A CLINICAL STUDY OF THE ANALGESIC EFFECT OF SHIGRU TWAKA GHANA VATI IN POST-OPERATIVE PAIN MANAGEMENT

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ABSTRACT

Mankind has since its origin battled with the distinct physical feeling of unease and over the years nomenclated that particular feeling as “pain”. With the technological advent many attempts for newer modes of virtually painless surgical techniques and equipment were made thus bearing testament to the importance of pain management. Effective post-operative pain management has always been a struggle for the most excellent of surgeons right from the age of the great Acharya Sushruta. This struggle gave birth to many drugs by modern science such as NSAID e.g. Aceclofenac. These drugs though potent in pain relieving properties caused many side effects such as nausea, vomiting, dyspepsia, gastritis, triggering asthmatic attacks in sensitive patients, various gastrointestinal conditions, opiates addiction etc. and in addition had a long list of contraindicative clauses such as uncontrolled hypertension, myocardial infarction, bypass surgery, peptic ulcers etc. Thus the need to discover a safer, natural, herbal, cost effective, abundantly available drug formulation that relieves pain without causing side effects. Ayurveda in its scriptures described a drug that fulfils all these criterions namely SHIGRU. Inguinal hernias are surgical problems that are handled in day to day operative procedures and in this surgery the common intensity of tissue injury provides a uniform group of samples for study. 32 patients were given Shigru Twaka Ghana Vati (250mg) in dose 2 B.D after breaking NBM on post-operative day for 7 days. Pain relief was assessed using VAS scale and significant pain relief was seen at the end of study.

KEYWORDS: Pain management, Inguinal Hernia, Shigru Twaka Ghana Vati, VAS scale.
INTRODUCTION

The International Association for the Study of Pain (IASP) says that pain is “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” Pain is one of the oldest and most common symptoms to have ever agitated the human body but still challenges eminent surgeons to this date. The perception of pain in every individual is complex and is controlled by a variety of variables. With the technological advent that propelled this era, attempts for newer modes of virtually painless surgical techniques and equipment along with safe anaesthesia were made thus bearing testament to the importance of pain management. This technological advance has led to a marked increase in operative procedures irrespective of age, gender and adjuvant pathologies of the patient.

Effective post-operative pain management has always been a struggle for the most excellent of surgeons right from the age of the great Acharya Sushruta himself. The main function of the sensory system in our body is to guard and keep up pain homeostasis.

The chore of medicine is to preserve and restore patient’s health and to minimize their suffering. This struggle gave birth to a plethora of drugs by modern science such as analgesics (acetaminophen), NSAID\(^1\) (Aceclofenac, Ibuprofen, Naproxen, aspirin), opioids (codeine) etc.

These drugs though potent in pain relieving properties caused many side effects on short term as well as long term usage such as nausea, vomiting, dyspepsia, gastritis, triggering asthmatic attacks in sensitive patients, various gastrointestinal conditions, opiates addiction etc. and on the other hand had a long list of contraindicative clauses such as uncontrolled hypertension, myocardial Infarction, bypass surgery, peptic ulcers, coronary artery disease, asthma, past stroke, kidney disease etc. to name a few.

The above mentioned list gives us more than enough impetus to discover a safer, natural, herbal, cost effective, abundantly available and potent drug formulation that relieves pain without causing hordes of side effects.

SHIGRU has been mentioned in Ayurveda text as having analgesic properties\(^2\), in addition to this modern research has attributed it properties like nourishing the immune system, promoting healthy circulation, supporting normal glucose levels, giving natural antiaging
benefits, promoting healthy digestion, promoting heightened mental clarity and encourages balanced metabolism.

Inguinal hernias are surgical problems that are handled in day to day operative procedures and in this surgery the common intensity of tissue injury provides a uniform group of samples for study in both intervention and control group so this was an apt surgical procedure for this research study.

