

**A SINGLE BLIND CONTROLLED STUDY OF *CHATURBEEJ* CAPLET  
AND DICLOFENAC SUPPOSITORY IN POST-OPERATIVE PAIN  
MANAGEMENT**

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**ABSTRACT**

Pain is a more terrible lord of mankind than even death himself

**- Albert Schweitzer**

God has bestowed mankind with the best of his gifts and made him the supreme most creature of the universe. Health is one such precious possession, wisdom and art. Strength and wealth are of no use if health is lacking. Thus it is the prime aim of Ayurveda and the one, all physician and surgeon should try for, i.e. protecting the health of the health and restoring health for the diseased. The post-operative pain management is special area where doctors has to deal with great patience particularly lower abdominal and in pelvic surgeries, ano rectal surgeries. Surgeries under spinal and epidural anesthesia has analgesic effect for hours after procedure. There are Paracetmol and Diclofenac suppository are available and working moderately. These drugs are having adverse effect like rectal bleeding, rectal ulceration etc. Rectal administration provides rapid absorption of many drug and easy alternative to IM/IV route. It is painless procedure. The most important consideration are slow onset of disintegration (minutes), absorption of medicine and the prolonged duration of effect(analgesia) in rectal route. **Aim:** To study the efficacy of *Chaturbeej* caplet and Diclofenac suppositories in post-operative pain management.

**Objectives**

1. To study the literature of pain and its management through rectal route.

2. To evaluate the efficacy of *Chaturbeej* caplet in post-operative patients as an rectal analgesic drug.
3. To compare the efficacy of *Chaturbeej* caplet with Diclofenac suppository.
4. To study the adverse effect of drug like ano-rectitis, rectal ulceration and necrosis.

Ayurveda has many drugs and formulations as vedanashamak activity. Following formulation from Bhavprakash is indicated as oral analgesic.<sup>[9]</sup> This study was carried out to find out one more option for analgesic suppository of natural origin for post operative pain management, this drug administered by Rectal route.

**KEYWORDS:** i) Pain – Shool ii) Suppository – Phalvarti iii) Chaturbeej - Methika, Chandrashur, Kalajaji & Yavanika iv) Rectum – Gudh.

## INTRODUCTION

The post operative pain management is special area where doctors has to deal with great patience particularly lower abdominal and in pelvic surgeries, ano rectal surgeries. Surgeries under spinal and epidural anesthesia has analgesic effect for hours after procedure. Epidural anesthesia can be continued and analgesia can be maintain but chances of infection may increase.

There are Paracetamol and Diclofenac suppository are available and working moderately. These drugs are having adverse effect like rectal bleeding, rectal ulceration etc. In NBM patients and in Paediatric age group rectal administration of drug having advantages.

Previous study of *vednashamak basti* has been carried out for post operative analgesic management. But this required large quantity of drug. In many cases like resection anastomosis, this is not preferable as it may increase peristaltic movement so early and can reach upto the illio-caecal valve, which is not acceptable.

Rectal administration provides rapid absorption of many drug and easy alternative to IM/IV route. It is painless procedure. The most important consideration are slow onset of disintegration(minutes), absorption of medicine and the prolonged duration of effect(analgesia) in rectal route.

There is some evidence that hepatic first pass elimination of high clearance drug is partially avoided after rectal administration and peak plasma concentration level of drug which remain

stable during the entire duration of application. Drug reach in circulatory system faster than oral route and less alteration and greater concentration.

Ayurveda has many drugs and formulations as *vedanashamak* activity. Following formulation from *Bhavprakash* is indicated as oral analgesic.<sup>[9]</sup>

*Chaturbeej* contains four drug that are *Methika*, *Chandrashur*, *Kalajaji* & *Yavanika*. All these four drug are *Vatashamak*. *Vata* causes acute pain in the body and *Chaturbeej* has *Vatashamak*. This study was carried out to find out one more option for analgesic suppository of natural origin for post-operative pain management, this drug administered by Rectal route.

Advantage of administering a drug rectally is that tends to produce less nausea compared to the oral route and also prevent any amount of the drug from being lost due to emesis.

### AIM

To study the efficacy of *Chaturbeej* caplet and Diclofenac suppositories in post-operative pain management.

