Abstract

Vatajayonivyapada having signs and symptoms such as pain along with abnormalities in menstrual bleeding matches with many of the gynaecological disorders in women of reproductive age group. It hampers their day-to-day chores and disturbing their interpersonal relationship and most importantly compromises quality of life. Therefore, an instant relief of symptoms is required along with an overall improvement in the general condition of those women. In such conditions, a better alternative non-hormonal Ayurvedic management is planned. Ksheerapaka (medicated milk preparations) of Rasna, Gokshura and Vasa having vedanahara (analgesic effect) is used in the study. In this research work our objective was to evaluate the therapeutic efficacy of oral Rasnadiksheerapaka in Vatajayonivyapada. Total 30 patients within 20-40 years of age irrespective of the marital status having classical symptoms of Vatajayonivyapada have been selected randomly from Prasuti Tantra OPD, S.S. Hospital, BHU, Varanasi. After detailed history, complete examination and investigations patients selected for the study on the basis of selection criteria. Patients were treated with Rasnadiksheerapaka 50ml orally once in a day for total duration of 45 days. Study was assessed after completion of follow-up period. Among the 28 cases, 5 patients became cured and 6 remained without any improvement and all the remaining 17 patients have got mild to marked improvement in the signs and symptoms. It is concluded that Rasnadiksheerapakahas got the therapeutic efficacy in the Vatajayonivyapadamanagement. Also helps in improving the overall health status and quality of life in such women.

Key words: Vatajayonivyapada, gynecological disorders, Rasnadiksheerapaka

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Introduction:

Ayurveda is categorized into eight different branches collectively known as \textit{ashtangas} of Ayurveda. \textit{Ashtanga} means eight parts or limbs. They are \textit{kaya}, \textit{bala}, \textit{graha}, \textit{urdwanga}, \textit{shalya}, \textit{damshtra}, \textit{jara}, \textit{vrisha}. Among these the second branch \textit{bala} deals with the pre-and post-natal care of baby and the woman before, during and after the pregnancy. Most of the gynecological disorders besides \textit{asrigdara}, \textit{artavadushti}, \textit{raktagulma}, \textit{yoni arsa}, \textit{yoni kanda} are described as \textit{yonivyapada} in Ayurvedic classics. \textit{Yoni} means female genital and \textit{Yiya} means diseases. The term \textit{yonivyapada} includes majority of gynaecological disorders in Ayurveda. Ayurveda described twenty \textit{yonivyapada} and among these the \textit{brihatrayees} have given primary importance to \textit{Vatajayonivyapada} and all the Acharyas mentioned it as the first one in all the classics. It is also mentioned that a woman never suffers from diseases of \textit{yoni} and related structures except as a result of affliction by the aggravated \textit{vata}. \textit{Vata} alone is the most predominant \textit{dosha} in most of the \textit{yonivyapada}.

