



## INTERNATIONAL JOURNAL OF MULTIDISCIPLINARY HEALTH SCIENCES

ISSN: 2394 9406

### “A Randomised Clinical Controlled Trial To Evaluate The Efficacy Of Ajamodadi Vati And Diclofenac Sodium In Post Haemorrhoidectomy Pain Management”.

**Dr. Shubhangi. S. N<sup>1</sup>**

1. Associate Professor, Shalyatantra Department,  
LRPAMCHPGI&RC, Islampur.

**Corresponding Authors e mail Id.: [shubhasn@gmail.com](mailto:shubhasn@gmail.com).**

#### **Abstract:**

**Background:** Post operative pain management aims not only to reduce the pain intensity, but also to increase patient comfort and to improve post-op outcome. In conventional practice, we have many modes of treating the pain by lignocaine jelly 2%, glycerin packing, diclofenac suppositories which reduces the pain but they may bring delayed wound healing. Hence to avoid such complications and side effects, an effort was made in reducing post haemorrhoidectomy pain by oral medication “Ajamodadi vati”

**Settings and Design:** A Randomized Clinical, controlled, Comparative Study

**Methods and Material:** A Randomized Clinical, controlled, Comparative Study was undertaken. The patients fulfilling the inclusion criteria were selected from OPD and IPD of Department of shalyatantra of K.L.E.U. shri B. M. Kankanwadi Ayurved Hospital, Shahapur – Belagavi and were divided in two equal and identical groups consisting of 15 patients in each group by using computerized block randomization table.

**Results:** Statistical comparison of results between the groups on pain shows there is a significant difference within both the groups ( $p < 0.0001$ ), which implies that there was a reduction in pain in both the groups.

**Conclusion:** The study indicates Control drug and Trial drug both are having equal effect on reducing post-operative pain.

As an analgesic drug, both control drug and trial drug were parallel to each other. Hence Ajamodadi vati can be preferred instead of diclofenac sodium.

**Keywords** – Ayurveda; Ajamodadi vati, Tablet Diclofenac sodium, Pain, pain Management.

**Key Messages:** For an analgesic drug, both control drug and trial drug were parallel to each other. Hence Ajamodadi vati can be preferred instead of diclofenac sodium.

## **INTRODUCTION:**

*Ayurveda* came into existence to eliminate pain and suffering of living beings. *Charaka* clearly says that “*Health is happiness and disease is pain*”<sup>1</sup> and on the same basis it has been classified as “*Sukh*” and “*Dukh*” (happiness and pain). *Acharya Charaka* while classifying drugs has mentioned *Vedanasthapan drugs*. For pain in *Ayurveda* there are many terms such as *Shool, Vedana, Ruja, Dukh, Pida* etc. This *Shool* or *Vedana* is described as symptom of many diseases or as a complication of some. *Shool* is mentioned in *Harita Samhita*. *Acharya Sushruta* mentioned it as *Sula*; because by this patient of colic felt severe pain as if nail is being pierced in.

Patients having *arsha*, experience excessive pain at the time of defecation. Pain may be present in the back, hip, flanks, penis and anus.

In conventional practice, we have many modes of treating the pain by lignocaine jelly 2%, glycerin packing, diclofenac suppositories which reduces the pain but they may bring delayed wound healing<sup>2,3</sup>.

“*Ajamodadi Vati*” explained by *Acharyasharangdhara* and *Acharyachakrapanidatta*, exhibits properties like *gudashulahara*, *vedanasthapan*, *shoolahara*, *Shothahara*,

*krimigna*. So the combination of its ingredients results in minimizing the post operative pain in a better way<sup>4</sup> Hence, the present clinical study was taken, to evaluate analgesic effect of *Ajamodadi Vati* in the management of post haemorrhoidectomy pain in comparison with *Diclofenac sodium*.

