



Research Article

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COMPARATIVE CLINICAL STUDY OF AYURVEDIC THERAPY AND INTERVENTION IN THE MANAGEMENT OF UTERINE FIBROID: AN OPEN LABEL, PROSPECTIVE RANDOMIZED PARALLEL GROUP STUDY

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ABSTRACT

As the disease uterine fibroid is the most common pelvic benign tumour, modern concepts were illustrated but not in Ayurveda. On the basis of specific clinical features of Mamsaja Arbuda as well as description of Arbuda in general, it can be said that all relatively big neoplasms developing from muscular and fibrous tissues (myoma and fibromas) come under Mamsaja Arbuda. Mainly Kapha-Vata Doshas, vitiate Dhatu particularly Rakta, Mamsa, Meda, also Dhatwagni mandya especially Mamsagni have found to be involved in the pathophysiology of Garbhashaya Arbuda compared with Sanga Pradhana Vyadhi. The present study was carried out to evaluate and compare the effect of Virechana followed by Triphaladi Yoga and Virechana followed by Intra Uterine Uttarbasti along with Triphaladi Yoga on Garbhashaya Arbuda (Uterine fibroid). 77 patients in the age group of 20-50 years were registered for the study, of these patients, 74 were completed the course of treatment. In the present study, total 98 fibromyomas were observed. 83.12% patients had one fibromyoma, 09.09% patients had 2 fibromyomas, 05.19% patients had 3 fibromyomas and 2.6% patients had >3 fibromyomas in their uterus. Out of 98 fibromyoma, total 19 fibromyoma were completely alleviated. Virechana followed by Triphaladi Yoga showed better results in reducing size and volume of fibroma as well as symptomatic relief i.e. excessive bleeding per vagina during menses, inter menstrual bleeding and irregular menses etc. No adverse reaction found during the study.

Keywords: Garbhashaya Arbuda, Triphaladi Yoga, Uterine fibroid, Uttarbasti, Virechana

INTRODUCTION

Uterine fibroid is not only the commonest benign tumour of uterus but also the commonest solid tumour in female that usually found in approximately 20 to 40% women of reproductive age group,¹ start as multiple, single cell seedlings distributed throughout the uterine wall. One in every five women of childbearing age suffers from uterine fibroids.^{2,3} Uterine fibroid represent the principal cause for hysterectomy and lead to specific symptoms including heavy menstrual bleeding, pelvic pressure, bladder irritability, infertility and pregnancy loss etc. interfere with home, social and work life of women due to tiredness, weakness, lack of control and unpredictability. They most commonly cause symptoms between the ages of 35-45 years but probably exist in microscopic form before the age of 30 years.⁴ The incidence is higher in black women, in women with increased body mass index, in nulliparous and in low parity women.¹ In India, the prevalence of uterine fibroids among women hovers between 30-50%.³ Regarding its treatment modern medical science kept it under the surgical domain. The method available in modern medical science to treat a patient of uterine fibroid mainly includes hormonal therapy, hysterectomy, myomectomy, myolysis, endometrial ablation and uterine artery embolization etc. Unfortunately none of these methods are considered as the sole reply to the disease. Over and above all these known methods have got unwelcome side effects. Because the economic burden due to fibroids has been increasing, these benign tumours are a significant health concern in women. Thus, now, women are looking for non-invasive treatment methods which do not required hospitalization and lengthy recovery. Due to the limitation of modern science, Ayurveda has great scope in this

field. It becomes the necessity of the time to find out an efficacious and harmless therapy to manage the condition. These are the factors why the topic is being selected for the present study. So many formulations are advised in Ayurvedic classics under the Granthi, Arbuda and Apachi Chikitsa along with some specific lifestyle restrictions for management of Arbuda (NAMSTE CODE-EE 2). In this study, "Virechana followed by Triphaladi Yoga and Virechana followed by Uttarbasti along with Triphaladi Yoga" have been selected. Virechana for Shroto shodhana, Anulomana of Vayu, Pacify Pitta, Kapha and Uttarbasti of Lekhaniya Mahakashaya Siddha Taila⁵ may cause Lekhana (scrapping) effect on Garbhashaya Arbuda and Triphaladi Yoga was selected for its Lekhana, Yogvahi, Shothahara, Ropana, Vedanasthapana action.

MATERIALS AND METHODS

The Patients were selected from the O.P.D and I.P.D. of Stree Roga and Prasuti Tantra department and referred from another department of IPGT & RA hospital. A total of 77 patients were registered. The study was approved by Institutional Ethics Committee (No. PGT/7-A/Ethics/2015-16/2625 and CTRI trial registration no. is CTRI/2016/02/006597.)

