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Clinical Evaluation of *Dashmularishta* (Ayurvedic formulation) in Restoring Normal Health of Postpartum Females

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Abstract

Background: Postpartum is a critical period of life in regards to the health of the mother and the newborn. Postpartum mothers experience certain physical health issues that may affect their quality of life, future health, and health of their children. **Aim:** Current clinical study was conducted with an objective to assess the efficacy of *Dashmularishta* in restoring normal health of postpartum females for early resumption of daily activities and improvement in the quality of life following delivery. **Materials & Methods:** Open labeled randomized comparative prospective study conducted in 100 postpartum females having normal deliveries. They were advised either *Dashmularishta* (Mfd: Dabur India Limited) at the doses of 30 ml twice daily with equal amount of water after meals (48 subjects) or the conventional therapy as per the common protocol followed in the hospital during the puerperal period (52 subjects). The patients were admitted in hospital for 7 days and then a followed up after discharge for 8 weeks over 4 visits. **Results:** Assessed on the basis of improvement in general health, postpartum reduction in weight, the size of uterus and the abdominal girth, the improvement in tone of abdominal and vaginal muscles, character of lochia discharge and contour of cervix. *Dashmularishta* and conventional therapy showed improvement in all the parameters assessed when compared from baseline. The difference between the effects of therapies was not significant. No serious adverse event / adverse drug reaction were reported during the study period in both the groups. **Conclusion:** The effect of *Dashmularishta* in improving the health condition and quality of life in postpartum females which would lead to early resumption of daily activities was at par with conventional therapy followed without any adverse effect.

Keywords: *Conventional Therapy, Dashmularishta, Postpartum Health, Quality of Life*

Introduction

Ayurveda, the traditional system of medicine is not only well recognized in India, but also is getting appreciated in the Western world nowadays. With the growing need for safer drugs, attention has been now drawn to the produce qualitative, effective and standard Ayurvedic formulations which are purported for the various needs and specific to women's reproductive process especially, problems occurring during pregnancy, delivery and puerperium [1, 2]. Postpartum period is a critical period for the health of the mother and the newborn. It is a known fact now that the postpartum mothers experience certain physical health problems that may affect their quality of life, future health, and health of their children[3]. In Ayurvedic literatures, various stages of puerperium are described under the aegis of *Sutikakaala* (postpartum period) wherein details of do's and don'ts for dietary regimen (*Aahara*), activities (*Vihara*) and the care required during this period are discussed. Around 64 types of puerperal diseases (*Sutika roga*) with their line of treatment are also been described in these texts[4,5]. The principle of management needed to be followed during normal puerperium are advised as follows,

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i) To give all out attention in restoring the health status of the mother
ii) To prevent infection
iii) To take care of the breasts, including promotion of lactation and nursing of the child
iv) To motivate the mother for contraceptive acceptance

Acharya Bhavaprakash has mentioned the use of *Dashamula* for treatment and care during the puerperium [6]. *Dashmularishta* is a classical polyherbal Ayurvedic formulation prepared by natural fermentation process of the decoction and finely powdered various herbs. It contains more than 50 herbs along with the group of ten herb roots known as *Dashamula*. Therapeutic uses of which is noted in conditions such as *Dhatu Ksaya* (Tissue wasting), *Pandu* (Anemia), *Daurbalya* (Weakness), *Aruci* (Tastelessness), *Chardi* (Emesis) etc [7].

With the above background the present study was planned with the primary objective to assess the clinical efficacy of *Dashamularishta* in early resumption of daily activities of postpartum females and improvement in their quality of life following delivery.

Material & Methods:

Design of study: Open labeled randomized comparative prospective study

Place of study & Source of patients: Department of *Prasooti Tantra & Stree Roga*, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India

Study Product: Samples of *Dashmularishta* (Batch No: 4005 Mfd: 2004) were provided by Dabur India Limited, Sahibabad (Ghaziabad) U.P 201010. The composition details of *Dashmularishta* are given in Table 1 [8].

