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STUDY OF EFFICACY OF RAKTBOL VATI AS ANALGESIC IN SUTIKA MAKKALLA

Renu¹, Narendra Khairnar², Swati Mohite³

¹P.G. Scholar, ²Asso. Professor and Guide, ³Professor and HOD, Department of Stree Roga & Prasuti Tantra, Bharati College of Ayurveda & Hospital, Pune, Maharashtra, India

Email: renuksingh12@gmail.com

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ABSTRACT

Sutika (puerperal woman) Makkalla (postpartum abdomen pain) occurs frequently in women who does not follows Sutika Paricharya (special puerperal lifestyle). Vitiated Vata is the main cause of this pain. Elevated Vata obstructs the blood flow from the uterus. **Objective**: To compare efficacy of *Raktbol vati* with Tablet Diclofenac Potassium 50 mg and Paracetamol 325 mg. Methods: 40 patients divided into control and trial group (each 20 patients). For control group Tablet Diclofenac Potassium 50 mg and Paracetamol 325 mg twice a day for 4 days and in trial group Raktbol Vati one gram twice a day for 4 days was given. Results: In trial group (n=20) desired pain relief was observed in 16 patients. Conclusion: Raktbol Vati proved to be having moderate analgesic action and patients in trial group does not required any additional analgesics.

Keywords: Analgesics, *Raktbol Vati*, *Sutika Makkalla*.

INTRODUCTION

Sutika Makkalla has been described as one of the postpartum diseases described in various Ayurvedic texts. A woman who has just given birth to a child followed by expulsion of the placenta is called *Sutika*¹. The root word for makkalla is 'makka' which means 'to move'

or 'to go'. It is a term used to denote pain produced due to Vitiated Vata obstructing Shonita (blood) in uterus causing complete evacuation of Prajanana shonita in the Sutika avastha. According to modern science puerperium is defined as the time from delivery of placenta and lasts for approximately six weeks. The main physiological event that occurs during the puerperium is involution process by which genital organs revert back approximately to prepregnant state physiologically and anatomically and ensure lactation².

According to various classical Ayurvedic texts Sutika awastha is a phase having Vata-Vruddhi, Dhatukshava (Rakta-strava, rasa-kshava), Vrani-Avastha (Wound at placental site, cervix, vagina and perineum), Agni Mandya (less digestive power), Shoonnya Sharir³ (physical stress of labour woman becomes like an old and torn cloth.) All these factors make the woman vulnerable to various types of disorders or diseases. These factors lower her immunity (Vyadhi-Kshamatva) and make the diseases difficult to treat (Kashta-Sadhya)⁴.

By following Sutika Paricharya like Ashwasan, Snehan with Mardan of the back and pressing of the flanks (*Udar-Peedan*) followed *By Pata-Bandhan*⁵ by which Vavu and residual Doshas are expelled and by consuming beneficial Ahara (Laghu, Sneegdha etc) and by following instructions about Vihara (avoiding exercise, coitus, anger etc.) one can avoid development of Sutika Rogas. If Sutika does not follow the above-mentioned regimen she will land up with the development of diseases (described by Acharya Kashyapa) occurring in Sutika. Sutika *Makkalla* is one of them

According to Acharya Sushruta, unpurified and unexpelled blood after delivery accumulates in Garbhasya (uterus) due To Vata Prakopa causing glandular/cystic growth in hypogastric region, flanks, bladder region or leading to pain in above mentioned area⁶. A humble effort to understand the condition in Ayurvedic aspect was done and found to be like postpartum pains on the basis of symptoms.

The routine protocol of modern medicine is to give analgesics to relieve the pain during puerperium which has various side effects such as upset stomach. dizziness. To provide safe, effective and natural alternative to modern analgesics the present study is designed. Hence, to scientifically assess the efficacy of this formulation, the present study was carried out.

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The assessment of clinical study was done on the parameters: Pain in abdomen, pain at episiotomy site, episiotomy wound healing, involution of uterus, Agni (digestive power), number of pads used (per vaginum bleeding) per day, colour and odour of lochia. The findings were compared and subjected statistical analysis to draw the conclusions. This clinical study has been carried under the rigid rules of clinical research methodology. Special case report format (CRF) was designed which contains record of clinical observations and measure safety of medicine.

Aim: Study of efficacy of Raktbol Vati in mild form of Sutika Makkalla.

Objectives:

- 1. To compare efficacy of Raktbol Vati with Tablet Diclofenac Potassium 50 mg and paracetamol 325
- 2. To find outside effects of Ayurvedic yoga if any.

Material and Methods:

Clinical Source: In Patient Department of Stree Roga & Prasuti Tantra Bharati College of Ayurveda & Hospital, Pune-411043, Maharastra, India.

Literary Source: Literary aspect of study was collected from Classical Ayurvedic text, modern texts, recent journals.

