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# An Open Labelled Prospective Cohort Study To Evaluate The Haemostatic Effect Of Polyherbal Nanogel In The Management Of Arshas (Hemorrhoids)

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***Abstract:***

*Arshas (Hemorrhoids) are the dilated veins within the anal canal formed by Superior, Inferior & Medial rectal veins because of downward sliding of the anal cushion due to straining. The disease is common among age group between 30-65 years with a prevalence rate of 4.4%. Treatment advancements like LHP, DGHAL, sclerotherapy & hemorrhoidopexy are less invasive & painless but has high reoccurrence rate. Being difficult to access the position of the colon, the drugs are targeted to the site by formulating the drug molecule in semi solid form with suitable polymers. The snigdha, tikshna & lekhana guna of Kasisadi Taila, helps in reducing size, pain & bleeding and Lajjalu (Mimosa pudica) being a raktstambhaka proves beneficial in Arshas (Hemorrhoids), when combined in a nanogel form helps in achieving safe & effective drug administration. The polyherbal nanogel was prepared by collecting the raw drug, drying, pulverising & converting it into nanogel. A group of 15 patients from Shalya Tantra OPD of Ayurveda College Coimbatore having 1st, 2nd & 3rd degree Arshas (Hemorrhoids) were selected for the study and the nanogel prepared out of Lajjalu (Mimosa pudica) & Kasisadi Taila was applied once daily for 7-15 days regularly in a dose of 200mg. The assessment on 21st day showed significant results in reducing bleeding, pile mass, pruritis & mucoid discharge, proving Polyherbal Nanogel is low-cost, non-invasive, safe & efficient for Arshas (Hemorrhoids).*

***Keywords: Arshas, Hemorrhoids, Lekhana, Raktastambhaka, Tikshna***

**Introduction:**

*Arshas* (Hemorrhoids) are abnormally enlarged anal cushions containing arteriovenous anastomosis occurring in 3, 7 & 11 o'clock positions. It develops due to abnormal downward displacement of the anal cushions residing in left lateral, right posterolateral, right anterolateral aspect of the anal canal.[1] causing venous dilatation. Other risk factors are constipation, straining & diarrhoea.

The prevalence rate of *Arshas* (Hemorrhoids) is about 4.4% worldwide, mostly seen between 30-65 yrs of age group.[2] Because of its position at the end of the anal canal, it is difficult to access the colon. The current technique of targeting drugs to the site is achieved formulating the desired drug molecules in a semi solid dosage form with suitable polymers to be administered directly into the anal canal.[3]

The *snigdha*, *tikshna* & *lekhana guna* of *Kasisadi Taila*, helps in reducing

size, pain & bleeding and *Lajjalu* (Mimosa pudica) being a *raktstambhaka* proves beneficial in *Arshas* (Hemorrhoids). When these are combined in a nanogel form, a safe & effective drug administration can be achieved[5,6] bypassing the disadvantage of oral route and maintaining plasma drug level consistently due to which, the action will be prolonged.[7,8] The production of formulation will be better & cost effective in comparison with oral dosage form.

**Disease Review:**

The word Haemorrhoids is derived from Greek word 'Haima' (bleed) & 'Rhoos' (flowering), which means bleeding. It is also called as piles derived from Latin word 'Pila' meaning a ball.[1]

Haemorrhoids are the dilated veins within the anal canal in sub-epithelial region formed by radicals of superior, medial & inferior rectal veins. It is the result of downward sliding of anal cushions abnormally due to straining or other causes. Hemorrhoids are classified into Internal, External & Interno-external, with Primary occurring at 3,7,11 o'clock positions and secondary occurring in between the primary sites. Bleeding as 'splash in pan', mass per anum, pruritis, mucoid discharge is some of the features. As per the recent treatment advancement like laser hemorrhoidoplasty (LHP), Doppler-guided hemorrhoidal artery ligation (DGHAL), and sclerotherapy with polidocanol foam, stapled hemorrhoidopexy etc, are minimally invasive & painless procedure but have reoccurrence risk

**Ayurvedic View:**

Hemorrhoids mentioned as Arshas in Ayurvedic classics.

As per Ashtanga Sangraha,

**अरिवत् प्राणिनो मांसकीलका विशसन्ति यत्।**
**अर्शांसि तस्मात् उच्यते गुद मार्ग निरोधजः ॥**[9]

Arshas are muscular growth causing obstruction of the anal route.

