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Effect of *Shirish* versus Diclofenac Sodium in Post-Operative Pain Management - A Randomized Comparative Clinical Trial

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ABSTRACT

Introduction: Post-operative pain is physiological pain which is caused due to tissue trauma. Drugs such as NSAIDs (Non Steroidal Anti Inflammatory Drugs) and Opioids are used for post-operative pain management but are associated with their own drawbacks. *Shirish* has been in use in Ayurvedic practice for analgesia. It is known to relieve pain and can be used to supplement anesthesia and also get rid of adverse effect of modern analgesic drugs. **Aims and Objective:** To study the comparative effect of *Shirish* and Diclofenac sodium in post-operative pain management. **Materials and Methods:** Randomized clinical trial with Group A (Control Group: Tab Diclofenac sodium 50 mg as a single dose) and Group B (Trial Group: Cap Shirish 500 mg as a single dose). Those who had undergone surgeries like hernia, appendicitis operation under spinal anesthesia were selected as per inclusion criteria. Vitals, desirable effect and undesirable effect, total surgical time, the assessment criteria observed and recorded. **Results:** Cap. *Shirish* does not show any undesirable or serious ill effects and altered values of vitals as per statistical analysis. As per visual assessment scale, pain felt by Trial group was earlier than control group. **Conclusions:** *Shirish Vati* has analgesic property but its analgesic property and pain threshold capacity is lesser than those of Diclofenac Sodium.

Key words: *Anesthesia, Hernia, Appendicitis, Shirish, Pain, Inguinoscrotal Surgeries.*

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage mainly due to tissue trauma.

Post-operative pain is not avoidable in surgery. The treatment of post-operative pain results in real benefits to the patients and surgical units. Although pain has a purpose in the wider evolutionary sense, it is a largely inappropriate maladaptive response in the post-operative period, which is associated with stress and systemic complications that include pulmonary, cardiovascular and gastrointestinal ones. Uncontrolled pain may cause struggling, crying, and restlessness and may result in hematoma formation and thereby delay wound healing. Adequate pain control leads to decreased manipulation of the surgical site and thus reduces swelling, hematoma formation, and infection.[1]

Some of the analgesics are tested to pacify surgical pain namely anesthetics and analgesic. Whereas others, to pacify post-operative pain and its complications. All these drugs are categorized under opioids, NSAIDs and other synthetic and semi synthetic groups. Most of them produce a potent analgesic action but none of them are devoid of their

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known systemic and hence are used with certain limitations.

In the texts of Ayurveda, a large number of drugs are mentioned under the heading *Vedanasthāpana* (~analgesic), *Śothahara* (anti-inflammatory), *Vātaśāmaka* (controlling of *Vāta*) and *Śūlapraśamana* (pain reliever) groups and at different places with their specific analgesic actions. According to Ayurveda, vitiation of *Vāta* is the prime factor producing pain perception along with other systemic consequences such as palpitation, depression, insomnia, vomiting, irritation, hypertension, excitement etc.[2]

Analgesia is a component of anesthesia. Ayurveda drugs which relieve pain could be used to supplement anesthesia as well as get rid of adverse effects of modern drugs. Some Ayurvedic physicians use herbal preparations for analgesia. One such preparation is *Shirish Vati*. According to Ayurvedic literature, *Shirish* is *Tridoṣahara* and indicated in *Śiras* (head), *Mukha* (mouth) and *Danta* (dental) *Tvak* (skin) diseases. Chemically *Shirish* contain tanin and saponin. Therefore, on the basis of Ayurveda references indicating *Vātahara* properties of these drugs and reverse pharmacology of these drugs, this study has been taken up to provide clinical evidence of analgesic property of *Shirish Vati* comparing it with Diclofenac sodium. In the present study, *Shirish Vati*[3]is prepared in the form of a capsule contains powder of seeds.

Materials and Methods

60 patients who were to undergo inguinoscrotal operation under spinal anesthesia were randomly selected using a random number table. They were of either sex with in Shalya Tantra ward. They were divided into two groups using sequentially numbered opaque envelopes i.e., group A and group B each consisting of 30 patients of either sex. Group A (Control) was given Diclofenac sodium and group B (Trial) was given *Shirish Vati* in the form of capsule. Both control drug and trial drug were given preoperatively one day before operation and 60-90 min preoperatively and postoperatively after appearance of pain at 8hr. intervals for three days. SOS medicine was also given per group. Assessment was done using subjective and objective parameters.

Collection and preparation of drug

Ingredient of *Shirish* is leaf, flower, seed, root. *Shirish* were collected from their respective natural habitats and were authenticated. Seed of *Shirish* was dried, powdered. The resultant powder was filled in 500 mg capsules and preserved in an air tight container. Thus, *Shirish* capsule (*Churna*) was prepared with the standard preparatory methods as mentioned in the texts of Ayurveda.