### OBJECTIVES

1. To study the literature of pain and its management through rectal route.
2. To evaluate the efficacy of *Chaturbeej* caplet in post-operative patients as an rectal analgesic drug.
3. To compare the efficacy of *Chaturbeej* caplet with Diclofenac suppository.
4. To study the adverse effect of drug like anorectitis, rectal ulceration and necrosis.
5. To study the literature of pain and its management through rectal route.
6. To evaluate the efficacy of *Chaturbeej* caplet in post-operative patients as an rectal analgesic drug.
7. To compare the efficacy of *Chaturbeej* caplet with Diclofenac suppository.
8. To study the adverse effect of drug like anorectitis, rectal ulceration and necrosis.

### MATERIAL AND METHODS

**A] CONCEPTUAL STUDY: Literary study of *Chaturbeej* Caplet and Shool was done.**

**Study design: Study is divided into two parts**

- 1. Pilot study.
- 2. Original study: Phase 2, Single blind, Randomized controlled pre-clinical study.

**B] CLINICAL STUDY**

1. Drug Preparation
2. Selection of Patient
3. Clinical trials
4. Assessment criteria

**Drug study**

- According to acharya Sharangdhara suppository is that which evacuates stool from rectum and its shape is like thumb called **Rectal Suppository**. (Phalvarti)<sup>[28]</sup>

**Details of drug *Chaturbeej***

- *Methika, Chandrashoor, kalaajaji, and Yavanika* these four drugs called *Chaturbeej*.<sup>[9]</sup>

**Details of drug *CHATURBEEJ***

Sr. No	<i>Yavani</i>	<i>Chandrashur</i>	<i>Kalaajaji</i>	<i>Medhika</i>
<b>Synonym</b>	<i>Ajwayan, ajmodika</i>	<i>Chandrika, vaypuspa</i>	<i>Kalaunji, kunchika</i>	<i>Methika, pitbeej</i>
<b>Family</b>	<i>Umbelliferae</i>	<i>Cruciferae</i>	<i>Ranunculaceae</i>	<i>Leguminosae</i>
<b>Latin name</b>	<i>Trachyspermum ammi</i>	<i>Lepidumsativam</i>	<i>Nigella sativa linn</i>	<i>Trigonella foenum</i>
<b>Rasa</b>	<i>Katu, Tikta</i>	<i>Katu, Tikta</i>	<i>Katu, Tikta</i>	<i>Katu</i>
<b>Virya</b>	<i>Ushna</i>	<i>Ushna</i>	<i>Ushna</i>	<i>Ushna</i>
<b>Vipak</b>	<i>Katu</i>	<i>Katu</i>	<i>Katu</i>	<i>Katu</i>
<b>Dosh karma</b>	<i>Kaphavatashamak</i>	<i>Kaphavatashamak</i>	<i>Kaphavatashamak</i>	<i>Vatashamak</i>
<b>Upayuktanga</b>	<i>Beej</i>	<i>Beej</i>	<i>Beej</i>	<i>Beej</i>
<b>Chemical composition</b>	Tanin, carvacrol, saponine	Benzyl cyanide, benzyl isocyanide	Saponine, carvone, melathine	Saponine, lecithium

**Method and Preparation of *Chaturbeej* Caplet**

Ingredients: *Methika, Chandrashoor, kalaajaji, and Yavanika* these four drugs were used in equal quantity in *Chaturbeej* Caplet.<sup>[9]</sup>

- Quantity – Equal.
- *Choorna* powder size – 60 mesh.

(*Choorna* powder 60 Mesh size were selected for Caplet preparation because more fine powder had more absorption).

- Caplets were formed by compression method.
- Study was carried out on 30 patients.

**Standard Operative Procedure(S.O.P) for preparation of *Chaturbeej* Caplet**

- *Methika, Chandrashur, Kalaajaji* and *Yavani* these four drug were purchased from Authenticated source.
- Authentication and Standardisation of drug were done.
- Quantity of drug was 1kg, In which all four ingredient were in equal parts (each drug had taken 250gm).
- All ingredients had taken 60 mesh fine powder. All four drug were mixed properly and with the help of Die-Punching machine Caplets were prepared by compression technique
- With the help of compression technique 1gm caplet were prepared Drug preparation were done in reknown Pharmacy,
- procedure described in [www.pharmaguideline.com/2011/05/sop](http://www.pharmaguideline.com/2011/05/sop).

**Pathophysiology of Rectum and Absorption**

- Rectum has rich blood and lymph supply, drug can cross the rectal mucosa like other lipid membrane, thus unionized and lipid soluble substance are readily absorbed.
- The portion absorbed from the upper rectal mucosa is carried by the superior haemorrhoidal veins into the portal circulation.
- The Portion absorbed from the lower rectum enters directly into the systemic circulation via Middle and inferior haemorrhoidal veins.

