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A prospective clinical study to evaluate the role of “Ayugesic” Guda Varti for pain management in post operative cases of Open Haemorrhoidectomy

Dr. Mayur Pawaskar¹, Dr. Aaliya Khan², Dr. Amarprakash Dwivedi³.

¹Associate Professor, ²Post Graduate Scholar, ³Professor & HOD, Department of Shalyatantra, D. Y. Patil School of Ayurveda, Nerul, Navi Mumbai, Maharashtra, INDIA.

ABSTRACT

Pain can be described as any physical suffering or discomfort caused by an illness or injury. Pain is a symptom which affects a patient mentally as well as physically. It is an unpleasant sensory and emotional experience arising from actual or potential tissue damage. In Ayurveda various terms such as *Ruja*, *Vedana* and *Shoola* are commonly used for pain. Amongst all the cases operated for ano rectal diseases miligan morgan’s haemorrhoidectomy has the maximum post operative pain. Keeping in mind this post-operative pain and limitations for giving oral medication in the immediate post operative period we have chosen to use Ayugesic Suppository made up of *Vedana Shamak* and *Shoolhara Dravya* mentioned by *Acharya Sushruta* for *Vedana Shamana*.

Key words: *Ayugesic, Guda Varti, Suppository, Haemorrhoidectomy.*

INTRODUCTION

In Ayurvedic texts, various terms such as, *Ruk*, *Ruja*, *Vedana* and *Shoola* are commonly used for pain, however, ‘*Shoola*’ is more appropriate term amongst all which means - a condition with state of discomfort to body and mind. Thereby, stating the definition of *Shool* as experience similar to driving a nail into the body of the person.^[1] It has been further elaborated that out of *Tridoshas*, vitiated ‘*Vata*’ is the main causative factor responsible for all painful conditions.^[2] This vitiation of *Vata* occurs in two ways, viz. *Dhatukshyajanya Vataprakopa* (increased catabolism) and *Margavarodhjanya Vataprakopa*

(increased catabolism) and *Margavarodhjanya Vataprakopa* (channel obstruction).^[3] Furthermore, the ‘*Ruksha*’ (Dryness) and ‘*Chala*’ (Vibrations) *Gunas* (characters) of *Vata* are mainly involved in the manifestation of pain.

Management of Pain in Ayurveda

Pain management in Ayurveda has a holistic view which incorporates several therapeutic procedures and behavioral modifications under the light of basic principles narrated in Ayurveda. Hence, prescription writing for pain in Ayurveda is varied as Ayurveda considers pain as subjective phenomenon which includes therapy to body and mind both. Pain has been utmost importance even in Ayurveda offering varied treatments to cure the same. In spite of recent advances in pain treatment including anesthesia, its management still remains challenged. It is hence mandatory to explore the concept of pain and practical utility requiring establishment in pain care reconnoitered in Ayurveda.

In Ayurveda, pain is not considered as a separate entity from *Vranas* and disease. Though *Acharya Sushruta* told *Shashti Upakramas* for treatment of

Address for correspondence:

Dr. Aaliya Khan

Post Graduate Scholar, Department of Shalyatantra, D. Y. Patil School of Ayurveda, Nerul, Navi Mumbai, Maharashtra, INDIA.

E-mail: aaliyakan6631@gmail.com

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Vrana, most of the technique help of the management of pain.

In literature of Ayurveda all *Samhitakaras* explained causes of pain, characters and its managements under respective orders and treatment. But in *Sushruta Samhita* it is explained as important troublesome symptom of all types of *Vranas* and there is detailed description about its management. *Shoola* is the main feature in *Vrana*. The plan of treatment of *Shoola* is told in *Shastiupakrama* by *Sushruta*.

