

**CLINICAL STUDY OF PATHA-YAVINI IN THE MANAGEMENT OF POSTOPERATIVE PAIN ON ANO-RECTAL SURGERY UNDER CAUDAL BLOCK**Paswan Anil Kumar<sup>1</sup>, Singh Ravindra Prasad<sup>2</sup>, Prakash Sashi<sup>1</sup>, Dutt Anil<sup>2\*</sup><sup>1</sup>Department of Anesthesia, IMS, BHU, Varanasi, U.P. India<sup>2</sup>Department Of Shalya Tantra, R.G.G.P.G. Ay. College, Paprola, India

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**ABSTRACT**

Purpose: To evaluate the comparative effects of Patha-yavani (ayurvedic medicine) and diclofenac sodium on postoperative pain and pentazocine requirement as rescue analgesic in anorectal surgery under caudal block with lidocaine 2% with adrenaline.

sixty patient ASA I and II patients were randomly assigned to receive patha-yavani 2 gram with honey and tab diclofenac sodium 50 mg postoperatively in a double-blind manner in anorectal surgery under caudal analgesia with lidocaine 2%. Postoperatively patients' pain scores were recorded on a visual analogue scale every 30 min, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 8 hr, 12 hr, and 24 hrs for a period of 24 hrs. Patients received pentazocine 0.5-1 mg/kg intravenously on demand. The total pentazocine consumption for each patient was recorded. Patients in the patha-yavani group had significantly higher VAS scores than patients in the diclofenac group in all time intervals and required significantly higher rescue analgesic for postoperative pain management. There was a significant difference between the two groups in the second time of patients' analgesic demand was 6.5 hr (range 5-8 hr) in diclofenac group in comparison to 4 hr (range 2-5) in patha-yavani group ( $p < 0.001$ ). The mean pentazocine consumption after surgery in the first 24 hr in the patha-yavani group ( $28 \pm 8.6$  mg) was significantly higher ( $P < 0.001$ ) than in the diclofenac ( $12.6 \pm$  mg). In conclusion; attenuation of postoperative pain by patha-yavani administration suggests a new alternative for pharmacological reduction of postoperative pain. Hence, patha-yavani provides pain relief of short duration after day care anorectal surgery.

**Key words:** Caudal Block, Ano-rectal surgery, Patha-Yavani, Diclofenac sodium.

**INTRODUCTION**

Pain is the most common symptom that brings patients to see a physician and it is the basic and most challenging problem for surgeons from primitive era. Management of post operative pain has been a global challenge since the inception of surgical with opiates especially. There are exaggerated fears regarding their potential for side effects and addiction procedure. Diclofenac and patha-yavani both have demonstrated analgesic effects in clinical trials in acute postoperative pain management; however experience with patha-yavani is limited. Diclofenac has various systemic side effects viz. Nausea/vomiting, GI bleeding, ulceration or perforation and adverse renal effects. Many attempts have been made for an effective and safe alternative to the conventional treatment of pain with least side effects. Goal of this study is find out suitable affordable alternative ayurvedic drug for effective control of post operative pain, with least side effects and to compare the efficacy of Patha-Yavani as analgesic with established known analgesic Diclofenac sodium in post operative pain of ano-rectal surgery. In present study Patha-Yavani Yog was selected to assess its role in the management of post operative pain in ano-rectal surgery under caudal block with 10 ml of lignocaine 2% with adrenaline. The patients were divided into two group Patha-Yavani and Diclofenac groups. First dose of patha-yavani and diclofenac sodium was given after the waning of effect of anaesthesia and at onset of pain (at VAS score  $>50$ ). Their comparative analgesic effects, rescue analgesic (pentazocine) as well as adverse effects, if any, were evaluated over a period of 24 hours.

**MATERIAL AND METHODS**

60 patients of ASA I & II physical status of both sexes between 18 and 50 years of age scheduled for elective anorectal surgery under caudal block with 2% lidocaine with adrenaline were enrolled into this prospective, double blind, randomized placebo controlled study in the Department of Shalya Tantra, R.G.G.P.G. Ayurvedic College and Hospital, Paprola. Study was explained about the anesthetic procedure to the patient and written informed consent was taken. Exclusion criteria are Patients on NSAID, not willing for the trial, Patients allergy to Diclofenac sodium, history of peptic ulceration, coagulopathy, mentally retarded patients. All the screened and selected cases were divided randomly into two groups as Patha-

