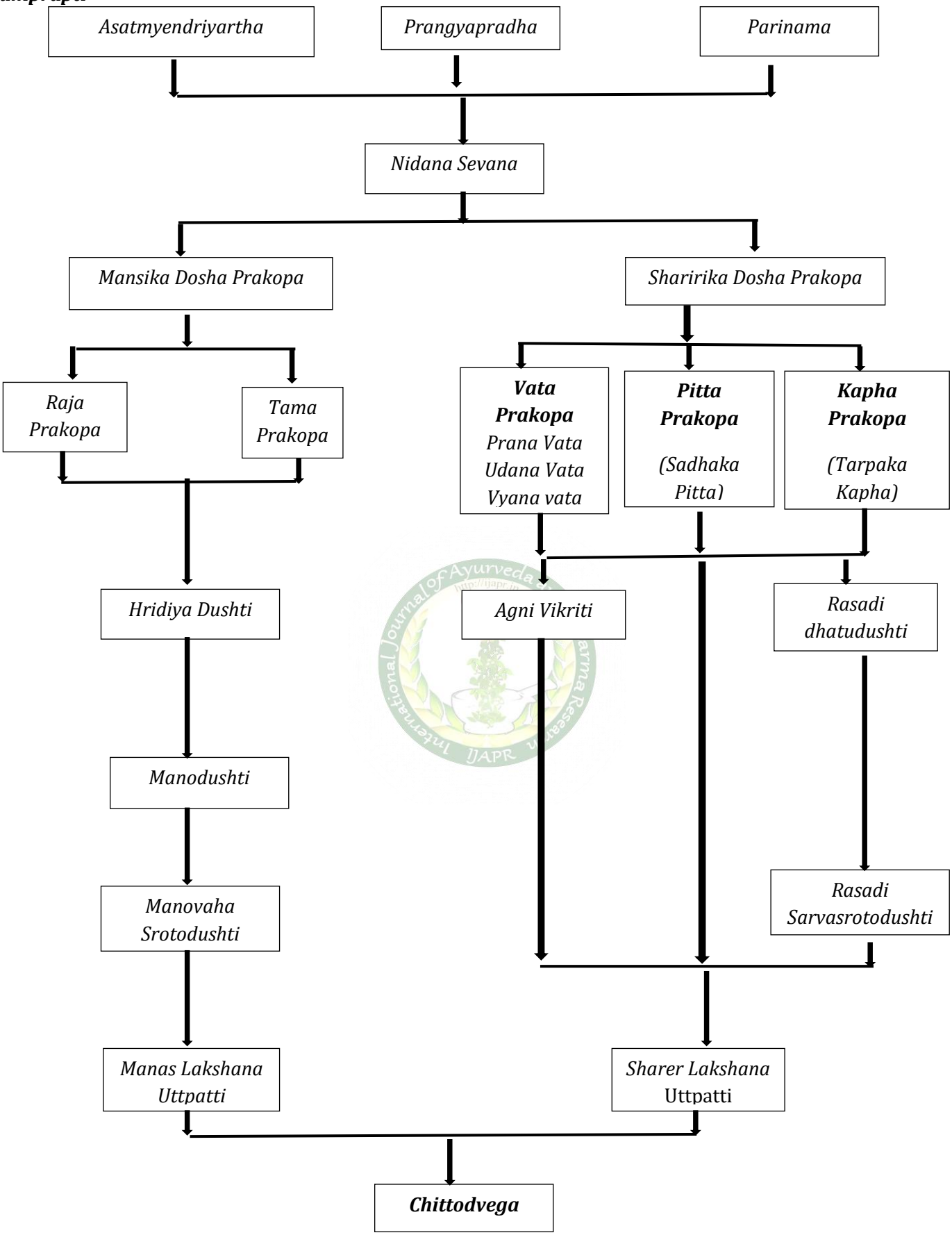
Asatmyendriyartha
Prangyapradha
Parinama
Nidana Sevana
Mansika Dosha Prakopa
Sharirika Dosha Prakopa
Raja Prakopa
Tama Prakopa
Vata Prakopa
Prana Vata
Udana Vata
Vyana vata
Pitta Prakopa
(Sadhaka Pitta)
Kapha Prakopa
(Tarpaka Kapha)
Hridiya Dushti
Agni Vikriti
Rasadi dhatudushti
Manodushti
Manovaha Srotodushti
Rasadi Sarvasrotodushti
Manas Lakshana Uttpatti
Sharer Lakshana Uttpatti
Chittodvega

Preoperative anxiety: Pre-operative anxiety is closely related to blood, injection, injury type phobia which comes under specific phobias of phobic anxiety disorders. Pre-operative anxiety or preoperational anxiety is a common reaction experienced by patients who are admitted to a hospital for surgery. It can be described as an unpleasant state of tension or uneasiness that results from a patient's doubts or fears before an operation. Causes are unknown, or they may be due to fear of surgical failure, lack of knowledge and experience of anaesthesia, loss of personal identity, pain, loss of control, unsuccessful recovery etc,.