**Ano Rectal route medicine mentioned in Ayurveda**

- According to acharya Sharangdhara suppository is that which evacuates stool from rectum and its shape is like thumb called **Rectal Suppository** (*Phalvarti*).<sup>9</sup>
- *Charak* had mentioned *siddhistan* about *Phalvarti* which is indicated in treatment of *Aadhmanand* pain in abdomen, which was develop due to *Vataprakopa*.<sup>3</sup>

**Pilot study****Introduction**

- Before start of actual study, pilot study was carried out on 30 patients to decide appropriate dose for caplet and record for any adverse effect. Reference of dose of caplet is not described in our text but *Gudavarti* is described as its shape like a thumb of an individual. To maintain uniformity dose of caplet were one gram, for that **Pilot study**.

**Aim**

To study the effect of *Chaturbeej* caplet and its adverse effects.

**Pilot study Objectives**

- 1) To calculate the dose of *Chaturbeej Choorna* Caplet.
- 2) To observe the disintegration of caplet of observation to observe any adverse effect locally.

**Study design**

Simple Randomized selection of 30 post-operative patients was taken for the study.

- These patients were selected irrespective of their sex, religion, educational, marital, and Socio economic status.

Detailed history of all patients was obtained as per prepared CRF.

**Conclusion of pilot study**

We were fixed the dose of *Chaturbeej* caplet 1gm TDS per rectal, this dose were effective in pain management without any adverse effect.

**STUDY DESIGN**

**TITLE-A SINGLE BLIND CONTROLLED STUDY OF *CHATURBEEJ* CAPLET AND DICLOFENAC SUPPOSITORY IN POST-OPERATIVE PAIN MANAGEMENT.**

**Introduction**

Before start of actual study, pilot study was carried out on 30 patients to decide appropriate dose for caplet and any adverse effect. From the pilot study we were fixed the dose of drug and no any adverse effect was observed locally.

**Study design**

Simple Randomized controlled single blind selection of 60 post-operative patients was done.

- These patients were selected irrespective of their sex, religion, educational, marital and Socio economic status.

Detailed history of all patients was obtained as per prepared proforma.

**Type of study:** Phase 2.

**A) Selection of patient**

For clinical study,

Total no. of patients – 60 patients of Post-operative pain management was selected for a clinical study was conducted in IPD department of *Shalya Tantra* in our hospital.

**B) Grouping of patients**

**Group A (Trial Group)**

- 30 Patients were received *Chaturbeej* Caplet of 1gm per rectal
- Written consent of the patient was taken prior to commencement of trial.
- Case was taken according to specifically prepared case record form.
- Clinical assessment i.e. follow-up was taken on 1<sup>st</sup>, 2<sup>nd</sup> & 3<sup>rd</sup> day.

**Group B (Control group)**

- 30 Patients were received Diclofenacsuppository of 100mg per rectal
- Written consent of the patient was taken prior to commencement of trial.
- Case was taken according to specifically prepared case record form.
- Clinical assessment i.e. follow-up was taken on 1<sup>st</sup>, 2<sup>nd</sup> & 3<sup>rd</sup> day.

**C) Criteria for inclusion**

- Patients of irrespective of gender in age group 18-70 years were included.
- Post-operative patient was operated on lower abdomen, pelvis and ano-rectal surgeries.

**D) Exclusion criteria**

- Patients having loose motion, diarrhea, acute fissure, active bleeding from rectum (per rectal bleeding).
- Known case of Immuno- compromised patient.

**E) Withdrawal criteria**

- If patient develops any adverse effect or unwilling for treatment.
- Not responding & develops aggravation of symptoms.
- Withdrawal patient will be replaced by patients fulfilling criteria of inclusion.

**F) Route of drug administration**

- Per rectal.

**G) Dose**

Group A- 1gm *Chaturbeej* Caplet TDS.

Group B- 100mg Diclofenac Suppository TDS.

**H) Duration**

- For 3days.

**Ethical Clearance**

Before starting of Clinical trials on patients with Post-operative pain, this synopsis was approved by IRBC and permission was granted.

Then clinical trial was conducted for the study in two groups.

Simple Randomized selection of 60 post-operative patients was selected for present study and was grouped into two as a Group A and Group B, consisting of 30 patients each of irrespective of gender.

