Determining the Efficacy of Combination of Three Ayurvedic Formulations and *dhoopana* (Medicinal Fumigation) in Prevention of Infections Post Vaginal Delivery with Episiotomy

Prof. Dr Swati¹, Surendra Mohite²

Bharati Vidyapeeth Deemed University, College of Ayurveda, Dhankawadi, Pune 411043, Maharashtra, India

Abstract: Background: Sutika paricharya or regimen for the puerperal state, as mentioned in the texts is specifically designed Ayurvedic regimen for restoring the health of the women after the exhausting and laborious process of vaginal delivery. In the present times, vaginal deliveries are routinely administered episiotomy to avoid vaginal trauma and tear. This also requires the use of antibiotics and analgesics to prevent infections and reduce patient discomfort. Ayurveda mentions specific vranashodhaka (~disinfecting and cleansing) and vedanahara (~ analgesic) treatments for sutika (~ women in the puerperal state) in sutika paricharya. Aim: The study aims at establishing the efficacy of vranashodhaka and vranaropaka (~ wound healing) attributes of therapy of dhoopana (~ medicinal fumigation) when administered along with oral medications. The present study also attempts to present an effective and viable alternative to the use of antibiotics to prevent the infections occurring post vaginal delivery with episiotomy. Methodology: Oral medications of saubhagya shunthi paaka, balant kaadha and shatavari kalpa were administered to patients post vaginal delivery with episiotomy, within 2 - 4 hrs after completion of labor, for 5 -7 days after delivery. This was followed by dhoopana therapy (~ medicinal fumigation) as per Ayurvedic protocol. <u>Results</u>: A total of 252 patients were included in the study. 28 patients (11.1%) showed signs of infection which were not related to reproductive organs, one patient had non-infected subcutaneous skin gapping which healed without antibiotics on 12th day and only 23 patients (9.1%) required analgesics. Average duration of stay at the IPD was 5 to 7 days. Conclusion: The administration of dhoopana therapy along with oral medications like balant kaadha, saubhagya shunthi paaka and shatavari kalpa as a combination was found to be very effective in preventing puerperal infection. The shatavari kalpa acts as a galactogouge to enhance breast milk secretion. This combination could be an effective alternative for prophylactic antibiotic treatment administered to patients undergoing vaginal delivery with episiotomy.

Keywords: Vaginal delivery episiotomy ayurvedic management

1. Introduction

Sutika is the state of a woman immediately after delivery and extends till the time she continues breastfeeding. The *'sutika'* refers to the puerperal/ post partum stage of a woman.⁽¹⁾ In this state, after the strenuous process of labor, the *dosha* are in a state of flux, the *vaata dosha* is aggravated and hence this state requires special nurture to regain the normal health. To restore the equilibrium of the *dosha* and to provide the mother with ample strength to take good care of the new born requires special care and dietary and lifestyle measures to be followed for the benefit of the mother and the child both. The classics therefore advise certain specific medications and therapies during this period.

Ayurvedic classics specifically mention the '*sutika paricharya*' or the diet and lifestyle regimen to be followed in this stage to maintain health and equilibrium of *dosha*. ⁽²⁾ This regimen apart from providing comfort and relief from the physical and mental trauma caused by labour also aims at preventing any kind of infection which may be caused as a result of trauma or tear to the perineum or vagina.

In present day practice, taking episiotomy incision is a routine practice to avoid vaginal trauma and the same has to be supported by the use of prophylactic antibiotics & analgesics to prevent infection and provide relief from pain. As the vaginal orifice lies between the excretory organs of urethra and anus the chances of infection are enhanced in this condition, thus making the administration of prophylactic antibiotics vital part of the patient management protocol. Infection is the most common puerperal complication which causes a severe burden in terms of maternal morbidity. Prophylactic antibiotics are used widely in India for preventing maternal infections. 'Prophylactic antibiotic' implies the use of antibiotics before, during, or after a diagnostic, therapeutic, or surgical procedure to prevent infectious complications.⁽³⁾. Every time an antibiotic is used whether appropriately or not, in human beings or in animals- the probability of the development and spread of antibiotic-resistant bacteria is increased. (4) Antibiotic resistance is now regarded as a major public health issue because it leads to infections by multi-drug resistant bacteria which in turn causes increased morbidity and increases the cost of therapy. ⁽⁵⁾ Antibiotic resistance, a global concern, is particularly pressing in developing nations, including India, where the burden of infectious disease is high and healthcare spending is low. ⁽⁶⁾The optimal duration of antibiotic administration is still controversial. There has been much concern in the medical fraternity regarding the misuse of antibiotics giving a sense of security leading to suboptimal aseptic precautions.⁽⁷⁾

