

A RANDOMISED CONTROLLED CLINICAL TRIAL TO EVALUATE EFFECT OF AYURVEDIC FORMULATION ON PERINEAL CARE IN POSTNATAL PERIOD

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ABSTRACT:

Aim: Postnatal care with *Ayurvedic* medicine is the basic concept behind this clinical trial. **Materials and Methods:** In the present study 20 uncomplicated vaginally delivered patients with episiotomy were taken from the study centre and divided into two groups. In Group A (n=10) patients were treated with *Gandhak Rasayana vati*, *Sookshma Triphala vati* & *Triphala Kwatha* & in Group B (n=10) Tab.Ciprofloxacin + Tinidazole (500+200) mg, Tab Serratiopeptidase 10mg, Betadine ointment & liquid Dettol for 7 days and results were observed. In observation clinical findings were noted on 0th, 3rd, 6th & 9th day. **Results:** In the Group A no generalized or localized sepsis observed in any patient. Quality of wound healing, involution of uterus, nature of lochia and local tenderness shows statistically equal 't' value i.e. 0, 0.710, 0.534 and 0.599 respectively when compared with Group B. **Conclusions:** It can be concluded that the *Ayurvedic* drugs are significantly effective in postnatal care when compared with modern drugs to combat infections. Hence *Gandhak Rasayana vati*, *SookshmaTriphala vati* & *Triphala Kwath* is practically reliable to use in postnatal care.

Key Words: Postnatal Care, *Gandhak Rasayana vati*, *Sookshma Trifala vati*, *Triphala Kwath*.

INTRODUCTION:

The glory of *Ayurveda* is in prevention of diseases, scientific path physiology and effective management of various systemic disorders. Comparing *Ayurveda* with modern medicine i.e. allopathy there are surprising similarities in between 'Sutika Paricharya (post delivery management)^[1] and 'Postnatal care'. Management of the 'Sutika' with *Ayurvedic* medicine is the basic objective behind this study. In the *Ayurvedic* texts *Acharyas* describes scientific management of postnatal care in the 'Sutika Paricharya'^[1] and defined the word 'Sutika' very precisely and scientifically. *Acharyas* gives proper advice about the diet, clothing, personal hygiene, caring contraception, again they discussed Post Natal Care diseases (*Sutika rogas*) and their effective management under 'Sutika Paricharya'^[1]. *Acharyas* knew the long term consequences on female and her reproduction when she advent for mismanagement in PNC. Modern drugs are very useful, easily available with precise mode of action and time-tested. It is observed that the modern drugs are costly and sometime show side effects on mother and child. *Ayurvedic* drugs are cost effective and precisely work when prepared from standard raw material and as per good manufacturing practises. This is an attempt to give better option for the health to mother and child.

MATERIALS & METHODS:

Study Design: Randomized- controlled- parallel – open (unblind) – clinical trial.

Study Sample: Healthy Vaginally delivered females admitted in the Strirog- Prasutantra Department, Bhaisaheb Sawant Ayurved College attached hospital Sawantwadi.

Sample Size: Uncomplicated Vaginally Delivered 20 Patients.

Study Setting: The study was carried out in the Rani Jankibai Saheb Sutika Graha, Sawantwadi from August 2006 to November 2006. Sawantwadi is a Taluka place with population around 27,000.

Inclusion Criteria:

Uncomplicated vaginally delivered patients with episiotomy.

Exclusion Criteria:

Patients with labor complications i.e. extensive perineal tear, PPH, Still birth, placental retention etc.

Patients of systemic disorders, Instrumental vaginal delivery.

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Grouping: Two groups Group-A (study group) and Group-B (control group)

Drug:

Tab. Gandhaka Rasayana 250mg (Rasashala Satara Batch-2004-05) orally with water, Tab. Sookshma Triphalavati 1gm (Rasashala Satara Batch-2004-05) orally with water, Triphala Churna(college pharmacy) 10 gm (decoction 1lit.) for perineal wash, Tab. Cifran CT 500mg (Ranbaxi) orally with water, Tab. Serronake (Sunpharma) orally with water, Betadine Ointment (Jonson & Jonson) for perineal application, Dettol antiseptic liquid for perineal wash (Jonson & Jonson).