Symptoms: Aromatic arousal symptoms include palpitations, sweating, trembling, dry mouth. Symptoms concerning with chest and abdomen are difficulty breathing, feeling of choking, chest pain or discomfort, nausea. Symptoms concerning with brain and mind are feeling dizzy, light headed, feelings that objects are unreal, hot flushes, numbness.

MATERIALS AND METHODS

It is controlled clinical study. 30 patients were selected who were posted for elective surgery. The patients were selected randomly and divided into two groups. In each group there were 15 patients of either sex between age group of 20–50 years. One is treated group of 15 patients were given *Tagar Churna* in dose of 1500mg twice daily for 2 days prior to surgery with lukewarm water half an hour before food. And other group is control group of 15 patients were given *Ashwagandha Churna* in dose of 3000mg twice daily for 2 days prior to surgery with milk half an hour before food.

Method of preparation of drug – the dried and cleaned roots of *Tagar* and *Ashwagandha* were grinded into fine powder to use.

Inclusion criteria

1. Age group between 20-50 years.
2. Patients undergoing elective surgeries in inguinal, scrotal and ano-rectal procedures under spinal anaesthesia and local anaesthesia.
3. Either sex

Exclusion criteria

1. Patients suffering from severe systemic diseases such as bronchial asthma, cardiac diseases, renal failure etc.
2. Patients who have previously undergone any surgical procedure.
3. Patients having uncontrolled hypertension.
4. Patients on anti-depressant and anti-psychotic drugs.

Statistical Analysis

Student's t-test has been used for analysing the data generated. P value <0.05 was considered as statistically significant.

OBSERVATIONS

In this study the symptoms were observed, in which palpitation was 100% in each group, Sweating was 26.7% in treated group and 20% in control group. Trembling and shaking was 33.3% in both groups and 20% in control groups, Dry mouth was 46.7% in both groups, derealisation and depersonalisation was present only in treated group which was only 6.7%, fear of losing control was 13.3% in treated group and 20% in control group, fear of dying was 53.3%, in treated group and 46.7% in control group. Hot flushes/ cold chills was 33.3% in treated groups and 13.3% in control group, numbness/tingling sensation was 33.3% in both groups.

RESULTS

Effect of *Tagar Churna* on the symptoms

At 1 hr, there was no relief in symptom, at 24hrs, 15% relief in symptoms were observed which was statistically not significant, but at 48 hrs there was statistically significant relief of 24.8% in the mean symptoms were observed. Before surgery, 34.6% relief in symptoms were observed which was statistically significant.

Table 1: Effect of *Tagar Churna* on the Symptoms of Treated Group

Time of observation	mean		% of relief	S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.					
1 hour	1.33	1.33	0	0	0	0	0
24hour	1.33	1.33	15	0.4144	0.107	1.8708	0.0824 (p>0.05)
48 hours	1.33	1.00	24.8	0.4880	0.126	2.6458	0.0192 (p<0.05)
B.S.	1.33	0.87	34.6	0.5151	0.133	3.5	0.0035 (p<0.05)

Effect of *Ashwagandha Churna* on the symptoms

At 1hr no relief in the symptoms was found but, at 24 hours, 19.3% relief in symptoms were observed which was statistically significant ((p<0.05), at 48 hours there was significant relief (p<0.05) of 33.6% in the mean symptoms were observed. Before surgery 42.8% relief in symptoms were observed which was statistically significant (p<0.05). This shows gradual decrease in the symptoms.

Table 2: Effect of *Ashwagandha Churna* on the Symptoms of Control Group

Time of observation	mean		% of relief	S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.					
1 hour	1.40	1.40	0	0	0	0	0
24hour	1.40	1.13	19.3	0.4570	0.118	2.2563	0.0405 (p<0.05)
48 hours	1.40	0.93	33.6	0.5151	0.133	3.5	0.0035 (p<0.05)
B.S.	1.40	0.80	42.8	0.5074	0.131	4.5826	0.0004 (p<0.05)

Effect of *Tagar Churna* on the Mean Arterial Pressure (M.A.P)

Before drug administration, mean M.A.P was 97.50mmHg. after 1hr of drug administration M.A.P decreased to 96.69mmHg, after 24 hrs it decreases to 96.15mmHg, at 48 hrs it falls to 95.59mmHg and decrease in M.A.P before surgery was 97.20mmHg. These shows decrease in blood pressure after drug administration which was statistically significant at 1hr, 24 hrs, and 48 hrs (p<0.05) but decrease in M.A.P before surgery was not significant (p>0.05)

