



INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN:2320-2831

IJPAP | Vol.8 | Issue 3 | Jul - Sep - 2019

Journal Home page: www.ijpar.com

Research article

Open Access

“A comparative clinical study of vednasthapan mahakashaya in postoperative pain management”

Dr.Neelam Sahu¹, Dr.Vishal Verma², Dr.Sheetal Verma³, Dr.Sourmi⁴, Dr.Pankaj Thakur⁵, Dr.Anjali Tamori⁶

¹M.S.(Ay) Final Year Scholar, P.G. Department of Shalya Tantra, Rishikul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India.

²Professor, P.G. Department of Shalya Tantra, Rishikul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India..

³Associate Professor, Department of Maulika Siddhanta,, Gurukul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India.

⁴Medical officer, Rishikul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India.

⁵M.S.(Ay) Final Year Scholar, P.G. Department of Shalya Tantra, Rishikul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India.

⁶M.S.(Ay) Second Year Scholar, P.G. Department of Shalya Tantra, Rishikul Ayurvedic P.G College Campus, Uttarakhand Ayurveda University, Haridwar, India.

*Corresponding Author: Dr.Neelam Sahu

ABSTRACT

Vedna (pain) plays important role in our life as there is no birth without vedna (pain). From the time of vedic civilization, there have been many attempts to find relief with healing touch and the extracts from the plants. The most common reason for which a person approaches to the doctor is Pain. **The International Association for the Study of Pain** gives the definition of pain as “**It is an unpleasant sensory and emotional experience associated with actual or potential tissue damage**”. Pain can also be described as any physical suffering or discomfort caused by illness or injury. No matter however mild the pain is anywhere in the body, it lands you in a state of discomfort and affects your activities. In post-operative cases pain is unavoidable thing. Excessive pain will be unbearable and will lead to other effects like sinking sensation, apprehension, sweating, nausea, palpitation and increase or decrease of blood pressure (pain shock). In the present study 30 patients divided in two groups were studied. Group A was inj/tab. Diclofenac sodium; n=15, Group B was Vednasthapan mahakashaya; n = 15. Friedman's test and mann whitney U test were applied to see which group is better. Finally study concluded that Group A is better than Group B.

Keywords: Vednasthapan Mahakashaya, Postoperative pain, Diclofenac Sodium, Vedna

INTRODUCTION

When speaking about surgery we should also think about postoperative pain., which is a very important issue that concerns the patient and the surgeon, since this can become the trademark of his surgery. However, it is very difficult to determine the Post-operative pain in each person since different factors influence the Pain..Pain is an extraordinary complex sensation which is difficult to define and equally difficult to measure in an accurate,objective manner. Pain is derived from a Greek word “**poine**” which means penalty and a Latin word which means Punishment. In *Ayurveda shoola, vedna, ruja, pida* and *dukha* are used to denote pain [1].

Despite the availability of effective Analgesics drugs,Treatment of post surgical pain is often inadequate.Sophisticated Analgesia techniques are neither necessary nor practical for most patients.Oral diclofenac sodium,is an established and effective analgesic for moderate to severe postoperative pain [2]. it is proved to be reliable postoperative analgesics.It is among the better tolerated **NSAIDS** .However ,**NSAIDS** are generally considered to be inadequate as sole agents in the control of immediate postoperative pain [3].It have various systemic side effects viz. GI bleeding,ulceration or perforation , adverse renal effects caused by the reduction in synthesis of prostaglandins [4] ,various degree of cognitive dysfunction, confusion ,behavioural disturbance and dizziness [5], precipitation and exacerbation of asthma in sensitive patients [6].

In *Ayurvedic* texts a number of references are available where various type of pain and its treatment modalities are mentioned.Keeping in view the above facts and figures of modern day analgesia and their effects thorough review was done. To find a suitable *Ayurvedic* oral analgesics as herbal drugs have been mentioned as *Vednahar* and *Vatashamak*, in both *Charaka Samhita* and *Sushruta Samhita* besides other *Ayurvedic* literature possessing the Analgesic and Anti-Inflammatory properties.

AIMS AND OBJECTIVE

- To compare the efficacy of *Vednasthapan mahakashaya* as analgesics with established

known analgesic diclofenac sodium in post-operative pain.

- To provide safe, effective and herbal formulation to the conventional treatment (diclofenac sodium) with least side effect.
- To determine onset of analgesic action of *Vednasthapan mahakashaya* (40 ml TDS) on subjective criteria of VAS.
- To compare satisfaction in pain relief of *Vednasthapan mahakashaya* (40ml TDS) with that of tab.\inj.diclofenac sodium 75mg BD.

