



Research Article

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A Randomized Controlled Double Blind clinical trial to evaluate the efficacy of *Vedanasthapana Mahakashaya* as an anxiolytic and analgesic polyherbal drug in perioperative anorectal cases

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ABSTRACT

Introduction: In surgery, pre-operatively anxiolytic drugs and analgesics are very essential for major or minor surgical procedures to better operative and post-operative outcomes. The *Vedanasthapana mahakashaya*, described by the *Acharya Charaka*, is a group of 10 herbs and those herbs are advocated as analgesic, and anxiolytic polyherbal composition by various text books of ayurveda. So, the aim of this study was to evaluate and compare the efficacy of the *Vedanasthapana mahakashaya* as an analgesic drug during post operative period and as an anxiolytic drug for pre operative anxiety. **Metarials & Methods:** The study was a prospective, randomized, double blind, controlled trial. 80 patients of anorectal diseases who undergone for surgical intervention were randomly allocated in one of two groups. Group-1 received *Vedanasthapana mahakashaya kwath* (Decoction), 30ml orally in preoperative and postoperative period while group-2 was treated with Tab. Alprazolam 0.25mg pre-operatively and Tab. Paracetamol 500 mg postoperatively. Anxiety was assessed on the basis of Anxiety score of Hospital Anxiety and Depression Scale (HADS) preoperatively and analgesia was assessed postoperatively by internationally validated Visual Analogue Scale. Inj. Diclofenac sodium 75mg IM was administered as a rescue analgesic. **Results:** Pain-baseline pain scores were not statistically differed in both groups. Both the groups showed statistically significant reduction in pain at the end of trial period. Both were found to be significantly similar (P 0.4856) but group-1 showed more reduction in pain 84.72% (P<0.0001) than the group-2 which have 80.08% reduction in VAS score (P<0.0001) Anxiety- The values of both the groups were showing statistically significant difference at different observational intervals but the reduction was significantly higher in group-2 (P<0.0158). **Conclusion:** Administration of the *Vedanasthapana mahakashaya* decoction is effective for post operative pain relief but less effective for preoperative anxiety.

Keywords: Preoperative Anxiety, Postoperative Analgesia, *Vedanasthapana Mahakashaya*.

INTRODUCTION

Pain is an important subjective sensation which can be experienced by an individual in various pathological conditions. Primarily it is a safety mechanism of our body and protects body to damage in tissues by any unfavorable stimulant with a sufficient threshold. Pain can interfere with the quality of life of an individual. So, an individual wants to get rid of pain at the earliest as pain makes his life more miserable [1-3]. Postoperative pain management plays a vital role in surgical practice. After any surgical procedure, tissues get damaged and causes pain. So, analgesics are required for control of post-operative pain. Good pain control encourages early mobilization and discharge from the hospital. Inadequately treated pain in the post-operative period can lead to other side effects like apprehension, sweating, nausea and increase in pulse rate, blood pressure and loss of sleep, etc [4]. There are various allopathic medicinal formulations available to relieve the post-operative pain such as opioids, NSAIDs (nonsteroidal anti-inflammatory drugs) and prostaglandin inhibitory drugs. But these medicines are not devoid of side effects. NSAIDs are known to cause gastritis and peptic ulcer while opioids can cause euphoria and prone to addiction [5].

Pre-anesthetic medication refers to the use of drugs before anaesthesia to decrease anxiety, secretions, vagal stimulation and to obtain an adequate anaesthesia for better operative and post-operative outcome [6]. In surgery, pre-operatively anxiolytic drugs and analgesics are very essential for major or minor surgical procedures but in classical literature we couldn't find any intervention done for this special purpose. Hence, there is a need to evaluate the ayurvedic formulations as an effective medicine for preoperative

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anxiety and for post-operative analgesia. *Acharya Charak* describes some herbal medicines named as *Vedanasthapana mahakashaya* which is a group of 10 drugs for the specific use of analgesia that is mentioned in *Charak Samhita* among 50 groups of *mahakashaya* [7]. Various text books of Ayurveda have repeatedly advocated that the contents of *Vedanasthapana mahakashaya* possesses sedative, analgesic, and anxiolytic properties [8-16]. So, this study was planned to evaluate and compare the analgesic and anxiolytic efficacy of *Vedanasthapana mahakashaya* and a safer drug for the same in patients of anorectal diseases (Haemorrhoids, fissure in ano, fistula in ano) who undergone for surgical interventions.

