A Comparative Evaluation of Efficacy of Mustadi Yapan Basti and Baladi Yapan Basti in the Management of Oligozoospermia—Study Protocol

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Authors’ contributions

This work was carried out in collaboration among all authors. Author AMA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors SP and MN managed the analyses of the study, and literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Nowadays most upcoming disease that affecting 8 to 12% of the world population is Infertility. The affected area of this problem have no bar irrespective of metro cities as well as small towns population. Modern treatment with steroids and other medication and interventions shows limited results. Bastichikitsa itself is the best remedies explained in Ayurved text for the treatment of ksheenshukra. Yapan Basti in Ayurveda is known for its action as balya, i.e. giving strength to the sharirdhatu. Incase of Oligozoospermia there is vitiation and loss of formation process of shukradhatu properly as per Ayurveda. Using YapanBasti, the strength of Shukradhatu can be regain and ultimately correction can be seen in oligozoospermia cases. By doing bastikarma, we are trying to establish and confirm the role of yapanbasti explained in Ayurvedonoligozoospermia.

Aims and objectives: To study the efficacy of Mustadi Yapan Bastion sperm count sperm motility, semen volume, SemenPH, abnormal sperm count along with serum testosterone, GH and FSH level in the management of Oligozoospermia in comparison with Baladi Yapan Basti.
Methodology: Age ranging between 25 to 50 years will be considered for the study. Secondly, Sperm count < 15 million/ml will be consider for the study, also the patients who shows cardinal symptom i.e Pratyatmakalakshana of Kshina Shukra, Pathological sample of Semen sample must suggestive of oligozoospermia will be considered for the study. 30 Patients in each group will be given Basti for 16 days as explained in classics of Ayurveda. The process of giving basti will be using bastiputak. Basti will be prepared as per the niruhabasti preparation method. Bastigamankal and bastipratyagamankal will be observed properly. Follow-up will be taken after 28th day from starting of treatment.

Results: Results will be drawn from the observations of objective parameters.

Conclusion: Mustadi Yapan Basti will be effective in oligozoospermia.

Keywords: Kshina shukra; oligozoospermia; pratyatmakalakshana; basti; yapan basti; brahan basti; baladi yapan basti.

1. INTRODUCTION

Infertility is a rising problem all over the world and it affects on 8 to 12% of the total world population [1]. Basti specially work at apan region [1] and from this region it control and correct the vitiated condition of dosha. There are many references in Ayurveda explaining the importance of basti in oligozoospermia. “Kshinderiyaye chnarahakrushasha sbastihipra shastahapram chteshu” [2] It means bastichikitsa itself is useful in ksheenshukra that is oligozoospermia. Sushrutacharya explain optional name to niruhabasti as yapanabasti [3] While explaining the importance of yapanabasti Charakacharya clearly explains its usefulness as shukramansbalpradhana [4] While explaining Shukra dushti Acharya Sushrut explain Ksheen Shukra. Inksheen Shukravatdosha along with pitta dosha vitiate the system and create disturbance in the normal qualities and quantities of shukra dhatu [5] Acharya Charaka has mentioned various basti which are useful in the treatment of Alpa, dushtraretas which directly act on Shukra by shukrajanan of them [6] In this study, an attempt will be made to investigate the role of Mustadi Yapan Basti [7] in oligozoospermia. For the control trial Baladi Yapan Basti [8] will be given whose efficacy is already established in previous clinical trial. A clinical study of Role of Baladi Vrushya Basti and Satavaryadi Yoga in the management of Ksheena Shukra. [9] The comparative study of Mustadi Yapan Basti over Baladi Yapan Basti helps to find the best shukrajanan Yapan Basti explained byacharchyas.

2. OBJECTIVE

To Study the effect of Mustadi Yapan Basti on sperm count sperm motility, semen volume, Semen PH, abnormal sperm count along with serum testosterone, GH and FSH level.

To Study the effect of Baladi Yapan Basti on sperm count sperm motility, semen volume, Semen PH, abnormal sperm count along with serum testosterone, GH and FSH level.

Compare the effect of Mustadi Yapan Basti and Baladi Yapan Basti in sperm count sperm motility, semen volume, Semen PH, abnormal sperm count along with serum testosterone, GH and FSH level.

Case Definition: A diagnosed case of Oligozoospermia having low sperm count along with variations in sperm count, motility, semen volume, Semen PH, along with serum testosterone, GH and FSH level.

Research Question: Weather Mustadi Yapan Basti is more effective as compare to Baladi Yapan Basti in the management of Oligozoospermia.

Hypothesis: Weather Mustadi Yapan Basti is more effective as compare to Baladi Yapan Basti in the management of Oligozoospermia.