MATERIAL & METHODS

Plan of study

Selection of patients

Patients were selected irrespective of caste and religion from the O.P.D. / I.P.D. department of Shalya tantra, Rishikul Campus, Haridwar.it consisted of 30 patients posted for surgery in the dept. of shalya tantra enrolled after obtaining informed consent based on following criteria.

INCLUSION CRITERIA

- Patients willing for trial and ready to give written and informed consent.
- Postoperative patients of Age group >14 years and < 60 yrs irrespective of sex.
- Only Anorectal surgeries

EXCLUSION CRITERIA

- Patients not willing for trial and ready to give written and informed consent.
- Patients allergic to diclofenac sodium or other NSAIDS.
- Patients below 14 yrs of age.
- Patients with history of peptic ulceration
- Exploratory laparotomy and all major operative cases

RESCUE ANALGESIA AND CONCOMITANT THERAPY

Patients were informed that further analgesia was available if pain relief was inadequate. Inj diclofenac 75 mg\Inj.tramadol 50 mg I.M was used as rescue analgesia.

STUDY DESIGN

- **GROUP-1:** 15 patients were recommended randomly for tab.\inj.diclofenac sodium (75 mg) BD .
- **GROUP-2:** In this group patients were treated with **decoction of Vednasthapan mahakashaya 40 ml TDS .**
- Period of Study: 10 Days
- Follow up: 30 days.

CRITERIA OF ASSESSMENT

Assessment will be done on the basis of subjective and objective criteria.

Subjective criteria

VAS -Pain on 10 point visual analogue scale will evaluated by taking 0 for no pain and 10 for worst excruciating pain.



Assessment of pain was done at base line before the administration of the first dose .after the first dose ,pain was recorded every 30 min , 1 hr, 2hr, 4hr ,8 hr , 10 hr, 12 hr, 24hr hours. Pain recording was done before the administration of next dose.

Onset of action - Time taken for the first fall in VAS score after the first dose.

and undesirable effects like nausea , vomiting, gastric irritation, flatulence, headache were also taken into account.

EXTENT OF RELIEF

Onset of analgesia,Maximum fall in VAS scores after 1st dose, Maximum fall in VAS score during the study period,Duration of analgesia,Number of patients requiring rescue medication during the study period were taken into the study.

DRUG SELECTION & PREPARATION

शालकटफलकदम्बपद्मकतुम्बमोचरसशिरीष

वज्जुलैलवालुकाशोकाइतिदशेमानी

वेदनास्थापनानीभवन्ति³ ¼च.सू.8/86⁷

CONTENTS USED IN DECOCTION –

Sal,Katfal,,Kadamba,Padmak,Mocharasa,Shirish

Vajjul,Ashoka

METHOD OF PREPARATION OF DRUGS

पानीयं षोडशगुणं क्षुण्णो

द्रव्यपले क्षिपेत् ।

मृतपात्रे

क्वाथयेद् ग्राह्यमअष्टमांशावशोशितम ॥

तज्जलं

पाययेदधिमाकोष्णं मृदुअग्निसाधितम ।

श्रुतः क्वाथः कषाय च निर्युह

च निगद्यते ॥⁸(शा . पू. १\१ -२)

OBJECTIVE CRITERIA

- Pulse rate
- Blood pressure
- Respiratory rate

Preparation and assessment of patients

The relevant routine investigations which were essential prerequisite for the conduct of surgery was done.Before administrating the scheduled premedication pulse rate , blood pressure, respiratory rate and psychological condition were recorded. These reading were considered as base line reading.

The patients were assessed before treatment and after giving standard and trial drugs after onset of pain , at the interval of 30 min , 1 hr ,2 hr, 4hr, 8hr, 12hr and 24 hr hrs.Desirable effects like analgesia

STATISTICAL ANALYSIS

The incidence of desirable and adverse reaction was compared statistically between both the groups

and intragroups .the mean BP ,pulse rate , respiratory rate ,requirement time of 1st dose of analgesics , desirable and undesirable effects of drugs were analyzed by applying t -test, Friedman test, Mann-whitney U test. The obtained results were interpreted as

Non-significant (NS) P > 0.05
Significant(S) P< 0.05 or
P<0.01
Highly significant (HS) P<0.001

CRITERIA FOR OVERALL ASSESSMENT OF THERAPY

1. Complete improvement : 100% improvement
2. Marked Improvement : 75% to <100% improvement
3. Moderate Improvement : 50% to <75%improvement
4. Mild Improvement : less than 50% improvement