Selection criteria of study participants

Inclusion Criteria

Patients of age group between (20-50 years), either married or unmarried having fibroid size ≤ 5 cm as per USG report and also having Single or multiple fibroids, sub mucous fibroid and

intramural fibroid. The patients with fibroids either asymptomatic or having clinical signs and symptoms of fibroid were included in the study.

Exclusion Criteria

Patient age < 20 years and age > 50 years, having fibroid size > 5 cm as per USG report, Pregnant women with fibroid, Women with Hb < 7 gm%, Pedunculated fibroid, Ovarian tumour, Tubo-ovarian mass and malignant tumors along with fibroid and patient with uncontrolled hypertension, tuberculosis, Diabetes Mellitus and any other severe systemic diseases were excluded from the study.

Investigations

To rule out any other pathology, routine hematological and urinary analysis was done before and after the treatment.

Especially investigations like HIV (Human Immunodeficiency Virus), HbsAg (Australia antigen for hepatitis B) and VDRL (Venereal Disease Research Laboratory), were also done in all patients.

Specific investigation

USG (Trans vaginal and Abdominal -in case of unmarried patient)

Ultrasound (Abdominal and Trans vaginal) is a useful and diagnostic tool to confirm the diagnosis of fibroid and to differentiate it from ovarian mass and pregnancy. Transvaginal sonography can accurately assess the Leiomyoma location, dimensions, blood flow and also any adnexal pathology. It had done on 3-6th day of menstrual cycle to diagnose size, site and number of uterine fibroids.

Criteria for assessment

Duration of Blood loss

Duration of Blood loss	Grade
1-3 days	0
4-6 days	1
7-10 days	2
> 10 days	3

Inter menstrual bleeding

Inter menstrual bleeding	Grade
Once in 21 -35 days	0
Once in 15-20 days	1
Once in 10-15 days	2
Less than 10 days	3

Menstrual pain

Menstrual pain	Grade
No Pain	0
Painful, no analgesic Required	1
Painful, daily activity affected; analgesic required	2
Analgesic required but have no effect	3

Pain in lower abdomen

Pain in lower abdomen	Grade
Absent	0
Mild (Local tolerable pain, Subsides with rest only)	1
Moderate (Local tolerable pain at rest also, Subsides with medicine)	2
Severe (Pain dose not subsides even by use of medicine)	3

Constipation

Constipation	Grade
No constipation	0
Passes hard and soft stool regularly	1
Passes hard stool all the time but no need of laxative	2
Needs laxative to pass stool	3

Menorrhagia

Menorrhagia	Grade
< 5 pads/day without clots	0
5-6 full soaked pads / day without clots	1
5-6 pads/day with clots	2
> 6 pads/day with or without clots	3

Weakness / Fatigue

Weakness / Fatigue	Grade
Occasional on doing heavy work.	0
After doing extra work	1
After doing routine work.	2
Even without doing work.	3

Backache

Backache	Grade
No Pain	0
Painful, no analgesic required	1
Painful, daily activity affected; analgesic required	2
Analgesic required but have no effect	3

Size of fibroid

Size of fibroid	Grade
Up to 1 cm.	0
1 to 2 cm.	1
2 to 3 cm.	2
3 to 4 cm.	3
4 to 5 cm.	4

*Scoring pattern of Size of Fibroid is applied for vertical, horizontal and antero-posterior diameter taken by Trans Vaginal Sonography.

Treatment Protocol

Group A

Virechana with Trivrit Avaleha⁶ followed by Triphaladi Yoga was administered in Group A.

Group B

Virechana followed by Uttarbasti along with Triphaladi Yoga was administered in Group B.

In both groups Virechana was given on the next day of cessation of menstrual flow. The procedure details are provided in Table 1. Samsarjana Karma was advised to the patients after Virechana Karma and Triphaladi Yoga, i.e., 10 g in two divided doses (given empty stomach in the morning and evening) with honey (as Sahapana) and lukewarm water (as Anupana), which was administered orally for 2 months.