\textit{Vatajayonivyapada} having signs and symptoms such as pain along with abnormalities in menstrual bleeding matches with many of the gynecological conditions in women of reproductive age group. It hampers their day-to-day chores and disturbing their interpersonal relationship and most importantly compromises quality of life. Therefore, an instant relief of symptoms is required along with an overall improvement in the general condition of those women. Keeping in view the above symptoms, a better alternative non-hormonal Ayurvedic management is planned. \textit{Rasnadiksheerapaka}(medicated milk preparations) is used in the study. \textit{RasnadiKsheera} contains \textit{Rasna}, \textit{Gokhura} and \textit{Vasa}. According to various studies on these drugs, \textit{Rasna}\textit{(Pluchea lanceolata)} and \textit{Vasa}\textit{(Adathodavasica)} are having analgesic effect and also considered valuable in the anti-inflammatory diseases management. \textit{Gokshura}\textit{(Tribulus terrestris)} is having antioxidant, analgesic, antibacterial and anti-inflammatory activities and has got positive effect on the female reproductive system due to the presence of a secondary metabolite called protodioscin; a steroidal sapogenin compound. These drugs which have authentic reference and economically low cost and safe. These are also easily available drugs in almost all seasons. According to Ayurveda, \textit{Rasnatinikta rasa}, \textit{guru guna}, \textit{ushnavirya}, \textit{katuvipaka}, \textit{kaphavatashamanadoshakarma} and indicated \textit{inswas}, \textit{shoitha}, \textit{amavata}, \textit{udarashool}, \textit{kasa}, \textit{jwara}, \textit{visha} and \textit{asheetivatavikara}. \textit{Gokshura madhura rasa}, \textit{guru}, \textit{snigdhaguna}, \textit{shitavirya}, \textit{madhura vipaka}, \textit{tridoshashamanadoshakarma} and indicated \textit{sotha}, \textit{mutraroga}, \textit{bastiroga}, \textit{prameha}, \textit{swasa}, \textit{kasa}, \textit{ashmari}, \textit{arsasand vataroga}. \textit{Vasa hastikta rasa}, \textit{laghuguna}, \textit{sheetavirya}, \textit{katuvipaka}, \textit{kaphapittaasrashamanadoshakarma} and indicated \textit{in jwara}, \textit{kushta}, \textit{kslaya}, \textit{kasa}, \textit{swasa}, \textit{meha}, \textit{aruchi}, \textit{chardi} \textit{etc.} In general all are having effect in \textit{vataroga}, and \textit{ksheera} is found to be beneficial in the management of \textit{yonivyapada} that is why these drugs are selected for the present study.

Objective:

In this research work our objective was to evaluate the therapeutic efficacy of oral \textit{RasnadiKsheerapaka} in \textit{Vatajayonivyapada}.

Materials and methods

Research Design

A research study is a single group pretest-posttest quasi-experimental clinical trial with a sample size of 30. The CONSORT Flow diagram of the study is provided in Chart 1.
Ayurvedic literature, research papers, scientific journals and authentic web sources related to this concept have been referred for the study.

Research Participants
A total of 30 patients who are fulfilling the inclusion criteria were selected from the Prasuti Tantra OPD, SS Hospital, BHU, Varanasi as research participants for the present study.

Inclusion criteria
(i) Age group 20-40 years. (ii) Patient complaining of toda and vedana of yoni (pricking and other pain of vagina), stambhata (stiffness), pипeeликасрушпитим (sensation of creeping of ants), karkashata (dryness), supti (numbness) and ayasa (fatigue or lethargy) and also phenila (frothy menstrual blood), arunakrishna (reddish black menstrual blood), alpa (hypomenorrhea), tanu (thin menstrual blood), rukshaartavasruti (menstruation appears dry), associated with vyadha of vankshana and parsva (pain in groins and flanks) for minimum 2 consecutive cycles.

Organized by Pharmacy (AY.) Course, Faculty of Ayurveda, Institute of Medical Sciences & Medical Laboratory Technology Course, Ddu, Kaushal Kendra, Rajiv Gandhi South Campus, Barkachha, Mirzapur
Banaras Hindu University

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Criteria for exclusion of cases
(i) Pregnant women, women with chronic ailments (systemic diseases like Tuberculosis, Diabetes mellitus, jaundice, bronchial asthma, cardiovascular diseases, renal problems) piles, fistula, fissure or having any history of psychological disorders. (ii) Women who are suffering from svasa, kasa, hikka, alaska, visuchika, madhumeha, kushta, sheepada, galaganda. (iii) Patient not giving consent to participation in the study. (iv) Patient who can’t attend follow-up regularly.

Diagnostic criteria
The recruited participants in the research study were clinically examined and detailed history was taken. The data were recorded systematically. Recruitments were done on lakshana.