**Group A: Trial group**

- 30 Patients were received *Chaturbeej* Caplet of 1gm per rectal.
- During this clinical trial concomitant therapy was continued like, antihypertensive etc.
- Case was taken according to specifically prepared case record form.
- Clinical assessment i.e. follow-up was taken on 1<sup>st</sup>, 2<sup>nd</sup> & 3<sup>rd</sup> day.

**Group B: Control group**

- 30 Patients were received Diclofenac suppository of 100mg per rectal.
- During this clinical trial concomitant therapy was continued like, antihypertensive etc.
- Case was taken according to specifically prepared case record form.
- Clinical assessment i.e. follow-up was taken on 1<sup>st</sup>, 2<sup>nd</sup> & 3<sup>rd</sup> day.

Group	Operative Measure	Treatment	Route of drug administration	Duration
A	Lower abdominal surgeries	<i>Chaturbeej</i> Caplet 1gm -8hourly	Per rectal	3 days
B	Lower abdominal surgeries	Diclofenac suppository 100mg - 8hourly	Per rectal	3 days

**Material Required**

1. Sterile surgical gloves – 7 no.
2. *Chaturbeej* Caplet 1gm.
3. Diclofenac Suppository 100mg.

**Procedure**

For both the groups

- Required material kept ready.
- Procedure was explained to the patient and consent was taken

**Group A**

- After the operative procedure and withdrawal the analgesic effect of anesthesia, in left lateral position *Chaturbeej* caplet of 1gm was administered per rectal 8 hourly 3 days.
- On Day 1 follow up was taken every 3 hourly.
- On Day 2<sup>nd</sup> follow up was taken every 6 hourly
- On Day 3<sup>rd</sup> follow up was taken every 12 hourly

**Group B**

- After the operative procedure and withdrawal the analgesic effect of anesthesia, in left lateral position Diclofenac suppository of 100mg was administered per rectal 8hourly for 3days.
- On Day 1<sup>st</sup> follow up was taken every 3 hourly.
- On Day 2<sup>nd</sup> follow up was taken every 6 hourly
- On Day 3<sup>rd</sup> follow up was taken every 12 hourly.

For both the groups Changes in the pain and tenderness before and after treatment were observed. This observation was recorded in the proforma of case sheet.

**ASSESSMENT PARAMETERS****Subjective parameters****Assessment of post-operative pain**

Onset of pain -	++++
Progress of pain-	
• Complete intolerance of pain (pain in all position)	+++++ (7-10)
• Moderate tolerable, But disturbing routine activity	+++ (3-6)

- Mild, particular at operated site ++ (1-3)
- No pain - 0

### Objective parameters

No any objective parameters.

### Investigations

Operative profile were done before preoperative procedure.

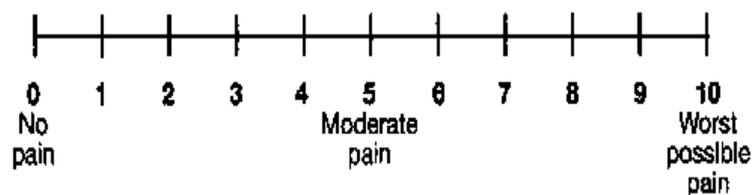
(Haemogram, Blood urea, Serum creatinine, Random blood sugar, Urine routine, HbsAg, HIV I & II, chest x-ray, ECG).

### Consent

Informed written consent of each patient was taken for the pilot study.

### Assessment criteria

Grade	Grade no.
No Pain	0
Mild Pain	1-3
Moderate pain	4-7
severe pain	8-10



### Visual Analog Scale

Criteria of assessment were based on visual analog scale. Review of intensity of post-operative pain every 3 hourly on 1st day, every 6 hourly on 2<sup>nd</sup> day, 12 hourly on 3<sup>rd</sup> day. Findings subjected for statistical analyses.

Probable disadvantage- The patient may expel the caplet.

## OBSERVATION AND RESULTS

### Aim

To study the efficacy of *Chaturbeej* caplet and Diclofenac suppositories in post-operative pain management.

### Sample population

Two group of Patient i.e. Trial and Control were Considered.