Table 1: Virechana Protocol

No	Procedure	Drug and dose	Duration
1	Deepana – Pachana	Shunthi, Haritaki, Guduchi (1:2:3) Churna – 6 gm.bd before meal with warm water	3 to 5 days
2	Snehapana	Go- Ghrita (30 ml to 250 ml; according to Koshtha of patient)	3 to 5 days
3	Abhyanga and Swedana	Bala Taila, Sarvanga Bashpa Swedana	1 to 3 days
4	Virechana Karma	Trivrit Avaleha [Trivrit (<i>Operculina turpethum</i> Linn.), Tamal patra (<i>Cinnamomum tamala</i> Nees and Eberm.), Twak (<i>Cinnamomum zeylanicum</i> Breyn.), Ela (<i>Elettaria cardamomum</i> Maton.), Honey, Sugar. 60 to 100 gm (as per the Koshtha)	Single dose
5	Samsarjana Karma	Diet as per Shuddhi given below:	3 to 7 days

Triphaladi Yoga is an Anubhuta Yoga (experientially formulation) which contains Triphala Churna (Haritaki–Bibhitaki–Amalaki in 1:1:1 proportion) five parts and Shuddha Tankana one part.

In Group B Uttarbasti was given on the next day of menstrual bleeding stopped.

Poorvakarma

Abhyanga- Bala Taila (Udara evum Kati Pradesh)
Swedana- Nadi Swedana
Yoni Prakshalana- Triphala Kwath

dysmenorrhoea was observed in 88.31% patients. 79.22% and 40.26% had history of irregular menses and inter-menstrual bleeding respectively.

Pradhana Karma

Intra Uterine Uttarbasti by Lekhaniya Mahakashaya Siddha Taila - 3 ml was given after cessation of menstruation once daily for 6 days for 2 consecutive menstrual cycles.

Primary infertility was found in 25.97% patients whereas 09.09% patients were having secondary infertility. Other related symptoms like pain in lower abdomen and pelvic pain/backache were observed in 90.91% each. The data shows that, associated complaint like Weakness, Constipation and Anemia was observed in 68.83%, 58.44% and 57.14% of the patients respectively.

Pashchata Karma

Head Low Position and Hot Water Bag on lower abdomen

RESULT

Follow up period

Follow up study was conducted for one month after completion of the treatment.

Vata is unstable during perimenopausal period causes impaired ovarian hormone secretion which leads to Kha-Vaigunya in Garbhashaya means makes Garbhashaya susceptible for Garbhashaya Arbuda. Again, vitiated Vata enhances rate of cell division result in formation of Garbhashaya Arbuda. In perimenopausal age group most of the patients suffer from irregular menses, menorrhagia, scanty menses etc. So, they visit to hospital and fibroids are detected during gynecological examination by USG etc.

Statistical estimation of results

The obtained data were analyzed statistically. The values were expressed as percentage of relief and Standard Error Mean. The data were analyzed by Paired 't' test and Wilcoxon Sign ranked test.

Maximum patients were Hindus as study was conducted in Hindu dominant area. The majority of patients i.e. 81.82% were from middle class. It makes us think that middle class people follow western culture in their lifestyle and food habits which leads to obesity and the economic problem leads to stress which will again affects the mental status causing disturbances in the hormonal balance.

OBSERVATIONS

The age of most of the patients registered for the study was in between 31 to 40 years and 41 to 50 years i.e. 45.45% and 35.06% respectively. The 85.71% patients were Hindus, while 14.29% were Muslims. The 90.91% patients were housewives, while 09.09% were working ladies. The 81.82% patients were from middle class. All patients were married. 29.87% patients were nulliparous, and 70.13% patients were parous. Among 77 registered patients, total 98 fibroids were observed. 83.12% patients had history of one fibroid while 09.09% patients had two fibroids. 05.19% patients had three fibroids and 02.60% patients had more than three fibroids. Mostly patients (57.14%) had fibroid on anterior wall side. The data shows that majority i.e. 87.01% patients had excessive bleeding per vagina and

Site of Fibromyoma

Present study shows that, site of fibromyoma was maximum in the wall of uterus i.e. intramural, in which fibromyoma situated in anterior wall in 57.14% patients, in 29.87% of patients fibromyoma situated in posterior wall, at fundus in 18.18% patients. Intramural fibroids are located within the muscular wall of the uterus and are the most common type. Unless they are large, they may be asymptomatic. Intramural fibroids begin as small nodules in the muscular wall of the uterus. With time, intramural fibroids may expand inwards, causing distortion and elongation

of the uterine cavity. Eventually in about 70% cases⁷ these persist in their position. This data supports the description about developmental site of fibroid is maximum (87.0%) in the wall of uterus i.e. intramural. Submucous fibromyoma was found in 05.19% patients, reason behind this may be due to the patient suffers mostly from the clinical feature like severe menorrhagia in submucous fibromyoma and they prefer surgical intervention rather than oral medicine.

