Comparative Clinical Evaluation of “Kshara Injection Technique” in the Management of Internal Hemorrhoids

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INTRODUCTION

The disease Arshas or Hemorrhoids is as old as mankind. Still, a large proportion of the world’s population is troubled by Hemorrhoids. This may be perhaps to the inconsistency of the human diet and to the social obligations demanded by civilization. This disease is generally not a threat of life, but causes considerable discomfort, enforced bed rest, absence from work with consequent economic strain and the long range effects of this disease are induced weakness and finally saps the energy and enthusiasm of the society to which he belongs.

Susruta (800 B.C), the father of ancient surgery mentions, this disease as a ‘surgical domain’, since the final resort of the treatment is surgery. But, even surgery sometimes do not give gratifying results at the hands of experience surgeons and reoccurrences established.

Since, Hemorrhoidal problem is not a threat to Life, so the least invasive treatment is the most desirable. Till today, a wide range of treatments like injection therapy, Sclero therapy, Rubberband ligation, Anal dilatation, Photocoagulation, Cryosurgery, Formal hemorrhoidectomy and etc., are available. This increasing numbers of techniques itself effects to the lack of universal acceptance of a particular treatment.

Under the above circumstances, there is a need to find out a new, innovative and simpler procedure that which ideally suits in offering relief for the sufferers of this disease.

This prevent work is an attempt for the fulfillment of the above requirements with the technique of Kshara Injuction, prepared from the plant of Achyranthus aspera. The Kshara prepared out of this plant at 5% and 10% concentration in the distilled water is injected sub mucosally to the Internal hemorrhoidal masses. This study consists a comparative clinical evaluation of Kshara Injection with a control group and the final results were subjected for a statistical evaluation for a scientific validation.

This paper also comprises method of Kshara injection preparation, procedure of administration, summary, concluding remarks and references are also reported.

MATERIALS AND METHODS

A clinical study was conducted on 45 subjects to find out the effect of Kshara injection of 5% and 10% solution in the internal hemorrhoids with their comparative
evaluation with the control group at S.V. Ayurvedic College – Tirupati in between January 1995 to December 1998.

I. CRITERIA FOR THE SELECTION OF PATIENTS: In this present study, a format and detailed case sheet was made to examine all the systems of the patients to ascertain the diagnosis. The case sheet not only include all the basic examinations but also certain specific examinations like Proctoscopic and Perrectal examinations to assist the correct diagnosis.

1. Cases were selected randomly with regards to sex.
2. The study included only patients aged in between 30 – 60 yrs.
3. The patients who were having only Internal Hemorrhoids with I and II were only considered.
4. Attention was paid not to include any patients sufferings from any other systemic diseases.
5. Kshara injection solution was prepared out of Apamarga (Achyranthus aspera) Kshara at 5% and 10% concentration solutions.
6. The parameters for this study were Bleeding (srava), Pain (vedana), Inflammation (sotha) and Itching (kandu) and on other side the regression of the size of the masses was also considered.
7. Patients were categorized into three groups
   I. Group A (Trial Group – I) – where 10% Kshara injection was given.
   II. Group B (Trial Group – II) – where 5% of Kshara injection was given.
   III. Group C (Control Group) – where injection of distilled water was given as Placebo.
8. The total duration of the study was 30 days.
9. Admission was restricted to those subjects who had severe symptoms otherwise treated as out-patients only.

II. METHOD OF “KSHARA INJECTION” PREPARATION: For this total Achyranthus aspera plant with its root, stem, leaves and branches were dried and burnt on a cemented floor to collect the ashes and was mixed with 7 times of water to prepare a Kshara solution. This was filtered with the fine filter paper and heated on a gas furnace in a stainless steel pot, till the water evaporates and the final sedimented crystalline substance is left, which known as ksharadravya. Taking of 5 gms. Ksharadravya into 100 ml of distilled water was mixed properly. This was boiled and filtered again to get 5% sterile solution. Same procedure was also adopted by adding 10gms. Kshara dravya into 100 ml of distilled water to prepare 10% Kshara injection water.