Null Hypothesis: Mustadi Yapan Basti is not more effective as compare to Baladi Yapanbasti in the management of Oligozoospermia.

3. MATERIALS AND METHODS

Trial Design: Interventional single blind clinical trial.

Study Setting: The study will be conducted in academic hospital of Mahatma Gandhi Ayurveda College Hospital And Research Centre Salod (H), Wardha.
The study will be conducted in an academic hospital MGACH &RC, Salod (H), Wardha.

**Composition of trial drugs:** All the herbs required for the trial will be purchased from an authenticated pharmacy and will be used as per textual reference.

For the preparation of basti following method is applied which is explained in Ashtanghradya sutra thand adhya nineteen –Makshikam is taken first add lavanam in it. Triturate it properly. Secondly add snehadravya triturate it again. After having homogenous solution add kalkadravyas as explained in both basti. Triturate it again and finally add quathdravyas(Decoction prepared).

**3.1 Eligibility Criteria**

**Inclusion criteria:**
Age between 25 to 50 years
Sperm count below 15 million/ml,
*Pratyatmak Lakshan* (Cardinal Symptom) of *ksheen Shukra*

**Exclusion criteria:**
Age below 25 and above 50 years
Sperm count below above 15 millions/ml
Azoospermia/Aspermia
Genetic defects like Klinefelter’s Syndrome
Case with varicocele, Accessory Gland infection, Sexually transmitted diseases,

Systemic diseases like Diabetes etc will be excluded from the study

**Screening Parameters:** Semen Analysis

**Specific Investigations:** Blood investigations for hormonal study including Testosterone level, LH, FSH

**Variables (parameters):** None

**Interventions:** The total duration of interventions will be the same for both group which will be 16 days and follow ups will be on 28th day in both group.

**3.2 Criteria for Discontinuing or Modifying Allocated Interventions**

The subject will be withdrawn from the study if any untoward incidence, features of drugs sensitivity or any other diseases or problem arises, the subject will be offered free treatment till the problem subsides.

**Follow-ups:** 0 and 16th day and 28

**Primary Outcomes:** We will see the impact of *Mustadi Yapan basti* and *Baladi Yapan basti* on total sperm count, sperm motility, and semen volume, abnormal sperm. Information will be communicated as a standard mistake of mean 5% level of noteworthiness. It is hypothesized that *Mustadi yapan basti* is more effective than *baladi yapan basti* in cases of Oligozoospermia.

| **Table 1. Materials of baladi yapan basti** |
|---------------------------------------------|
| **Ingredients of Basti** | **Quantity** |
| MUSTA SIDDHA KSHEER | 400ML |
| Musta | 40gm each |
| Ushir |  |
| Bala |  |
| Aragvadh |  |
| Kutaki |  |
| Trayamana |  |
| Punarnarva |  |
| Bibhitak |  |
| Guduchi |  |
| Laghpupanchamul | 200GM |
| KALK:SHATAPUSHPA,YASHTI,YANDRAYAV,RASANJAN,PRIYANGU. | 80GM, |
| Madhu | 110ml |
| Saindhav | 10gm |
| Ghrit | 120ml |
| Mansaras | 240ml |
| **Total** | **960ml** |
Table 2. Composition of baladi yapan basti

| Ingredients of Basti | Quantity |
|----------------------|----------|
| Baladi Quath         | 400 ml   |
| Bala                 |          |
| Atibala              |          |
| Rasna-1Pal=40 gm,    |          |
| Ashwagandha-1Pal=40 gm, |      |
| Madanphal-1Pal=40 gm, |        |
| Aragvadh-1Pal=40 gm, |          |
| Bilvamaja-1Pal=40 gm,|          |
| Guduchi-1Pal=40 gm,  | 40 gm    |
| punarnarva-1Pal=40 gm,| 40 gm   |
| Palash-1Pal=40 gm,   |          |
| Devdaru-1Pal=40 gm,  |          |
| Laghupanchamul-1Pal=40 gm, |     |
| Brhitpanchamul-1Pal=40 gm, |   |
| KALKDRAVYA:80 GM,YASHTI,MADANPHAL | 80 gm   |
| Shatpusa,PraylineRasi,SHATPUSPA, KUSHTA, PIPPALI, VACHA, INDRAYAV, RASANJAN, PRIYANGU, YAVANI | |
| Madhu-70 gm,         | 70 gm    |
| Souvarchal-10 gm,    | 10 gm    |
| Ghrit-80 gm,         | 80 gm    |
| Tail -80 gm,         |          |
| Gud-40 gm,           | 40 ml    |
| Mansras-80 ml,       | 40 ml    |
| Kanji-80 ml          | 80 ml    |