**Objective:** To evaluate the efficacy of *Ajamodadi vati* and *Tab.Diclofenac sodium* in post operatively haemorrhoidectomy pain management

## **Subjects and Methods:**

**Research Design:** Grouping of patients

Total 30 patients were selected for the present clinical study, were randomly divided in two equal and identical groups consisting of 15 patients in each group by using computerised block randomisation table.

### **Group A (Study group)**

The patients of group A were given *Ajamodadi vati* 4grms. TID for post-operative 3days.

### **Group B (Control group)**

The patients of group B were given tablet *diclofenac sodium* 50mg TID for post-operative 3days.

Type of randomization – Computerized block randomization.

## **METHODOLOGY:**

### **Inclusion criteria:**

- Patients with age group between 16-60yrs of either sex..
- Haemorrhoidectomy under local anaesthesia.

**Exclusion criteria:**

- Patients suffering from severe systemic diseases such as bronchial asthma, cardiac diseases, renal failure, etc.
- Known case of Diabetes and hypertension
- Patients on anti-depressant and anti-psychotic drugs.
- Operation under spinal and general anaesthesia.

**Assessment Criteria:**

The results were evaluated by subjective parameters, mainly based on clinical observations before and after treatment by VAS grading.

**Intervention:**

Duration: Treatment was given up to post-operative 3<sup>rd</sup> day

Follow up study: Follow up of patients was done up to post-operative 3<sup>rd</sup> day.

i.e., 0<sup>th</sup> day, 1<sup>st</sup> day, 2<sup>nd</sup> day, 3<sup>rd</sup> day, to assess the effect of treatment.

Statistical Analysis: Two way ANOVAs test

**RESULTS:**

In this series of 30 patients of Arsha, divided in two groups each comprising of 15 patients. The patients of one group

were treated with Ajamodadi vati while the patients of the second group were treated with Tablet Diclofenac sodium as a standard control. In both the groups medication was given for every 8<sup>th</sup> hourly up to post-operative 3<sup>rd</sup> day. The group wise results in detail are being described separately.

Effects of Ajamodadi Vati on pain (Table No.1)

After the Medication, post-operatively for 3 days, the pain was significantly Decreased. There was significant reduction in the pain with mean difference of 0.33

Effects of Tab.Diclofenac sodium on pain (Table No.2)

After the Medication, post-operatively for 3 days, the pain was significantly Decreased.

There was significant reduction in the pain with mean difference of 0.60

Comparison of results between Study group (Ajamodadi vati) and Control group (Tab.Diclofenac sodium)

Comparison of results between the groups on Pain (Table No.3)

Statistical comparison of results between the groups on pain shows there is a significant difference within both the groups ( $p < 0.0001$ ), which implies that

there was a reduction in pain in both the groups.

Discussion:

Description of arsha available in Ayurvedic literature and definitions of piles and haemorrhoids in modern literature are similar. Therefore we can say that arsha includes piles and haemorrhoids. Though these two modern terms denote different clinical features of arsha, both may co-exist.

Anatomy-physiological aspects of anorectal region are important in understanding pathogenesis of the disease. The function of anorectal region is defecation. This function is disturbed in haemorrhoids and in turn disturbance in defecation itself may prove a causative factor for haemorrhoids.

In Ayurvedic literature, Bhaishaja, Shastra, Kshara and Agni Karma are the treatments indicated for haemorrhoids; out of these, nowadays Ayurvedic surgeons are practicing mainly Kshara and Kshara Sutra, which in turn causes pain at operated site.

Post operative pain is non avoidable thing in surgery. The treatment of post operative pain will result in real benefits to the patient and surgical units. Patients experience pain and discomfort during the immediate post operative period. One

should be aware that excessive pain medication may lead to constipation and hard bowel movements. Due to constipation, other complications may arise, which may result in severe pain at the time of bowel movement or excessive bleeding or fissure, etc.

Very minimal research work is carried out regarding Ajamodadi vati. Its having Kaphavatahara properties and mentioned in Gudashulahara which is revealed in literary part. Hence, the present study was undertaken to evaluate the efficacy of Ajamodadi Vati in the management of Arsha.