Table 1: Composition of *Dashmularishta*

Contents of cach 100 ml of Dabur *Dashmularishta*:	Quantity (g)
Aegle marmelos (St. Bk.), *Oroxylum indicum* (St. Bk.), *Gmelina arborea* (St. Bk.), *Stereospermum suaveolens* (St. Bk.), *Premna integrifolia* (St. Bk.), *Desmodium gangeticum* (Pl.), *Uraria picta* (Pl.), *Solanum indicum* (Pl.), *Solanum surattense* (Pl.), *Tribulus terrestris* (Fr.)	**0.52 *each***
Plumbago zeylanica (Rt.), *Inula racemosa* (Rt.)	**2.6 *each***
Tinospora cordifolia (St.), *Symplocos racemos* (St. Bk.)	**2.08 *each***
Emblica officinalis (P.)	**1.6**
Fagonia cretica (Pl.)	**1.25**
Acacia catechu (Wd.), *Pterocarpus marsupium* (Ht. Wd.), *Terminalia chebula* (P.)	**0.834 *each***
Saussurea lappa (Rt.), *Rubia cordifolia* (Rt.), *Cedrus deodara* (Ht. Wd.), *Embelia ribes* (Fr.), *Glycyrrhiza glabra* (Rt.), *Clerodendrum serratum* (Rt.), *Feronia limonia* (Bk/P.), *Terminalia belerica* (P.), *Boerhavia diffusa* (Rt.), *Piper chaba,* (St.), *Callicarpa macrophylla* (Fl.), *Hemidesmus indicus* (Rt.), *Carum carvi* (Fr.), *Operculina turpethum* (Rt.), *Vitex aagnus castus* (Fr.), *Pluchea lanceolata* (Lf.), *Piper longum* (Fr.), *Areca catechu* (Sd.), *Hedychium spicatum* (Rz.), *Curcuma longa* (Rz.), *Anethum sowa* (Fr.), *Prunus cerasoides* (St.), *Mesua ferrea,* (Stmn.), *Cyperus rotundus* (Rz.), *Holarrhena antidysenterica* (Sd.), *Pistacia integerrima* (Gl.), *Pueraria tuberosa,* (Rt.Tr.) as *Jivaka* official substitute, *Pueraria tuberosa,* (Rt.Tr.) as *Rishbhaka* official substitute, *Asparagus racemosus,* (Rt.) as *Meda* official substitute, *Asparagus racemosus* (Rt), as *Mahameda* official substitute, *Withania somnifera* (Rt.) as *Kakoli* official substitute, *Withania somnifera* (Rt.) as *Ksirakakoli* official substitute (Rt.), *Dioscorea bulbifera* (Rt.Tr.) as *Riddhi* official substitute, *Dioscorea bulbifera* (Rt.Tr.) as *Vriddhi* official substitute; *Piper cubeba* (Fr.), *Coleus vettiveroides* (Rt.), *Santalum album* (Ht. Wd.), *Myristica fragrans* (Sd.), *Syzygium aromaticum* (Fl. Bd.), *Mesua ferrea* (Stmn.), *Cinnamomum zeylanicum* (Bk.), *Elettaria cardamomum* (Fr.), *Cinnamomum tamala* (Lf.), *Piper longum* (Fr.)	***0.208 each***
Vitis vinifera (Dr. Fr.)	***6.25***
Piper cubeba (Fr.) *as Kasturi* official substitute	***0.006***
Honey	***3.3***
Jaggery	***41.7***
Woodfordia fruticosa, (Fl.)	**3.12**
Water	**Q.S.**

Part used: Bk. = Bark, Dr. Fr.= Dried Fruit, Fl.= Flower, Fl. Bd,= Flower bud, , Fr.= Fruit, Gl. = Gall, Ht. Wd. = Heart wood; Rt. = root, Lf.= Leaf; P = Pericarp; Pl.= Plant, Rt. = Root, Rt. Tr. =Root tuber, Rz. = Rhizome, Sd.=Seed, St = Stem, St. Bk. = Stem bark, Stmn. = Stamen; Wd. = Wood