MATERIALS AND METHODS

This study was conducted in the academic hospital between academic years 2018-2019.

Ethical approval: The Ethical approval was taken from the Institutional Ethical Committee of the college before commencing the study.

Inclusion Criteria: Total 80 Patients of 18-70 years age groups of either sex posted for surgery of anorectal disorders (Haemorrhoids, Fissure in ano and Fistula in ano) and confirming to inclusion criteria of ASA grade I & II were selected for this study.

Exclusion Criteria: Patients with known hypersensitivity or contraindication to any of the drug used in this study, pregnant patients & breast feeding mothers, drug abuse patients (e.g. Alcoholic, Opioid addiction, chronic analgesic medication) patients with known renal and hepatic diseased (e.g. Impaired Renal Function, Hepatitis, Obstructive Jaundice) patients with hyper-reactive airway disorders and unable to rate their pain on VAS due to psychiatric or other reasons were excluded from the study.

Study design and grouping of the patients

The study was a prospective, randomized, double blind, controlled trial. The 80 patients, who had to undergone surgical procedure for anorectal diseases were randomly allocated to one of the two groups by simple random number table method (computer generated) and allocation was concealed using sealed envelope technique. Randomly allocation, drug preparation and masking, and administration to the participants was done by a person, who was not involved in the study. All the related details and data were obtained and recorded in the especially designed Performa. A written informed consent was obtained from the patients who were willing to be a part of the study. All the patients were familiarized with pain and anxiety scoring.

Study drugs

Group-1: *Vedanasthapana mahakashaya kwath* (decoction). The details of drugs of *Vedanasthapana mahakashaya* are mentioned in Table 1.

Method of preparation of kwath (decoction)

The raw material of *Vedanasthapana mahakashaya* was purchased from the market, washed in 4-6 times in water (except *Mochrasa* and *Shala* resin) and dried in sunlight. Coarse powdered separately and mixed in the equal proportion. The 30 gm coarse powder (*Yavkoot*) was added in 8 times water and boiled till then it reduces to 1/8th part [17-19].

Method of drug uses

Preoperatively- Patients of group-1 receiving *Vedanasthapana mahakashaya kwath* (Decoction) 30 ml orally, at previous night of surgery & 4 hours prior to the operation.

Postoperatively- Just after surgical procedure after that 6 hourly up to 3 days of the post-operative period.

Group-2: Tab Alprazolam 0.25 mg preoperatively and Tab Paracetamol 500 mg post-operatively.

Method of drug uses

Preoperatively- Patients of group-2 was receiving Tab Alprazolam 0.25 mg, orally, dissolved in 30 ml of lukewarm water at previous night of surgery & 4 hours prior to the operation.

Postoperatively- Tab Paracetamol 500 mg, orally, dissolved in 30 ml of lukewarm water, just after surgical procedure after that 6 hourly up to 3 days of the post-operative period.

Masking- To mask the treatment allocation, natural color (beetroot) was added to control drugs and drugs of both the groups were administered in a non-transparent disposable milkshake sealed cup with a straw.

Method of procedures

All the patients were operated under local anaesthesia. During the operative phase, lord's dilation procedure was done for fissure in ano followed by *ksharsutra* ligation in sentinel tags. In cases of haemorrhoids *ksharsutra* trans fixation and ligation was done and fistula in ano after probing *ksharsutra* ligation was done.

Outcome Assessment

Analgesia was assessed postoperatively by internationally validated Visual Analogue Scale (100 mm=10 cm) at rest at the following intervals – Immediate postoperatively (0 hour), 1st hour, 2nd hour, 4th hour, 6th hour and after completion of the 6th hour, every 6th hour till 3rd day. Inj. Diclofenac sodium 75 mg IM was administered when the VAS scores crossed 4 and/or the patient demanded the rescue analgesic. The time and number of given rescue doses of Inj. Diclofenac sodium in both groups was noted in the postoperative period.