#### **DISCUSSION ON RESULTS:**

Study shows there is a significant difference within both the groups ( $p < 0.0001$ ), which implies that there was a reduction in pain in both the groups.

But there was no significant difference between the groups at all the timelines. This shows that there was pain reduction in the trial drug same as that of control drug.

Mean of each day was calculated, and total mean was taken of both groups individually, trial drug had shown more significance than the control drug. Whereas, the results between the group was non-significant. (Graph No.1)

There was 94% of reduction in pain is seen in case of Group B (Tab.Diclofenac sodium) and 96.7% of reduction in Group A (Ajamodadi vati). (Graph No.2)

This indicates, control drug and trial drug has shown equal effect on reducing post-operative pain.

Discussion on the probable mode of action: Ayurvedic Approach

As the drugs of ajamodadi vati were having the Laghu, ruksha guna and ushna vearya, it decreases Vitiated Kapha.

As it acts as Deepana and Pachana, improves appetite and Digestion.

Due to its Rechaka and Vatanulomaka karma, it reduces Vata and helps in easy laxation.

Due to its activities like Shothahara, shulahara and vedanasthapaka, it reduces pain and inflammation.

Discussion on the probable mode of action: Modern Approach

Due to presence of active principle “Cardiac glycosides”, it reduces haemorrhoidal congestion, thus decreases oedema and improves circulation. As it contains Saponin glycosides in it, is responsible for immune system and acts as anti-inflammatory. Flavonoids present in it acts as anti-oxidant and anti-inflammatory. Alkaloid present in it acts

as Analgesic; muscle relaxant; local anaesthetic. Sodium present in it, is responsible for regulating the Blood volume and stimulating neuron functions.

Due to Inhibition of prostaglandin biosynthesis, there will be reduction of pain. The same mechanism is applicable to both Tab.Diclofenac and Ajamodadi vati. Diclofenac Sodium acts as analgesic and anti-inflammatory, so it reduces pain and inflammation. Ajamodadi vati not only acts as analgesic (Shulahara) and anti-inflammatory (Shothahara), but also acts as Anti-microbial (krimigna/Jantugna); relieves constipation (Vibandhahara); Improves appetite and Digestion (Deepana and Pachana); improves Immune System (Balyakara).

#### **CONCLUSION:**

The study indicates Control drug and Trial drug both are having equal effect on reducing post-operative pain.

There was 94% of reduction in pain is seen in case of Group B (Tab.Diclofenac sodium) and 96.7% of reduction in Group A (Ajamodadi vati)

As an analgesic drug, both control drug and trial drug were parallel to each other. Hence Ajamodadi vati can be preferred instead of diclofenac sodium.

**Other Information:** CTRI Reference No. : REF/2015/01/008234

**“A Randomised Clinical Controlled Trial To Evaluate The Efficacy Of Ajamodadi Vati And Diclofenac Sodium In Post Haemorrhoidectomy Pain Management”.**

*IJMHS*; Vol. X, Issue: I, JAN-MAR 2024

Study Number/ Ethical Committee Clearance No.: BMK/13/PG/SH/12

3. Diclofenac-Rectal Suppository, <http://www.netdoctor.co.uk/medicines/100004287.html>

**REFERENCES:**

1. Shukla AV, R Tripathi; Charak samhita; 2<sup>nd</sup> ed.2000
2. Xylocaine Jelly - Clinical Pharmacology, <http://www.drugs.com/sfx/xylocaine-jelly-side-effects.html>

