



A Cohort Study to find out the Efficacy of Specific Ayurvedic Treatment Protocol in the Management of Pelvic Pain in Pelvic Endometriosis.

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Abstract

Aim: The aim of the study was to examine the efficacy of a specific *Ayurvedic* treatment protocol in the management of pelvic pain in pelvic endometriosis. **Materials & Methods:** The non-interventional cohort study with pre-test and post-test design was conducted in 30 women aged between 18 and 45 years. The participants who were allocated for the study were observed to receive a specific *Ayurvedic* treatment protocol including *Mṛdu Virecana* (mild purgation therapy) followed by internal medications for 3 consecutive menstrual cycles. Visual analogue scale (VAS) scores were recorded at baseline and after each menstrual cycle consecutively for 3 months during the treatment and follow-up after one month. Quality of life (QoL) was recorded using Endometriosis Health Profile Questionnaire (EHP-30) at baseline and follow-up assessment was done one month after cessation of treatment. **Results:** Pelvic pain assessed with Visual analogue scale (VAS) scale at baseline and after each menstrual cycle during treatment for three months and at follow up were 9.96 ± 0.17 , 5 ± 0.73 , 1.43 ± 0.15 , 1.43 ± 0.15 , 1.43 ± 0.15 respectively which was found to be statistically significant at $P < 0.0125$. The Quality of life (QoL) assessed with Endometriosis Health Profile Questionnaire (EHP-30), before treatment and after follow up was found to be 42.35 ± 0.001 and 84.93 ± 0.053 respectively which was statistically significant with $P < 0.05$. **Conclusion:** The specific Ayurveda protocol was effective in the management of pelvic pain in pelvic endometriosis thereby improving the Quality of Life.

KEYWORDS: Ayurveda, Chronic Pelvic Pain, Cohort Study, EHP-30, Endometriosis, Quality of Life

1. Introduction

Endometriosis is a hormonal dependent, progressive, long-term disorder which is defined as the presence of functioning endometrium in sites other than uterine mucosa with a prevalence increasing day by day¹. It can adversely affect a woman's ability to have children and the pain, commonly described as Chronic Pelvic Pain (CPP) which severely interrupts her daily existence. It is defined as noncyclic pain that lasts six months or more and is localized to the pelvis, the anterior abdominal wall at or below the umbilicus. CPP is the cause for approximately 40% of laparoscopies and 10% to 15% of hysterectomies². The global prevalence of the clinical condition at all ages is 43.3%³. The symptoms in endometriosis has close resemblance with the clinical presentation of *Vātiki Yonīvyāpat* mentioned in *Āyurveda* classics. Analgesics, hormonal therapy and surgical procedures are still the hallmark of endometriosis management. The increased recurrence of the disease even after the invasive management made the scientists to think for conservative affordable and acceptable alternatives in dealing with this mysterious disease presentation. *Āyurvedic* treatment provides a comprehensive outlook to the whole scenario in the field of endometriosis research. Hence this study was undertaken with genuine interest to raise a ray of hope for the affected community suffering from endometriosis. The objective of this study was to observe and document the efficacy of a specific *Āyurvedic* treatment protocol in the management of pelvic pain in pelvic endometriosis and its symptoms without affecting the normal physiology of the woman.

2. Materials and Methods

2.1 Study design & Setting

Single arm, non-interventional cohort study with pre-test and post-test design was conducted at the Department of Stri Roga and Prasuti Tantra (Gynaecology and Obstetrics), Amrita Ayurveda Hospital, Kerala, India, between June 2018 and May 2019. The trial protocol was approved by the Institution's Ethics Committee (IEC-AIMS-2017-AYUR-257) and was in compliance with the Declaration of Helsinki. The Trial got registered with the Indian Registry of Clinical Trials (CTRI/2018/05/013960) and all participants were provided verbal and written informed consent.