Feeling of anxiety was assessed on the basis of Anxiety score of Hospital Anxiety and Depression Scale (HADS) at the following intervals –T₀- Just before to medication, T₁- before shifting patient to operation theatre, T₂- At arrival in the operation room, T₃- discharge from post-operative care room. Patients who did not know English, for them questionnaires were read out in Hindi with choice of answer.

Hemodynamic parameters i.e., Blood pressure and Pulse rate both were observed before procedure in every 30 minutes from 2 hours prior to surgical procedure, during procedure at every 5 minutes and after procedure at first 4 hours on every 30 minutes then next 4 hours at the hourly interval. SPO₂ (oxygen concentration) was observed only intra operatively at 5 minutes intervals.

All the scores were compared directly at various observation intervals, and effects of therapy were also assessed on the basis of before and after treatment values. Total duration of surgery was noted in both groups. All patients were observed closely for any adverse effects. Patients were followed up till the three post-operative days.

The overall effect of the therapy was assessed in terms as-

Complete relief -75-100% relief in sign and symptoms

Marked relief -50-75% relief in sign and symptoms

Moderate relief -25-50% relief in sign and symptoms

Unsatisfactory relief -0-25% relief in sign and symptoms

Statistical analysis

All the data were collected, tabulated and analyzed. Continuous variables were summarized as mean, standard deviation and standard error of mean while categorical variables were summarized as frequency and percentages. All the results were analyzed by using Software InStat GraphPad InStat 3 Trial and all the statistical analyses involved two-tailed tests. Microsoft word and excel have been used to generate graphs and tables, etc. For calculating inter group comparison the Mann-Whitney Test was used for nonparametric data & an Unpaired 't' test for parametric data. A difference with P value < 0.05 was considered statistically significant.

RESULTS

Total 80 patients of Anorectal diseases (Anal fissure, Fistula in Ano & Haemorrhoids) who were undergone for surgical procedures were enrolled in the study. Demographic characteristics such as incidence of age, gender, religion, educational status, dietary pattern, socio-economic status, occupational status and psychological & constitutional profile such as *satva*, *sharir prakriti*, *sara*, etc. and duration of surgery, rescue doses with time were comparable. The Pulse, Systolic/Diastolic BP and SPO₂ were also compared. The data were summarized into a master chart.

The maximum no. of patients was between 21 and 30 years (35%) (Table 2). The mean age was not different between the both groups. Out of 80 cases, 58 patients were males and 22 were females. Majority of patients were having *Parikartika* (fissure-in-ano) 47.5%, followed by *Raktarsha* (bleeding haemorrhoids) 31.25%, *Bhagandara* (fistula in ano) 18.75% and *Vatarsha* (external haemorrhoids) 2.5%. 26 (77.5%) patients were literate while (18) 22.5% were illiterate. Among 80 patients 42 (52.5%) patients were having *Vata-pittaja prakriti* followed by 21 (26.25%) patients were having *Vata-kaphaja prakriti* while 17 (21.25%) patients were having *Kapha-pittaja prakriti*. Out of 80 patients 49 (61.25%) were of *Madhyama Satva* followed by 22 (27.5%) were of *Avara Satva* and 9 (11.25%) were of *Pravara Satva*.

Effect on Anxiety scores

At the baseline, there was not any significant difference between both groups (P 0.4806). The mean score of anxiety score of Hospital Anxiety and Depression Scale reduced significantly in both the groups at different observation level of trial period (Figure-1) but group-2 (Tab

Alprazolam) shows significantly much reduction in Anxiety score at the end of study than the group-1 (*Vedanasthapana mahakashaya* decoction) (P< 0.0158). Change in anxiety score of Hospital Anxiety and Depression Scale for the trial period is shown in Table 3. Overall satisfaction or relief in symptom of anxiety in both the groups is shown in Table 4.