Yavani Group I and Diclofenac sodium Group II with 30 patients each. Group I was considered as trial group and the patients of Group II were considered as control group. All patients were given oral ranitidine 150 mg and oral alprazolam 0.5 mg in the evening before surgery and on the morning of surgery. All patients cannulated with 18G i.v. canula and preloaded with 10 ml/kg lactated ringer solution. All patients were attached with basic routine monitoring with pulse oximetry, NIBP and ECG. Caudal block was done with 10 ml of 2% lidocaine with adrenaline in lateral position and after adequate analgesia, allow for surgery. After completion surgery patients were shifted to recovery room and postoperatively given Patha-Yavani 2 gm with honey in group I and tab Diclofenac sodium 50mg of Group II (when VAS  $>50$ ). The roots of patha and fruits of Yavani were collected locally, identified, prepared and authenticated by experts in Dravya guna department. VAS Scoring was conducted the postanesthesia care unit (PACU) by an Observer blinded to patient group assignment. Postoperative analgesia was assessed by using visual analogue scale (VAS 0-10 cm, 0 = no pain and 10 = worst possible pain). The patients were assessed before treatment and after giving control and trial drugs at the interval of 30 min, 1 hr, 2 hr, 4 hr, 5 hr, 8 hr, 12 hr, and 24 hrs. Postoperative rescue analgesic was available to the patients as pentazocine (opioid) 0.5 mg/kg-1 administered i.v. as an analgesic supplement if the recorded VAS pains core was 50 or greater. Number of patient requires rescue pentazocine in 24 hr was recorded.

**Patha classification**

- Botanical name - *Cissampelos pareira* Linn.
- Sanskrit - Patha, Laghu patha.
- Parts used<sup>7</sup> - Roots and leaves

**Yavini Classification**

- Botanical name - *Trachyspermum ammi*
- Hindi - Ajwain, Ajowan
- Sanskrit - Yavani

Fruits of Ajowan are used for medication.

Fruits of Ajowan have an aromatic smell and pungent taste. Found all over India and many part of Egypt, Persia, Afghanistan. Good quality of Ajowan cultivated in Indore, Ujjain and Gwalior.

The occurrence of side effects such as hypotension, bradycardia, nausea, vomiting, sedation, or pruritis was recorded for each patient at the same time points as those defined for VAS assessment. Variation in blood pressure, pulse rate, respiratory rate, oxygen saturation, were noted and any adverse events like bradycardia, hypotension, pruritis, gastric irritation, postoperative nausea and vomiting, headache, respiratory depression were noted. After completion of study observed data entered into statistical software package SPSS<sup>9</sup>.

**Statistical analysis**

The data were analyzed with SPSS version 15.0 (SPSS Inc, Chicago, IL, USA). Categorical data were compared using Chi-square test. Comparison between the two groups was done using student student 't' test. The data were considered significant if p values were equal to or less than 0.05.

**RESULTS**

60 patients were enrolled for the study; there were no demographic differences between two groups (Table I). 0-2 hr postoperatively VAS score of group I & II was 2.1 ± 1.4 and 1.2 ± 1.0 and there was no requirement of any analgesic. The total postoperative analgesic duration (time from caudal analgesia to first dose of analgesic) was 4.231±75 hr in both groups. Patients in the patha-yavani group had significantly higher VAS scores than patients in the diclofenac group in all time intervals and required significantly higher rescue analgesic for postoperative pain management. (Table IV & V P < 0.05). After the first dose of analgesic, pain was

recorded every 30 min, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 8 hr, 12 hr, and 24 hrs for a period of 24 hrs. The time to first postoperative analgesic request almost similar in both groups. Total number of analgesic doses given in first 24 hr was lower in Group II as compare to Group I and statistically significant. There was a significant difference between the two groups in the second time of patients' analgesic demand was 6.5 hr (range 5-8 hr) in group II in comparison to 4 hr (range 2-5) in I group (p < 0.001). Comparing between group I and group II the duration of postoperative analgesia was significantly longer (p < 0.05) in group II. There by it signifies that group II patients had longest period of effective analgesia in the postoperative period followed by longer period of analgesia in group I. The number of patient where i.v pentazocine as rescue analgesic was used 4(13.3%), 12 (40%), and 6 (20%) in Patha group and 3(10%), 6(20%) and 2 (6.6%) in diclofenac group at 1, 2 and 4 hour respectively after the operation (Table IV). Thus, the use of pentazocine hydrochloride was significantly (P < 0.05) more in Group I than Group II. Supplementary analgesic consumption during the first 24h was greater in group I as compared to group II. The mean pentazocine consumption after surgery in the first 24 hr in the group I (28 ± 8.6 mg) was significantly higher than in the group II (12.6 ± mg), (P < 0.001). Intraoperative there was no any major adverse event reported. Five patients experienced mild nausea after patha-yavani group, and seven patients after diclofenac sodium group, none of them requiring treatment