RESULTS AND DISCUSSION-

Effect of therapy on postoperative pain with mean VAS -Table No.1

Group	Mean Pain Level (Mean±SD)								
	A	B	C	D	E	F	G	H	I
Group I	0.00±0.0	8.68±1.8	3.60±2.1	3.10±1.9	2.45±2.8	2.40±2.6	1.10±1.2	0.90±1.6	0.80±1.1
Group II	0.00±0.0	8.88±2.3	7.69±1.7	7.57±1.9	8.24±2.7	6.92±4.2	6.74±3.7	4.86±2.8	4.33±2.9

Statistical Comparison of mean pain level (A) after 4 hours, (G) after 8 hours, (H) after 12 hours, Pre operative, (B) at onset of pain (post op), (C) (I) after 24 hours of therapy. after 1 hour, (D) after 2 hours, (E) after 3 hours, (F)

Statistical comparison of effect of therapy on pain within the group-Table No.2

Group	Comparison	Mean Diff	SD	SE	t-Value	P-Value	Result
Group I	A vs B	-8.68	1.32	0.34	4.346	0.001	Sig
	B vs C	5.08	2.33	0.60	3.191	0.007	Sig
	B vs D	5.58	2.59	0.67	3.090	0.008	Sig
	B vs E	2.23	2.69	0.69	3.496	0.004	Sig
	B vs F	6.28	2.23	0.58	3.360	0.005	Sig
	B vs G	7.58	1.37	0.36	3.229	0.006	Sig
	G vs H	0.20	1.51	0.39	3.172	0.007	Sig
	G vs I	0.30	1.78	0.46	3.062	0.008	Sig
Group II	A vsB	-8.88	1.56	0.40	4.497	0.001	Sig
	B vs C	1.19	2.69	0.69	3.458	0.004	Sig
	B vs D	1.31	1.64	0.42	3.497	0.004	Sig
	B vs E	0.64	2.38	0.61	3.240	0.006	Sig
	B vs F	1.96	2.76	0.71	2.990	0.010	Sig
	B vs G	3.28	2.61	0.67	3.289	0.005	Sig
	G vs H	0.74	1.41	0.36	3.426	0.004	Sig
	G vs I	1.27	2.16	0.56	3.411	0.004	Sig

Above table shows comparison of mean pain level, in Group I effect on rise in mean pain level from pre operative value to onset of pain was

highly significant. Effect of therapy on mean pain level at 1 hour was statistically significant, from one hour to 24 hours the effect was observed

significant. In Group II effect on rise in mean pain level from pre operative value to onset of pain was highly significant. Effect of therapy on mean pain

level from onset of pain to 1 hour was statistically significant, from one hour to 24 hours the effect was significant.

Statistical intergroup comparison of effect of therapy on pain –Table No.3

	Comparison	Diff	t-Value	P-Value	Result
Group I vs Group II	A vs B	0.20319	1.935	0.063	NS
	B vs C	3.88952	3.047	0.005	Sig
	B vs D	4.26704	3.090	0.004	Sig
	B vs E	1.58781	3.195	0.003	Sig
	B vs F	4.3187	3.303	0.003	Sig
	B vs G	4.29681	3.491	0.002	Sig
	G vs H	0.54164	2.276	0.031	Sig
	G vs I	0.9681	2.384	0.024	Sig

From above table we can observe that P-Values for Group I and Group II comparison are less than 0.05. Hence we conclude that there is significant

difference observed in effect of Group I and Group II. Further we can observe that effect observed in Group I is more than Group II.

Effect of therapy on Mean Systolic B.P. -Table NO.4

Group	Mean Systolic Blood Pressure (Mean±SD)								
	A	B	C	D	E	F	G	H	I
Group I	122.6±10	130.4±7.	132.6±6.	131.7±8.	129.7±5.	128.5±6.	125.8±7.	123.6±7.	123.1±7.
I	.8	6	8	3	9	8	4	8	2
Group II	125.4±12	137.9±10	136.5±9.	135.8±9.	133.6±8.	130.6±7.	129.3±8.	127.5±8.	125.7±7.
II	.4	.3	5	8	7	9	6	8	6

Statistical Comparison of mean systolic blood pressure (A) Pre operative, (B) at onset of pain (post op), (C) after 1 hour, (D) after 2 hours, (E)

after 3 hours, (F) after 4 hours, (G) after 8 hours, (H) after 12 hours, (I) after 24 hours of therapy.