Effect on Pain (VAS) Scores

Baseline VAS scores of both the groups were have not significant difference (P >0.6785). At 1st hour VAS scores of both groups were also statistically similar (p >0.0815). Pain scores were significantly different at 2nd, 4th and 30th hr. Rest scores were not having significant difference. Between 2nd and 4th hr time interval there was a statistically significant difference (p<0.0001) in VAS score of both groups but reduction in VAS was higher in group-2 compared to group-1. At 6th hr observation level reduction in VAS was greater with group-1 than the group-2 but the difference was not statistically significant (P>0.9496) (Figure-2).

Both the groups showed statistically significant reduction in pain at the end of trial period. Both were found to be significantly similar (P 0.4856) but group-1 showed more reduction in pain 84.72% (P<0.0001) than the group-2 which have 80.08% reduction in VAS score (P<0.0001) (Table 5).

Overall satisfaction or relief in symptom of pain in both the groups is shown in Table 6.

Effect on hemodynamic parameters and SPO₂

There were no statistically significant differences found in Systolic BP, Diastolic BP, Pulse rate and SPO₂ in both groups at different observation level.

Surgical procedure time and total number of rescue doses in both groups

In present study there was no statistically significant difference found in surgical procedure time (P>0.3603) (Table 7) and total number of rescue doses (P>0.5329) in both groups.

DISCUSSION

The first objective of the present study was to determine the post-operative analgesic effect of *Vedanasthapana mahakashaya* decoction as compared to Tab. Paracetamol and secondary objective of this study was to determine the pre-operatively anxiolytic effect of same decoction as compared to Tab. Alprazolam in patients of anorectal diseases who were undergoing surgical interventions. The drugs Tab Alprazolam and Tab Paracetamol has been chosen for comparison with *Vedanasthapana mahakashaya* decoction because these are the most common standard drugs for anxiolytic action and analgesia respectively [20,21].

The demographic data like age, sex and weight was found to be comparable of study population of both groups in this study and there were no significant differences found in these parameters in both groups. The duration of surgery in both groups was statistically similar.

In this study, there were no major statistically significant differences found in Systolic BP, Diastolic BP, Pulse rate and SPO₂ in both groups.

Pre-operative Anxiety

Present study showed that Tab Alprazolam and decoction of *Vedanasthapana mahakashaya* both have significant reduction in pre-operative Anxiety but *Vedanasthapana mahakashaya* found comparatively less effective to reduce the pre-operative anxiety than the Tab. Alprazolam. A placebo-controlled study with large sample size is needed for further evolution of anxiolytic efficacy of this multi-herb drug.

Post-operative Analgesia

The present study reveals that both the drugs have statistically significant reduction in pain score. The patients with *Vedanasthapana mahakashaya* decoction had received rescue analgesic 1 hr 13 minutes prior to the patients with Tab. Paracetamol but total demanding rescue analgesic doses in each of the groups were found to be statistically similar. The onset of action of oral Paracetamol was faster than the decoction of *Vedanasthapana mahakashaya* and its maximum effect lasts between 4 to 6 hours after that pain score increases with paracetamol group while at the same time *Vedanasthapana mahakashaya* shows a continuous pain reducing effect (Figure-2) which lasts even after six hours. This denotes that the action of *Vedanasthapana mahakashaya* decoction take more time to start than the Tab. Paracetamol but remains to continue for more hours. Thus, the *Vedanasthapana mahakashaya* decoction has long-lasting effect than the Tab. Paracetamol. Overall effects of both the drugs have no significant difference that means both the drugs have similar analgesic efficacy on post-operative pain. Further studies with large samples would probably throw more light on efficacy of this herbal composition for post-operative analgesia. However, there are no such studies found, which compare this multi-herb drug with modern standard drugs. Dr. Swapnil Vitthalrao More and Prof. Dr. Shubhada R. Lonikar (2015) conducted a non-comparative study with objective to study the efficacy of *Vedanasthapana mahakashaya* (Ghan vati) in post-operative pain management [22]. This study found that *Vedanasthapana Ghanvati* has significant effect on mild to moderate post-operative pain & tenderness.

Further a significant decrease in pain in the patient of osteoarthritis with uses of some of the drugs of *Vedanasthapana mahakashaya* was evident in a study done by Jyotirupa Sarmah *et al* [23].