Investigations
CBC, ESR, Random blood sugar, LFT, RFT, HIV 1 and 2, VDRL, HBsAg, Urine – Routine & Microscopic

Treatment Protocol
The proper written consent was taken from each participant after orienting the nature and course of the study. During the study, the patients were asked to follow the treatment protocol and report any adverse event to the investigators.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Time of Administration</th>
<th>Duration</th>
<th>Follow ups</th>
<th>Follow ups Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>RasnadiKsheerapaka</td>
<td>48 ml</td>
<td>Oral</td>
<td>Early morning before taking food</td>
<td>45 days</td>
<td>Total 5 follow ups with a regular interval of 15 days</td>
<td>3 follow ups with medication and 2 follow ups without medication.</td>
</tr>
</tbody>
</table>

Drug preparation
Rasnadi ksheerapaka
Rasnadi ksheerapakawhich contains Rasna, Vasa and Gokshura. Coarse powder of equal quantity of Rasna, Vasa and Gokshura was prepared in the Pharmacy, Department of Rasashastra, Banaras Hindu University, Varanasi. The patients were given instructions to prepare ksheerapakas as follows. Take ¼ pala(12 g) of coarse powdered drug and boil with 1 pala(48 mL) milk and 1 pala(48 mL) water and reduced till the quantity of milk remains and filtered.

Assessment Criteria
Primary outcomes- Parameters were assessed with various grading systems. Grading of the signs and symptoms of Vatajayonivyapada are given below

Scoring and grading Toda and Vedana of Yoni (Pricking and other pain of vagina)
0 Nil: No pain
1-2 Mild: Can be ignored
3-6 Moderate: Interferes with tasks
7-8 Severe: Interferes with basic needs
9-10 Worst pain: Bed rest required

Scoring and Grading of Stambha (Stiffness)
0 Absent: No complaint of stiffness in vagina
1 Present: Complaint of stiffness in vagina

Scoring and Grading of Pipeelikasruptim (Sensation of creeping of ants)
0 Absent: Intensity of sensation of creeping of insects 0
1 Mild: Intensity of sensation of creeping of insects 1
2 Moderate: Intensity of sensation of creeping of insects 2
3 Severe: Intensity of sensation of creeping of insects 3
Scoring and Grading of Karkashata (dryness)

0  Absent:  No complaint
1  Mild:  Dryness causing no or minimal interference with usual sexual, social and functional activities
2  Moderate:  Dryness causing greater than minimal interference with usual sexual, social and functional activities
3  Severe:  Not applicable

Scoring and Grading of Supti (Numbness)

0  Absent:  Intensity of numbness 0
1  Mild:  Intensity of numbness 1
2  Moderate:  Intensity of numbness 2
3  Severe:  Intensity of numbness 3

Scoring and Grading of Ayasa (Fatigue or lethargy)

0  Absent:  None
1  Mild:  Fatigue without interfering normal activities
2  Moderate:  Difficulty in carrying out some activities
3  Severe:  Loss of capacity to carry out some activities

Scoring and Grading of Phenilaartava (Frothy menstrual blood)

0  Absent:  No complaint
1  Present:  Complaints of froth in menstrual blood

Scoring and Grading of Arunakrishnaartava (Reddish black menstrual blood)

0  Absent:  Blood red color
1  Mild:  Dark red color
2  Moderate:  Reddish brown color
3  Severe: Reddish black color

Scoring and Grading of Alpaartava (Hypomenorrhea)

0  Absent: >2 days duration of menses
1  Mild:  2 days duration of menses
2  Moderate:  1 day duration of menses
3  Severe: Only spotting during menses

Scoring and Grading of Tanuartava (Thin menstrual blood)

0  Absent:  Normal consistency of menstrual blood
1  Present:  Thin and watery menstrual blood

Scoring and Grading of Rukshaartavasruti (Menstruation appears dry)

0  Absent:  Normal appearance of menstrual blood
1  Present:  Menstrual blood appears dry

Scoring and Grading of Vamkshana and parsvavyadha (Pain in groins and flanks)

0  Absent:  No pain
1  Mild:  Bearable pain
2  Moderate:  Requirement of oral analgesics
3  Severe: No relief after analgesics

Criteria for overall assessment – relief in signs and symptoms

(i) Cured: Patient gets 80-100% relief. (ii) Marked improvement: Patient gets 60-80% relief. (iii) Moderate improvement: Patients gets 40-60% relief. (iv) Mild improvement: Patients gets 20-40% relief. (v) Unchanged: Patient gets less than 20% relief.
### Observation and Results