III. METHODOLOGY OF “KSHARA INJECTION” IN INTERNAL HEMORRHHOIDS: After taking all aseptic precautions, the patients were made to lay down in lithotomy position and sterile dry swab is inserted into the anal canal and dragged slowly to visualise the internal masses or otherwise patients were asked to strain out the masses naturally. Then 1-2ml of Kshara solution was injected submucosally into the masses, one by one, these masses were pushed back to their normal position. Daily dressing with gauze sling soaked with Jatyadi tialam and was followed by T.Bandage.
IV. FOLLOW-UP: Kshara injection was given on every 7th day thus assessing the parameter chart subjectively and objectively.

V. ASSESSMENT OF THE RESULTS:
The results were assessed by two methods 1. General assessment 2. Special assessment. General assessment was done on 30th day assessing the improvement of its parameters by four gradation scale.

1. Severe - III grade
2. Moderate - II grade
3. Mild - I grade
4. Nil (Remission) - grade

2. SPECIAL ASSESSMENT: This was done to reconfirm the finding of the general assessment. In this, the subjects were grouped into four categories.

1. Excellent Response Group – (E.R.G) – Who improved completely within 20 days.
2. Good – Who improved completely within 25 days.
3. Fair– Who improved completely within 30 days.
4. Poor – Who did not show any improvement either in all the parameters or in any one of them.

VI. STATISTICAL ANALYSIS : This was also done with Karl pearson’s ‘CHI-SQUARE TEST’ with Yates correction to find out the statistical significance.

VII. POST TREATMENT FOLLOW-UP:
This was done up to one year with a gap of one month to ascertain the nature of reoccurrence and also to review the other complications.

RESULTS

Table No.1
SHOWING AGE AND SEX DISTRIBUTIONS OF CASES IN CLINICAL GROUPS

| Age  | Group A | | Group B | | Group C |
|------|---------|------|---------|------|---------|
|      | Male    | Female | Male    | Female | Male    | Female |
| 30-34| 2       | -     | 2       | 1      | 1       | 1      |
| 35-39| 2       | -     | 1       | -      | 2       | -      |
| 40-44| 1       | -     | 2       | 1      | 2       | -      |
| 45-49| 2       | -     | 2       | -      | 1       | 2      |
| 50-54| 1       | -     | 1       | 1      | 2       | -      |
| 55-59| 2       | -     | 2       | -      | 2       | -      |
| 60   | 3       | -     | 2       | -      | 2       | -      |
| Total| 13      | -     | 12      | 3      | 12      | 3      |
Table No.2
SHOWING THE CHRONICITY OF THE DISEASE HEMORRHOIDS IN CLINICAL GROUPS

| Duration | Group A | Group B | Group C |
|----------|---------|---------|---------|
|          | Male    | Female  | Male    | Female  | Male    | Female  |
| 0-4 years| 6       | 1       | 5       | 1       | 5       | 1       |
| 5-9 years| 5       | -       | 4       | 1       | 3       | 2       |
| 9 and above| 2     | 1       | 3       | 1       | 4       | -       |
| Total    | 13      | 2       | 12      | 3       | 12      | 3       |

Table No.3
SHOWING THE OCCUPATION OF SUBJECTS IN CLINICAL GROUPS

| Occupation   | Group A | Group B | Group C | Total |
|--------------|---------|---------|---------|-------|
|              | Male    | Female  | Male    | Female |       |
| Business     | 3       | -       | 2       | -      | 8 (17.7) |
| Clerks       | 2       | -       | 2       | 1      | 9 (20) |
| Coolies      | 2       | -       | 2       | -      | 6 (13.3) |
| House wives  | -       | 1       | -       | 1      | 3 (6.6) |
| Officers     | 2       | -       | 1       | -      | 4 (8.8) |
| Students     | 1       | -       | 2       | -      | 4 (8.8) |
| Tailors      | 3       | 1       | 3       | 1      | 11 (24.4) |