Statistical comparison within group of mean systolic B.P.-Table No.5

Group	Comparison	Mean Diff	SD	SE	t-Value	P-Value	Result
Group I	A vs B	-12.8	4.27	1.10	4.931	0.000	HS
	B vs C	2.8	6.68	1.72	4.172	0.001	Sig
	B vs D	3.7	4.55	1.17	3.665	0.003	Sig
	B vs E	5.7	4.90	1.27	3.448	0.004	Sig
	B vs F	6.9	6.66	1.72	4.769	0.000	Sig
	B vs G	9.6	6.79	1.75	5.005	0.000	HS
	G vs H	2.2	6.59	1.70	3.559	0.003	Sig
	G vs I	2.7	4.82	1.24	4.498	0.001	Sig
Group II	A vs B	-12.5	5.75	1.48	5.450	0.000	HS
	B vs C	1.4	3.69	0.95	3.498	0.004	Sig
	B vs D	2.1	6.36	1.64	3.605	0.003	Sig
	B vs E	4.3	3.34	0.86	4.835	0.000	HS
	B vs F	7.3	5.18	1.34	4.776	0.000	HS
	B vs G	8.6	2.35	0.61	3.502	0.004	Sig
	G vs H	1.8	6.87	1.77	3.445	0.004	Sig
	G vs I	3.6	3.90	1.01	3.812	0.002	Sig

Above table shows comparison of mean systolic blood pressure, in Group I effect on rise in mean B.P. from pre operative value to onset of pain was highly significant. Effect of therapy on mean systolic B.P. from onset of pain to 1 hour was statistically significant, from one hour to 24 hours

the effect was highly significant. In Group II effect on rise in mean B.P. from pre operative value to onset of pain was highly significant. Effect of therapy on mean systolic B.P. from onset of pain to 1 hour was statistically significant, from one hour to 24 hours the effect was significant.

Statistical intergroup comparison of mean systolic B.P.-Table No.6

	Comparison	Diff	t-Value	P-Value	Result
Group I vs Group II	A vs B	0.3	1.841	0.076	NS
	B vs C	1.4	2.153	0.040	Sig
	B vs D	1.6	2.134	0.042	Sig
	B vs E	1.4	2.172	0.039	Sig
	B vs F	0.4	2.142	0.041	Sig
	B vs G	1	2.133	0.042	Sig
	G vs H	0.4	2.156	0.040	Sig
	G vs I	0.9	2.304	0.029	Sig

From above table we can observe that P-Values for Group I and Group II comparison are less than 0.05. Hence we conclude that there is significant

difference observed in effect of Group I and Group II. Further we can observe that effect observed in Group I is more than Group II.

Effect of therapy on Diastolic B.P. –Table No.7

Group	Mean Diastolic Blood Pressure								
	A	B	C	D	E	F	G	H	I
Group I	79.4	88.5	85.6	83.6	82.3	80.4	79.7	78	77.2
Group II	81.3	90.2	89.4	88.1	85.6	83.3	82.6	80	79.1

Statistical Comparison of mean diastolic blood pressure (A) Pre operative, (B) at onset of pain (post op), (C) after 1 hour, (D) after 2 hours, (E)

after 3 hours, (F) after 4 hours, (G) after 8 hours, (H) after 12 hours, (I) after 24 hours of therapy.

Statistical comparison within group of mean diastolic B.P.-Table No.8

Group	Comparison	Mean Diff	SD	SE	t-Value	P-Value	Result
Group I	A vs B	-9.1	2.64	0.68	2.682	0.018	Sig
	B vs C	2.9	4.59	1.18	2.593	0.021	Sig
	B vs D	4.9	3.80	0.98	2.621	0.020	Sig
	B vs E	6.2	3.80	0.98	3.111	0.008	Sig
	B vs F	8.1	3.16	0.82	2.910	0.011	Sig
	B vs G	8.8	2.51	0.65	2.594	0.021	Sig
	G vs H	1.7	4.29	1.11	2.882	0.012	Sig
	G vs I	2.5	3.26	0.84	2.746	0.016	Sig
Group II	A vs B	-8.9	2.13	0.55	2.590	0.021	Sig
	B vs C	0.8	3.12	0.80	2.909	0.011	Sig
	B vs D	2.1	4.32	1.12	3.206	0.006	Sig
	B vs E	4.6	2.57	0.66	2.796	0.014	Sig
	B vs F	6.9	4.57	1.18	2.560	0.023	Sig
	B vs G	7.6	2.52	0.65	3.105	0.008	Sig
	G vs H	2.6	4.84	1.25	3.163	0.007	Sig
	G vs I	3.5	2.25	0.58	3.156	0.007	Sig

Above table shows comparison of mean diastolic blood pressure, in Group I effect on rise in mean B.P. from pre operative value to onset of pain was significant. Effect of therapy on mean diastolic B.P. from onset of pain to 1 hour was statistically significant, from one hour to 24 hours

the effect was highly significant. In Group II effect on rise in mean B.P. from pre operative value to onset of pain was highly significant. Effect of therapy on mean diastolic B.P. from onset of pain to 1 hour was statistically significant, from one hour to 24 hours the effect was significant.