It is of paramount importance, now more than ever, to find a solution to antibiotic resistance. Ayurveda can surely provide a solution in such a scenario.

To avoid the rampant usage of antibiotics, substituting these with Ayurvedic medications with known antimicrobial activity can be one of the solutions. Ayurvedic herbal

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preparations and extracts have great potential as antimicrobial activity against bacterial pathogens and they can be used in the treatment of infectious diseases. Clinical trials of different medications used routinely by Ayurvedic physicians for the management of infections may provide answers to such problems.

The aim of the study was to determine the role and efficacy of such a combination of drugs with *vranashodhaka* (~ eliminates discharge from wound, cleanses and disinfects), *vranaropana* (~ absorbs secretions from wound & facilitates healing) and *grahabadha nashaka* (~ acting against infections caused due to unknown causes/ curse from celestial bodies etc.) attributes, which have been used for ages as a part of *sutika paricharya*.

Amongst the range of different medications described in the classics for treatment of diseases affecting the *sutika*, *Balant Kadha* and *Soubhagya Shunthi Pak* and *shatavari kalpa* were selected and administered to *sutika* who had undergone vaginal deliveries with episiotomy. These medications were selected owing to their specific attributes and their known successful use by several experienced and practicing physicians since olden times. This combination has been found to be very effective in preventing infection and to maintain healthy status of *sutika*.

2. Aims

To assess the efficacy of combination of *Balant Kadha* and *Soubhagya shunthi pak* and *shatavari kalpa*, *dhoopan* in prevention of post partum infection caused in vaginal deliveries with episiotomy.

3. Methods and Material

3.1 Material

- 1) *Balant Kadha*, 20 ml, twice a day, with equal quantity of water.
- 2) Soubhagya shunthi paak 10 gm, twice a day, along with warm water if desired.
- Shatavari kalpa 10 gm twice a day, along with 30-40 ml of milk

3.2 Method

The study is a retrospective study of data collected at the 'Prasuti and Streerog Department' of Bharati Ayurveda Hospital, Pune. The total number of patients studied was 727, out of which only 252 patients were considered for this study. The data was collected during a period of a year, January to December 2012. All the 252 patients who delivered vaginally with episiotomy were studied and the data was analyzed. These patients undergoing vaginal deliveries with episiotomy were administered the above medications one hour after the delivery and the same were continued up to five days post partum, during the stay at the hospital. Only the oral medications were advised for about 45 days after discharge from the hospital.

Distribution of patient according to parity was - 93/252 patients (36.18%) were primipara, and 159/252 patients (63.82%) were multipara. A detail history, general

examination, obstetrics or gynecological examination and laboratory investigations like hemogram, urine examination, blood sugar levels, and serology of each patient was done. All patients were monitored daily during hospital stay for vital signs, per abdominal examination, inspection of episiotomy site for any foul smelling vaginal discharge. For all patients, hemogram was also done on third day i.e. after 48 hours after delivery.

- a) <u>Inclusion criteria</u>- Patients undergone normal delivery with episiotomy were considered for the study. Both primipara and multipara patients were included for the study.
- b) <u>Exclusion criteria</u>- Patients suffering from severe anaemia (Hb less than 7gm%), gestational diabetes, patients with history of leaking for more than six hours before labour, patients not willing to take Ayurvedic medications were not included.
- c) <u>Discontinuation criteria</u>- Patients who developed gastritis after administration of medications, were discontinued and shifted on antacids.

Duration of treatment – The combination of oral medications was offered immediately after two to four hours post labour, and regular dosage at stipulated timings was administered for the next five days. The first dhoopana therapy was administered 24 hrs after delivery and every morning for five days during hospital stay. The patients were also advised to continue oral medications for at least 40 days after discharge from the hospital.