Effect of “Virechana along with Triphaladi Yoga” on Chief and Associated complaints in Group A

On quantity of menses, improvement was observed 48.48% while 100% and 83.72% relief were found in inter menstrual bleeding and dysmenorrhoea. 90.32% reduction has shown in irregular menses and 93.75% decrease has shown in duration of blood loss. Pain or discomfort in lower abdomen and backache was relived in 92.68% and 95.24% patients respectively. On weakness improvement was seen about 78.13% and 100% relief was found in constipation.

Effect of “Virechana followed by Uttarbasti along with oral therapy” on Chief and Associated complaints in Group B

On quantity of menses, improvement was observed 48.28% while 100% and 91.18% relief were found in inter menstrual bleeding and dysmenorrhoea. 96.43% reduction has shown in irregular menses and 92.10% decrease has shown in duration of blood loss. Pain or discomfort in lower abdomen and backache was relived in 92.11% and 94.29% patients respectively. On weakness, improvement was seen about 72.73% and 100% relief was found in constipation.

The treatment has significant relief in all chief complaints and associated complaints in both groups. Virechana reduce the excessive estrogen and normalize the level of ovarian hormone and it leads to regular menstrual cycle.

Effect on Lipid profile

In patients, there was statistically insignificant ($P > 0.05$) effect on Serum (S.). Cholesterol, S. Triglycerides, S. High-density lipoprotein (S.HDL), S. Low density lipoprotein (S. LDL) and S. very low-density lipoprotein (S. VLDL) levels in both groups.

Though treatment has shown relief in biochemical parameter, but all the changes were within the normal limit. So results in statistically were insignificant in both groups.

Comparative effect of therapy

Table 2: Comparison of result on chief complaints

Chief complaints	Mean ± SEM		‘t’	P	Significance
	Group A	Group B			
Excessive quantity of menses	00.91 ± 00.06	00.90 ± 00.07	00.12	> 0.05	IS
Inter menstrual bleeding	01.00 ± 00.00	01.00 ± 00.00	00.00	> 0.05	IS
Dysmenorrhoea	01.09 ± 00.10	00.93 ± 00.06	01.29	> 0.05	IS
Irregular menses	00.90 ± 00.05	00.96 ± 00.04	-00.92	> 0.05	IS
Duration of blood loss	01.32 ± 00.08	01.06 ± 00.04	02.84	> 0.05	IS

Table 3: Comparison of result on associated complaints

Associated complaints	Mean ± SEM		‘t’	P	Significance
	Group A	Group B			
Pain in lower abdomen	01.15 ± 00.09	01.00 ± 00.07	01.26	> 0.05	IS
Backache	01.18 ± 00.09	01.00 ± 00.06	01.62	> 0.05	IS
Weakness	00.78 ± 00.09	00.76 ± 00.14	00.13	> 0.05	IS
Constipation	01.06 ± 00.06	01.03 ± 00.03	00.43	> 0.05	IS

Overall effect of therapy, 40.54% patients showed marked improvement, 51.35% patients showed moderate improvement and 8.11% patients showed mild improvement. None of the patients showed complete improvement or remained unchanged after treatment in Group A. In Group B, 37.84% patients got marked improvement and 54.05% patients got moderate improvement. 08.11% patients got mild improvement. None of

the patient showed complete improvement or remained unchanged after treatment in Group B.

In comparison of chief complaints and associated complaints, both the treatments had insignificant difference in improvement between the both Group A and B. (Table 2 and 3)

Table 4: Comparison of result on size of fibromyomas

Diameter	Mean ± SEM		‘t’	P	Significance
	Group A	Group B			
Vertical diameter	14.19 ± 01.07	13.05 ± 00.98	01.14	> 0.05	IS
Horizontal diameter	11.39 ± 01.11	10.81 ± 00.99	00.39	> 0.05	IS
AP diameter	11.78 ± 01.02	11.55 ± 01.15	00.16	> 0.05	IS

Reduction of 43.05% in size was observed in vertical diameter of fibroid, decrease of 39.81% was observed in horizontal diameter while decrease of 39.27% was observed in antero-posterior diameter in Group A. There was reduction in size of fibroid 40.31% in vertical diameter; decrease of 36.62% was observed in horizontal diameter while decrease of 36.85% was observed in AP diameter in Group B. All the parameters were showed statistically highly significant in both groups.