2.2 Participants

2.2.1 Inclusion criteria

- (1) Married / Unmarried woman aged between 18 and 45 years with regular menstrual cycles.
- (2) Patients with pelvic pain more than six months and diagnosed with endometriosis in Ultra sonography (USG).

2.2.2 Exclusion criteria

- (1) Pregnancy.
- (2) Known case of malignancy, chronic systemic illness.

2.3 Sampling method and Randomization

The sample size was calculated considering the per annum inflow of the patients with the diagnosis. The necessary sample size was finally determined to be 30. The patients satisfying the inclusion criteria were selected for the study. Primary outcome variable at the level of pelvic pain was measured on the 5th day of each menstrual cycle commencing from the first menstrual cycle for three consecutive menstrual cycles after treatment and after one month follow up. Secondary outcome variable at the level of Quality of Life was measured prior to the medication and on the Day 5 of the 4th menstrual cycle.

2.4 Data sources/Measurement

Patient data were recorded on the case record forms designed specifically for the purpose of the study. Assessment of pelvic pain was based on Visual Analogue Scale (VAS)⁴ with VAS scores interpreted as 0=no pain, 1-3=mild, 4-6=moderate, 7-9=severe, 10=worst possible pain. Quality of life was measured based on Endometriosis Health Profile Questionnaire (EHP-30)⁵. It comprises of the first part with a core questionnaire with 30 items and five scales including pain, powerlessness, emotional wellbeing, social support and self-image and second part with six domains which have 23 questions covering areas such as work, relationship with children, sexual activity, infertility, medical profession and treatment which are not mandatory to all women with Endometriosis.

2.5 Statistical methods

Statistical analysis was done using SPSS VER. 20. Wilcoxon signed rank test with Post hoc Bonferroni Correction was done in assessment of pelvic pain to interpret the significant change. One Sample t- test was done for analyzing the significant change in Quality of Life (QoL) with 95% confidence interval, p values ($p < 0.05$) were considered statistically significant. All the relevant data were expressed as mean \pm standard deviation.

3. Results & Discussion

In the present study, 56.7% subjects belonged to the age group of 26-35 years. About 76.7% women participated in this study belonged to rural area. Among the 10 unmarried recruited cases, 4 were sexually inactive. Among the 20 married women, 30% were between the ages of 24-26 years. This data supports the earlier study suggesting the late marriage and late conception as the predisposing risk factors for endometriosis. In the present study, 50 % of the subjects were housewives. This may be probably due to less concern to own health and increased stress seen in housewives⁶. The study observed that more than half of the patients attained menarche below the age of 13 years. 83.3% subjects were habituated for the consumption of too spicy, fermented, fried and non-vegetarian food which might have contributed to the etiology of the clinical condition. Based on the observation, more than half of the subjects suffered from metabolic disturbances. Regarding the bowel habits, equal distribution of normal, constipated and loose bowels among the subjects has been observed. Altered metabolism in these subjects might be the factor for hormonal imbalance leading to the pathology. 17 subjects had history of pelvic surgery among which 10 patients had LSCS, 7 patients had history of laparoscopy and 4 had a history of both laparoscopy and LSCS. All of them were presented with all the cardinal pain symptoms of endometriosis like pelvic pain, dysmenorrhea, and dyspareunia. Studies related to recurrence of pain in endometriosis also emphasize the importance of pain management in this condition. The contraception history of the subjects revealed that more than half of the patients adopted barrier methods and one fourth adopted oral contraceptives. In the present study, 36.7% subjects had dyspareunia which had badly affected their family life and also the Quality of Life. 66.7% of subjects had dyschezia. *Prakṛti* (constitution) of the patients were assessed based on the major physical, psychological and behavioral features. Based on that, 50% belonged to *Vāta Pitta Prakṛti*, 30% belonged to *Vāta Kapha Prakṛti* and 20% belonged to *Kapha Vāta Prakṛti*.