METHOD:

In the present study 20 uncomplicated vaginally delivered patients with episiotomy were selected randomly according to their age, parity and onset of labour & divided into Group A (n=10) & Group B (n=10). Group A (n=10) *Gandhak Rasayanavati* 250mg twice a day, *Sookshma Triphalavati* 1gm twice a day after meal with water & *Triphala Kwath* 1 litre for perineal wash given to the patient for 7 days dressing of episiotomy wound not done & in Group B (n=10) Tab.Ciprofloxacin + Tinidazole (500+200) mg twice a daily, Tab Serratiopeptidase 10mg twice a daily, Betadine ointment twice a daily locally & liquid Dettol perineal wash given for 7 days & results were observed. In observation clinical findings were noted on 0th – 3rd – 6th& 9th day. Subjective and objective parameters were selected to decide affectivity of drugs. The *Ayurvedic* formulations were selected for this clinical trial are according to their property, composition, safety, cost and mode of action. Clinical findings were noted after completion of labor and documented as 0thday, then consecutively on 3rd, 6th& 9th day. Severity of local tenderness, pain, bleeding, discharges,condition of episiotomy wound, signs of local temperature, gaping, sepsis were documented.

Follow up: Follow ups taken on 0th – 3rd – 6th& 9th day post labor.

Assessment criteria

Assessment criteria were based on the improvement in the specially prepared scoring system of cardinal symptoms and other most common symptoms manifested by selected patients before, during and after the treatment. The cardinal symptoms were, episiotomy healing, lochia, involution of uterus & local tenderness.

1. Episiotomy healing.

Complete Healed- 0, Slight gape- 1, Medium gape- 2, Complete gape- 3.

2. Lochia.

Normal- 0 (4pads), Mild - 1 (6pads), Medium (8pads) - 2, Severe - 3 (10pads).

3. Involution of uterus.

Uterine fundal height from symph- pubis Below 10cms- 0, 10-12cm-1, 12-14cm-2, 14-16cm- 3

4. Perineal tenderness.

No pain Nil- 0, Daily activities are not affected, no need of analgesics. Mild - 1, Daily activities are affected, need to take analgesics. Moderate - 2, Daily activities are inhibited, pain continuous after administration of analgesics. Severe - 3

RESULTS:

The improvement in the cardinal symptoms were compared and analyzed statistically between the end of the treatment and baseline by using student's paired 't' test. The investigations also analyzed using student's unpaired 't' test.

The patients receiving treatment were followed upon 0th, 3rd, 6th, 9th post delivery day. In Group-A on 3rd day the severity of local tenderness was more when compared with Group B. In Group-A post delivery vaginal bleeding was low and high rate of involution of uterus was observed. Mild local tenderness observed on 6th day at the site of episiotomy wound. Healing was satisfactory in both, study group & control group. Involution rate was quite high in study group. On 9th day no local tenderness was observed in the Group-A. Episiotomy wound healed good in both group. The clinical study showed that treatment is equally effective in both groups.

In Group-B mild to moderate gastritis observed in 9 patients while in group Group-A in only 2 patients. In Group-A normal defecation established after 3rd day following delivery while in Group-B patients needed laxatives.

DISCUSSION:

It is proved that *Gandhaka Rasayana* show astringent, antibiotic property hence acts as bacteriostatic^[3]. The *Triphala Kwath* also acts as a bacteriostatic agent and hence useful to avoid local infection^[3]. *Sookshma triphala vati* contains *triphala churna* & *kajjali*^[3].

- *Triphala* is rich in Vit-C it shows antibacterial action when given locally & orally^[4].
- Shows astringent, anti inflammatory & antiseptic action so it hastens wound healing process^[4].
- Contains collagen which acts as cementing material & required in the process of blood clotting^[5].

- *Triphala* hastens the process of phagocytises hence dead cells & debris are easily eliminated from uterus & wound^[6].
- *Triphala* increases blood supply towards uterus & accelerates healing of scarred endometrium^[7].

Kajjali is a *khalvi rasayana* it acts as catalyst hence enhances absorption of herbal pharmacological molecules so increases bioavailability ingested drug^[13]. Drug effect is more after addition of *kajjali* so helpful in reducing doses of drug^[8]. It binds with mucosal coat of GIT hence produces pharmacological sustained release of drug better crosses blood intestinal barrier^[9]. It shows anti IgE mediated reaction & scavenges circulating immune complexes^[10]. It shows immune enhancing effect, cellular rejuvenating effect, systemic detoxification & antioxidant effect^[11]. Again it maintains half life of the herbal drug molecules for longer period^[12]. *Kajjali* shows a bacteriostatic & bactericidal action when given orally^[13]. All these properties of *Gandhaka Rasayana*, *Sookshm triphala vati* & *TriphalaKwath* are utilized.

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