Drug source: Vati made of Raktbol, Jirnagud and Ghrita is effective in Sutika Makkalla according to Acarya Yogratnakara's Stirog Chikitsa Adhyaya⁷. All the three drugs were purchased from reputed ayurvedic pharmaceutical shop, authentication and standardisation was done. Vati was prepared by following standard methods of prepration (according Sharangdhar's method)⁸ from a pharmaceutical company. Raktbola, Guda are taken in equal quantity and Ghrita was added in 1/4th the amount.

INSTRUCTION FOR ADMINISTRATION:

Form: Vati (Tablet)

Route of Administration: Orally

Dose: 1 Gram Twice daily

Duration: 2nd To 5th Day Post-Partum (4days). (Patient admitted in hospital for 5 days only after vaginal delivery. These pains felt in lower abdomen after delivery for a variable period of 2-4 days⁹. After pains decrease in intensity and become mild by the third day so, given medicine from 2^{nd} to 5^{th} day 10).

Methods of Collection of Data:

Number of Patients: 20 Each Group (40 Total).

Type of Study: Single Blind Clinical Study and Randomized Controlled Trial Study.

Groups: 2

Control Group (A): Tablet Diclofenac Potassium 50 milligram and Paracetamol 325 milligram was given twice a day for 4 days.

Trial Group (B): *Vati* Made of *Raktbola*, *Ghita And Jirna Gud* was given twice a day for 4 days (1 Gram).

Selection Criteria

1) Inclusion Criteria:

- 1. Patients of vaginal delivery (irrespective of parity) having pain in abdomen after delivery.
- 2. From 2^{nd} day post-partum till 5^{th} day.

2) Exclusion Criteria:

- 1. Patients of cesarean section.
- 2. Patients who refuse to participate willingly in the study.
- 3. Patients with severe anaemia (Hb% less than gm).
- 4. Patients with GDM.
- 5. Immuno-compromised patients.

3) Discontinuation Criteria:

- 1. Non-compliance of patient.
- 2. Development of any untoward side effects.

Table 1: Contents of Raktbol Vati: Raktbol^{11,12}, Ghrit^{13,14}, Jirna (Old) Guda¹⁵

Sr. No.	Drug	Latin name	Family	Rasa	Vipak	Virya	Doshghanata	Karya
1.	RaktBol	Commiphora Myrrha	Burseraceae	Tikta Katu Kashy	Katu	Ushna	Tridosh hara	vedanastahpana, Shothahara, garbhasyasvishodhana, aartavjananna, vatashamak, anulomaka, deepanpaachan, raktashoodhak, krimihara
2.	Ghrita	Clarified butter	Ghritavarga	Madhura	Madhura	Seetvirya	Vata-pita nashaka	Aanahahara, agnideepak, Balvridhhikar.
3	JirnaGud	Old jaggery	Ikshuvarga	Madhura	Madhura	Naati Sheeta	Vatnashaka	Vatanashak, raktprasadak, pathyakar, mutra and raktshoodhak, balvridhhikar.

Assessment of Results: Parameters before and after the treatment was compared and statistically analysed.

Parameters:

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- 1) Pain in abdomen on Visual Analog Scale (VAS)
 1 (mild)= VAS 0-3; 2 (moderate)= VAS4-6; 3
 (severe)= VAS 7-10
- 2) Episiotomy wound pain on Visual Analog Scale (VAS)

1 (mild)= VAS 0-3; 2 (moderate)= VAS4-6; 3 (severe)= VAS 7-10

3) Episiotomy wound healing

1=completely healthy; 2= with mild inflammation; 3=serous or pus discharge seen; 4=gape

4) Uterine Involution (Garbhasyarhass)

1=Sub-involution (less than 1.2 cm/day) ;2=Normal (1.2-1.4 cm/day); 3=Super-involution (more than 1.4 cm/day)

Each morning at same time after emptying the urinary bladder, the involution was assessed by measuring the distance between pubic symphysis and uterine fundus (centralized) by measuring tape in centimeters.

5) Digestive power (Agni)

- 1 (Mridu agni) = hungry in 10 hours.
- 2 (Madhyam agni) = hungry in 8 hours.
- 3 (Tikshan agni) = hungry in 6 hours

6) Yonigata Strava Pramana (number of pads used per day):

- 0 (minimal)=1 pad;
- 1 (mild)=2 pads;
- 2 (moderate)=3 pads;
- 3 (severe)=4 or more pads

7) Yonigata Strava Varna (Lochia Colour)

- 1 (Rubra)=Red;
- 2 (Serosa)=Yellow;
- 3 (Alba)=White

8) Yonigata Strava Gandha (Lochia Odour)

1=Visragandha; 2=Durgandha

Assessment of Response: Assessment of condition has been done based on detailed performa, adopting standard scoring methods of parameters and analysed using paired t test, two sample test, wilcoxon test and Mann Whitney test

Result Interpretation:

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Pain in abdomen- group A 100%, group B- 80% relief seen,

Episiotomy wound pain- group A 100%, group B-80% relief seen,

Episiotomy wound healing- group A 100%, group B-100% relief seen,

Normal Uterine involution- group A 90%, group B-85% seen;10% in group A and 15% in group B had subinvolution.