Statistical inter group comparison of mean Diastolic B.P -Table No.9

	Comparison	Diff	t-Value	P-Value	Result
Group I vs Group II	A vs B	0.2	1.986	0.057	NS
	B vs C	2.1	2.498	0.019	Sig
	B vs D	2.8	2.379	0.024	Sig
	B vs E	1.6	2.602	0.015	Sig
	B vs F	1.2	2.658	0.013	Sig
	B vs G	1.2	2.571	0.016	Sig
	G vs H	0.9	2.661	0.013	Sig
	G vs I	1	2.460	0.020	Sig

From above table we can observe that P-Values for Group I and Group II comparison are less than 0.05. Hence we conclude that there is significant

difference observed in effect of Group I and Group II. Effect observed in Group I is more than Group II

Effect of therapy on Pulse Rate -Table No.10

Group	Mean Pulse Rate								
	A	B	C	D	E	F	G	H	I
Group I	78.2	86.4	83.1	80.1	79.4	78.2	77.6	77	76.3
Group II	79.2	87.4	86.2	84.4	82.9	80.3	78.9	77.2	76.6

Statistical Comparison of mean pulse rate (A) Pre operative, (B) at onset of pain (post op), (C) after 1 hour, (D) after 2 hours, (E) after 3 hours, (F)

after 4 hours, (G) after 8 hours, (H) after 12 hours, (I) after 24 hours of therapy.

Statistical comparison within groups of mean pulse rate -Table No.11

Group	Comparison	Mean Diff	SD	SE	t-Value	P-Value	Result
Group I	A vs B	-8.2	3.15	0.81	2.917	0.011	Sig
	B vs C	3.3	2.88	0.74	2.841	0.013	Sig
	B vs D	6.3	2.33	0.60	3.064	0.008	Sig
	B vs E	7	2.34	0.60	2.670	0.018	Sig
	B vs F	8.2	3.45	0.89	2.689	0.018	Sig
	B vs G	8.8	3.19	0.82	3.226	0.006	Sig
	G vs H	0.6	3.97	1.03	2.679	0.018	Sig
	G vs I	1.3	2.64	0.68	2.713	0.017	Sig
Group II	A vs B	-8.2	4.15	1.07	3.337	0.005	Sig
	B vs C	1.2	4.81	1.24	3.070	0.008	Sig
	B vs D	3	4.16	1.08	3.227	0.006	Sig
	B vs E	4.5	2.84	0.73	2.847	0.013	Sig
	B vs F	7.1	2.25	0.58	2.864	0.012	Sig
	B vs G	8.5	2.05	0.53	3.123	0.007	Sig
	G vs H	1.7	3.83	0.99	2.660	0.019	Sig
	G vs I	2.3	3.58	0.92	3.203	0.006	Sig

Above table shows comparison of mean pulse rate, in Group I effect on rise in mean pulse rate from pre operative value to onset of pain was significant. Effect of therapy on mean pulse rate from onset of pain to 1 hour was statistically significant, from one hour to 24 hours the effect

was significant. In Group II effect on rise in mean pulse rate from pre operative value to onset of pain was significant. Effect of therapy on mean pulse rate from onset of pain to 1 hour was statistically significant, from one hour to 24 hours the effect was significant.

Statistical inter group comparison of mean pulse rate -Table No.12

	Comparison	Diff	t-Value	P-Value	Result
Group I vs Group II	A vs B	0	0.001	0.999	NS
	B vs C	2.1	2.708	0.011	Sig
	B vs D	3.3	2.607	0.014	Sig
	B vs E	2.5	2.638	0.013	Sig
	B vs F	1.1	2.584	0.015	Sig
	B vs G	0.3	2.560	0.016	Sig
	G vs H	1.1	2.530	0.017	Sig
	G vs I	1	2.498	0.019	Sig

From above table we can observe that P-Values for Group I and Group II comparison are less than 0.05. Hence we conclude that there is significant

difference observed in effect of Group I and Group II. Further we can observe that effect observed in Group I is more than Group II.

Effect of therapy on pain in postoperative 10 days -Table No.13

Pain	Mean Rank	
	Group A	Group B
Day 1	9.20	9.90
Day 2	8.67	8.57
Day 3	8.20	7.90
Day 4	7.93	7.63
Day 5	6.00	6.00
Day 6	4.40	4.77
Day 7	3.37	3.20
Day 8	3.10	2.90
Day 9	3.03	2.83
Day 10	1.10	1.30
N	15	15
Friedman's Test	130.729	131.787
P-Value	0.000	0.000
% Effect	85.52	65.14

Since observations are on ordinal scale (gradations), we have used Friedman's test to test efficacy in Group A and Group B. P-Values for

Group A and Group B are less than 0.05. Hence we conclude that effect observed in both groups are significant.