#### Table 2: Effect of the therapy

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<th>Therapy Grade</th>
<th>BT (No)</th>
<th>BT (%)</th>
<th>AT (No)</th>
<th>AT (%)</th>
<th>Z-score</th>
<th>p-value</th>
</tr>
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<td>14</td>
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</table>
Discussion

In Ayurveda, most of the gynaecological disorders are included in broad term ‘Yonivyapada’. The total number of yonivyapada described as twenty in all the classics. Vatajayonivyapadais one of them. It cannot be directly compared with any of the gynaecological conditions but it matches with many of the gynaecological conditions mentioned in the comprehensive textbooks of conventional medicine. Looking to the pathogenesis of Vatajayonivyapada it is a cluster of symptomatology in which vitiated vatadosha get greatly aggravated by vata inducing diet and other activities and this vata reaches the reproductive system of the woman of vataprakriti and process troublesome signs and symptoms of Vatajayonivyapada.\(^1\) Ksheerapakakalpana is one of the unique dosage forms of Ayurveda which is an upakalpana of kwathakalpana. Ksheerapaka is useful as a medicament as well as nutrient. Ksheerapakakalpana is recommended in shoola and amajanya vyadhi.\(^1\) For the present study Rasnadiksheerapakais prepared in 1:4:4 proportion of drug, milk and water and it reduces till milk part is remain. Rasna, Gokshura and Vasa having vatashamana and shulahara property and the Rasnadiksheerapaka is mentioned in classics specially as a formulation in yonishula. All these attributes of the drug have played the role in the relief of pain in the subsequent follow-ups. Ksheerahaving snigdha gunacan counteract the rukshagunand kharatvaof vata\(^2\).

### Probable mode of action of the trial drug

Pain in any part is always due to vitiation of vata dosha. Rasna, Gokshuraand Vasa having vatashamana and shulahara property and the Rasnadiksheerapaka is mentioned in classics specially as a formulation in yonishula. All these attributes of the drug have played the role in the relief of pain in the subsequent follow-ups. Ksheerahaving snigdha gunacan counteract the rukshaguna and kharatva of vata which

<table>
<thead>
<tr>
<th>Pippeelika asrupti grade</th>
<th>BT</th>
<th>AT</th>
<th>Within the group comparison (Initial v/s follow-up)</th>
</tr>
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<tbody>
<tr>
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</table>

![OVERALL EFFECT](image)

**Figure 1: Overall effect of the treatment**

**Discussion on the clinical results**

The result was calculated by statistical analysis by using the Wilcoxon Signed-Rank test. It was used for the assessment of improvement in subjective nonparametric symptoms of the trial group. In respect of yonitoda and vedana, alpaartava and arunakrishneearartava it was observed that these symptoms were present in 21, 17 and 15 patients respectively. The drug is found highly significant after 5 follow-ups ie, \( P < 0.01 \). Hence the effect of the drug is highly significant. In respect of ayasa and supti, it was observed that both the symptoms were present in 6 patients and the drug is found significant after 5 follow-ups ie, \( P < 0.05 \). Hence its effect is significant. In respect of karkasha, pipeelikaasrupti and vankshanaparshwavadya, it was observed that these symptoms were present in 4, 3 and 15 cases respectively. The drug is found non-significant after 5 follow-ups i.e., \( P > 0.05 \). Hence the effect is non-significant here.
caused the *rukhata* or dryness in the *yoni*. *Rasnais brimhana* and rasayana, *Gokshurais balya, brimhana* and *vrishya* and *ksheera* also *brimhana*, *balya, vrishya* and *rasayana*. All these can collectively alleviate *ayasa*.

**Conclusion**

From the observation and result it can be concluded that oral administration of *Rasnadiksheerapakacan* give significant relief from majority of the signs and symptoms of *Vatajayonivyapada* without causing any adverse drug reaction and toxicity in the body. *Rasnadiksheerapakacan* can be an effective oral medicine in *Vatajayonivyapadamanagement*. It is concluded that *Rasnadiksheerapakahas* got the therapeutic efficacy in the treatment of *VatajaYonivyapada*. Also helps in improving the overall general health and quality of life in such women.

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