Grouping of patients

After obtaining Institutional Ethical committee approval, the trial was registered the Clinical Trial Registry of India, CTRI. All 60 patients were randomly divided in two equal and identical groups consisting of 30 patients by using sequential numbering using opaque envelopes.

Groups	Group A	Group B
Drug	Diclofenac sodium	*Shirish Vati*
Sample size	30	30
Drop out	No	No
Dose(mg)	50	500
Route	Orally	Orally

Group A (Control Group)

Patients were given tablet Diclofenac sodium 50 mg as single dose orally with an ounce of plain water pre and post operatively in inguinoscrotal operation under spinal anesthesia as per the following schedule: One tablet the night before operation with 10 - 20 ml of water; one tab 60 to 90 min before operation with 10-20 ml of water. Post-operative follow up was as follows: Day 1: 50 mg Diclofenac sodium given when patient complains of pain and the drug is repeated at 8-hour intervals; Day 2 and 3: 50 mg Diclofenac sodium given at 8-hour intervals.

Group B (Trial Group)

Patients were given 3 capsules of 500 mg each *Shirish Vati* as a single dose orally with an ounce of plain water pre and post operatively in inguinoscrotal

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operation under spinal anesthesia as per the following schedule: three capsules of 500 mg each with 10 – 20 ml of water the night before operation, three capsules of 500 mg each with 10-20 ml of water 60-90 min before operation. Post-operative follow up was as follows Day 1: three capsules of 500 mg as one dose given when patient complains of pain and the drug is repeated at 8-hour intervals, Day 2 and day 3: 500 mg three capsules one dose given at 8-hour intervals.

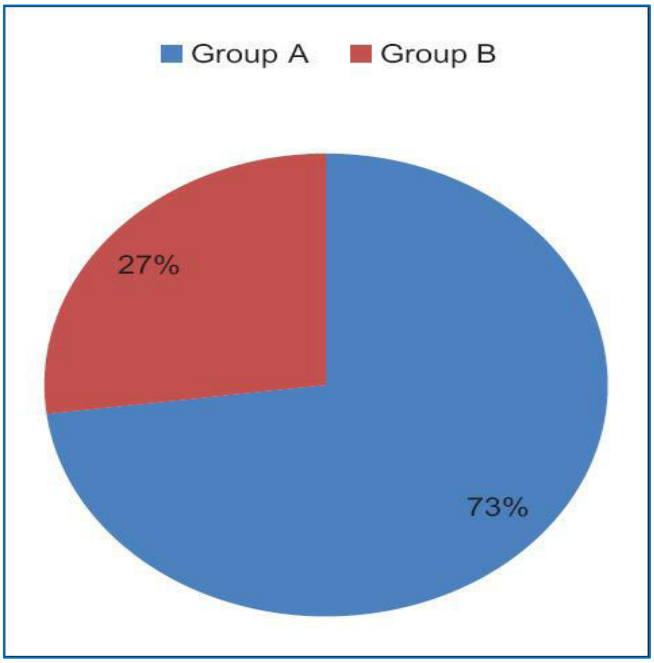
Preoperative preparation and premeditation

All the patients were assessed thoroughly and consent was taken about the proposed research work. Their age (years), weight (kg) and vital signs viz. pulse rate, blood pressure, respiratory rate, oxygen-saturation and axillary temperature were recorded. General condition, physiological and psychological conditions were also recorded. After complete satisfaction, the grouping was done as discussed earlier.

Post operatively time for first analgesic and pain before administration of first analgesic was recorded as per case proforma. Three days follow up was done according to case proforma. During this follow up, capsules *Shirish* and tablets Diclofenac sodium were given to respective groups as per drug dosage schedule. Pain assessment was done using Visual Analog Scale before every dose of control and study group medication. Effects such as sedation, apprehension, excitement, dizziness, nausea etc., were observed and recorded as per case proforma.

Results

All the data collected viz. age, blood pressure, pulse rate, respiratory rate, total surgical time, difference of visual analogue scale (VAS) 1 of first post-operative day with VAS 1 of third post-operative day and VAS 3 of first post-operative day with VAS 3 of third post-operative day between groups etc., were also recorded. Mean, standard deviation (SD), applying unpaired t-test, t-value, standard error, P value, using percentage of incidence and degree of freedom etc., were calculated. Requirement of Rescue Analgesic in both Groups are depicted.