Percentage are given in parenthesis

Table No.4
SHOWING FOOD RELATIONS OF SUBJECTS IN CLINICAL GROUPS

| Food Relations | Group A | Group B | Group C | Total |
|----------------|---------|---------|---------|-------|
|                | Male    | Female  | Male    | Female |       |
| Vegetarians    | 5       | 1       | 6       | 2      | 22 (48.8) |
| N. Vegetarians | 8       | 1       | 6       | 1      | 23 (51.11) |

Percentage are given in parenthesis
Table No.5

SHOWING THE PROGRESS IN DIFFERENT PARAMETERS AT THE END OF THE CLINICAL STUDY

| Parameters   | Group A |       | Group B |       | Group C |       |
|--------------|---------|-------|---------|-------|---------|-------|
|              | N  | %    | N   | %    | N  | %    |
| Bleeding     | 15 | 100  | 15  | 100  | 3  | 20   |
| Plain        | 12 | 80   | 10  | 6.6  | 3  | 20   |
| Inflammation | 13 | 86.6 | 14  | 9.3  | 2  | 13.6 |
| Itching      | 13 | 86.6 | 13  | 86.6 | 1  | 6.6  |
| **Total %**  |     | **88.3** |     | **86.6** |     | **15** |

Cure rate:
- Group A - 88.3%
- Group B - 86.6%
- Group C - 15%

N = Number of relieved subjects

Table No.6

SHOWING THE ASSESSMENT OF RESULTS IN CLINICAL GROUPS – AT THE END OF CLINICAL STUDY.

| Groups     | E.R.G |       | G.R.G |       | F.R.G |       | P.R.G |       |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|
|            | N  | %    | N   | %    | N  | %    | N  | %    |
| Group A    | 6  | 40   | 8   | 53.3 | 12 | 80   | 3  | 20   |
| Group B    | 7  | 46.6 | 9   | 60   | 14 | 93.3 | 1  | 6.6  |
| Group C    | -  | 1    | -   | -    | 1  | 6.6  | 14 | 93.3 |

E.R.G - Excellent Response Group
G.R.G - Good Response Group
F.R.G - Fair Response Group
P.R.G - Poor Response Group
N - Number of Subjects
Table No.7
SHOWING THE GRADULA REGRESSION OF THE INTERNAL MASSES IN CLINICAL GROUPS

| Duration in Days | Group A | Group B | Group C |
|------------------|---------|---------|---------|
| 7                | 2       | 2       | -       |
| 14               | 4       | 4       | 1       |
| 21               | 10      | 9       | 2       |
| 28               | 14 (93.2) | 13 (86.5) | 3 (20%) |

Table No.8
SHOWING STATISTICAL SIGNIFICANCE IN DIFFERENT PARAMETERS IN TRIAL AND CONTROL GROUPS AT THE END OF THE STUDY

| Groups | Bleeding | Pain | Inflammation | Itching |
|--------|----------|------|--------------|---------|
| Group A & Group C | + | + | + | + |
| Group B & Group C | + | + | + | + |
| Group A & Group B | - | - | - | - |

‘+’ – Indicates the statistical significance at the level of 3.75 P value

These findings reveals that ‘KSHARA INJECTION’ is provided to have better effects in the management of Internal Hemorrhoids, Comparatively Group A was better than Group B, where 10% Kshara injection proved to be superior.

ASSESSMENT OF THE RESULTS

The assessment of the results was based on the improvement of parameters with special reference to the regression of the Internal Hemorrhoids.

Clinical evaluation reflects that the subject in between the age group of 30-40 years responded quickly to the treatment. Random selection of sex drawn no particular conclusion. It was also observed that the less duration of the chronicity shown more quicker the response.

In general assessment, there was 88.3% relief rate of the parameters in Group A, 6 (40%) in Group B and nil in Group C. Fair response Group (F.R.G) was 14 (93.3) in Group A, 12 (80%) in Group B and 1 (6.6%) in Group C (Table No.6).
STATISTICAL ANALYSIS

The data further analysed to know the statistical significance in Trial and Control groups by using Karl Pearson’s ‘CIII-SQUARE TEST’ with Yates correction the p value of 3.75 in between Control and Trial groups. But there was no statistical significance in between Group A or Group B.