Statistical comparison of therapy on postoperative pain with mean VAS – Table No.14

Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Group A	15	23.23	198.50	178.500	0.015
Group B	15	17.77	266.50		
Total	30				

For comparison between Group A and Group B we have used Mann Whitney U test. From above table we can observe that P-Value is less than 0.05. Hence we conclude that there is significant

difference in effect of Group A and Group B. Further we can observe that mean rank for Group A is greater than 0.05. Hence we conclude that effect observed in Group A is more than Group B.

Comparison between Group A and Group B- Table No.15

	Group	N	Mean Diff	SD	Se	t-Value	P-Value	Result
SBP	Group A	15	15.67	12.80	3.30	2.368	0.025	Sig
	Group B	15	10.00	11.34	2.93			
DBP	Group A	15	7.00	7.56	1.95	3.046	0.005	Sig
	Group B	15	2.67	9.61	2.48			
RR	Group A	15	7.60	2.35	0.61	2.973	0.006	Sig
	Group B	15	1.13	2.03	0.52			
Pulse Rate	Group A	15	7.93	0.26	0.07	3.408	0.002	Sig
	Group B	15	3.93	0.26	0.07			

For comparison between Group A and Group B. We have used unpaired t-test. From above table we can observe that P-Values are less than 0.05. Hence we conclude that there is significant difference

observed in Group A and Group B. Further we can observe that mean difference in Group A is greater than Group B. Hence we conclude that effect observed in Group A is more than Group B.

Overall effect of therapy - Table No.16

Overall Effect	Group I		Group II	
	N	%	N	%
Marked Improvement	13	86.67%	6	40
Moderate Improvement	2	13.33%	8	53.33%
Mild Improvement	0	0	1	6.67%
No Change	0	0	0	0
TOTAL	15	100	15	100

In Group I Marked Improvement was observed in 13 (86.67%) patients and Moderate Improvement was observed in 2 (13.33%) patients. While in Group II, Marked Improvement was observed in 6 (40%) patients, Moderate Improvement was observed in 8 (53.33%) patients and Mild improvement was observed in 1 (6.67%) patients.

DISCUSSION ON CLINICAL PROFILE

Tyspe of Surgical case

Maximum patients were of haemorrhoid i.e 21 pts, 7 patients were of fissure in ano, 2 pts. were of fistula in ano.

Effect of therapy on mean Systolic blood pressure & Diastolic blood pressure

In Group A Effect of therapy on mean systolic B.P. from onset of pain to 1 hr was statistically

significant. From 1 hr to 24 hrs the effect was highly significant and in Group B effect of therapy on mean SBP from onset of pain to 1 hr and 1 to 24 hr was significant. Same effect observed in diastolic blood pressure.

Intergroup comparison are less than 0.05. Hence we conclude that there is significant difference observed in effect of Group I and Group II.

This increase in blood pressure at onset of pain could be due to sympathetic stimulation resulting from postoperative pain. The decrease in systolic blood pressure after initiation of therapy can be attributed to some analgesic effects resulting in decrease in sympathetic activity. An increase in blood pressure may be attributed to vital role played by the vata and pitta. Hence vatapittahar properties may have been responsible for this reduction in systolic blood pressure. Intergroup comparison shows that there is significant change in systolic blood pressure during study. But to draw

concrete conclusion in this regard large sample survey is required for a longer duration of time.

Effect of therapy on pulse rate,Respiratory rate

From Table no.10,11,12 we can observe that P-value for Group A and Group B are less than 0.05. For 10 days of period of study p-value is 0.002. Hence we conclude that effect observed in both groups are significant

Inter group comparison shows that variation in mean respiratory rate was found statistically insignificant in all the steps of study.

Intergroup comparison showed that variation in mean pulse rate was statistically significant in all the steps of study. There was increase in pulse rate,Respiratory rate which can be attributed to anxiety associated with pain. Pulse rate came down after administration of standard and trial drug. This probably was due to analgesic property of ingredients of *Vednasthapan mahakashya* suggesting effective control of pain in post operative period.

Effect of therapy on VAS

Statistical comparison of mean VAS within the Groups was highly significant from the base value of onset of pain throughout the study period.

Effect on pain in 24 hour

At the time of onset of pain, mean pain level on VAS scale in group A was 8.68 and in group B was 8.88 on visual analogue scale.In 24 hour of therapy the mean pain level in group was 0.80 and in group B was 4.33.effect of therapy on mean pain level from onset of pain to 24 hour was significant and P-Values for Group I and Group II comparison are less than 0.05. Hence we conclude that there is significant difference observed in effect of Group I and Group II. Effect observed in Group I is more than Group II. Both groups are significant.