4. Shailaja.Srivatsav.Sharangdhara Samhita – Churna Kalpana pg.no. 187-188.

**Table No.1: Effect of Ajamodadi Vati on Pain**

| Post-operative days | Mean score |      | Mean difference | %age of Recovery | P value  | P value summary | Significant difference? |
|---------------------|------------|------|-----------------|------------------|----------|-----------------|-------------------------|
|                     | BT         | AT   |                 |                  |          |                 |                         |
| 0th day 1st dose    | 5.73       | 3.06 | 2.67            | 73.3             | P<0.0001 | *****           | Yes                     |
| 0th day 2nd dose    | 3.66       | 1.20 | 2.46            | 75.4             | P<0.0001 | *****           | Yes                     |
| 0th day 3rd dose    | 1.33       | 0.20 | 1.13            | 88.7             | P<0.0001 | *****           | Yes                     |
| 1st day 1st dose    | 2.86       | 0.93 | 1.93            | 80.7             | P<0.0001 | *****           | Yes                     |
| 1st day 2nd dose    | 2.13       | 0.40 | 1.73            | 82.7             | P<0.0001 | *****           | Yes                     |
| 1st day 3rd dose    | 2.00       | 0.46 | 1.54            | 84.6             | P<0.0001 | *****           | Yes                     |
| 2nd day 1st dose    | 1.33       | 0.20 | 1.13            | 88.7             | P<0.0001 | *****           | Yes                     |
| 2nd day 2nd dose    | 1.26       | 0.13 | 1.13            | 88.7             | P<0.0001 | *****           | Yes                     |
| 2nd day 3rd dose    | 1.13       | 0.13 | 1.00            | 90               | P<0.0001 | *****           | Yes                     |

**“A Randomised Clinical Controlled Trial To Evaluate The Efficacy Of Ajamodadi Vati And Diclofenac Sodium In Post Haemorrhoidectomy Pain Management”.**

*IJMHS*; Vol. X, Issue: I, JAN-MAR 2024

|                  |      |      |      |      |          |      |     |
|------------------|------|------|------|------|----------|------|-----|
| 3rd day 1st dose | 1.00 | 0.20 | 0.8  | 92   | P<0.0001 | **** | Yes |
| 3rd day 2nd dose | 0.53 | 0.13 | 0.4  | 96   | P<0.0001 | **** | Yes |
| 3rd day 3rd dose | 0.33 | 0.00 | 0.33 | 96.7 | P<0.0001 | **** | Yes |

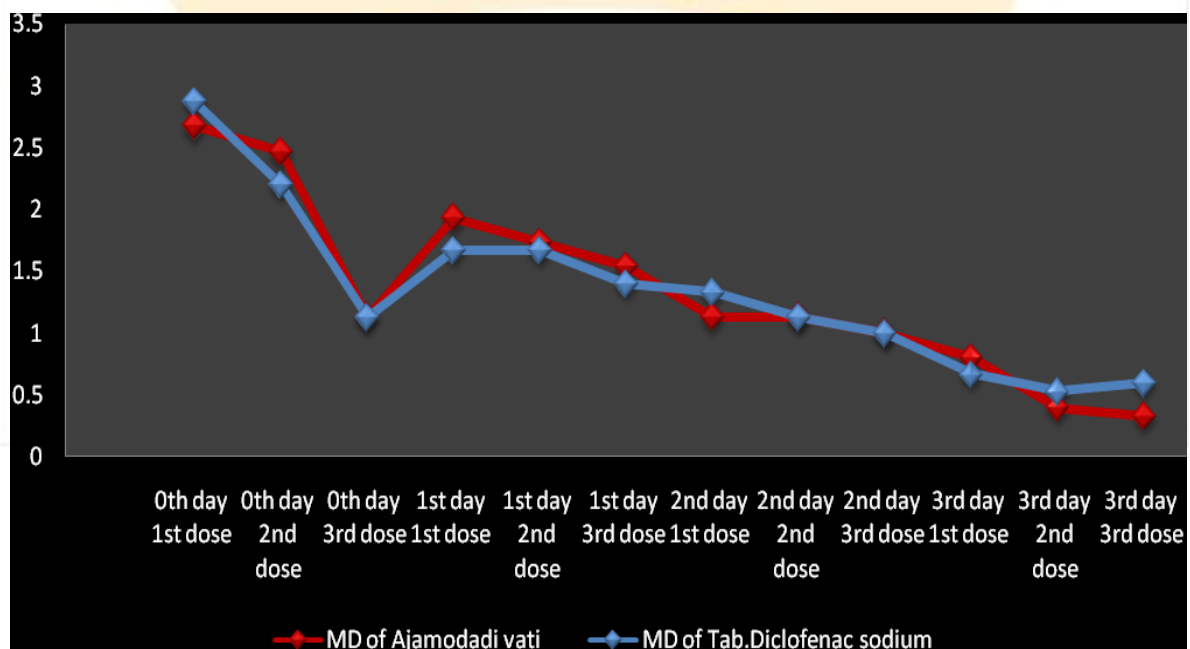
**Table No.2: Effect of Diclofenac sodium on pain**