Effect of *Tagar Churna* on M.A.P of Treated group

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	97.50	96.69	1.069	0.276	2.8692	0.0124 (p<0.05)
24hour	97.50	96.15	2.033	0.525	2..5391	0.0236 (p<0.05)
48 hours	97.50	95.59	2.587	0.668	2.8467	0.0129 (p<0.05)
B.S.	97.50	97.20	2.835	0.732	0.3541	0.7285 (p<0.05)

Effect of *Ashwagandha Churna* on the Mean Arterial Pressure (M.A.P)

Before drug administration mean M.A.P was 99.18mmHg, there is statistically significant (p<0.05) decrease in the blood pressure after drug administration at 24 hrs, 48 hrs, and before surgery but decrease in the blood pressure at 1st hr was nit significant (p>0.05).

Effect of *Ashwagandha Churna* on M.A.P of control group

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	99.18	98.65	1.406	0.363	1.4536	0.1681 (p<0.05)
24hour	99.18	96.48	3.493	0.902	2.9989	0.0096 (p<0.05)
48 hours	99.18	96.44	2.355	0.608	4.5106	0.0005 (p<0.05)
B.S.	99.18	97.37	1.890	0.488	3.7157	0.0023 (p<0.05)

Effect on pulse rate of *Tagar Churna* (per minute)

Before drug administration pulse rate was 86.5/min. after drug administration there is gradual decrease in the pulse rate. However decrease in mean pulse rate before surgery was not significant.

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	86.5	84.5	1.689	0.436	4.5826	0.0004 (p<0.05)
24hour	86.5	83.0	1.189	0.307	11.3089	0.0001 (p<0.05)
48 hours	86.5	81.9	1.921	0.496	0.1336	0.0001 (p<0.05)
B.S.	86.5	85.8	2.746	0.709	0.5641	0.5816 (p<0.05)

Effect of *Ashwagandha Churna* on the pulse rate

Before drug administration PR was 86.8/min. after drug administration, decrease in PR at 1hr, 24hr, 48hr and before surgery was statistically significant (p<0.05).

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	86.5	84.5	1.689	0.436	4.5826	0.0004 (p<0.05)
24hour	86.5	83.0	1.189	0.307	11.3089	0.0001 (p<0.05)
48 hours	86.5	81.9	1.921	0.496	0.1336	0.0001 (p<0.05)
B.S.	86.5	85.8	2.746	0.709	0.5641	0.5816 (p<0.05)

Effect of *Tagar Churna* on respiratory rate (per minute)

Before drug administration, mean RR was 21.60/min. after drug administration RR decreased gradually.

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	21.60	20.07	0.833	0.215	2.4773	0.0266 (p<0.05)
24hour	21.60	20.87	0.457	0.118	6.2048	0.0001 (p<0.05)
48 hours	21.60	20.47	0.639	0.165	6.8590	0.0001 (p<0.05)
B.S.	21.60	21.53	0.960	0.248	0.2686	0.7921 (p>0.05)

Effect of *Ashwagandha Churna* on the Respiratory rate (per minute)

Before drug administration mean RR was 21.60/min. after drug administration of drug, there is gradual decrease in mean RR at 1hr, 24 hrs, 48 hrs and before surgery was statistically significant.

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	21.60	20.87	1.161	0.300	2.4423	0.0285 (p<0.05)
24hour	21.60	19.67	1.278	0.330	5.8504	0.0001 (p<0.05)
48 hours	21.60	19.40	1.321	0.341	6.4541	0.0001 (p<0.05)
B.S.	21.60	20.93	1.173	0.303	2.1972	0.0453 (p>0.05)

Effect of *Tagar churna* on the oxygen concentration (SpO_2)

Before drug administration spo2 was 98.5% but after drug administration there is gradual increase at 1hr, 24hrs and 48hrs which was statistically not significant, but increase in mean spO_2 concentration before surgery was statistically significant.

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	98.5	98.5	0.798	0.206	0.3232	0.7513 (p>0.05)
24hour	98.5	98.7	0.864	0.223	0.8987	0.3840 (p>0.05)
48 hours	98.5	98.6	0.639	0.165	0.8069	0.4332 (p>0.05)
B.S.	98.5	99.0	0.639	0.165	3.2278	0.0061 (p<0.05)

Effect of *Ashwagandha Churna* on oxygen concentration of control group

Before drug administration, mean oxygen concentration was 98.5%. After drug administration, there is gradual increase in spo2 but increase in oxygen concentration was significant at 48hrs and before surgery.