Effect on Pain in 10 days

In table no 13 P-Values for Group A and Group B are less than 0.05. Hence we conclude that effect observed in both groups are significant. Both groups are significant

Intergroup comparison of mean VAS shows that variation in mean VAS was found statistically significant in 24 hrs of study and insignificant in 10 days period of study.

The analgesic effect of *Vednasthapan mahakashya*" can be attributed to *Vednahara* (analgesic) properties of decoction of *Vednasthapan* drugs.

Desirable and undesirable effect of therapy

None of patient reported any undesirable effects like nausea,vomiting,gastric discomfort,pruritus.

Probable mode of action of "*Vednasthapan mahakashya*"

The constituents of the formulation used for trial are Sal,Katfal , Kadamba, Padmak, Mochrasa, Shirish, Vajjul, Ashoka.

- Sal have katu, Madhur,sheet and kaphapittashamak properties and by prabhav it works as Vednasthapan.
- Katfal have tikta,katu,ushna and kaphavatashamak properties,work as Vednasthapan ,kandughan & shothhar.it contains methanol and ethanol compound,myricitin possess analgesic,anti-inflammatory activity,anti-asthmatic and anti-microbial activity.
- Kadamba have tikta,katu & kaphapittashamak property work as vednasthapan,shothhar,vranashodhak and vranaropak .the bark of anthocephalus kadamba contains methanolic extract i.e. glycosidic indole alkaloids,cadambine etc .having good therapeutic values work as good analgesic ,antipyretic and anti-inflammatory .
- Padmaka have tikta,katu,sheet & kaphapittashamak properties work as vednasthapan ,shothhar ,dahprashman.its stem bark contains flavones & isoflavones possess analgesic and antipyretic activity.
- Mocharasa have Madhur, sheet & kaphapittashamak property, work as steroids having analgesic and antipyretic activity.
- Shirish have tikshna, tikta,Madhur,katu,ushna & tridoshshamak property work as vednasthapan,shothhar,vishaghan..A novel phenolic glycosides,albizinin and flavanols epicatechin,procyanidin,saponins possess anti-inflammatory , anti-microbial activity and antihistaminic activity.
- Jalvetas possess Kashaya ,tikta ,katu and kaphapittashamak property work as vednasthapan,medhya,jwarghan &

dahprashman.its bark contain delphinine, salicine, phenolic glycosides etc. having anti-inflammatory and analgesic activity.

- Ashoka have tikta, katu & kaphapittashamak property work as vednasthapak, shothhar, vishagha.its bark contains haematoxylin, glycosides, carbonic calcium & steroid possess antipyretic, anti-inflammatory & analgesic antimicrobial activity.
- If we look from modern medical science point of view, the possible mechanism of action of Vednasthapan Mahakashaya as an anti-inflammatory and analgesic could be attributed to the inhibition of PG synthesis by inhibiting cyclo-oxygenase enzyme.

Total Effect of Therapy

- As the present study was comparative study and for comparison of both groups, to find out which group was best we have used another test Mann whitney - U test. Following results were found in overall comparison:-
- In Group I Marked Improvement was observed in 13 (86.67%) patients and Moderate Improvement was observed in 2 (13.33%) patients While in Group II, Marked Improvement was observed in 6 (40%) patients, Moderate Improvement was observed in 8 patients (53.33%) patients and Mild improvement was observed in 1 patient(6.67 %).

EFFECT OBSERVED IN GROUP A IS MORE THAN GROUP B CONCLUSION

Misconceptions and fears regarding certain analgesics can result in under treatment of pain in post operative setting. With opiates specially, there are exaggerated fears regarding their potential for side effects and addiction and effective analgesic for moderate to severe pain post operatively²³. However NSAIDs are generally considered to be

inadequate as sole agents in the control of immediate postoperative pain²⁴, besides having various systemic side effects viz. gastric ulceration, G.I. bleeding, perforation²⁵, adverse renal effects caused by the reduction in synthesis of renal prostaglandins²⁶, various degree of cognitive dysfunction, confusion, behavioural disturbances and dizziness²⁷, precipitation of asthma in sensitive patient etc. Diclofenac sodium is a potent inhibitor of the enzyme cyclooxygenase present in platelets, essential for formation of Thromboxane A₂, which is essential for platelet aggregation and vasoconstriction thereby prolonging bleeding²⁸.

The Ayurvedic formulation "**VEDNASTHAPAN MAHAKASHAYA**" was selected for present study to evaluate its efficacy for relief of Post-operative pain after surgery and compare it with that of Inj./tab. Diclofenac sodium.