DISCUSSION

In the past, surgical procedure was regarded as the only cure for Hemorrhoids. But it is quite apparent at this time that the other forms of non surgical treatments should be seriously considered. The question as to which procedure one should undertakes the issue. Since, Hemorrhoidal problems are not generally fatal; the least invasive treatment is the most desirable. So, the answer no doubt is using the therapy that best suits the patients’ needs and that which gives the best results. This disease has got various types of treatments. Evaluation of any form of therapy used at one’s own institution yields varied opinions. But conentious, careful patient selection, accurate execution of any procedure and unbiased evaluation will always gives the best results.

In this present study, Group A patients were injected with 10% Kshara solution, in Group B 5% solution and in Group C distilled water (placebo) was injected. Follow up was assessed with an interval of 7 days till the end of stipulated 30 days, in terms of relief of its parameters with special reference to the regression of the size of the Internal Hemorrhoids. Results were assessed for statistical analysis with Chi-square test and thus validated with statistical significance.

This reveals the efficacy of the ‘Kshara injection’ in Group A was 88.3%, in Group B 86.6% and in Group C was 15%. Group C shown poor response to the application of the placebo. Even these slight variations may be attributed to their change in dietary and bowel habits. Thus, it would appear from the results of the present study that “Kshara injection” either 5% or 10% concentration causes shrinkage in the masses, may safely adopted in the management of Internal Hemorrhoids. The shrinkage mechanism by “Kshara injection” may be inferred by the following views.

1. May be causing local dehydration in Hemorrhoidal tissues with its proteolytic enzymes.
2. Denaturation of Lipid-protein complexes in the tissues.
3. Causes sudden electrolytic imbalances in the tissues.
4. By clearing vascular stasis in the hemorrhoidal plexus.
5. By relieving the congestion in the hemorrhoidal plexus.
6. The ‘Kshara injection’ method is safe because, the proteolytic enzymes present are proved to be curative, caustic, antimicrobial and having bactericidal properties.

CONCLUSIONS

1. This new approach of ‘KSHARA INJECTION’ would be an integrated approach having safe and simpler procedure in its application.
2. The success rate is 88.3% in Group A and 86.6% in Group B with the statistical significance at the level of 3.75 P value.
3. No Anaesthesia is required.
4. Less scarring with less treatment induced patient discomfort.
5. Comparatively cheaper with less over all health-care-lost.

RECOMMENDATIONS

1. Follow-up should be done for a longer period to evaluate the recurrences.
2. Research may also be done to find out the mechanism of action of ‘Kshara injection’.
3. Histo Pathological Studies may also be needed to ascertain the reliability of the inferences.

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REFERENCES

1. Bhaskar Rao.M – 1988 – Comparative clinical evaluation of Ksharasutra and Kshara paste in the Management of Bahyarshas (External Hemorrhoids) a Dissertation work presented in Bangalore University.
2. Charless V. Mann and R.G. C. Russel – 1991 ‘Baily and Love’ short practice of surgery 21st edition.
3. Krishna Murthy V and Sharma M.R.K, 1989 – Shalyatantra Moolasiddhantalu (Telugu), I edition A.P. Ayurvedic Literature trust – Hyderabad.
4. Ramnath Dwived – 1983 – Sousriti – Chowkamba Amaravathi Prakasham – Varanasi – Edition.
5. Susruta 1000 B.C: Sutrata Samhita – English commentary, 1991 – by Bhishagratna – K.L. Chowkamba Sanskrit Studies.
6. Singhal G.D., 1985 – Surgical Ethics in Ayurveda – Chowkamba Sanskrit series – Varanasi, II edition.
7. Vagbhata 700 A.D Astanga Sangraham, Hindi Commentary, Tripati R.D., Chowkamba Shastri Pratistan – Varanasi 1992.

Dedicating this article to my Professor G.G. Hiremath, Head of the Department, Shalya Shalakya, G.C.I.M – Bangalore who demised suddenly in an accident