Each group consists of 30 patients, which were monitored for clinical assessment over different time points as follows:

1. POD 1 (Before treatment).
2. POD 1 (After treatment) every 3hourly.
3. POD 2 every 6hourly.
4. POD 3 every 12 hourly.

### Demographic Data

Frequency Analysis done based on following demographic attributes:

1. Age.
2. Sex.
3. Marital status.
4. Education.
5. Occupation.
6. Operative Procedure.
7. Clinical assessment tool pain.

### Frequency Analysis

#### Distribution of Patient according to Age

Patient from both the group divided into 8 classes as per their age (in years). While both the group was reported a majority of patients from the younger age classes.

**Table no. 1: showing distribution of patient according to Age.**

Age Group	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
18-25	8	26.7	11	36.7
25-32	11	36.7	7	23.3
32-39	2	6.7	6	20
39-46	3	10	1	3.3
46-53	0	0	2	6.7
53-60	3	10	2	6.7
60-67	1	3.3	1	3.3
67-74	2	6.7	0	0
TOTAL	30	100	30	100

This may be due to younger age group more prone to surgery.

### Distribution of patient data according to Gender

Patient from both the control and trial group not showed similar distribution across both the gender, with control & trial group having more males than females.

**Table no. 2: Showing distribution of patient according to Gender.**

Gender	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
Male	20	66.7	24	80
Female	10	33.3	6	20
TOTAL	30	100	30	100

### Distribution of patient data according to marital status

The distribution of patients in the control & trial group as per marital status showed that married patients more than unmarried.

**Table no. 3: showing distribution according to marital status.**

Marital Status	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
Married	24	80	26	86.7
Unmarried	6	20	4	13.3
TOTAL	30	100	30	100

### Distribution of patient data according to Education

The distribution of patient in both the group mostly literate patients were seen.

**Table no. 4: showing distribution of patient according to education.**

Education	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
Graduate	6	20	4	13.3
H.S.C.	14	46.7	11	36.7
S.S.C.	7	23.3	8	26.7
Below S.S.C.	3	10	7	23.3
TOTAL	30	100	30	100

### Distribution of patient data according to Occupation

A majority of the patients from both the control & trial group reported occupation as etc.

**Table no. 5: showing distribution of patient according to Occupation.**

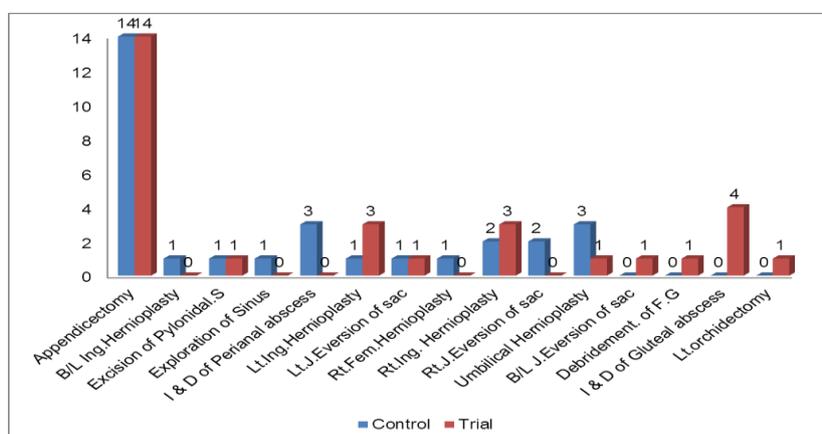
Occupation	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
Business	2	6.7	5	16.7
Farmer	5	16.7	4	13.3
Housewife	8	26.7	5	16.7
Job	4	13.3	7	23.3
Student	6	20	5	16.7
Other	5	16.7	4	13.3
TOTAL	30	100	30	100

**Distribution of patient data according to Operative procedure**

Appendectomy operated patients mostly were seen in both group, had same maximum frequency (14) & percentage (46.7%) in both control and trial group.

**Table no. 6: showing distribution of patient according to operative procedure**

Operative procedure	Control		Trial	
	Frequency	Percentage	Frequency	Percentage
Appendectomy	14	46.7	14	46.7
B/L Ing.Hernioplasty	1	3.3	0	0
Excision of Pylonidal.S	1	3.3	1	3.3
Exploration of Sinus	1	3.3	0	0
I & D of Perianal abscess	3	10	0	0
Lt.Ing.Hernioplasty	1	3.3	3	10
Lt.J.Eversion of sac	1	3.3	1	3.3
Rt.Fem.Hernioplasty	1	3.3	0	0
Rt.Ing. Hernioplasty	2	6.7	3	10
Rt.J.Eversion of sac	2	6.7	0	0
Umbilical Hernioplasty	3	10	1	3.3
B/L J.Eversion of sac	0	0	1	3.3
Debridement. of F.G	0	0	1	3.3
I & D of Gluteal abscess	0	0	4	13.3
Lt.orchidectomy	0	0	1	3.3
TOTAL	30	100	30	100