Understanding concept of pain through modern perspective

Classification of Pain

Pain can be classified as per Duration (Acute, Subacute and Chronic); Nociceptive Pain, Neuropathic Pain, Psychogenic Pain, Break through Pain (ex., Oncological pain), Pain asymbolia (ex., Diabetic Neuropathy). Nociceptive type of Pain is caused when noxious stimuli is perceived by the free nerve endings of afferent sensory nerve axon. From Anatomical point of view, Nociceptive Pain can be classified as per the axons involved in perception of pain as Fast pain (mediated by A δ fibre) which is sharp and Slow Pain (mediated by C fibre) which is diffuse dull aching. Apart from A δ and C fibres, A β fibres carry non-noxious stimuli.^[4] From Location point of view Nociceptive Pain is classified as Somatic (superficial and deep) and Visceral. From Receptor point of view, Nociceptive Pain is classified as Thermal (Transducer such as TRPV1), Mechanical (receptors responding to excess pressure), Chemical (receptors responding to chemicals like capsaicin), Silent (receptors responding only when inflammation sets in) and Polymodal (many neurons performing single function).^[5]

Pain Sensitization Mechanism

The Ascending Spinothalamic tract (sensory afferent neuron system) pathway helps us to understand conduction mechanism of Pain (lateral tract- A δ and C Fibres), Pressure (ventral tract Ruffini endings), Temperature (lateral tract).^[6-7] Similarly, the Gate Control Theory of central Pain Modulation and Descending modulation of Pain (Efferent Analgesic

system) is an alternative mechanism of understanding pain sensitization mechanism.^[8-10] Moreover, the role of noxious stimulus altering the conformation of proteins (G-Protein Coupled Receptors)^[11] in the cell membrane of A δ and C fibres and the role of inflammatory pain mediators such as Serotonin (5 HT), Bradykinin, Leukotrienes, Prostaglandins etc. helps in understanding the sensitization mechanism of pain in depth.^[12]

Management of Pain

According to Pain Care Bill of Rights, USA, the patient suffering from Pain have right to get thoroughly assessed and promptly treated.^[13] To address this concern, there are four main treatment groups viz., Neuropathic Pain, Muscle Pain, Inflammatory Pain and Mechanical / Compressive Pain. Pharmacological Management of these groups is categorized under Non steroidal anti inflammatory Drugs (NSAIDs), Opioid Analgesics, Adjuvant Drugs like Muscle relaxants, anxiolytics etc.

Post operative pain management

Post operative pain management is a challenge for every Surgeon and Successful Post operative pain management is the need of the hour. There are multiple modes of administration for analgesics in the post operative period. In the immediate post operative period patient is kept NBM for 6 hours, so there is a limitation to give oral analgesics moreover even after 6 hours oral analgesics are known to cause gastric irritation leading to nausea and vomiting.

AIMS AND OBJECTIVES

Aim:

A prospective clinical study to evaluate the role of "Ayugesic" *Gudavarti* for pain management in post operative cases of open haemorrhoidectomy.

Objective

1. To validate the ancient mode of treatment in this scientific era.
2. To provide cost effective, analgesia in the form of a *Gudavarti*

MATERIALS AND METHODS

After authentication of all drugs *Kwatha* was prepared as per *Bhashajya Ratnawali* and then *Ghruta Siddhi* was done from *Kwatha* and after adding bee wax moulding was done and Ayugesic Suppository was prepared of each 2gm.^[14-15]

Table 1: Ingredients of drug

Dravya	Latin name	Rasa	Guna	Virya	Vipaka	Karma
<i>Bilva</i>	<i>Agele marmelos</i>	<i>Tikta, Kasha ya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Deepana, Pachana, Arshoghna, Grahi</i>
<i>Agnim antha</i>	<i>Clerodendrum phlomid i</i>	<i>Katu, Tikta, Kasha ya, Madhura</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphavata shamaka</i>
<i>Shyonaka</i>	<i>Oroxylum indicum</i>	<i>Madhura, Tikta, Kasha ya</i>	<i>Laghuru ksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphavata shamaka</i>
<i>Bhrihati</i>	<i>Terminalia bellirica</i>	<i>Kasha ya</i>	<i>Laghu Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kaphapitt A Shamaka</i>
<i>Kantakari</i>	<i>Solanum Surattense</i>	<i>Katu Tikta</i>	<i>Laghu Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Shothahara Shoolhara</i>
<i>Shaliparni</i>	<i>Desmodium gangeticum</i>	<i>Tikta</i>	<i>Guru Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridoshas hamaka</i>
<i>Prishniparni</i>	<i>Uraria picta</i>	<i>Tikta, Madhura</i>	<i>Laghu</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridoshas hamaka</i>
<i>Gokshura</i>	<i>Teribulus terrestris</i>	<i>Madhura</i>	<i>Guru Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vatapitta shamaka</i>
<i>Shallaki</i>	<i>Boswellia sacra</i>	<i>Tikta, Katu, Madhura</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphapitt A Shamaka</i>
<i>Mochrasa</i>	<i>Bombax malabar</i>	<i>Kasha ya</i>	<i>Laghu, Snigdha,</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Kapha Pitta</i>