Hence this research is a sincere effort to highlight the analgesic effect of Shigru in Post-operative pain management as a natural, herbal, abundantly available and cost effective drug in post-operative pain management.

AIM OF STUDY
To study the analgesic effect of SHIGRU TWAKA GHANA VATI in Post-operative pain management.

MATERIAL AND METHODS
Selection of Patients: An open clinical trial was conducted at Shalyatantra I.P.D of R.A Podar Ayurveda College, Worli, Mumbai-18. A total of 32 patients of Post-operative Inguinal hernia were randomly selected with different pain scale intensity in this study.

DRUG: SHIGRU
Latin name – Moringa Oleifera Lam.
Family - Moringaceae
English name – Horse radish tree, Drum-stick tree
Sanskrit - Shobhanjana, Bahola, Sakapatra
Gana - Charaka- Krimighna, Svedopaga, Shirovirechanopaga, Katuka Skanda
Sushruta - varunadi, Shirovirechana.

Part used: Shigru Stem Bark.[3]

Inclusion Criteria
1) Age: 16 to 75 years.
2) Patients to be selected irrespective of their gender, religion and socio-economic status.
3) Post-operative patients especially of Inguinal Herniorrhaphy and Hernioplasty.
4) Patients ready to abide trial procedure & to give informed written consent.
Exclusion Criteria
1. Patients who are Immuno-compromised (HIV positive) or with tuberculosis, Asthma, HBsAg positive, uncontrolled Diabetes Mellitus and uncontrolled hypertension.
2. Pregnant females and lactating mothers.
3. Unwillingness to participate in the study.
4. Psychologically impaired patients.

Withdrawal Criteria
1. If any patient developed any adverse effects or any other complication during study or did not responding to treatment with aggravation of pain then the Patient was withdrawn from the study with replacement by another patient & violated patient was shifted for further active management.
2. If patient did not co-operate and refused treatment.

Plan of Study and Treatment
- It is an Open Randomized Clinical Study
- Proforma compiled with detailed clinical history and physical exam of the patients.
- After confirming the diagnosis of Inguinal hernia of 32 patients, appropriate Surgical Procedure was performed.
- Ghana Vati of the drug SHIGRU was prepared under the guidance of the “Bhaishajyakalpana” Department of Podar institute by the method mentioned in the classical text reference of Sharangdhar Samhita, Madhyamkhand.[4]

METHOD
No. of patients- 32
Drug- SHIGRU TWAKA GHANA VATI (250mg)
Dosage- 2 Tablets twice a day (2 B.D) after lunch and dinner with Luke warm water after breaking NBM on post-operative day for 7 days.

Follow Up: During 7 day of duration of study follow up was taken on day 0 (after breaking NBM), 1st, 2nd, 3rd, 4th, 5th, 6th and 7th day. Depending on the pain intensity of every patient observations were made in the case record form with VAS (visual analogue scale). All patients received same duration treatment.
Criteria for Assessment

Visual Analog Scale (5) was used to get an assessment of pain relief after each sitting.

VISUAL ANALOG SCALE are rated as

0----1------- 2------- 3------- 4------- 5------- 6------- 7------- 8------- 9------- 10

0 - No pain, 1-3: Mild pain, 4-7: Moderate pain, 8-10: Severe pain

OBSERVATION, RESULTS AND DISCUSSION

Out of 32 patients, 3 patients were in the age group of 20-30 years (9.375%), 9 patients were in the age group of 31-40 years (28.12%), 7 patients were in the age group of 41-50 years (21.85%), 10 patients were in the age group of 51-60 years (46.87%), 3 patients were in the age group of 61-70 years (9.375%).

Out of 32 patients, all 32 were male i.e. 100%.

Out of 32 patients, occupation of 7 pts was Service (21.18%), occupation of 15 was Worker (46.87%), 3 were students (9.375%), 3 were Drivers (9.375%), 4 were Retired personnel (12.5%).

