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

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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.
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 Vednabhar 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 postoperative 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 (40 ml TDS) with that of tab.inj.diclofenac sodium 75 mg 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 a 10 point visual analogue scale will be evaluated by taking 0 for no pain and 10 for worst excruciating pain.

**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 administering the scheduled premedication pulse rate, blood pressure, respiratory rate and psychological condition were recorded. These readings 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, 4 hr, 6 hr, 10 hr, 12 hr, 24 hr hrs. Desirable effects like analgesia and undesirable effects like nausea, vomiting, gastric irritation, flatulence, headache were also taken into account.

DRUG SELECTION & PREPARATION

- *Vednasthapan mahakashaya 40 ml TDS*  
  - Contents used in decoction: Sal, Katfal, Kadamba, Padmak, Mocharasa, Shirish Vajjul, Ashoka

METHOD OF PREPARATION OF DRUGS

- *क्षणश्वासमन्तरमण्डितार्काकल्लुपयुक्ते (श. प. १०६-१०७)*

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

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

Statistical Comparison of mean pain level (A) after 4 hours, (G) after 8 hours, (H) after 12 hours, (I) after 24 hours of therapy. 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.

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

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

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**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Diff</th>
<th>t-Value</th>
<th>P-Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I vs Group II</td>
<td>A vs B</td>
<td>0.20319</td>
<td>1.935</td>
<td>0.063</td>
</tr>
<tr>
<td></td>
<td>B vs C</td>
<td>3.88952</td>
<td>3.047</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>B vs D</td>
<td>4.26704</td>
<td>3.090</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>B vs E</td>
<td>1.58781</td>
<td>3.195</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>B vs F</td>
<td>4.3187</td>
<td>3.303</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>B vs G</td>
<td>4.29681</td>
<td>3.491</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>G vs H</td>
<td>0.54164</td>
<td>2.276</td>
<td>0.031</td>
</tr>
<tr>
<td></td>
<td>G vs I</td>
<td>0.9681</td>
<td>2.384</td>
<td>0.024</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Systolic Blood Pressure (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Group I</td>
<td>122.6±10</td>
</tr>
<tr>
<td>I</td>
<td>.8</td>
</tr>
<tr>
<td>Group II</td>
<td>125.4±12</td>
</tr>
<tr>
<td>II</td>
<td>.4</td>
</tr>
</tbody>
</table>

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**

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

<table>
<thead>
<tr>
<th>Statistical intergroup comparison of mean systolic B.P. - Table No.6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparison</strong></td>
</tr>
<tr>
<td>Group I vs Group II</td>
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<td></td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Diastolic Blood Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Group I</td>
<td>79.4</td>
</tr>
<tr>
<td>Group II</td>
<td>81.3</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Statistical comparison within group of mean diastolic B.P. - Table No.8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
</tr>
<tr>
<td>Group I</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td>Group II</td>
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</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Statistical inter group comparison of mean Diastolic B.P. - Table No.9</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparison</strong></td>
</tr>
<tr>
<td>Group I vs Group II</td>
</tr>
<tr>
<td>B vs C</td>
</tr>
<tr>
<td>B vs D</td>
</tr>
<tr>
<td>B vs E</td>
</tr>
<tr>
<td>B vs F</td>
</tr>
<tr>
<td>B vs G</td>
</tr>
<tr>
<td>G vs H</td>
</tr>
<tr>
<td>G vs I</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Effect of therapy on Pulse Rate - Table No.10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>Group I</td>
</tr>
<tr>
<td>Group II</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Statistical comparison within groups of mean pulse rate - Table No.11</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
</tr>
<tr>
<td>Group I</td>
</tr>
<tr>
<td>B vs C</td>
</tr>
<tr>
<td>B vs D</td>
</tr>
<tr>
<td>B vs E</td>
</tr>
<tr>
<td>B vs F</td>
</tr>
<tr>
<td>B vs G</td>
</tr>
<tr>
<td>G vs H</td>
</tr>
<tr>
<td>G vs I</td>
</tr>
<tr>
<td>Group II</td>
</tr>
<tr>
<td>B vs C</td>
</tr>
<tr>
<td>B vs D</td>
</tr>
<tr>
<td>B vs E</td>
</tr>
<tr>
<td>B vs F</td>
</tr>
<tr>
<td>B vs G</td>
</tr>
<tr>
<td>G vs H</td>
</tr>
<tr>
<td>G vs I</td>
</tr>
</tbody>
</table>
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.