Sushruta mentioned 6 types- Vataja, Pittaja, Kaphaja, Shonitaja, Sannipataja, Sahaja.[10]

Charaka explained Sahaja (Congenital) & Jatasya uttarakalaja (developed later in life).

Based on the bleeding nature it is again of two types Shushka & Ardra.

All arshas are located 4 ½ Angula of anal of anal area, divided in three folds located at equal distance and their adhishthana being Medo, Mamsa & Twak.[11]

**Drug Review:**

The Preparation of nanogel and the tests done for evaluation of the nanogel is as follows -

**Ingredients:**

- Kasisadi Tailam- 1ml
- Lajjalu Extract- 1ml
- Ethanol- 500ml
- Carbopol 934- 1g
- Propylene Glycol- 1ml
- Methyl Paraben- 0.5g
- Triethanol Amine – 1ml
- Water- 100ml

**Preparation of Polyherbal Nanogel From *Lajjalu* (Mimosa Pudica) & *Kasisadi Taila*:**

**1. Collection of Raw Drug:**

- Ingredients of *Kasisadi Taila*: *Kasisa* ($FeSO_4.7H_2O$), *Harathala* ($As_2S_3$), *Karanja* (Pongamia Pinnata), *Karaveera* (Nerium Indicum), *Jambu* (Syzygium

Cumini), *Kritavedana* (Luffacutangula Lin Roxb), *Chitraka* (Plumbago Zylanica), *Danti moola* (Baliospermum Montanum), *Arka ksheeram* (Latex of Calotropis Procera), *Snuhi ksheera* (Latex of Euphoria Nerifolia), *Saindava* (Rock salt), *Tila Taila* (Sesame oil)

- *Lajjalu* (Mimosa pudica): raw drugs are collected from nearby Sulur area.

**2. Standardization of the Drugs:**

- ***Kasisadi Taila***: Reduction in the size of *Arshas* (Hemorrhoids) by the local application of *Kasisadi Taila* due to its corrosive effect on the wall of affected veins by acidic nature (ph – 3.7) as well as *Lekhana* property of contents of *Kasisadi Taila*. Pain and bleeding may be reduced due to decreased pressure of stool on veins and sphincters by smoothening effect of *Kasisadi Taila*. [5,12]
- ***Lajjalu (Mimosa pudica)***: Based on studies, Tannin has been isolated from the root of the plant. Because of its styptic and astringent properties, it has been used for *Arshas* (Hemorrhoids). It has analgesic activity due to presence of Flavonoids. It also has Spasmogenic potential, Anti-inflammatory, Antimicrobial and Anti-fungal properties. Leaves are bitter & sudorific and are useful in *Arshas* (Hemorrhoids). Paste of root fried in castor oil arrests bleeding in deep cut wounds

**3. Drying of the Drugs:**

Raw drugs are collected and dried under sunlight.

**4. Pulverization of the Drugs:**

Dry drugs are made into fine particles using Pulverizer

**5. Converting into Nanogel Form:**

- **Extraction:** The instrument used for extraction procedure is soxhlet apparatus with continuous hot extraction. In dry extracts all solvent has been removed.

  The dried powder (50g) of Mimosa pudica was extracted successively with 500ml of ethanol in soxhlet apparatus for 8 hrs. The solvent was evaporated at 300 - 350 C. The yield was a dark green residue about 200 ml


- **Formulation of Nanogel:**

  Step I - Accurately weighed quantity of 5 ml propylene glycol & 0.1 g methyl paraben along with 1ml Kasisadi taila & 1g Lajjalu extract are stirred for 20 mins on magnetic stirrer (organic phase)

  Step II - Aqueous phase is prepared by using Carbopol -940 dissolved in

100 ml water with continuous stirring and heat for a 30 min in a magnetic stirring, and the drug phase is sonicated under ultrasonic bath sonicator for 10 min.

Step III - Organic phase is added drop by drop into aqueous phase with homogenistion for 15 mins to form emulsion. The emulsion is converted into nano droplet by homogenizer results in o/w emulsion formed.

Step IV- o/w emulsion is homogenized for 30 mins at 6000 rpm and 1ml triethanolamine is added with continuous stirring to form nanogel.