3.3Assessment Criteria

- a) <u>Subjective criteria</u>-Pain at episiotomy wound, episiotomy wound was checked daily, neonatal well being observed to asses milk secretions.
- b) <u>Objective criteria</u> Haemogram reports before labour and on third day post partum were considered.
- c) <u>Treatment protocol</u> As per the puerperal management mentioned in Ayurveda, the treatment protocol for the patients was designed as –

Internal medications -

- 1) *Balanta Kaadha* 1st dose, 20ml/ with water, within 2-4 hrs post partum. Thereafter followed as 20ml/ twice daily, along with water.
- Saubhagya Shunthi Paaka 1st dose, 10 gm, within 2-4 hrs post partum. Thereafter followed as 10 gm/ twice daily, along with water.
- Shatavari Kalpa 1st dose after 6-7 hrs post partum, along with milk. Thereafter followed as 10 gm/ twice daily along with milk.

Local therapy – *Dhoopana* – (Medicinal fumigation) First therapy of *dhoopana* was administered --- 24 hrs after delivery. Procedure for administration of *dhoopana* therapy – The *dhoopana* therapy was administered every morning for 5 days after delivery. The patients were asked to empty the bladder and bowels before the therapy. The perineum was properly cleaned and dried. The patient was asked to sit on a chair with a hole in the centre. The lower part of the

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chair was covered/ draped by cloth from all sides to direct the fumes upwards and prevent any deviation by winds. A small earthen vessel with burning embers was placed under the chair. *Dhoopana* medications were sprinkled on these embers to make smoke.

Dhoopana medications *Vidanga*, *Shatapushpa*, *Jatamansi* 2 gm each, *Gugullu* 5 gm were sprinkled on these embers. Medicinal fumes arising from the embers helped fumigate the perineum. The treatment was administered for about 3 -5 mins. The perineum was not cleaned immediately, the patient was asked to wear clothes and clean perineum when she experiences an urge to clear the bladder.

3.4 Observations

Observations were recorded on the basis of subjective and objective criteria mentioned above.

A. Subjective criteria-

 Pain assessment was conducted on a daily basis – as per VAS scale for pain.

9.1% (23/252) had severe episiotomy pain, which had been treated by Nimusulide 50 mg / twice a day 91% (229/252) did not experience pain during the five days.

- Episiotomy wound on first & fifth day -0.3% (1/252) patient had superficial skin gapping, which was healed without any treatment.
- 3) The episiotomy wounds of the rest of the patients healed without any infection or complications.
- 4) Breast milk secretions, assessed daily
- 5) Milk secretions were adequate for all neonates.
- 6) Fever -

10.7% (27/252) cases had fever within 3-5 days after delivery & antibiotics were given. Their leucocytes count was in the range of 15000 - 22000/cubic mm. 8 cases had urinary tract infection, 7 cases had upper respiratory tract infection and 12/252 cases had breast engorgement for which anti-inflammatory medication was administered.

B. Objective Criteria

Hemogram on first & third day

- i) The hemogram reports of 89.3% patients were within normal limits both on first & fifth day.
- ii) The leucocyte counts of 10.7% patients were increased and it ranged between 15000-22000 /cubic mm.

4. Result

Results showed that 91% of patients did not report of any pain after the administration of the medication. Also that the infections/ fever reported by 10.7% were largely caused due to non- related factors or due to reasons other than infection at site of episiotomy or reproductive organs. The study recorded that 11.1%(28/252) patients developed fever within three to five days, due to factors like urinary tract infection, upper respiratory tract infection, and breast engorgement. Breast milk secretions were adequate in all patients.