	<i>icum</i>		<i>Pichchila</i>			<i>Shamaka</i>
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Methodology

Source of data

D . Y. Patil Ayurved Hospital. Samhita's and modern books of surgery, Pharmacy attached to college for the preparations of the drugs, international and national medical journal and surgical journals and magazine's , OPD , IPD , Labs , X-Ray , other provisions of the hospitals were availed to do this intended work.

Ethical Clearance- Ethical clearance was taken from ethical committee of Pad.D.Y. Patil Ayurvedic Hospital.

Consent- An understanding was given to the patients about the trial and a written consent was taken from the patients.

Sample size- 50 patients were selected for the trial.

Material/Drug- For this clinical study important materials which were used in the study was *AYUGESIC Gudavarti*

Site of administration and dosage of Gudavarti- 2 Vartis (2gm each) Per Rectum immediate post operative followed by 12 hourly followed by 24 hourly on 1 day followed by sos dose on 2nd, 3rd, 4th, 5th day.

Storage of Gudavarti- Air tight (Alluminium foil) in cool and dry place.

Follow up- Patients were assessed every day for 5 days.

Duration of study- 20days

Inclusion criteria

- Post operative haemorrhoidectomy cases
- Age - between 21 years to 60years
- Gender - Both male and female

Exclusion criteria

- Patients who are unfit for open haemorrhoidectomy will be excluded for this study.

- Ulcerative colitis
- Crohn’s disease
- Rectal Prolapse
- CA Rectum
- HIV positive
- HbsAg positive

Laboratory investigations

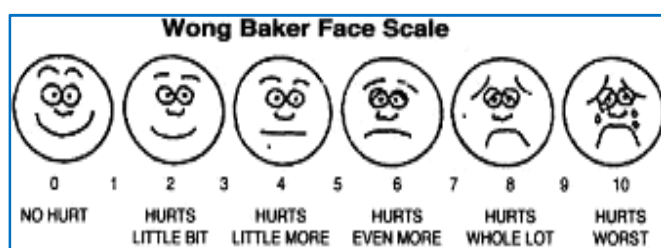
- CBC
- ESR
- HIV
- HbsAg
- BSLF
- PPBS
- Urine routine and microscopic

Assessment Criteria

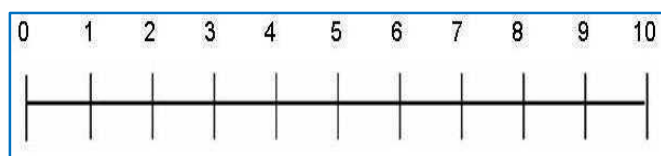
Assessment had been made with the following parameters.

Subjective Parameters

Pain- pain assessment was done on the basis of visual analogue scale.



Gradation chart for subjective parameters



OBSERVATIONS AND RESULTS

A total number of 50 patients were screened for the study. All the patients were examined before and after treatment. The data recorded under the demographic data.

Table 2: Showing no. of patients and time for pain reduction after insertion of suppository.

SN	No. of Patient	Decrease in pain
1.	18	1 Hour
2.	13	30 min
3.	06	45 min
4.	09	40 min
5.	04	2 hour

Table 3: Showing no. of patient and time of onset of pain.

SN	No. of Patient	Onset of pain
1.	14	5 Hour
2.	17	6 Hour
3.	17	7 Hour
4.	02	8 Hour

Table 4: Showing no. of patients and total no. of suppositories used

SN	No. of Patient	Total No. of Suppositories
1.	20	5
2.	14	6
3.	6	4
4.	7	7
5.	3	8

RESULT

The result were found highly significant during our clinical study out of 50 patients we had observed that there was highly significant decrease in pain. This

graphical presentation shows decrease in the pain before and after treatment.