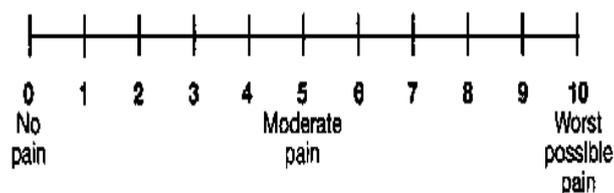
**Graph no. 5: showing distribution of patients according to Operative procedure.**

### Clinical data assessment tool

Efficacy of *Chaturbeej* caplet and Diclofenac suppository were tested based on following criteria:

#### 1. Pain

Visual Analogue scale used for assessment criteria of Pain.



**Visual Analog Scale**

Onset of pain -	++++	
• Progress of pain-		
Complete intolerance of pain (pain in all position)	+++++	(7-10)
Moderate tolerable, But disturbing routine activity	+++	(3-6)
Mild, particular at operated site	++	(1-3)
No pain	-	0

### Assesment Criteria

1. The frequency distribution of demographic data was done.
2. Efficacy testing of the treatment was performed using One way Anova for repeated measures i.e. the Friedman's test.

### Frequency Analysis

#### Observation Related to Clinical assessment tool Pain

Pain: Statistical analysis of pain is as follow.

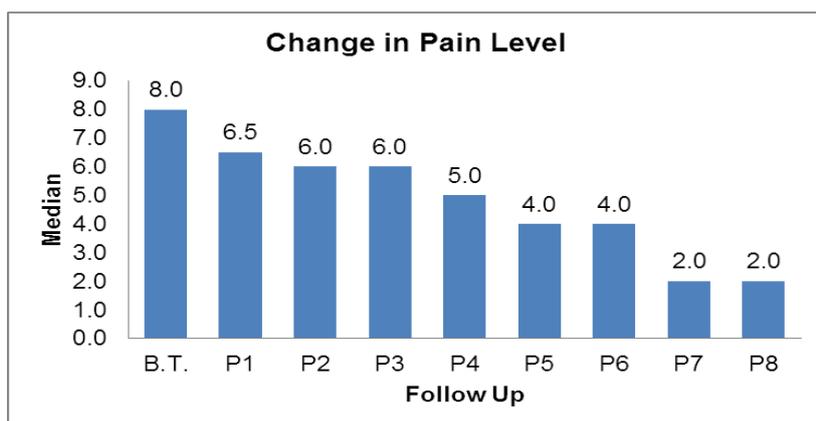
**Table no. 7: showing result of pain by One way Anova.**

Control Group			N	Mean	Std. Deviation	Median	Minimum	Maximum
Pain Bt			30	7.9	0.9	8.0	6.00	9.00
Pain At POD1	6hrs	P1	30	6.5	0.8	6.5	5.00	8.00
	9hrs	P2	30	6.0	0.6	6.0	4.00	7.00
	12hrs	P3	30	5.7	0.7	6.0	4.00	7.00
Pain At POD2	6hrs	P4	30	4.9	0.9	5.0	3.00	6.00
	12hrs	P5	30	4.2	0.7	4.0	3.00	6.00
	18hrs	P6	30	3.7	0.5	4.0	2.00	4.00
Pain aft POD3	12 hrs	P7	30	2.5	0.9	2.0	.00	4.00
	24 hrs	P8	30	2.0	0.6	2.0	.00	4.00

Before treatment Median Score for Pain was 8, At POD1 6 hours median pain level decreased to 6.5, at 9 hours median decreased to 6 at 12 hours median was 6.

POD2 at 6 hours median Pain level was 5, at 12 hours decreased to 4 remains same up to 18 hours at POD2.

After POD 3 at 12 hours median Pain level was 2 remains same till 24 after POD3.



**Graph no.7: Showing Change in Pain level.**

Since observations are on ordinal scale repeated measures ANOVA is used, Using Friedman's Test we can observe from the above table P-Value is less than 0.05 hence we conclude that effect on Pain Level is significant.

## RESULT AND CONCLUSION

Pain: Statistical analysis of pain is as follow.