5. Discussion

Ayurvedic classics mention special dietary and lifestyle regimens for each of the 'stree visitha awastha' (~ life stages unique to females) such as rajaswala (~ menstruation), garbhini (~ pregnancy), sutika (~ puerperal state) etc. The classics states that the state of the *dhatu* in the body of the women in the garbhini stage is severely altered; she requires extra nourishment and care to facilitate the development of foetus in her womb. In the sutika stage, post the arduous labor and the sudden elimination of the fetus she bears for nine months, the body becomes empty and exhausted due to labor pains, excretion of moisture and blood from the body. This adversely affects the digestive power of the woman and the muscle mass and bodily strength decrease. This makes the woman vulnerable to a host of diseases. To restore the normal state of the dhaatu and to regain the lost strength, the woman requires special care and medications. The classics thereby advise a specific sutika paricharya (~ regimen to be followed during the puerperal state) which helps prevent anomalies arising in this stage.⁽³⁾ This regimen helps maintain the health and fitness of the mother as well as the child which totally depends on the lactating mother for nourishment. Amongst several dietary and lifestyle changes advised in the texts, some medications and therapies are particularly meant to prevent infection and restore strength of the body. These include deepana (~ enhance the digestive capacity) and pachana (~ aid digestion) medications which restore the state of the agni and thereby enhance the immunity and the strength of the body. Certain therapies like dhoopana are local therapies particularly meant to disinfect and prevent infections of the perineum.⁽⁸⁾ A range of different medications have been mentioned in the classics, out of which the most commonly used medications have been administered and studied here for their efficacy to prevent and deal with infections arising in the puerperal state and to

enhance the strength

The *sutika paricharya* particularly mentions the administration of *balant kadha* and *saubhagya shunthi paak* for restoring the health and fitness of the mother and improving the breast milk secretions. These medications, though not particularly mentioned in the classics as a combination have been used since ages and have become a part of the *'vruddha vaidya parampara'*(~ medicines traditionally used by senior Ayurvedic physicians)

The *balant kadha* is prepared with a combination of several *vaata* pacifying drugs as mentioned in the table 1.1. It is known for its special attributes of *garbhashaya balya* (~

imparts strength to the uterus) and *swasthyakara* (~ maintain health of the *sutika*). $^{(9)}$

The *soubhagya shunthi paaka* is a medicine mentioned in the Bhaishajya Ratnavali text in the chapter of Sutika Chikitsaa Prakarana.⁽¹⁰⁾ Primarily indicated for the treatment of the diseases affecting the *sutika*, the attributes of the formulation include as *angiprada* (~ enhances the digestive power), *sutikagadaapaha* (~ alleviates the diseases affecting the *sutika*) among other applications like treating diseases like *krumi* (~ worm infestations), *daaha* (~ burning sensation), *shula* (~ pain) affecting the mother.⁽¹¹⁾

The text recommends Soubhagya shunthi paaka for establishing the equilibrium of *dosha* in the post partum state. The contents of the same are described in Table 1.2. This formulation contains Shunthi (dry ginger) as the main active ingredient along with goghruta which act as deepana and pachana medications and restore the state of agni (~ digestive capacity).⁽¹²⁾ As per Ayurvedic philosophy, the root cause of any disease is the vitiated state of the agni which leads to indigestion and *aama* (~ accumulation of incompletely digested wastes) in the body.⁽¹³⁾ This further leads to an imbalance of the dosha and onset of disease. The restoration of agni thereby also helps prevent infection in the body by enhancing the inherent bodily strength and immunity. The other contents like godugdha, shatapushpa, shatavari, lohabhasma and abhraka bhasma help in nourishment of the dhaatu, the upadhaatu and enhance the secretion of the breast milk. Shunthi helps pacify the aggravated vaata dosha and is a part of the Shulaprashman gana (~ group of medications that alleviate pain) and helps in alleviating pain. Shunthi is known for its vedanahara (~ analgesic) and vranashodhaka (~ wound healing) properties. With several phytochemical and pharmacological studies conducted till date ginger has been analyzed and proved to be good analgesic. ⁽¹⁴⁾ Thus, the Soubhagya shunthi paaka is an important drug in the management of sutika avastha. It not only helps in alleviating pain, preventing infection but also helps improves breast milk secretions for the nourishment of neonate.

Thus, this particular combination of *balant kadha* and *saubhagya shunti paaka* proved effective to prevent infections in the wound, to alleviate pain and to improve lactation. The established antimicrobial action and analgesic properties of *shunthi* and other ingredients of *balant kadha* endorse the benefits of use of this combination in the puerperal state.⁽¹⁵⁾

The *dhoopana chikitsaa* is an important therapy used for the treatment of several diseases. The Charaka samhita describes it to be useful for treating all types of *vrana* (~ wounds/ injuries).⁽¹⁶⁾ It states that *dhoopana* dries out the wounds and is *krumighna* (~ disinfectant) in action. It also helps restore normal skin by enhancing the elasticity and softness of the skin.