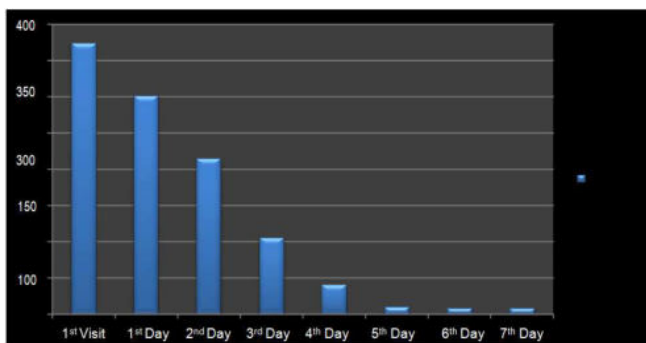


Table 5: Showing effect of AYUGESIC suppository on pain

Title	BT	AT
Mean	7.48	0.16
Standard deviation (SD)	0.7887	0.4677
Sample size (N)	50	50
Std. error of mean (SEM)	0.115	0.0665
Lower 95% conf. limit	7.256	0.02694
Upper 95% conf. limit	7.704	0.2931
Minimum	6.000	0.000
Median(50 percentile)	8.000	0.000
Maximum	8.000	2.000
Normality test KS	0.4051	0.5138
Normality test P value	<0.0001	<0.0001

Observations was noted and result was calculated statistically which showed p value < 0.0001 which is highly significant.

DISCUSSION

50 patients were registered for the study. All the patients were subjected through pre-clinical laboratoric investigation and undergone through Haemorrhoidectomy. All patients appeared for the

assessment of the results. After scrutinizing the whole literature of Ayurveda and Modern Medicine, the subjective parameters for clinical assessment like pain, all patients were subjected to administered to 2 Ayugesic Suppositories in immediately post operative followed by 2nd dose 12 hourly and 3rd dose after 24 hourly and followed by SOS when required and patients were observed for decrease in pain and final assessment was done. It was seen that after insertion of suppository immediate post operatively and once the anaesthesia effect is gone the duration onset of the pain was increased of about 2-3 hours once the anaesthesia effect is gone and once pain was started then again the 1 suppository was inserted which disintegrated completely within an hour and clinically it was observed that the pain started to reduce in 30minutes to 1hour. It is seen that per rectal action of drug was faster than oral route with no adverse reaction or discomfort.

Pain reduction time: It was observed that out of 50 patient in 18 patient pain started to reduce in 1 hour, in 13 patient 30 minutes, in 06 patient 45 minutes, in 09 patient 40 minutes and in 04 patient in 2 hour pain started to reduce.

Pain onset time: It was observed that out of 50 patient in 14 patient onset of pain was 5 hour, in 17 patient onset of pain was 6 hour, in 17 patient onset of pain was 7 hour and in 02 patient onset of pain was 8 hour.

No. of suppositories used: It was observed that out of 50 patient in 20 patient No. of suppositories used were 05, in 14 patient No. of suppositories used were 06, in 06 patient No. of suppositories used were 04, in 07 patient No. of suppositories used were 07 and in 03 No. of suppositories used were 08.

Probable mode of action

In cases of nausea and vomiting act taking medication orally may induce emesis so that drug is vomited before it absorbed. Irritation to the stomach and small intestine associated with certain drugs can be avoided. Hepatic first pass elimination of high clearance drug may be avoided partially. Its contact

with digestive fluid is avoided, thereby preventing acidic and enzymatic degradation of some drug.

By screening the ingredients of *AYUGESIC* suppository it can be seen that it gives relief in pain post operatively in haemorrhoidectomy caes after administration per rectaly. It melts at 36°C and disintegrates within 30 minutes to 1 hour and absorbs through external haemorrhoidal veins and by passes liver and goes into the porto systemic circulation and acts faster than oral route.

CONCLUSION

In *Shastra Karma* we include haemorrhoidectomy for 3rd and 4th degree prolapsed haemorrhoid which causes severe pain post operatively. Pain has been utmost importance even in Ayurveda offering varied treatments to cure the same. And this study shows significant effect in pain management in post operative cases of haemorrhoidectomy. *Ayugesic* suppository prepared by using of *Vatashamak* and *Vednasthapak Dravya* is found very effective in the context of pain (*Shool*). During the observation we can see that after using *Ayugesic* suppository pain was reducing and it was very convenient method to reduce pain in post operative NBM period. During our clinical study none of patient had developed any adverse drug reaction, no side effect was seen.

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