In Vertical, Horizontal and AP diameter, there was no statistically significant difference in reduction between the both groups A and B. (Table 4)

Table 5: Overall effect on number of fibromyomas in the patients of both Groups (n = 98)

Group	Total no. of fibromyoma	Reduced no. of fibromyoma	Total	%
Group A	46	08	38	17.39
Group B	52	11	41	21.15
Total	98	19	79	19.38

In reducing number of fibromyoma, total 08 (17.39%) fibromyoma were treated in Group A while 11 (21.15%) were treated in Group B. (Table 5)

Probable mode of action of trial treatment protocol

After Deepana-Pachana, Virechana was carried out with Trivrit Avaleha for Srotoshodhana, Anulomana of Vayu, Pacify Pitta and Kapha. Virechana removes Pitta and Bahu Drava Shleshma. It also does the Rakta prasadana. It increases Agni and helps to promote Prashasta dhatu formation and removes "Ama" from the body. Extra ovarian estrogen can be considered as Ama, which should be removed.

Mostly Yonirogas are Virechana Sadhya as Virechana causes Vatanulomana and normalizes Apana Vayu which further remove the Sanga from Srotas (Artavavaha Srotas) and may be helpful in decreasing the size of Garbhashaya Arbuda (uterine fibroid). In this preparation, the main content is Trivrit, which is included in the group of 'ten purgative herbs' (i.e. Bhedaniya Mahakashaya), group of 'ten antidote herbs' (i.e. Vishaghna Mahakashaya), group of 'ten herbs supportive for therapeutic enema' (i.e. Ashtapanopaga Mahakashaya)⁸, group of 'colon cleanser, antitumor and antidote herbs' (i.e. Shyamadi Gana) and in the group of 'herbs eliminating the toxins (i.e. vitiated Dosha) from lower half of the body' i.e. Adhobhagahar Gana⁹.

As it is already mentioned in disease review, that Garbhashaya Arbuda has been considered as the Tridoshaja condition dominantly Vata-Kapha Dosha. Local administration of any drug is containing Sukshma, Laghu, Sara, Vyavayi, Vikasi, Pramathi etc. Guna, Katu Vipaka and Ushna Virya can be assumed to have some effective role in scraping of Arbuda.

The most suitable method to administer such drug can be Intra Uterine Uttarbasti. Hence, it was taken for the study. Lekhaniya Mahakashaya is mentioned by Acharya Charaka in Shadvirechanashatashritiya chapter. In this Mahakashaya, there are ten contents i.e. Mustaka, Kushtha, Ativisha, Haridra, Daruharidra, Haritaki, Chitraka, Chirbilwa, Vacha, Katuruhini. The Lekhaniya Mahakashaya works with its Lekhana properties in removal of Arbuda. So, Lekhaniya Mahakashaya Siddha Taila was selected for this purpose, as it has most of the qualities, which were required for the present study.

Effect of Uttarbasti depends on various points; like method, instrument, drug used etc. Uttarbasti acts locally also. With the Lekhana drugs as based of IUUB work on endometrium by scraping effect. Apart from this, Uttarbasti may also stimulate certain receptors in the endometrium, leading to correction of all the physiological processes of reproductive system. In cases of Garbhashaya Arbuda, Intra uterine Uttarbasti with Lekhana Dravyas help in decreasing the size of it.

Triphaladi Yoga includes Triphala and Shuddha Tankana and given with Anupana of Madhu in present study. All these drugs having Kashaya Rasa, Laghu, Ruksha Guna, Ushna Virya and Kapha-Pitta Shamaka property. This is Anubhuta Yoga; successfully used in OPD of PTSR department of I.P.G.T. and R.A. Triphala¹⁰ has Tridosha shamaka property by which it normalizes the function of Tridosha. It possesses Lekhana, Shothahara Vedanasthapana action also and it may reduce Shotha from the wall of the uterus. Shuddha Tankana¹¹ has also Lekhana property by which it may scrapes fibroid from Artavavaha Srotas. By its antioxidant and anticancer properties of acting as free radical scavenger, it may help to decrease the size of Garbhashaya Arbuda.¹²

CONCLUSION

In present study, Group A (Virechana followed by Triphaladi Yoga) showed better results in reducing size and volume of fibroma as well as symptomatic relief i.e. Excessive bleeding per vagina during menses, inter menstrual bleeding and irregular menses as compared to Group B (Virechana followed by Uttarbasti of Lekhaniya Mahakashaya Siddha Taila along with Triphaladi Yoga).

Thus, it can be said that null hypothesis is rejected, and Alternative hypothesis is proved. No adverse reaction found during the study.

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