Total matra of Baladi Yapan Basti: 960 ml

Table 3. Intervention in both groups

| Particular          | Study Group (Mustadi Yapan Basti) | Control Group (Baladi Yapan Basti) |
|---------------------|-----------------------------------|-----------------------------------|
| Sample size         | 30                                | 30                                |
| Intervention        | Mustadi Yapan Basti               | Baladi Yapan Basti                |
| Duration            | 16 Days                           | 16 Days                           |
| Follow up           | Next day after completion of basti, 28th day from first day of basti | Next day after completion of basti, 28th day from first day of basti |
| Total duration      | 28 days                           | 28 days                           |

Secondary outcome: We will see the effect of Mustadi Yapan Basti and Baladi Yapan Basti on Serum Testosterone level, LH, and FSH level.

Basti Pratyagaman Kal also be notifying and will try to find if there is any correlations of basti deyakal, basti pratyagaman kal on the result.

3.3 Statistical Analysis

The progressions from the pattern will be dissected by utilizing paired and unpaired t Test for target standards.

Time duration till following ups: The patient will be followed up during treatment 28 days.

Follow up period: 0 and 16th day and 28th day

Schedule of enrolment, interventions: Yapan Basti will be given from 0 to 16th day

Recruitment: 30 patients in each group will be selected by straightforward arbitrary testing lottery strategy, and PI will assign and enlist the patient.

Methods: It included data collection and data analysis. The information will be obtained on the basis of observation. The data will be collected and analysed statistically. Both groups will be compared at baseline with applying F ratio test for quantitative data and Chi-square test for
qualitative data. Students paired test will be applied for the quantitative data in each group to access the efficacy of the treatment. Unpaired T test will be applied to compare efficacy of treatment.

For qualitative ordinal data Wilcoxon test will be applied in each group to access efficacy of treatment. Manwhitney’s test between two groups. The results will be interpreted at p<0.05 and p<0.01 significance level.

The obtained results will be interpreted as:

- Insignificant P >0.05
- Significant P<0.05
- Highly Significant P < 0.01

**Objective Criteria:** Effect of *Mustadi Yapan Basti* on sperm count sperm motility, semen volume, Semen PH, abnormal sperm count along with serum testosterone, GH and FSH level. All Parameters will be assessed before and after the treatment. All patients will stay at hospital.

**Data Management:** The information passage coding will be finished by PI

**Dissemination policy:** The information will be dispersed by paper distribution. Creation qualification rules and any proposed utilization of expert scholars.

**Informed consent materials:** With all the data model assent structure and other related documentation will be given to members.

### 4. DISCUSSION

**4.1 Role of Basti Karma and its Probable Action on Oligozoosperma**

*Basti chikitsa* acts on Pakwashaya that is intestinal area and also acts on *grahani* that is small intestine. And as per Ayurveda pakwashaya is Ashrayasthan of Purushdhar kala and small intestine is ashraystanth of pitta dharakala. *Pitadharaka kala* is same as *Majadhara kala* [10] This helps us to correlate basti action on nervous system and relevantly its action on releasing and maintaining physiology of hormonal balance. It is suppose that action of basti is happened with vascular route by absorbing the principal ingredient of bastidravya [11]. Bastidravya are prepared in specific manner by using makshikam (Honey), Lavanam (Salt) Snehanam (Oil/Ghrita). Firstly triturate properly to make homogenous mixture.

Another concept of mode of action of Basti karma is Nural stimulation control through ENS that is enteric nervous system. Understanding the ENS concept we can be able to understand justify the systemic effect of basti Karma irrespective of its presence in circulation [12]. The latest concept of system biology clarify how the basti can act on various system. It clearly explain us that if we alter the pathology at one level, the pathology at another level also changes. Thus, whatever the effect of basti is on GI System, it will definitely affect another system and helps to achieve the bodily internal homostatis. [13].The excretory mechanism which helps to understand the mode of action of basti can be explained as follow-Being Hyper osmotic solution Niruhabasti causes movement of solvent from cell of colon to the lumen. Basti Dravya facilities the absorptions of endotoxin and produce detoxifications during elimination [14] Kalk used in niruhabasti causes irritation to colon and due to which it getdistended. The distended colon produces pressure which produces evacuatoryreflex. Parasympathetic fibre are significantly supplied to sigmoidal,rectal and anal region of large intestine as compare with other part of intestine. -Parasympathetic fibresat rectal sigmoidal and anal regionare mostly stimulatory in action and function especially in defecation reflexes which stimulated when basti is interfere. A100 cces gas volume is estimated to be present in the tract which is readily expelled by Basti. [15]