The observed treatment protocol was *mrdu virecana* (purgation therapy) on three consecutive menstrual cycles followed by internal medications. The duration of the observed treatment protocol for *mrdu virecana* was found to be 6-7 days as shown in Table 1.

Table 1. Observed Treatment protocol for Mrdu Virecana

Sl. no	Treatment	Method of administration	Duration
1.	Deepana Pacana (increasing the digestion) with Vaiśvānara cūrṇa	10 g twice daily before food with warm water, started 10 days prior to the menstruation	2 days
2.	Snehapana (internal oleation therapy) with Satapuspa taila + Mahānārāyaṇa taila	Arohana karma after assessing the Agni & Koshta	3-4 days
3.	Snehana (external oleation) with Mahanarayana taila & Swedana (sudation)	Sarvanga abhyanga with Mahanarayana taila followed by Nadi sweda	1 day
4.	Mrdu Virecana (purgation therapy) with Gandharvahasthadi Eranda taila (20ml) + Triphala Kashaya (50 ml)	Performed on the same day after Snehana and Swedana	1 day

After the *Mrdu Virecana* (purgation therapy)⁷, patients were advised to take rest for one day. After that, they were given with *śhamana* therapy (internal medications) starting from 3rd day of *mrdu virecana* irrespective of the day of menstruation. The same treatment protocol including *mrdu virecana* and *śhamana* therapy was continued for the next two consecutive menstrual cycles. The selection of internal medication and its dosage varied from person to person based on their digestive capacity, constitution and intensity of pain.

The internal medications given were in the form of oil, ghee and powder.

Taila (medicated oils) given were- *Ṣatapuṣpa Taila*⁸, *Mahānārāyaṇa Taila*⁹

Gṛita (medicated ghee) given were- *Sukumara ghrta*

Cūrṇa (medicated powders) given-*Vaiśvānara cūrṇa*¹⁰ *Hinguvacādi cūrṇa*

Internal medications observed during the study were of four different combinations including, *Hinguvacādi cūrṇa* along with *Ṣatapuṣpa taila* and *Mahānārāyaṇa taila* for 8 patients, *Vaiśvānara cūrṇa* along with *Ṣatapuṣpa taila* and *Mahānārāyaṇa taila* for 9 patients, *Hinguvacadi cūrṇa* and *Sukumara Ghrta* for 8 patients, *Vaiśvānara cūrṇa* and *Sukumara ghrta* for 5 patients. On observation, the patients who had symptoms associated with metabolic error, those who reported heavy menstrual bleeding with pain were given combination of *Vaiśvānara cūrṇa* along with *Ṣatapuṣpa taila* and *Mahānārāyaṇa taila*. The patients who had advanced stage of Endometriosis on Laparoscopy were found to be given with combination of *Vaiśvānara cūrṇa* and *Sukumara ghrta*. It was observed in the study

that, majority of the patients who belongs to the reproductive age whose fertility is concerned were found to be given with combination of *Hinguvacādi cūrṇa* along with *Ṣatapuṣpa taila* and *Mahānārāyaṇa taila*. For majority of patients who had reported the worst possible pain, those who had chronicity more than 5 years were given with combination of *Hinguvacādi cūrṇa* and *Sukumara grita*.

The improvement in pelvic pain was done using Visual Analogue Scale (VAS). Wilcoxon signed rank test showed statistically significant reduction in pelvic pain assessed after each menstrual cycle during treatment and got a result as 9.96 ± 0.17 (Baseline), 5 ± 0.73 (VAS AT 1), 1.43 ± 0.15 (VAS AT 2), 1.43 ± 0.15 (VAS AT 3), 1.43 ± 0.15 (VAS FU) which was found to be statistically significant at $P < 0.0125$ (Bonferroni Correction) at all stages as shown in Table 2.