Duration of study: 8 weeks

Ethics committee approval
The study was conducted with approval from the institutional ethics committee of Institute of Medical Sciences, Banaras Hindu University vide letter no Dean/2004-05/Ethical committee/5078 dated 30th December 2004 and in accordance with the ethical principles of Declaration of I-Helsinki. The Ethics Committee notifications as per the Good Clinical Practice Guideline issued by CDSCO and Ethical guideline for biomedical research on Human subjects, issued by ICMR were followed. Subject confidentiality was maintained at all times during the course of study. The study was submitted retrospectively to the CTRI vide REF/2016/04/011084All.

Inclusion Criteria
Primigravida and multigravida Female between the ages of 18-40 years with normal deliveries, willingness to sign informed consent and to come for regular follow up examination as and when required.

Exclusion Criteria
History of complicated labor including vacuum and forceps delivery/caesarean section/any other complication related to pregnancy, like eclampsia, preeclampsia, Patients participating in any other clinical trials, Patients with systemic diseases like diabetes mellitus, bleeding diathesis, TB, severe anemia(<7gm %), HIV + status.

Dosage and Treatment Schedule
Conventional Therapy (CT) Group: Care of perineum, general hygiene, dietary recommendations, avoidance of constipation by drinking plenty of fluids and eating high fiber diet as per the common protocol followed in the indoor and hospital during the puerperal period or as directed by the principal investigator for 8 weeks.

***Dashmularishta* (DSM) Group:** 30 ml of *Dashmularishta* twice daily with equal amount of water after meals for 8 weeks in addition to conventional therapy as per common hospital protocol.

Method of the Study:
Eligible subjects were recruited in the study as per inclusion and exclusion criteria. Recruited subjects were randomized into two groups, one group receiving *Dashmularishta* and the other group receiving conventional indoor treatment administered to postpartum females as per hospital protocol or as directed by the principal investigator.

Recruited subjects were admitted for 7 days and then a followed up after discharge for 8 weeks.

During different visits in the study
Visit 1 (Day 1 of post partum): Assessment of inclusion and exclusion criteria - written informed consent, Medical history, Concomitant illness and medication, General and Systemic examinations, Per abdominal, per vaginal, pelvic and breast examinations, Investigational Product dispensing, Ultrasonography - on 7th day before the discharge of patient.

Visit 2 - 4 (3, 5 & 8 weeks post partum): Any concomitant illness and medication, general, systemic, per abdominal, per vaginal, pelvic and breast examinations, Investigational Product dispensing, Adverse event/reaction monitoring.

Assessment Parameters
Patient was admitted and kept under observation for 1 week post delivery. Daily assessment was done as per the protocol. Patients were followed up for three visits and the following parameters were recorded:

1. General examination: Pulse, Temperature, Weight, Abdominal girth

2. Per abdominal examination to assess-
(i) the tone of abdominal muscles
(ii) height of uterus

3. Examination of Characteristics of lochia to assess -
(I) color,
(ii) odor and
(iii) amount of discharge

4. Per vaginal examination to assess-
(i) tone of vaginal muscles,
(ii) discharges and
(iii) contour of cervix

5. Ultrasonography on seventh day before discharge for assessing the size of uterus

Statistical Analysis: The statistical analysis were made by hierarchical ANOVA and multiple comparisons among the successive time periods of each group were analyzed by Dunnet's procedure at 95% confidence level.

Patients were examined during their stay in the hospital as a routine check up for bowel habits,

sleep, backache, headache and others symptoms of postpartum period. Pelvic examination for any discharges was noted and care of episiotomy wound was also done. Daily examination of the breasts was done for proper lactation. A few parameters such as blood investigations (except hemoglobin), urine examination, mental state etc were not included due to absence of detailed data on the same.