N	30
Friedman's Statistic	227.930
Df	8
P-Value	0.000
Test Statistic <sup>a</sup>	

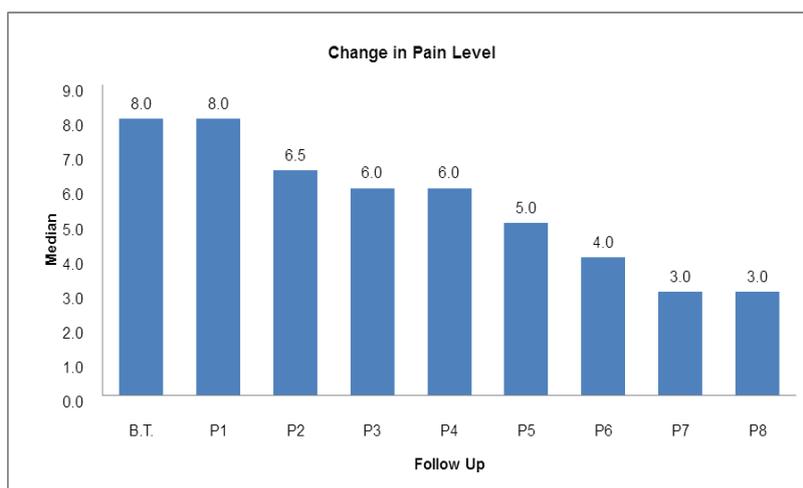
**Table no. 8: showing result of pain by One way Anova.**

Trial Group			N	Mean	Std. Deviation	Median	Minimum	Maximum
Pain Bt			30	8.2	0.9	8.0	7.00	10.00
Pain At POD1	6hrs	P1	30	7.3	0.9	8.0	5.00	8.00
	9hrs	P2	30	6.8	1.0	6.5	5.00	8.00
	12hrs	P3	30	6.3	0.8	6.0	5.00	8.00
Pain At POD2	6hrs	P4	30	5.4	0.9	6.0	3.00	6.00
	12hrs	P5	30	5.0	1.0	5.0	3.00	6.00
	18hrs	P6	30	4.0	0.8	4.0	2.00	6.00
Pain aft POD3	12 hrs	P7	30	3.2	1.0	3.0	2.00	6.00
	24 hrs	P8	30	3.0	1.0	3.0	2.00	6.00

In Trial Group Before treatment Median Score for Pain was 8, At POD1 6 hours median pain level was same 8, at 9 hours median decreased to 6.5 at 12 hours median was 6.

POD2 at 6 hours median Pain level was 6, at 12 hours decreased to 5, at 18 hours it was 4 at POD2.

After POD 3 at 12 hours median Pain level was 3 remains same till 24 after POD3.



**Graph no. 8: showing Change in pain level.**

Test Statistics <sup>a</sup>	
N	30
Friedman's Statistic	225.647
Df	8
P-Value	.000

Since observations are on ordinal scale repeated measures ANOVA is used, Using Friedman's Test we can observe from the above table P-Value is less than 0.05 hence we conclude that effect on Pain Level is significant

## Hypothesis Testing

### Hypothesis

To compare the efficacy of *Chaturbeej* caplet and Diclofenac suppository in Post-operative pain management.

### Null hypothesis

H<sub>0</sub>- *Chaturbeej* caplet is not significantly as effective as Diclofenac suppository in relieving pain in post-operative pain management.

H<sub>0</sub>:  $P \geq 0.05$ .

**Alternative hypothesis**

$H_1$ -*Chaturbeej* caplet is less significantly effective in post-operative pain management than Diclofenac Suppository.

$H_1: P < 0.05$ .

**Significance Threshold**

$P < 0.05$ .

**Statistical test for effectiveness testing**

- All the clinical variables assessed in the hypothesis testing are of non-parametric, ordinal type. As a result, a non-parametric test must be used for the within group comparison. Since, the data have been captured across multiple time-points, viz., Before treatment, Day1, Day2, Day3 a repeated measures test should be used. Hence, the non-parametric alternative of One way ANOVA for repeated measures i.e. the Friedman's test has been used for this analysis.

**RESULTS AND CONCLUSION**

Pain: Statistical analysis of Pain between control & trial group is as follow.