Time of observation	mean		S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.				
1 hour	98.6	98.7	0.259	0.067	1.000	0.3343 (p>0.05)
24hour	98.6	98.8	0.414	0.107	1.8708	0.0824 (p>0.05)
48 hours	98.6	99.1	0.515	0.133	3.5	0.0035 (p<0.05)
B.S.	98.6	99.3	0.724	0.187	3.5675	0.0031 (p<0.05)

Effect of *Tagar Churna* on Hamilton Anxiety Rating Scale (HAM-A)

Before drug administration, mean HAM-A score was 14.67. But after drug administration there was decrease in the HAM-A score at 1hr which was not significant but at 24hrs, 48 hrs and before surgery there was gradual decrease which was statistically significant.

Time of observation	mean		% of relief	S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.					
1 hour	14.67	14.47	1.36	0.414	0.107	1.8708	0.0824 (p>0.05)
24hour	14.67	12.27	16	0.631	0.163	14.6969	0.0001 (p<0.05)
48 hours	14.67	10.60	27.7	0.798	0.206	19.7170	0.0001 (p<0.05)
B.S.	14.67	9.60	34.4	0.883	0.228	22.2053	0.0001 (p<0.05)

Effect of *Ashwagandha churna* on Hamilton Anxiety Rating Scale (HAM-A)

Before drug administration, mean HAM-A score was 14.27. But after drug administration there is no significant decrease at first 1hr but after 24 hrs, 48 hrs and before surgery there is significant decrease in HAM-A score.

Time of observation	mean		% of relief	S.D. (+/-)	S.E. (+/-)	'T' value	'P' value
	B.T.	A.T.					
1 hour	14.27	14.20	0.5	0.592	0.153	0.4350	0.6702 (p>0.05)
24hour	14.27	11.47	19.6	0.561	0.145	19.3438	0.0001 (p<0.05)
48 hours	14.27	9.53	33.2	0.798	0.206	22.9493	0.0001 (p<0.05)
B.S.	14.27	8.60	39.73	0.817	0.211	26.8794	0.0001 (p<0.05)

DISCUSSION

Chittodvega can be correlated with anxiety w.s.r to preoperative anxiety on the basis of etymology (anxious state of mind), type of psychological disorders (neurotic disorder) and symptomatology (both are psychosomatic disorders). In modern contemporary science, to relieve preoperative anxiety the anxiolytics like benzodiazepines, opioids etc. are prescribed. These drugs are good sedative, due to which the stress level anxiety comes down. In this stud *Tagar churna* was given to patients in treated group to observe its anxiolytic effect. *Tagar* because of its *Vatashamak* property, it is indicated in *Manovaha-srotodushti vikara* like *Unmada, Apasmarar*, *Mada, Bhuta. Tagar* is also *Mastishka Shamaka* (sedative and hypnotic) due to *Vatashamaka* property.

Valproic acid, an analogue of valeric acid which is an constituent of *Tagar*, used as an anticonvulsant and mood stabilizing agent, also GABA amino acid is found in *Tagar*, which can be responsible for sedative effect of *Tagar*. This made the basis for the selection of *Tagar* as trial drug for observing its anxiolytic effect to find out effective treatment of preoperative anxiety.

While looking into the mechanism of action of drugs, the difference in mean of graded symptoms of both groups (treated group & control group) was not significant, which means *Tagar Churna* was as effective as *Ashwagandha churna* in relieving the symptoms of preoperative anxiety.

In case of Vitals, the difference in M.A,P and RR of both groups was not significant at 24hrs, 48 hrs and before surgery, except 1st hr after administration of drug, which means *Tagar Churna* was as effective as *Ashwagandha Churna* in controlling BP before surgery which was due to fearful anticipation. The difference in mean P.R between both groups was significant at 24hrs, 48hrs and before surgery except 1st hr after drug administration, which means P.R was better controlled in control group before surgery. The difference in mean pf SPO_2 of both groups was not significant throughout the observation which means *Tagar Churna* was as effective as *Ashwagandha Churna* in improving oxygen saturation level and ventilation.

As per HAM-A, there were 87% of patients of mild anxiety in treated group and 93% in control group while 13% patients of moderate anxiety in treated group and 7% in control group. The difference in mean HAM-A score of both groups was significant at 24 hrs, 48hrs and before surgery except 1st hr after drug administration of drugs. It means that the severity of preoperative anxiety was better controlled in control group.

CONCLUSION

It is obvious from foregoing study that *Tagar Churna* and *Aswagandha Churna* provided significant relief in signs and symptoms of preoperative anxiety and the result are good when given 2 days prior to surgery. However, severity of anxiety was better relieved in control group. *Tagar Churna* can be given to the patients having preoperative anxiety of any age group and any sex. It can be safely be used in non-hypertensive patients presenting with mild to moderate symptoms of anxiety.

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