There were no any untoward effects found in patients of both groups. Gastritis and nausea were not found in any patients of the group-1 due to the decoction. A study was conducted by Dileep Kumar K. J *et al* in 2014 on animal model which proves that *Vedanasthapana mahakashaya* (in *Ghanavati* form) have no any significant toxic effect in Swiss albino mice even at the highest dose level 5000 mg/kg body weight [24]. So, in this study it is found that *Vedanasthapana mahakashaya* decoction is as effective analgesic as Tab. Paracetamol but it is significantly less effective as an anxiolytic agent than of Tab. Alprazolam.

Strengths and limitations

Though the study has strengths due to its randomised, double blind, control design, but it has several limitations like the baseline pain score was under mild to moderate range so the results may not apply to cases with severe pain score. There were no untoward effects found in this study with trial drug but further study with large sample size can elaborate the same. This study was done with a fixed dose of the trial drug, further study with higher dose of trial drug may show the potential analgesic effect of this herbal composition.

Probable mode of action

The word '*Vedana*' is used in Ayurveda for general sensation. It is of two types i.e. pleasant and unpleasant [25]. Pain is a subjective sensation and mostly caused by an underlying pathology but it can be associated with psychological and emotional factors such as fear, anxiety and depression so in ayurveda the word '*vedana*' denotes not only the subjective sensation of pain but also the fear and anxiety. The drugs which can establish the pleasant sensation by calming the unpleasant sensations are called as the *Vedanasthapana* drugs [26]. The convection and the enforcement of all the sensations of the body are enforced by the *Vata* [27]. but in the vitiation and outbreak of *vata*, these sensations are manifested in the form of anguish. That is why the pain, whether it is somewhere in the body, cannot be without *Vata* [28]. In this way, the *Vedana* is the characteristic symptom of *vata* outbreak, hence *Vedanasthapana* drugs must be the suppressor of the *vata dosha*, because without the *vata's* balance, *Vedana* cannot be suppressed. Thus, the drugs of the *Vedanasthapana mahakashaya* are particularly having *ushna veerya and snigdha guna*. Among the drugs of this *mahakashaya* some drugs such as *Katfal, Tumba*, etc. are having *ushna veerya* and some are having *snigdha* properties such as *Mochrasa*. Due to the *Snigdha* and *Ushna guna* of these drugs, *vata* is being inhibited, so as the result unpleasant sensation get rid of.

In context to Anxiety (*Bhaya*), the *katu, ushna* and *snigdha* properties of some of the drugs of the *Vedanasthapana mahakashaya* can balance the vitiated *vata dosha*. Then naturalised *vata dosha* can control the *raja* and *tama dosha* and get them to their natural state. They are also helpful in sleep due to the increase of *Kapha* from the *snigdha guna*. Thus, this process provides the relief in Anxiety (*Bhaya*). However, the *vedanasthapana* properties of these drugs are considered due to *Prabhava* of these drugs.

CONCLUSION

The present study shows that the *Vedanasthapana mahakashaya* decoction is an efficacious polyherbal composition for post-operative analgesia in patients of anorectal diseases (Haemorrhoids, fissure in ano, fistula in ano) who undergone for surgical interventions but has less anxiolytic properties compared to the standard modern medicine. It can be a good herbal alternative to Tab Paracetamol and can be used for a long period to subside pain of mild to moderate intensity without fear of any adverse effects.

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Conflict of Interest

None declared.

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None declared.

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Table 1: Composition of Vedanasthapana mahakashaya kwath (decoction):- (Figure-3)