| Post-operative days | Mean score |      | Difference of mean score | %age of Recovery | P value  | P value summary | Significant difference |
|---------------------|------------|------|--------------------------|------------------|----------|-----------------|------------------------|
|                     | BT         | AT   |                          |                  |          |                 |                        |
| 0th day 1st dose    | 5.40       | 2.53 | 2.87                     | 71.30            | P<0.0001 | ****            | Yes                    |
| 0th day 2nd dose    | 3.53       | 1.33 |                          | 78.00            | P<0.0001 | ****            | Yes                    |
| 0th day 3rd dose    | 1.53       | 0.40 | 1.13                     | 88.70            | P<0.0001 | ****            | Yes                    |
| 1st day 1st dose    | 2.80       | 1.13 | 1.67                     | 83.30            | P<0.0001 | ****            | Yes                    |
| 1st day 2nd dose    | 2.40       | 0.73 | 1.67                     | 83.30            | P<0.0001 | ****            | Yes                    |
| 1st day 3rd dose    | 1.86       | 0.46 | 1.40                     | 86.00            | P<0.0001 | ****            | Yes                    |
| 2nd day 1st dose    | 1.66       | 0.33 | 1.33                     | 86.70            | P<0.0001 | ****            | Yes                    |
| 2nd day 2nd dose    | 1.46       | 0.33 | 1.13                     | 88.70            | P<0.0001 | ****            | Yes                    |
| 2nd day 3rd dose    | 1.33       | 0.33 | 1.00                     | 90.00            | P<0.0001 | ****            | Yes                    |
| 3rd day 1st dose    | 1.20       | 0.53 | 0.67                     | 93.30            | P<0.0001 | ****            | Yes                    |
| 3rd day 2nd dose    | 1.06       | 0.53 | 0.53                     | 94.70            | P<0.0001 | ****            | Yes                    |
| 3rd day 3rd dose    | 0.86       | 0.26 | 0.60                     | 94.00            | P<0.0001 | ****            | Yes                    |