**Table 1**

GROUPS	AGE (Yrs)	SEX (male/female) %	RELIGION	MARITAL STATUS	Education profile (litrate/illtrate)
Groups I (n=30)	25-50	80%&20% (n=24/6)	Hindu	Married	90%&10% (n=27/3)
Groups II (n=30)	23-55	73.33%&26.67% (n=22/8)	Hindu	married	13.33% (n=26/4)

**Table II: Type of surgery -**

Type of surgery	Gr. I	Gr. II
Haemorrhoidectomy	20(66.67%)	16(53.33%)
Fissurectomy	8 (26.67%)	10(33.33%)
Fistulectomy	2 (6.67%)	4(13.66%)

Table II showed number of surgery was higher in haemorrhoid.

**Table III: showed Mean surgical time was insignificant (p=>0.5)**

Group	Means ± SD	Inter group comparison		Remarks
		't' value	p value	
I	45.33 ± 8.43	0.83	>0.05	N.S.
II	47.62 ± 8.11			

**Table IV Postoperative VAS Score:-**

VAS SCORE (Time)	Group I	Group II
0-2hr	2.1 ± 1.4	1.2 ± 1.0
3 h	8.06± 1.23	8.30±0.90
4 h	6.0±1.05	5.18±0.84*
5 h	6.85±0.95	3.92±0.65*
6 h	3.46±1.02	3.21±0.70
8 h	2.5 ± 1.3	3.2 ± 1.1
12 h	3.4 ± 1.0	3.3 ± 1.3
24	2.2 ± 1.0	3.2 ± 2.0

\*P < 0.05 Patha-Yavani vs. Diclofenac sodium.

**Table V Show incidences of uses of rescue drug pentazocine during each Period**

Duration	Group I (n=30)	Group II (n=30)
1-2 h	4 (13.3%)	3 (10%) *
2-4 h	12 (40%)	6 (20%) *
4-6 h	6 (20%)	2 (6.6%) *
6-8 h	3 (10%)	2 (6.6%)
8-12 h	2 (6.6%)	2(6.6%)
12-18 h	2 (6.6%)	1(3.3%)
18-24 h	1(3.3%)	0

\*P < 0.05 compared with group I (Patha-yavani).

**Table VI** Show Effect of therapy on systolic B.P.

Group	Mean systolic B.P. (mean $\pm$ SD)								
	A	B	C	D	E	F	G	H	I
I	131.90 $\pm$ 14.10	137.94 $\pm$ 12.15	136.00 $\pm$ 11.55	135.15 $\pm$ 11.98	134.00 $\pm$ 10.20	135.30 $\pm$ 9.85	136.50 $\pm$ 9.20	134.12 $\pm$ 10.00	133.50 $\pm$ 9.30
	126.34 $\pm$ 14.52	135.56 $\pm$ 12.50	132.16 $\pm$ 12.70	130.72 $\pm$ 10.30	128.10 $\pm$ 9.45	126.85 $\pm$ 9.27	128.72 $\pm$ 9.68	126.30 $\pm$ 6.35	122.10 $\pm$ 5.24

Statistical comparison of mean systolic blood pressure (A) Pre operative blood pressure, (B) At onset of pain (post op), (C) After 30mins of therapy (D) After 1 hr of therapy, (E) After 2 hrs of therapy, (F) After 4 hr of therapy, (G) After 8 hr of therapy, (H) After 12 hr of therapy, (I) After 24 hr of therapy

Table VI and graph showed that statistical comparison of mean systolic B.P. In Group I variation in mean systolic B.P. was found statistically insignificant in all the steps of study, however systolic blood pressure higher in Patha group throughout the study period.