S. No.	Sanskrit Name	Part used	Latin name	Quantity
1	<i>Shala</i>	Resin	<i>Shorea robusta</i> Roth	1 part
2	<i>Katphala</i>	Bark	<i>Myrica esculenta</i> Buch.-Ham.	1 part
3	<i>Kadamba</i>	Bark	<i>Anthocephalus indicus</i> H.L.Li	1 part
4	<i>Padmaka</i>	Hard wood	<i>Prunus cerasoides</i> D.Don	2 part
5	<i>Tumba</i>	Seed	<i>Zanthoxylum alatum</i> Roxb.	1 part
6	<i>Mochrasa</i>	Resin	<i>Salmalia malabarica</i> (DC.) Schott & Endl.	1 part
7	<i>Shirisha</i>	Bark	<i>Albizia lebbeck</i> (L.) Benth.	1 part
8	<i>Ashoka</i>	Bark	<i>Saraca indica</i> L.	1 part
9	<i>Vanjula*</i>	-	<i>Salix tetrasperma</i> Roxb.	-
10	<i>Alavaluka*</i>	-	<i>Prunus cerasus</i> L.	-

*Because of unavailability of *Alavaluka* (*Prunus cerasus* L.), and *Vanjula* (*Salix tetrasperma* Roxb.) these were not included in this study. *Padmaka* (*Prunus cerasoides* D.Don) was taken as representative of *Alavaluka* (*Prunus cerasus* L.).

Table 2: Age incidence

S. No.	Age Group	Group 1 (n =40)	Group 2 (n =40)	Total	%
1.	10-20	2	0	2	2.5
2.	21-30	16	12	28	35
3.	31-40	7	12	19	23.75
4.	41-50	9	4	13	16.25
5.	51-60	4	6	10	12.5
6.	61-70	2	6	8	10
	Total	40	40	80	100

Table 3: Showing the comparative reduction in Anxiety at the end of treatment in both groups

Variable	Group	Mean		Mean diff.	% Relief	± SD	± SEM	P value*	Sig.
		BT (T ₀)	AT (T ₃)						
Anxiety	Group 1	8.4	5.4	3.025	35.90%	2.082	0.3291	<0.0001	S
	Group 2	8.1	3.7	4.400	54.32%	2.716	0.4294	<0.0001	S

diff.-Difference, S- Significant * Wilcoxon Matched Signed-Ranks test

Table 4: Overall satisfaction or relief in symptom of anxiety at the end of treatment in both groups

Observation	Number of patients in Group 1	% Relief in Group 1	Number of patients in Group 2	% Relief in Group 2
Complete relief	3	7.5%	15	37.5%
Marked relief	2	5%	4	10%
Moderate	21	52.5%	10	25%
Unsatisfactory relief	14	35%	11	27.5%
TOTAL	40	100	40	100

Table 5: Showing the comparative reduction in pain at the end of treatment in both groups

Variable	Group	Mean		Mean diff.	% Relief	± SD	± SEM	P value*	Sig.
		BT (0hr)	AT (72hr)						
PAIN	Group 1	3.470	0.5275	2.943	84.72%	0.9179	0.1451	<0.0001	S
	Group 2	3.440	0.6850	2.755	80.08%	1.302	0.2059	<0.0001	S

Sig.- Significance, S- Significant, * (Wilcoxon matched-pairs signed-ranks test)

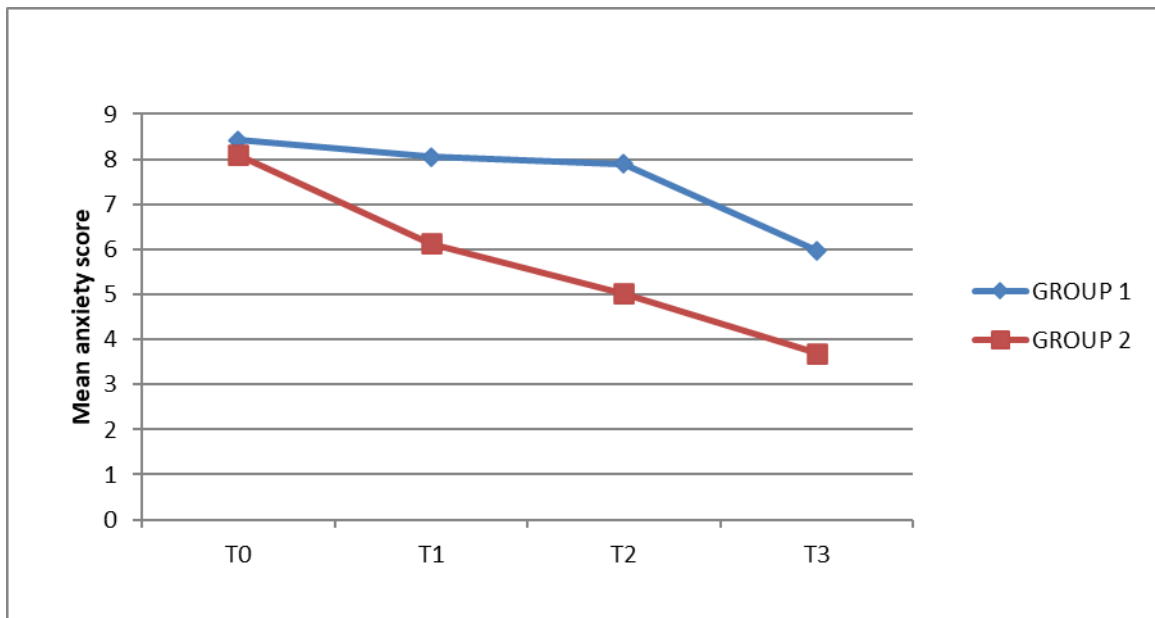
Table 6: Overall satisfaction or relief in symptom of pain at the end of treatment in both groups