**6. Evaluation of the Product:**

- **Appearance:** The prepared gel bases were inspected visually for clarity, colour, presence of any particles.
- **Homogeneity:** The developed nanogels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.
- **pH:** The pH of various nanogel formulations was determined by using digital pH meter.
- **Spreadability:** It was determined by wooden block and glass slide apparatus, Weights about 20g were added to the pan and the time were noted for upper slide (movable) to separate completely from the fixed slides

Spreadability was then calculated by using the formula: S-ML/T

Where, S - Spreadability. M- Weight tide to upper slide, L- Length of glass slide T - Time taken to separate the slide completely from each other

- **Viscosity:** The viscosity of the formulations (gel) was determined at 25°C by using Brookfield viscometer with spindle no.S-96 at 1 rpm and viscosity was measured in cps. The measurement of each formulation was done in triplicate and average values calculated.

**Fourier-Transform Infrared Spectroscopy:**

**Results:**

| **Evaluation Parameters** | **F1** | **F2** |
|---|---|---|
| **Appearance** | Clear | Clear |
| **Skin irritation test** | No irritation | No irritation |
| **Spreadability** | 268 | 285 |
| **Viscosity** | 8502 | 8864 |
| **pH** | 5 | 6.6 |
| **Arsenic** | 27.23 | 21.34 |
| **Particle size** | 3601 | 1887 |

**Particle Size:** Particle size of the optimized formulation was 1887nm

**Zeta Potential:** The reduced zeta potential value of -65mV indicated that the prepared nanogel possess a higher degree of long-term stability.

**Methodology:**

**Hypothesis:**

**Alternative Hypothesis:** Polyherbal nanogel has a hemostatic effect in the management of *Arshas* (Hemorrhoids).

**Null Hypothesis:** Polyherbal nanogel doesnot have hemostatic effect in the management of *Arshas* (Hemorrhoids).

**Methodology:**

A group of 15 patients from Shalya Tantra OPD of Ayurveda College Coimbatore having 1st, 2nd & 3rd degree *Arshas* (Hemorrhoids) between age group 25-65 yrs were selected for the study. Then the nanogel prepared out of *Lajjalu* (Mimosa pudica) & *Kasisadi Taila* was applied for 7-15 days regularly in a dose of 200mg. Drug treatment was given once daily through topical route of administration & 1st assessment was done immediately after the application, 2nd assessment on 7th day and follow up after 2 weeks on 21st day.

**Inclusion Criteria:**

- Age: 21 – 50 years
- 1st & 2nd degree internal Arshas (Hemorrhoids)

**Exclusion Criteria:**

- Arshas (Hemorrhoids) due to hereditary causes, birth defects, anatomical changes due to surgery/ injury
- Associated with other ano-rectal conditions like fissure, fistula in ano, sinus, malignancy, enlarged prostrate
- Hemorrhoids that are thrombosed and strangulated/ gangrenous
- Hemorrhoid associated with other chronic & acute systemic diseases
- 3rd & 4th degree hemorrhoids
- Age below 20 years.

**Assessment criteria:**

**Subjective Parameters:**

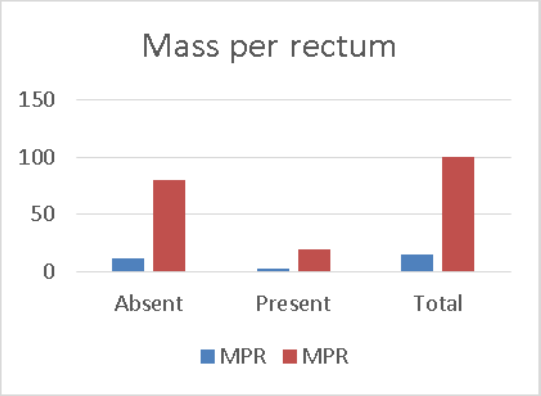
- Bleeding per rectum
- Internal mass
- Pruritis Ani
- Mucoid discharge

**Observations:**

**Mass per Rectum:**

Table shows that 80% of the participants did not have mass per rectum and 20% had mass per rectum.

| **Mass per rectum** | | |
|---|---|---|
| | Frequency | Percent |
| Absent | 12 | 80 |
| Present | 3 | 20 |
| Total | 15 | 100 |




**Results:**

**Comparison of mean of bleeding per rectum on 7th day:**

| | |
|---|---|
| Bleeding per rectum BT mean | 1.00 |
| Bleeding per rectum 7th day mean | 0.27 |