## DISCUSSION

Pain is a subjective experience so it should be treated according to what the patient feels and not what their attendant's think<sup>1</sup>. Effective post operative analgesia has been associated with decreased stress responses to surgery, and improved pulmonary and cardiovascular function<sup>2</sup>. The commonly used analgesics in modern medicine have many side effects and contraindication and thus a need for a safe Ayurvedic analgesic agent continues. Non-steroidal anti-inflammatory (diclofenac) drugs are well established, inexpensive, effective analgesics, anti-inflammatory, and antipyretic effect by inhibiting cyclooxygenase I and cyclooxygenase II<sup>3</sup>. It is useful for minor surgery and are adjunctive analgesics in patients undergoing major surgery, decreasing pain and opioid requirements. Diclofenac use may be limited by adverse renal, gastrointestinal, and haemostatic effects. Many vedanahar and vatashamaka drugs have been mentioned in Ayurvedic literature. Acharya Sushruta indicates use of alcohol for relief of pain in patients undergoing surgical procedure<sup>4</sup>.

The present study has demonstrated the significant analgesic effect of patha-yavani 2 gm with honey and diclofenac sodium 50 mg after anorectal surgery under caudal block with lidocaine 2% with adrenaline. A decrease in total analgesic consumption along with a significant decrease in VAS pain scores was found in patients who received diclofenac sodium (VAS score >5) after surgery in comparison to patients who received patha - yavani (Table III). The VAS score in the diclofenac group was significantly less in Comparison to patha group (5 hr of VAS  $3.92 \pm 0.65$  vs  $6.85 \pm 0.95$ ) suggests that the postoperative administration of patha yavani has a less prolonged analgesic effect than diclofenac resulted in a significant reduction of the postoperative pentazocine consumption during the first 24 hours (table IV). There was a higher incidence of nausea/vomiting in patients who received diclofenac but none of the patients required treatment and the side effects were well tolerated. This study demonstrates that patha-yavani administration decreases postoperative pain after anorectal surgery but for shorter duration. Mechanism of action analgesic properties patha-yavani is unknown. Some studies showed that inhibition of prostaglandin synthesis to produce analgesia<sup>5,6</sup>. This is supported by a significant decrease in VAS scores during the first four postoperative hours and additional analgesic requirement. The anti-inflammatory action in the peripheral tissues occurs through antagonizing the release of inflammatory mediators such as histamine, cytokines and serotonin, which in turn excite nociceptors.<sup>5,16</sup>

Uses of patha in different problems:<sup>4-14</sup>

- Pain - Churna of patha mixed with yavani churna is usefull in Haemorrhoidal pain.
- Inflammation – In internal or deep seated inflammation root of this plant taken with honey and rice water.
- Diarrhea - Patha used in diarrhea.
- Itching – Leaves are used as external application for itch.

- Chronic wound and sinus – Leaves and roots made into a paste with some bland oil and used locally in cases of unhealthy sores, sinuses.

- It is use as potent diuretic, hence used in chronic cystitis, dysurea and hematuria.

It is well known as Midwife's herb as mainly used for treating women's diseases. It has been used since the ancient times as a cure for menstrual problems, hormonal imbalance, and to ease childbirth, postpartum pain, prevent miscarriage, and control uterine hemorrhages, hormonal acne and premenstrual syndrome (PMS)

Uses of Yavani in different problems:<sup>5-16</sup>

- Pain - Churna of Yavani mixed with patha churn is usefull in Haemorrhoidal pain.
- Colic pain- Yavani mixed with Hingu, Saindhav and Saurchal Salt and taken with Suramand, which relieves colic pain.
- Urticaria - Ajowan daily intake is said to cure urticaria within a week.
- Germicide - Yavani is a potent Germicide (Krimighna) activity against Hookworm.
- Indigestion - Used in Ajirna (indigestion) and as an appetizer.

Diclofenac sodium is rapidly absorbed from the gastro intestinal tract. It has bioavailability<sup>16, 17</sup> of 54%, volume of distribution is 0.17. It undergoes high protein binding (up to 99.5%) and is metabolized in the liver. The rate of elimination is reduced in the elderly and in those with renal impairment. After oral administration peak concentration in plasma 1.5 gm/ml is recorded within 2-3 hours. John et al (1979) suggested that diclofenac takes 30 minutes to achieve peak blood level when given intra muscularly. Diclofenac sodium has anti inflammatory, anti pyretic and analgesic properties and is widely used in Rheumatoid arthritis, degenerative joint diseases, ankylosing spondylitis, degenerative joint disease, trauma, dysmenorrhoea, low back pain and sufficiently effective as sole analgesic after a minor to intermediate surgery.

## CONCLUSION

Attenuation of postoperative pain by patha- yavani administration suggests a new alternative for pharmacological reduction of postoperative pain. However patha-yavani provides pain relief of short duration after day care anorectal surgery.

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