RESULTS

- Thus it can be concluded that "Vednasthapan mahakashaya" possesses analgesic properties without any side effects.
- However this is a preliminary study and requires more comprehensive observations and investigations to reach the final conclusion.

Recommendation and suggestions-

- It is currently recommended that analgesic regimens that operate through different mechanisms (multimodal analgesia) must be combined.
- Hence the concomitant effects of "Vednasthapan mahakashaya" with opiates/NSAIDs may need to be evaluated for future studies.
- Also prolonged use of "Vednasthapan mahakashaya" should be tried in pain control to evaluate its beneficial/adverse effects

REFERENCES

- [1]. *SHUSHRUTA SAMHITA* Edited With Ayurveda-Tattva-Sandipika By Kaviraja Ambika Dutta Shashtri, Chaukhambha Publications Reprint Sutrasthan 2010, 15/48.
- [2]. Barden J, Edwards J, Moore RA, Mac Quay HJ – single dose oral diclofenac for post operative pain. cochrane database syst. Revised (2), 2004, 004768.
- [3]. Powel I, Noble DW, Douglas, Spence AA.- comparison of IM ketorolac trometamol and morphine sulphate for pain relief after cholecystectomy. Br J Anesth 65, 1990, 448-445

- [4]. Carson JR, Strom BL, Soper KA et al – The association of NSAIDs with upper GI tract bleeding. Arch Inter Med. 1987, 147 -62304.
- [5]. Goodwin JS, Regan M – Cognitive Dysfunction associated with naproxen and ibuprofen in the elderly – Arthritis Rheum 25:1013 -5.
- [6]. Sampson AP, Cowburn AS, Sladek K – Profound over expression of leukotriene C4 synthase on bronchial biopsies from Aspirin Intolerant Asthmatic patients Int. Arch Allergy Immunol 1997;113: 355 -357
- [7]. Charak Samhita Vidyotini Hindi Vyakhyopeta by Pandit Kashinath Pandey and Gorakshnath Chaturvedi, Chaukhamba Publication reprint Sutra Sthana'. 2010.
- [8]. SHARANGDHARA SAMHITA noted With DIPIKA Hindi Commentary By Dr Brahmanand Tripathi, Choukhamba Surabhaarati Prakashana Varanasi Reprint 2010(1/1-2)
- [9]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, 671-673.
- [10]. Database on Medicinal plants 3, 112-113
- [11]. Dravya guna vigyanam, part II: Acharya P.V. Sharma, 407-408.
- [12]. Database on Medicinal plants 3
- [13]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, 41-43
- [14]. ILLUSTRATED DRAVYAGUNA VIJANA, STUDY OF ESSENTIAL MEDICINAL PLANTS IN AYURVEDA, By Dr. J.L. N. Shastri, Vol. 2, Chaukhamba Orientalia, Varanasi, Reprint 2014
- [15]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, 43-45
- [16]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, 43-45
- [17]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, 491-493
- [18]. Database on Medicinal plants Vol- 3
- [19]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, pg no 773-775
- [20]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, pg no 773 -775 Dravya guna vigyanam, Part II: Acharya P.V. Sharma, pg no 617-619
- [21]. ILLUSTRATED DRAVYAGUNA VIJANA, STUDY OF ESSENTIAL MEDICINAL PLANTS IN AYURVEDA, By Dr. J.L. N. Shastri, Vol. 2, Chaukhamba Orientalia, Varanasi, Reprint 2014
- [22]. Dravya guna vigyanam, Part II: Acharya P.V. Sharma, pg no 48-491
- [23]. Barden J, Edwards J, Moore RA, McQuay HJ – Single dose oral diclofenac for postoperative pain, Cochrane database syst. Rev. 2, 2004, 004768.
- [24]. Power I, Noble DW, Douglas E, Spence AA – comparison of IM ketorolac trometamol and morphine sulphate for pain relief after cholecystectomy. Br. J Anaesthesia 65, 1990, 445 – 448.
- [25]. Carson JR, Strom BL, Soper KA et al 1987 – the association of NSAIDs with upper GI tract bleeding. Arch Inter Med. 147 – 62304.
- [26]. Barter D C renal effects of cyclooxygenase – 2 selective inhibitors” J. Pain symptom manage 23 (4 suppl.) 2002, 515 -20, discussion 521.
- [27]. S Goodwin JS, Regan M, 1982 – Cognitive dysfunction associated with naproxen and ibuprofen in elderly – Arthritis Rheum 25, 1013.
- [28]. Schafer AI – Effects of NSAIDs therapy on platelets. Amj. Med 106, 1919, 525 – 35