When bleeding per rectum compared before treatment (mean :1.00) to after treatment on day 7 (mean:0.27) with Wilcoxon signed rank test, 11 subjects showed negative ranks, no subjects showed positive ranks and 4 subjects showed tie with z value -3.317.and p value 0.001 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| Bleeding per rectum BT- 7th day | N | MR | SR | N | | | | | | |
| | 11 | 6.00 | 66.00 | 0 | 0.00 | 0.00 | 4 | -3.317 | 0.001 | HS |

**Comparison of mean of bleeding per rectum on 21st day:**

| | |
|---|---|
| Bleeding per rectum BT mean | 1.00 |
| Bleeding per rectum 21st day mean | 0.00 |

When bleeding per rectum compared before treatment (mean :1.00) to after treatment on day 21 (mean:0.00) with Wilcoxon signed rank test, all the 15 subjects showed negative ranks, no subjects showed positive ranks and no ties with z value -3.873 and p value 0.000 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| Bleeding per rectum BT- 21st day | N | MR | SR | N | | | | | | |
| | 15 | 8.00 | 120.00 | 0 | 0.00 | 0.00 | 2 | -3.873 | 0.000 | HS |

**Comparison of mean of internal mass on 7th day:**

| | |
|---|---|
| Internal mass BT mean | 0.73 |
| Internal mass 7th day mean | 0.73 |

When internal mass compared before treatment (mean :0.73) to after treatment on day 7 (mean:0.73) with Wilcoxon signed rank test no subjects showed any changes with z value 0.000 and p value 1.000 which is statistically significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| internal mass BT- 7th day | N | MR | SR | N | | | | | | |
| | 0 | 0.00 | 0.00 | 0 | 0.00 | 0.00 | 15 | 0.000 | 1.000 | S |

**Comparison of mean of internal mass on 21st day:**

| | |
|---|---|
| Internal mass BT mean | 0.73 |
| Internal mass 7th day mean | 0.73 |

When internal mass compared before treatment (mean :0.73) to after treatment on day 21 (mean:0.73) with Wilcoxon signed rank test no subjects showed any changes with z value 0.000 and p value 1.000 which is statistically significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| internal mass BT-7th day | N | MR | SR | N | | | | | | |
| | 0 | 0.00 | 0.00 | 0 | 0.00 | 0.00 | 15 | 0.000 | 1.000 | S |

**Comparison of mean of pruritis ani on 7th day:**

| | |
|---|---|
| pruritis ani BT mean | 0.13 |
| pruritis ani 7th day mean | 0.07 |

When pruritis ani compared before treatment (mean :0.13) to after treatment on day 7 (mean:0.07) with Wilcoxon signed rank test 1 subjects showed any changes with z value -1.000 and p value 0.317 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| pruritis ani BT- 7th day | N | MR | SR | N | | | | | | |
| | 1 | 1.00 | 1.00 | 0 | 0.00 | 0.00 | 14 | -1.000 | 0.317 | HS |

**Comparison of mean of pruritis ani on 21st s day:**

| | |
|---|---|
| pruritis ani BT mean | 0.13 |
| pruritis ani 21st day mean | 0.00 |

When pruritis ani compared before treatment (mean :0.13) to after treatment on day 21 (mean:0.00) with Wilcoxon signed rank test no subjects showed any changes with z value -1.414 and p value 0.157 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| pruritis ani BT- 21th day | N | MR | SR | N | | | | | | |
| | 2 | 1.50 | 3.00 | 0 | 0.00 | 0.00 | 13 | -1.414 | 0.157 | HS |

**Comparison of mean of mucoid discharge on 7th day:**

| | |
|---|---|
| Mucoid discharge BT mean | 0.33 |
| Mucoid discharge 7th day mean | 0.13 |

When mucoid discharge compared before treatment (mean :0.33) to after treatment on day 7 (mean:0.13) with Wilcoxon signed rank test, 3 subjects showed negative ranks , no subjects showed positive ranks and 12 ties with z value -1.732 and p value 0.083 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| Mucoid discharge BT- 7th day | N | MR | SR | N | | | | | | |
| | 3 | 2.00 | 6.00 | 0 | 0.00 | 0.00 | 12 | -1.732 | 0.083 | HS |