The medicines used for dhoopana like *vidanga*, *shepa and jatamansi* have been indicated in the texts as *dhoopana dravyas*. The *ruksha* attribute of all these medications helps dry out the secretions and aid in healing of episiotomy wound. *Vidanga* (Embelica ribes) is known for its astringent

and krumighna attributes. It helps pacify the kapha and vaata dosha and has been described as aratinut (~ analgesic).⁽¹⁷⁾ Balanta shepa (Foeniculum vulgare) used for therapy display specific dhoopana attributes of vranashulaghna (~ analgesic and wound healing properties). ⁽¹⁸⁾ Jatamansi (Nordystachus Jatamansi) is known for its vimlapana action (~ local anti inflammatory, wound cleansing and healing).⁽¹⁹⁾ The guggulu (Comniphera Mukul) resin used for fumigation is also known for its shothaghna (~ anti inflammatory), bhagna sandhanakruta (~ helps join or unite ruptures), vranam jayeta (~ wound healing), krimighna (~ disinfectant) and rakshoghna (~ from infections protects from unknown causes) properties.⁽²⁰⁾ The drugs like jatamansi and guggulu have been proven to exhibit antimicrobial and antifungal properties.^(21, 22)

The *shatavari kalpa* had been administered to the patients twice daily along with milk. *Shatavari* (*Asperagus Racemosus*) has been described in the text Bhavprakash as *rasaayana* (~ rejuvenates), *pushtidaa* (~ nourishes) and *stanyakari* (~ *galactogouge*) medication which imparts strength to the body.⁽²³⁾ The *kalpa* formulation is a preparation of *shatavari* decoction cooked in sugar till it forms small crystals. This formula for administration of *shatavari* along with sugar has been used since decades by the Ayurvedic physicians. Apart from all the attributes of *shatavari*, the sugar in the formulation also helps restore strength and provides energy to the body.

All the above internal medications administered in combination with *dhoopana* therapy to patients of vaginal delivery with episiotomy showed excellent results in preventing any kind of wound infection and enhancing healing. The mother was comfortable and the breast milk secretion was sufficient for every neonate. Overall health of the mother and child was found to be good.

One of the common maternal morbidities in the post puerperal febrile condition is caused due to bacterial infections and antibiotic therapy is generally initiated as a prophylactic measure in majority of the patients undergoing vaginal delivery with episiotomy.⁽²⁴⁾ However, each hospital needs to formulate its own post puerperal protocol by clinical study. Considering the present scenario of unnecessary use of antibiotics this is an important data created by our hospital. Post puerperal infection also depends on other important factors like nutritional status, hygiene of the patient, blood loss during procedures and duration as well as conduction of labour. One should never forget the proper protocols of scrubbing techniques, aseptic precautions, and preparation of episiotomy area before procedures which also may contribute to post puerperal infections. In spite of clear evidence from Cochrane Database of Clinical Reviews that use of penicillin or first generation cephalosporins in single dose therapy is effective; the actual practice is contrary with use of multiagent antibiotics for long periods, being very rampant in actual clinical practice.⁽²⁵⁾

The present study clearly presents the efficacy of the Ayurvedic medications in preventing infection in post puerperal condition. This study may therefore provide a platform to initiate post puerperal management protocol with the use of Ayurvedic medications and dhoopana therapy.

6. Conclusion

The study concludes that the use of combination of *Balant Kadha* and *Soubhagya Shunthi Paaka* is effective in management of *Sutikavastha*. It helps prevent infections, alleviates pain and is a potent galactogogue. The use of *shatavari kalpa* helps restore maternal health, provide energy and strength and is also a known galactogouge. However, more detailed studies and clinical trials for the same can be conducted to establish the validity of this claim and efficacy of the medications.