Out of 32 patients, 5 patients were alcohol addicts (15.62%), 6 patients were tobacco addicts (18.75%), 8 were addict of both alcohol and tobacco (25%), 10 patients were Smoking addicts (31.25%), 3 patients were non addicts (9.375%).

Out of 32 patients, 16 patients had Right Inguinal Hernia (50%), 15 patients had Left Inguinal Hernia (46.875%), 1 patients had Bilateral Inguinal Hernia (3.125%).

Statistical analysis of the effect of therapy on subjective parameter of pain by wilcoxon signed rank test

Wilcoxon matched-pairs signed-ranks test

Summary of Data

<table>
<thead>
<tr>
<th>Parameter:</th>
<th>Pain BT</th>
<th>Pain AT</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean:</td>
<td>7.000</td>
<td>2.531</td>
<td>4.469</td>
</tr>
<tr>
<td># of points:</td>
<td>32</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Standard deviation:</td>
<td>1.164</td>
<td>1.000</td>
<td>0.164</td>
</tr>
<tr>
<td>Standard error:</td>
<td>0.2058</td>
<td>0.1488</td>
<td>0.1419</td>
</tr>
<tr>
<td>Minimum:</td>
<td>5.000</td>
<td>1.000</td>
<td>3.000</td>
</tr>
<tr>
<td>Maximum:</td>
<td>9.000</td>
<td>4.000</td>
<td>6.000</td>
</tr>
<tr>
<td>Median:</td>
<td>7.000</td>
<td>2.500</td>
<td>4.500</td>
</tr>
<tr>
<td>Lower 95% CI:</td>
<td>6.580</td>
<td>2.228</td>
<td>4.352</td>
</tr>
<tr>
<td>Upper 95% CI:</td>
<td>7.420</td>
<td>2.835</td>
<td>4.585</td>
</tr>
</tbody>
</table>

Calculation details:

- Sum of all signed ranks (W) = 528.00
- Sum of positive ranks (T+) = 528.00
- Sum of negative ranks (T-) = 0.000
- Number of pairs = 32
- Nonparametric Spearman correlation coefficient (r) = 0.7270

The P value is < 0.0001, considered extremely significant.
DISCUSSION
In Ayurvedic texts Shigru per se is described as a potent pain subsidiser (पर्फर्मिंग) according to Acharya Bhavprakasha. Also according to the Doshaj theory of Ayurveda, pain occurs due to local accumulation of Dosha at site of injury.\(^7\) As Shigru is Vata and kapha shamak it reduces pain at site of injury due to operative procedure. Also Shigru is Usna veerya and this too helps it reducing the vitiated vata and thereby causing effective pain management at operative site. On further phytochemical evaluation of stem bark of Shigru it is seen that it contains alkaloids, flavonoids, carotenoids, β-sitosterol, moringine & moringinine which inhibits Cyclooxygenase-2 (COX-2) and lipoxygenase, further leading to Inhibition of prostaglandins and leukotriene synthesis that in totality leads to effect Analgesia at site of Injury.

**Total effect of therapy**

<table>
<thead>
<tr>
<th>Pain Relief</th>
<th>No. of Patients n=32</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Relief</td>
<td>3</td>
<td>9.375</td>
</tr>
<tr>
<td>Marked Relief</td>
<td>26</td>
<td>81.25</td>
</tr>
<tr>
<td>Mild Relief</td>
<td>3</td>
<td>9.375</td>
</tr>
<tr>
<td>No Relief</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

- Out of 32 Patients, patients CURED were 3 (9.375%),
- Marked Pain Relief was seen in 26 patients (81.25%),
- Mild Pain Relief was seen in 3 patients (9.375%) and
- No Pain relief was seen in none.
Thus Shigru Twaka Ghana Vati stands as a potent Analgesic in Post-operative pain management as it is easily available, cost effective, natural and safe analgesic.

BIBLIOGRAPHY