**Comparison of mean of mucoid discharge on 21st day:**

| | |
|---|---|
| Mucoid discharge BT mean | 0.33 |
| Mucoid discharge 7th day mean | 0.00 |

When mucoid discharge compared before treatment (mean :0.33) to after treatment on day 21 (mean:0.00) with Wilcoxon signed rank test, 5 subjects showed negative ranks , no subjects showed positive ranks and no ties with z value -2.236 and p value 0.025 which is statistically highly significant.

| Parameters | Negative ranks | | | Positive ranks | | | Tie | Z value | P value | Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|
| Mucoid discharge BT- 21st day | N | MR | SR | N | | | | | | |
| | 5 | 3.00 | 15.00 | 0 | 0.00 | 0.00 | 10 | -2.236 | 0.025 | HS |

**Discussion:**

The present study was aimed to evaluate the efficacy of the Polyherbal nanogel prepared out of Lajjalu(Mimosa pudica) & Kasisadi Taila in the management of Arshas (Hemorrhoids).

**Discussion on Results:**

**Effect on Bleeding Per Rectum:**

Statistical analysis showed that the mean score which was 1.00 before the treatment was reduced to 0.27 after the treatment with 27% improvement. After the follow up it became 0.00 with 100% improvement and which is statistically highly significant(P<0.001)

**Summary:**

In all patients bleeding per rectum was the initiating event followed with mass per rectum, mucoid discharges etc. it has been observed that severity of the symptom was reduced gradually. Significant reduction in the bleeding was observed after 15th day.

Kasisadi taila having the Tikshna, lekhana & shothahara property which may help to reduce the bleeding by reducing the pressure of stools on veins. Also, Lajjalu(Mimosa pudica) by its own property has a property to arrest bleeding.

**Effect on Internal Mass:**

Statistical analysis showed that the mean score which was 0.73 before the treatment and after the follow up no changes were shown after the treatment. Which is statistically significant(P<0.001).

**Summary:**

Eventhough the study showed only a small difference in the size reduction of internal mass, the results didn't aggravate the conditions which is considered to be clinically significant.

Kasisadi taila have the property of Tikshna guna which may reduce size of internal mass if mode of use or dosage or duration is changed as it didn't show any negative impact on the internal mass.

**Effect on pruritis ani:**

Statistical analysis showed that the mean score which was 0.13 before the treatment was reduced to 0.07 after the treatment with 53% improvement. After the follow up it became 0.00 with 100% improvement and which is statistically highly significant(P<0.001)

**Summary:**

Significant reduction in itching was noticed on 7th day and by 15th day follow up complete reduction in the symptom was noticed

The predominant rasa in kasisadi taila is Kashaya and amla and katu which is having property of samshamana, sangrahi, kaphanasahaka which played a major role in reducing the itching.

**Effect on Mucoid Discharge:**

Statistical analysis showed that the mean score which was 0.33 before the treatment was reduced to 0.13 after the treatment with 39% improvement. After the follow up it became 0.00 with 100% improvement and which is statistically highly significant(P<0.001)

**Summary:**

Associated complaints like mucoid discharge per rectum showed significant reduction after the treatment also after the follow up.

Kasisadi taila by its own possess Tikshna, kledaharatwa, sothahara properties which may reduce the mucoid discharge significantly.

**Conclusion:**

Hemorrhoids are the dilated & inflamed rectal veins at 3,7& 11o'clock position. These are often caused by increased pressure in the lower rectum due to straining during bowel movements, prolonged sitting, chronic constipation or diarrhoea etc. They can either be external or internal. It has been mentioned in the classics that Kasisadi tailam is having shodhana & ropana property, Also Tikshna, lekhana & shothahara property which may

help in size reduction alongwith reduction in the bleeding by reducing the pressure of stools on veins.

In various researches it has been shown that Lajjalu (Mimosa pudica) is useful in arresting the bleeding& fastens wound healing process. Nanogels are versatile & advanced drug delivery system made of hydrogel nanoparticles. It helps in enhanced drug loading & release, targeted delivery.

So, the polyherbal nanogel prepared with Kasisadi tailam & Lajjalu helped in arresting the bleeding.

- Polyherbal Nanogel is safe & efficient for Arshas (Hemorrhoids)
- It is the indigenous low-cost, non-invasive method of administration
- Easy to use system with a techno-friendly environment to the user at any time.
- An effective drug release in the targeted site & retain the effect of drug for long duration.

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