**Table 4. Data collection method:** Assessment criteria the results will be measured according to grades given in the box

| Result                 | Criteria-Attainment % changes in parameters |
|------------------------|---------------------------------------------|
| Complete remission     | 100                                         |
| Marked improvement     | 75                                          |
| Moderate Improvement   | 50-75                                       |
| Mild Improvement       | 25-50                                       |
| No Change              | found less than 25% changes in the parameters |
4.2 Mustadi Yapan and Baladi Yapan Basti

Basti chikitsa especially nīruha basti is known shukrajanaṇ basti. In upakalpa siddhi of Bhel Samhita we find direct reference to the usefulness of basti in impotency. Using basti even a impotent men become man in all sense. ‘Basti Shandospipunambhatvāt sarvasheśāh’ He also indicates that basti removes obstruction in the path of semen ejaculation, it protects the body from emaciation due to sex, and it ignites desire for women in those deficient in semen [16] Charakacharya also explained yapanbasti that plays major role in shukrajanaṇ. The most known of these are Baladi Yapan basti and Mustadi Yapan Basti. Considering the above fact in to consideration a comparative study of these Basti will be taken for the study.

4.3 Mustadiyapanbasti

Musta, Ushir, Bala, Aragwadh, Kutki, Trayaman, Bibhitak, Laghupanchamul, Punamarva, Guduchi Siddha ksheer will be prepared.

Kalka dravya used in Mustadiyapan Basti are shatapushpa Yashti, Endrayav, Rasanjan, priyangu.

Aragwadh is koshtashudhikar, mrudurechak ,Guru ,Madhur, Shital in nature [17] Katuki is also rechan and koshtashodhniya property. [18] Trayamana is tikta Kashaya rasyuktapittakphanashak, hradyroghamam in property [19] Punamarva is kapha pitta nashak ,vishaghna, pandughna, shothhar property [20] Guduchi is rasayan, vishaghna, jwarghna property [21] Yatimadhukalk is used in Mustadi yapan basti which is vrishya, shothhar, rasayan in nature [22] Indrayavakalk is used in Mustidiyapan basti which is vrishya, Balya, raktasangrahak property [23] Rasanjankalk is used in Mustidiyapanbasti which is Rasayan in nature [24] priyangulkalk is used in Mustadi yapan basti which is Shitviryatmak, Balakarak, Sangrahiproperty [25]. Yavanikaalk is used in Mustudiyapanbasti which is Uttejak, Balya property [26]. The Musta [27], Bala is having sheet virya, Ushir is known shukrashodhpan Bala is dwatupushthikar and prajasthapan [28]

4.4 Yapan Basti

Guduchi, Aragwadh, Punamarva, Laghupan chamula quath dravya are also found in Baladi Yapan Basti, but along with that Bala, Atibal, Ashwagandha, Rasna, Erandmul, Sahachar, Palash, Brahaptanamul are the other ingredients used for making siddha ksheer in Baladi Yapan Basti.

Kalka dravya used in Baladiyapan Basti are almost same except addition of kushta, pippali and vacha Madhu. Saindhav, Ghrit, Mansras are used in both Basti preparation. But gud, tail and kanji is additionally used in Baladi Yapan Basti. Other related studies were reviewed [29,30]. Studies on related aspects were reported by Abbafati et.al. [31,32], Lozano et.al. [33], Abhay et. al. [34] and Acharya et. al. [35].

Scope: This study may contribute as a treatment in oligozoospermia. Other study can be promoted on larger scale in various geographical areas and the efficacy of Mustadi Yapan Basti in the management of Oligozoospermia.

Implications: This study will help to set Basti Therapy as a standard protocol in the management of Oligozoospermia.

Translatory Component: If Mustadi Yapan basti is proved effective, it can be used as effective modality in management of Oligozoospermia. It will help to understand mode of action of Basti as Shukrajanaṇ. Further researches on various vrishya Bastichikitsa can be carried out in the management of Oligozoospermia.

Strength: The basti chikitsa if shows its usefulness on the hormonal level that will be the benchmark for proving role of basti in hormonal balance. Also it will be the alternative option for modern hormonal therapy.

Weakness: Sample size is small. For better result sample size can be added.

5. CONCLUSION

Basti treatment is established therapy in oligozoospermia. Various kind of basti are explained in Ayurveda classics for oligozoospermia. Yapan Basti chikitsa is useful in oligozoospermia. A comparison between two yapanbasti on objective parameters of semen analysis along with hormonal level will be a benchmark to prove for role of Yapanbasti as a holistic approach in the treatment of oligozoospermia.
DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

The made consent will be taken from the patient before starting the assessment. During the investigation, the classification of every patient will be kept up.

ETHICAL APPROVAL

Research ethics approval from the research ethics committee has taken Ref. No- DMIMS (DU) PhD. Regn/2020/706

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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