Observation	Number of patients in Group 1	% Relief in Group 1	Number of patients in Group 2	% Relief in Group 2
Complete relief	24	60%	22	55%
Marked relief	14	35%	9	22.5%
Moderate	2	5%	7	17.5%
Unsatisfactory relief	0	0%	2	5%
TOTAL	40	100	40	100

Table 7: Comparison of surgical procedure time in both groups

Surgical Procedure Time									
	Group 1			Group 2			P Value	t- Value	Sig.
	Mean	SD	SE	Mean	SD	SE			
Time in minutes	25.525	3.397	0.5371	24.875	2.902	0.4588	0.3603	0.9202	NS

*NS-Not significant, Sig.- Significance



(T₀- Just before to medication, T₁- before shifting patient to operation theatre, T₂- At arrival in the operation room, T₃- At the time of discharge from post operative care room)

Figure 1: Comparison of mean Anxiety score in both groups at different observation levels pre-operatively

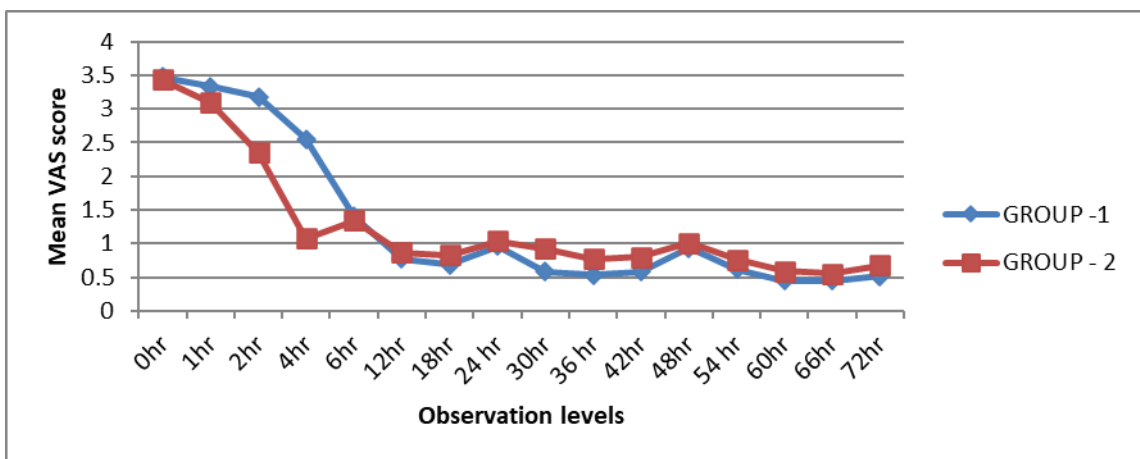


Figure 2: Comparison of mean VAS in both groups at different observation levels post-operatively



Figure 3: Various row ingredients of *Vedanasthapana mahakashaya kwath* (decoction)