Required of rescue analgesic in both groups

Discussion

In Ayurveda, analgesia is achieved by drugs mentioned in *Sāṅgyasthāpana Gaṇa, Vedanāsthāpana Gaṇa, Vātahara Dravya, Vātānulomana* and *Śūlapraśamana Dravya*. Mode of actions of these drugs are mainly based on *Rasa, Vīrya, Vipāka* and *Prabhāva*. *Vaidyas* use different herbal drugs in combinations for the purpose of analgesia. In the present study, *Shirish* was selected which is used for analgesia by *Vaidyas*. Capsule containing *Shirish* seed *Churṇa* which used to evaluate post-operative pain relief in inguinoscrotal operation under spinal anesthesia.[4]

Diclofenac Sodium, one of the widely used NSAIDs agent, is an insoluble compound in acidic solution, but dissolves in intestinal fluid and water. In order to eliminate the gastrointestinal adverse effects of this drug, several swellable controlled-release pharmaceutical dosage forms have been developed.

In Control group, altered mean blood pressure intra-operatively returned to basal sooner than study group. Therefore, it can be said that both drugs decrease pain and stress response preoperatively with the control drug being more effective. On the basis of these findings, it can be concluded that the study drug

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Shirish has no serious ill effects on cardio vascular system and it does not alter Blood Pressure.

Mean pulse rate during the course of the observations before premedication and after recovery from anesthesia within the group is significant in group B and insignificant in group A. In Group A, there is no change of pulse rate at the time of observation before premedication and post operatively. Hence the altered mean pulse rate during operation is treated to be basal for post-operative readings. In Group B postoperative mean pulse rate decreased compared to preoperative but still it was more than the basal pulse rate. Hence, in the Control group altered mean heart rate intra-operatively reverts to basal sooner than the study group.

Mean respiratory rate/min within both groups before premedication versus after premedication, before premedication versus intra-operative and before premedication versus after recovery from anesthesia were identical. The observations prove that there is no effect of either the study or control drugs on the respiratory rate.

The response of analgesic premedication plays a definite role during post-operative period with regard to duration of surgery. Observations recorded suggest that total surgical duration was identical in both groups and statistically insignificant when compared between the groups. The sustained release ability of Diclofenac sodium was demonstrated in an in-vivo study, showing the presence of the drug in plasma for about 14 h.

Mean VAS Scale (subjective) between the groups at corresponding times i.e. First (VAS 1), second (VAS 2) and third (VAS 3) reading at every 8hrs. of third post-operative day were observed. The results seem to suggest VAS 1 to be statistically insignificant and VAS 2, VAS 3 to be significant between the group A (Control) and Group B (study).

Pain has decreased from VAS 1 up to VAS 3 in both groups. But the reduction in the control group is more than that in the study group. Difference in VAS 1 and VAS 3 between both groups statistically insignificant and equal. Difference of VAS 1 of first post-operative day with VAS 1 of third post-operative day and VAS 3 of first post-operative day with VAS3 of third post-operative day between groups is equal and statistically insignificant. All the above proves the analgesic property of *Shirish Vati* compared to Diclofenac sodium. As VAS scale decreased on all three days between control group and study group equally, a statistically insignificant result is obtained. Except last day where VAS Scale decrease in control group is earlier than in the study group. This goes to prove the analgesic property of *Shirish Vati* and it being lesser than that of Diclofenac sodium.

Statistical comparison of difference in mean VAS Scale (Objective) between the groups at corresponding time i.e., first (VAS 1), second (VAS 2) and third (VAS 3) reading at every 8hrs. interval of first post-operative day was observed. VAS 1, VAS 2 is equal and insignificant in both groups but VAS3 is significant statistically. VAS 3 is more in Study group and that means that the patients experience discomfort. In control group, VAS 3 is zero and hence the patients experience no discomfort are completely at ease.

This shows that Control drug is associated with lesser pain than the study drug. No major difference is observed between the groups was observed on second and third day respectively and it is zero for all results in both groups. Both group patients were having no discomfort and patient completely at ease on second and third day. The above proves the analgesic property of both drugs. Difference of VAS1 of first post-operative day with VAS1 of third post-operative day which is statistically insignificant and difference of VAS 3 of first post-operative day with VAS 3 of third post-operative day between groups, both of which are statistically significant results, are obtained.

Rescue analgesic required was 27% in Study group which almost 3 times than in control group. This also shows that the study group patients felt more pain than control group in spite of the drug. This proves that *Shirish Vati* has less analgesic property than study group and it alone is not sufficient to control post-operative pain.

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Conclusion

Shirish Vati has analgesic property but it's analgesic property and pain threshold capacity is lesser than control drug. *Shirish* cap does not show any toxic effect in animals and neither does it show undesirable effects in humans. It is used solitarily, hence is not sufficient to control post-operative pain. Characterization of compounds responsible for analgesic property in *Shirish Vati* needs to be studied further to enhance the potency of *Shirish Vati* to make it a novel analgesic.

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