Observations & Results

A total of 109 subjects were recruited in the study of which 100 subjects completed the study. 9 subjects dropped out due to reasons not related to study/ study products. In DSM group, out of 48 subjects, 17 were primigravida and 31 were multigravida. In CT group, out of 52 subjects, 39 were primigravida and 13 were multigravida.

Parameters studied during the 7 days stay in hospital (before discharge)

Temperature

In DSM group 11 subjects had temperature more than 99 degrees F of which 6 had in the morning and 5 in the evening. In CT group, 6 subjects had temperature more than 99degrees F, of which 1 had in the morning and 5 in the evening. This variation was, however clinically not significant.

Average Weight Reduction

Average of 300 gm of weight reduction was measured in *DSM* group after the treatment. Also to add, 3 patients showed more than 1 Kg reduction. Average of 325 gm of weight reduction was noted in CT group after treatment. Also to add, 2 patients showed more than 1 Kg reduction. However, there was no significant difference found between the two groups.

Abdominal Girth

The abdominal girth was measured after seven days. In DSM group, mean reduction in abdominal girth was from 76.67 to 73.12 i.e. an average reduction of 3.55 cm. In CT group, mean reduction was from 79.12 to 74.68 i.e. an average reduction of 4.44 cm. Overall there was no significant difference between the effects of the two groups.

Height of uterus

In DSM group, the average height of uterus for primigravida was recorded as 13.285±0.54 cm and for multigravida was 13.57±0.51 cm. In CT group, the average height of uterus for primigravida was recorded as 13.40±0.38 cm and for multigravida was 13.37±0.43 cm.

Ultrasonography

On seventh day before the discharge of the patients, ultrasonography was done for assessing the size of uterus.

In DSM Group, the baseline volume of the uterus was found to be 1159.98 ± 293.36 cm^3 and post treatment it was found to be 120.42±45.65 cm^3. In CT group, the baseline volume of the uterus was found to be 1362.78 ±1267.47 cm^3 and post treatment and was found to be 124.49-±40.72 cm^3. Both the Groups showed a significant reduction (p<0.05) in uterus size from baseline. However, in the in between group analysis, the difference was not significant

Parameters measured in subsequent visits

Tone of vaginal & abdominal muscles was assessed clinically by the physician and graded. The results have been showed in **table 2**.

Table 2: Grading of tone of Vaginal & Abdominal muscle

Grades	No Change		Mild Improvement		Moderate Improvement		Good Improvement	
Schedule	CTG	DSM	CTG	DSM	CTG	DSM	CTG	DSM
Tone of Vaginal muscle								
Visit 1	49	48	-	-	3	-	-	-
Visit 2	-	-	52	48	-	-	-	-
Visit 3	-	-	5	1	47	47	-	1
Visit 4	-	11	52	6	0	1	0	30
Tone of Abdominal muscle								
Visit 1	52	47	-	1	-	-	-	-
Visit 2	49	48	3	-	-	-	-	-
Visit 3	-	-	52	-	-	48	-	-
Visit 4	-	-	-	-	49	-	3	48

CTG – Conventional therapy group, DSM – *Dashmularishtra* Group

Lochia Discharge

Assessment of lochia discharge was clinical, based upon inspection with respect to quantity and the number of sanitary pads used, inspection of perineum for the normal variation in color of the lochia depending up on its duration; and data gathered from the subject [9,10]. All the patients i.e. 48 in DSM group and 52 in CT group reported to have a normal discharge of lochia. Odor was found to be absent in all the patients of both the groups.

Contour of Cervix

During childbirth, contractions of the uterus occur and subsequently cervix may dilate up to 10 cm in diameter to allow the baby to pass through. In DSM group, 48 patients had 2 finger dilatation of cervix at visit 1 which reduced to 1 finger at visit 2 and further no dilatation or 0 fingers dilatation at visit 3. In CT group, 52 patients had 2 finger dilatation of cervix in visit 1 and the dilatation was 1 finger at visit 2 which further reduced and no dilatation at visit 3.