**Table No.3: Comparison of results between the groups on pain**

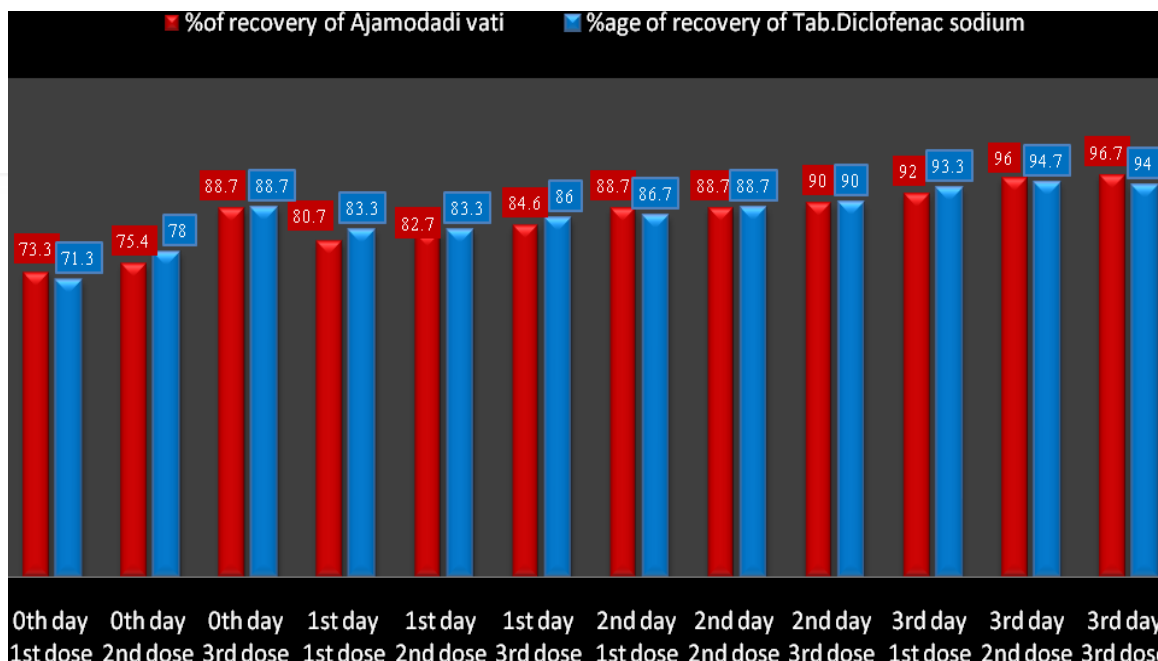
| Post operative Days | MD of Ajamodadi vati | MD of Tab.Diclofenac sodium | P value | P value summary | Significantly different? (P < 0.05) |
|---------------------|----------------------|-----------------------------|---------|-----------------|-------------------------------------|
| 0th day 1st dose    | 2.67                 | 2.87                        | 0.9754  | NS              | No                                  |
| 0th day 2nd dose    | 2.46                 | 2.2                         | 0.9754  | NS              | No                                  |
| 0th day 3rd dose    | 1.13                 | 1.13                        | 0.9754  | NS              | No                                  |
| 1st day 1st dose    | 1.93                 | 1.67                        | 0.9754  | NS              | No                                  |
| 1st day 2nd dose    | 1.73                 | 1.67                        | 0.9754  | NS              | No                                  |
| 1st day 3rd dose    | 1.54                 | 1.40                        | 0.9754  | NS              | No                                  |
| 2nd day 1st dose    | 1.13                 | 1.33                        | 0.9754  | NS              | No                                  |
| 2nd day 2nd dose    | 1.13                 | 1.13                        | 0.9754  | NS              | No                                  |
| 2nd day 3rd dose    | 1.00                 | 1.00                        | 0.9754  | NS              | No                                  |
| 3rd day 1st dose    | 0.8                  | 0.67                        | 0.9754  | NS              | No                                  |
| 3rd day 2nd dose    | 0.4                  | 0.53                        | 0.9754  | NS              | No                                  |
| 3rd day 3rd dose    | 0.33                 | 0.60                        | 0.9754  | NS              | No                                  |

**Graph No. 1: Comparison of mean of VAS of both the groups**





Graph No.2: Percentage of Recovery of Pain in Both the groups



**ACKNOWLEDGEMENT:**

Dr.B.S.Prasad, Principal, KLE University's Shri.B.M.Kankanwadi Ayurveda Mahavidhyalaya, Shahapur, Belagavi, Karnataka.

Dr.S.V.Emmi, Proffesor and HOD, Department of Shalya tantra, KLE University's Shri.B.M.Kaankanwadi Ayurveda Mahavidhyalaya, Shahapur, Belagavi, Karnataka.

Dr.Amruta.A.Wali, HOD, Department of Sangyaharana, KLE University's Shri.B.M.Kaankanwadi Ayurveda Mahavidhyalaya, Shahapur, Belagavi, Karnataka.

Dr.Ramesh.S.Killedar, Asso.professor, Department of Shalyatantra, KLE University's Shri.B.M.Kaankanwadi Ayurveda Mahavidhyalaya, Shahapur, Belagavi, Karnataka.

INTERNATIONAL JOURNAL OF MULTIDISCIPLINARY HEALTH SCIENCES