Agnivrdhan (digestive power)- group A 70%, group B-90% relief seen,

Increased lochia discharge - was seen in group B as compared to group A,

lochia colour and odour- No effect was seen on both the groups.

Comparison of group A and group B on pain in abdomen in Sutika Makkalla

Table 2

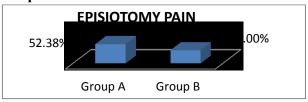
Group		Grade 1	Grade 2	Grade 3
A	(BT)	0	8	12
	(AT)	20	0	0
В	(BT)	0	9	11
	(AT)	16	4	0

Table 3

Pain Abdomen	In	% of improvement	Mann Whiteney	p value
Group A		61.54%	170	0.08
Group B		55.77%		

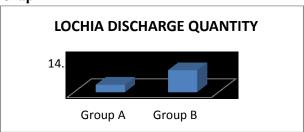
Comparison of group A and group B on episiotomy pain

Graph 1



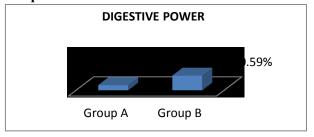
Comparison of group A and group B on lochia discharge quantity in *Sutika Makkalla*

Graph 2



Comparison of group A and group B on digestive power in *Sutika Makkalla*

Graph 3



DISCUSSION

When percentage of relief in the cardinal symptom of the disease is concerned (pain in abdomen) group A (control) was having marked response of 100% and in group B (trial) it was moderate response of 80%.

After studying various other parameters, it was observed that-

- 1. Improvement in quantity of lochial discharge was more in trail group. The increased quantity of lochial discharge is due to the *Garbhashya Shodhana* and *Vatahara* action of the *Raktbol vati*. This resulted in clearing of accumulated intra uterine blood (*Avarudha rakta*) and reduction of abdominal pain. Thus, the increased in lochial discharge is a sign of releasing obstruction.
- 2. Prostaglandins production and inflammation at any wound is the root cause of pain. According to modern pharmacological research papers ^{16,17,18} available *Raktbol* (Commiphora Myrrha) has anti-inflammatory and analgesic effect, its analgesic action was observed.
- 3. As there was no inflammation, proper wound healing was achieved.
- 4. Physiological locial colour, lochial odour and uterine involution was seen in both the groups.
- 5. According to *Ayurvedic* classical texts weak digestive power is the root cause of any disease. Enhancement of digestive power resulted in improvement of general condition of the *Sutika*.

Probable Mode of Action of *Raktbol Vati* As Per Ayurvedic And Modern Aspect:

Sutika Avastha is Vata Pradhana Avastha so, Vata Shaman is required. Shoola is because of Aavarodha (obstruction) of Rakta in Garbhasya. This Vati acts as a Garbhshya Shodhaka. Additional attributes of Raktbol Vati are Vedana Sthapana, Vata Anulomak, Garbhasyas vishodhana property of Rakt Bola, Tridosh Pidda nashak and Rasayana property of Jirna (Old) Guda and Vatahara quality of Ghrit which helps to treat Sutika Makkalla according to Acarya Yogratnakar's formulation.

Furanodienes is the active chemical component from comiphorra myrrha. There are several types of pain: nociceptive being one of them which is associated

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with stimulation of nociceptors. Nociception is a process through which signals caused by harmful stimuli are transmitted to the central nervous system (CNS). Nociceptors are located in the skin, blood vessels, muscles, joints and junctions which are pain sensitive neurons. Post-partum women experience muscular pain (due to contractions of uterus and at episiotomy site). Its activity is analgesic by blocking nociceptors^{19.}

CONCLUSION

On the basis of Ayurvedic texts, views of ancient scholars, facts and observations done in the present clinical research work some points can be concluded like-

- In this study maximum patients (in both the groups) were of *Vata-Pitta prakruti*, between 20-30 years of age group and were multipara.
- Sutika patients who does not follow Sutika Paricharya developed Sutika Makkalla after vaginal delivery.
- The vitiated *Vata Dosha* and *Shonita* are the main causative factors of *Makkalla*.
- The most evident symptom of Sutika Makkalla is pain in abdomen. Tablet Diclofenac Potassium 50 mg and Paracetamol 325 mg is more effective as compared to Raktbol Vati in episiotomy wound healing and decreasing episiotomy pain in Sutika.
- Raktbol Vati found to be moderately effective in treating Sutika Makkalla.
- In both the group intravenous and intramuscular analgesics were not needed.
- Raktbol Vati increases digestive power and lochia discharge thus, helped in treating Sutika Makkalla.
- No effect was seen on lochia colour and its odour.
- No side effects of *Raktbol Vati* were observed in study.

The present study concluded that Tablet Diclofenac Potassium 50 mg and Paracetamol 325 mg observed to be more effective as analgesic. *Raktbol Vati* has a moderate analgesic effect but as it is a natural remedy it is safe and has no side effects.

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