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

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

<table>
<thead>
<tr>
<th>Pain</th>
<th>Mean Rank Group A</th>
<th>Mean Rank Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>9.20</td>
<td>9.90</td>
</tr>
<tr>
<td>Day 2</td>
<td>8.67</td>
<td>8.57</td>
</tr>
<tr>
<td>Day 3</td>
<td>8.20</td>
<td>7.90</td>
</tr>
<tr>
<td>Day 4</td>
<td>7.93</td>
<td>7.63</td>
</tr>
<tr>
<td>Day 5</td>
<td>6.00</td>
<td>6.00</td>
</tr>
<tr>
<td>Day 6</td>
<td>4.40</td>
<td>4.77</td>
</tr>
<tr>
<td>Day 7</td>
<td>3.37</td>
<td>3.20</td>
</tr>
<tr>
<td>Day 8</td>
<td>3.10</td>
<td>2.90</td>
</tr>
<tr>
<td>Day 9</td>
<td>3.03</td>
<td>2.83</td>
</tr>
<tr>
<td>Day 10</td>
<td>1.10</td>
<td>1.30</td>
</tr>
<tr>
<td>N</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

Friedman's Test

<table>
<thead>
<tr>
<th></th>
<th>130.729</th>
<th>131.787</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-Value</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>% Effect</td>
<td>85.52</td>
<td>65.14</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean Rank</th>
<th>Sum of Ranks</th>
<th>Mann-Whitney U</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>15</td>
<td>23.23</td>
<td>198.50</td>
<td>178.500</td>
<td>0.015</td>
</tr>
<tr>
<td>Group B</td>
<td>15</td>
<td>17.77</td>
<td>266.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

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

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

<table>
<thead>
<tr>
<th>Overall Effect</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked Improvement</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Moderate Improvement</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>No Change</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

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

**Type of Surgical case**

Maximum patients were of haemorrhoid i.e 21 pts, 7 patients were of fissure in ano, 2 patient 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 nd 1 to 24 hr was significant. Same effect observed in diastolic blood pressure.

Intergroup comparison shows that there is significant change 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

Intergroup 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 *Vednasthapak* 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 Vednasthapak.
- 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 vednasthapak, 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 & kaphapittashamak property work as vednasthapak, shothhar, vranashodhak and vranaropak. The stem bark contains flavones & isoflavones possess analgesic and antipyretic activity.
- Mocharas have Madhur, sheet & kaphapittashamak property work as vednasthapak, shothhar, daphrashman, its stem bark contains flavones & isoflavones possess analgesic and antipyretic activity.
- Shirish have tikshna, tikta, Madhur, katu, ushna & tridoshshamak property work as vednasthapak, shothhar, Vishaghan.. A novel phenolic glycosides, albizin and flavanols epicatechin, procyanidin, saponins possess anti-inflammatory, anti-microbial activity and antihistaminic activity.
- Jalvetas possess Kashaya, tikta, katu and kaphapittashamak property work as vednasthapak, medhya, jwarghan &
daughters, its bark contain delphinidine, salicilic acid, phenolic glycosides etc. having anti-inflammatory and analgesic activity.

- Ashoka have tikta, katu & kaphapittasham property work as vednasthapak, shothhar, vishaghahan. 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 observe 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**

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 operatively. However NSAIDs are generally considered to be inadequate as sole agents in the control of immediate postoperative pain, besides having various systemic side effects viz. gastric ulceration, G.I. bleeding, perforation, adverse renal effects caused by the reduction in synthesis of renal prostaglandins, various degree of cognitive dysfunction, confusion, behavioural disturbances and dizziness, 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 bleeding.

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 ” posses 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

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