Hemoglobin Levels

In both the groups the hemoglobin level was found to be in normal range and was found to improve from visit 1 to visit 4 (**table 3**). However, there was no significant difference between the effect of the therapies.

Table 3: Mean Changes in Hemoglobin levels at different visits

Visits Groups	Visit 1	Visit 2	Visit 3	Visit 4
DSM group	10.16± 1.74	10.52±1.63	10.63±1.48	11.07±1.49
CT group	10.26±1.87	10.22±1.59	10.64±1.62	11.84±1.44

Discussion

Puerperium period is usually considered to be 6 weeks in which the body tissues, specially the pelvic organs revert back approximately to the pre-pregnant state both anatomically and physiologically. The retrogressive changes are mostly confined to the reproductive organs with an exception of the mammary glands that in fact show features of activity. By the end of 6 weeks, the uterus becomes regressed almost to the non-pregnant size.

Several factors contribute to the poor quality of life during this period. The physical and social functioning, physical activity, bodily pain, general health, vitality, mental and emotional health are the various aspects of health-related quality of life of a woman in postpartum those needed to be taken care of. Despite its importance, research on this period is limited [11,12].

The span of the study was from 2004 to 2015 on 109 subjects out of which 9 subjects dropped out due to the reasons not related to the study. *Dashmularishta* and conventional therapy showed similar improvement in all the parameters related to quality of life in postpartum women. Though the difference between the effects of the groups was not significant, the benefits of *Dashmularishta* as well as the conventional therapy were noted when compared from baseline in terms of reduction in average body weight, abdominal girth and size of the uterus postpartum. The lochia discharge reduced from moderate to mild in majority of patients within 3 weeks postpartum. There was a normal contraction of cervix and most of the patients showed better improvement in tone of abdominal and vaginal muscles within 8 weeks of postpartum. No serious adverse event /adverse drug reaction was reported during the study period in both the groups.

In the parameters assessed during the 7 days of stay in hospital (before discharge), 11 patients in DSM group and 6 patients in CT group had temperature more than 99 degrees F, however the rise was clinically not significant. Fever in the postpartum period is a relatively common occurrence, with a frequency of approximately 5-7% of deliveries and the majority of them are reported after two days. Postpartum fever is defined as a temperature of 38.7 degrees C (101.6 degrees F) or greater for the first 24 hours or greater than 38.0 degrees C (100.4 degrees F) on any two of the first 10 days of postpartum period. The occurrence of *Stanyotha Jvara* (fever due to breast milk secretion) is also described as a normal occurrence in Ayurveda.

Traditionally, *Dashmularishta* is indicated in GI, respiratory, urinary, ano-rectal and nervous disorders and in female infertility. It is also characterized by benefits of maintaining woman health[13]. It is reported to exhibit anti-inflammatory properties [14] and antibacterial [15] activity against enteric pathogens. Main constituents of *Dashmularishta* like *Aegle marmelos, Oroxylum indicum, Desmodioum gangeticum* and *Tinospora cordifolia* are also known for their free radical scavenging[16,17] anti-inflammatory[18] and immuno- stimulatory[19] activities. The compound formulation *Dashmularishta* is traditionally attributed with properties of ameliorating afflictions of postpartum period. Its beneficial effects in *Dhatukshaya / Daurbalya* (loss/weakness of body tissues) and as *Garbhasayshodhak* (Cleanser of uterus) and

vitality booster properties may have contributed to its beneficial effects in postpartum period.

Conclusion

The results of the present preliminary research revealed that the difference in the effect of *Dashmularishta* was non significant when compared to conventional therapy. This suggested that the effect of the trial drug was similar or on par with the conventional therapy. The trial drug can be considered as an alternative choice in those who find it difficult to follow the conventional therapy for longer period especially in working class women by helping them in early resumption of daily activities.

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