**Comparison Between the Groups**

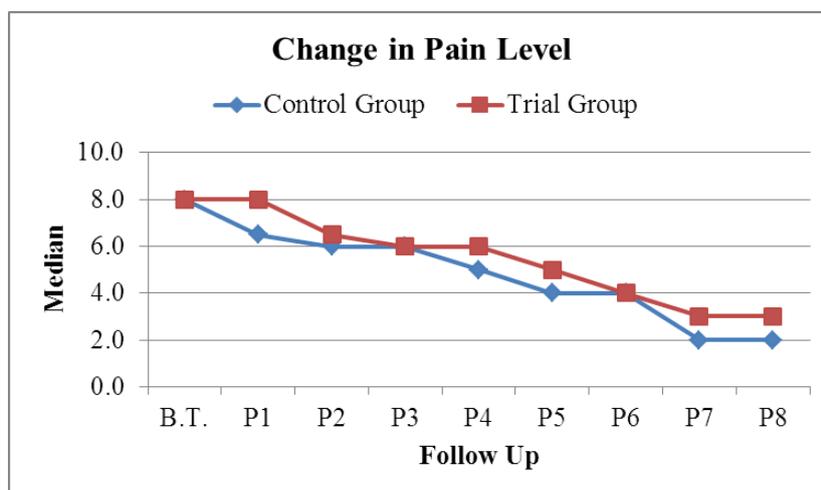
Kruskall Wallis Test.

**Table no. 9: Showing Comparison between the groups.**

	KruskallWalis Statistic	df	P-Value
BT	1.590	1	.207
P1	12.508	1	.000
P2	10.550	1	.001
P3	6.647	1	.010
P4	5.225	1	.022
P5	10.283	1	.001
P6	3.259	1	.041
P7	6.763	1	.009
P8	20.946	1	.000

For Comparison Between Control Group and Trial Group effect we have used Kruskall Wallis Test, From Above table we can observe that there was no significant difference in Control Group Pain level and Trial Group Pain level Before treatment, While for each of the

follow up P-Values are less than 0.05 hence we conclude that there is significant difference in Control Group effect and Trial Group Effect.



**Graph no. 9: Showing comparison of mean values of Pain.**

From above chart we can observe that Control Group is more effective than Trial Group Treatment.

### Interpretation

The within group comparison of Pain for the two treatment groups, viz., Diclofenac suppository treatment (control) and *Chaturbeej* Caplet treatment (trial) report significant P-Values indicating that both the treatment are effective in Post-operative pain Management. However, the P-value for Diclofenac Suppository treatment (control) is lower than *Chaturbeej* Caplet treatment(trial). Thus, it can be concluded that Diclofenac suppository is more significantly effective than *Chaturbeej* Caplet in post-operative pain management.

### Probable mode of action of drug in Trialgroup

*Chaturbeej* contains four drug that are *Methika*, *Chandrashur*, *Kalaajaji* & *Yavanika*. All these four drugs from *Shoolprashaman gun*.

*Doshagnata* of all this drug is *vatashamak*. *Vata* causes acute pain in the body, so according to the *vatashamak* activity of drug significantly reduced pain (shool).

*Roghagnata* of all drug is on *Jvar*, *shoth*, *vedana*, *Vatanuloman*, *raktashuddhikar*, so according to *roghagnata* antipyretic & analgesic action is seen.

All four drugs are *Ushnaveerya*, due to *ushnaveeryavata shaman* is happened.

Mainly chemical composition of these four drugare Tanin, saponine, carvacrol, lecithin, benzyl cyanide, hyoscyamine & atropine.

- Tanin is used in ointment and suppository for the treatment of Haemorrhoids.
- Saponine enhancing the function of several organ systems.
- Carvocrol acts as antimicrobial, anti-inflammatory, anti-tumour, anti-spasmodic.
- Benzyl cyanide acts like ano rectal, analgesic, anti-histaminic, spasmolytics.
- Hyoscyamine useful in pain control for neuropathic pain with opioids as it increase the level of analgesia.

So according to chemical composition & their action, drug is significantly good analgesic activity in pain management. And some other good effects are also there.

Hence trial group had shown significant result in post-operative pain management.

It means that we conclude that *Chaturbeej* caplet had shown significantly effective in post-operative pain management.

## CONCLUSION

1. From the overall study, it can be concluded that *Chaturbeej* caplet were significantly effective in post-operative pain management.
2. But Diclofenac suppository is significantly more effective in Post-Operative Pain management than *Chaturbeej* Caplet.

Hence final conclusion can be drawn is Diclofenac suppository is significantly more effective on Post-Operative Pain management.

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