7. Tables

Table 1.1: Each 10 1	ml of Balant.	Kadha contains
	D	A

No	Name (Latin name)	Proportion	Attributes
1	Bilva root (Aegle marmelos),	418.91 mg	Deepana, Pachana
2	Shyonaka root (Oroxylum indicum)	418.91 mg	Shothahar, Deepana
3	Agnimantha root (Premna integrifolia)	418.91 mg	Kaphahara, Vatahara, Shothahara
4	Patala root (Stereospermym suaveolens)	418.91 mg	Shothahara
5	Gambhari (Kashmari) root (<i>Gmelina arborea</i>)	418.91 mg	Deepana Pachana Shothahara
6	Bruhati root (Solanum indicum)	418.91 mg	Kushtha, Shula nashaka Agnivardhaka
7	Kantakari root (Solanum xanthocarpum),	418.91 mg	Deepana,Pachana
8	Shalaparni root (Desmodium gangeticum)	418.91 mg	Shothahara, Vishhara, Krumihara
9	Prushniparni root (Uraria picta)	418.91 mg	Shothaghna
10	Gokshura root (Tribulus terrestris).	418.91 mg	Shothahara, vatapittadoshahar
11	Gud	3.27 mg	Madhur, pushthikara
12	Dhataki (Woodfordia fruticosa)	327.27 mg	Kriminashaka

 Table 1.2: Soubhagya shunthi paka

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No	Ayurvedic name of drug &	Attributes
	Latin Name	
1	Shunthi(Zinziber officinale)	Deepana , Pachana, Shulhara,
2	Godugdha (Cow milk)	Bruhana, sheetala, madhura
3	Goghruta (Clarified milk)	Bruhana, agnivardhana
4	Kasheru(Scripus grossus)	Stanyavardhaka, Shukral, Aamnashaka
5	Shrungataka(Trpanatum bispinosa)	Balya, Vrushya
6	Varat	
7	Ela (Elletaria cardamonum)	Deepana Pachana
8	Dhanyaka(Coriendrum	Deepana Pachana
	sativum)	
9	Musta (Cyperus rotundus)	Deepana Pachana, Jantujeet
10	Jiraka(Cuminum cyminum)	Deepana , pachana,
		krumighna, garbhashaya
		shuddhikara
11	Jatiphala(Myristica fragrans)	Krumighna, rujanashaka
12	Lavanga(Syzygium	Deepana Pachana Shula
	aromaticum)	nashana
13	Shaileyasa (Parmelia perlata)	Vranadoshvinashini

14	Nagkeshar(Mesua ferra)	Aampachak, vishapaham
15	Tejpatra (Cinnamomum	Deepana Anulomana
	tamala)	
16	Twak (Cinnamomum	Kruminashana
	zeylanicum)	
17	Shatavha(Anethum sowa)	Shulnashana
18	Dhayati (Woodfordia	Kruminashaka
	fruticosa)	
19	Gajapippali & Pippali (Piper	Shulanashaka, deepana ,
	longum)	rasaayana, shothaghna
20	Maricha (Piper nigrum)	Deepana, Shulhara,
		Krumighna
21	Shatavari (Asparagus	Rasaayana, agnivardhaka,
	racemosus)	Shothjeet
22	Loha bhasma	Balya, dhatu vardhana,
		poshana
23	Abhraka bhasma	Bruhana, dhatu vardhana,
	- 10.	rasaayana

Table 1.3: Shatavari Kalpa

No	Ayurvedic name of	Proportion	Attributes
	drug		
1	Shatavari (Asparagus	2gm	Rasaayana, agnivardhak,
	racemosus)	N	Shothjeet, Stanya vardhaka
2	Ela(Elletaria	-	Deepana , Rochani
	cardamomum)	× 1	
3	Sharkara	2gm	Bruhaniya

Table 1.4: Dhoopan Medicines

No	Ayurvedic name of drug	Proportion	Attributes
1	Vidanga (Embelia ribes)	2 gm	Krumighna, rukshana, aratinut
2	Shatapushpa (Foeniculum vulgare)	2 gm	Shothghna, rukshana, vranashulaghna
3	Jatamansi (Nardostachys jatamansi)	2 gm	Vimlapana, rukshana
4	Gugullu (Commiphora Mukul)	5 gm	Shothagna, Bhagna sandhanakruta, vranam jayet , krimighna , rakshoghna

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