Table 2. Effect of specific Treatment protocol in Pelvic Pain

Assessment of Pain	N	Mean Rank	Mean	Z value	SD	P value
VAS (AT1) - VAS (Baseline)	30	15.50	5.00	-4.998	0.73	0.0001
VAS (AT2) - VAS (Baseline)	30	15.50	1.43	-5.324	0.15	0.0001
VAS (AT3) - VAS (Baseline)	30	15.50	1.43	-5.324	0.15	0.0001
VAS (FU) - VAS (Baseline)	30	15.50	1.43	1.43	0.15	0.0001

AT1- After first menstrual cycle during treatment, AT2- After 2nd menstrual cycle during treatment, AT3- After 3rd menstrual cycle during treatment, FU- Follow up after next menstrual cycle

The improvement in quality of life (QOL) of the patients was assessed using the Endometriosis Health Profile (EHP-30) Questionnaire. The assessment was done at baseline and after the follow-up (after 4 consecutive menstrual cycles). The significance value (2-Tailed) in Quality of Life (QOL) before treatment and after follow-up was found to be 42.35 ± 0.001 and 84.93 ± 0.053 respectively and was statistically significant with p-value < 0.05 as shown in Table 3.

Table 3. Effect of Specific Treatment Protocol at the level of Quality of Life (QoL)

Assessment Tool	Mean	N	SD	SE	t value	Sig. (2 tailed)
QoL- BT	42.35	30	0.0017	2.000	-21.286	0.0001
QoL- AT	84.93	30	0.053	0.0096		

QoL: Quality of Life, SD: Standard Deviation, SE: Standard Error

Virecana karma which is indicated for all *Yonī doṣha* helps in elimination of morbid *doṣha* in the body, mainly through *anulomana* action. *Mahānārāyaṇa taila* (Medicated oil) is *Vata Śhamaka*, *garbhāśaya sodhaka* and subsides *yonī śula*. The site specific action of *Sukumara ghrta* in *Yoni* (reproductive system) with its *gulma hara* property, helped in relieving *sula* particularly those who had advanced stage of endometriosis. The *Sulaprasamana*, *anulomana*, *Vāta -pitta shamaka*, *uṣṇa virya*, and *Agni Dīpana*, *Kapha Vātahara* action of the drugs used in the observed treatment protocol was found to be very effective in relieving the pain and thereby improving the Quality of Life of the patients. The present study has focused on observing a patient centered specific Ayurvedic treatment protocol based on the clinical presentation of pelvic endometriosis as a stepping stone for the future research works on the scope of alternative system of medicine in chronic pelvic pain management.

4. Sources of Funding

None declared

5. Conflicts of Interest

None declared.

6. REFERENCES

1. Hiralal Konar. DC Dutta's Textbook of Gynaecology. Endometriosis, 7th ed :The Health Sciences Publisher; 2016:248.
2. Gelbaya TA, El-Halwagy HE. Focus on primary care: chronic pelvic pain in women. *Obstet Gynecol Surv* 2001;56(12):757-64.
3. Pallavi Latthe, Manish Latthe, Lale Say, Metin Gulmezoglu, et al. WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity. *BMC public health* 2006;6:177.
4. Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. *Pain* 1986;27:117-126.
5. Jonas G, Kennedy S, Barnard A, Wong J, et al. Development of an Endometriosis quality of life instrument: The Endometriosis Health Profile-30. *Obstet Gynecol* 2001;98:258-64.
6. Houston BK, Kelly KE. Type A behaviour in housewives:Relation to work,marital adjustment, stress, tension, health, fear of failure and self-esteem. *Journal of Psychosomatic Research* 1987;31(1),55-61.

7. Vaidya Jadavji Trikamji, editor. *Susruta Samhita of Susruta with the Nibandhasangraha Commentary of Sri Dalhanacarya: Sutra Sthana: Chaukhambha Orientalia; 2014;195.*
8. Tewari PV. *Kashyapa Samhita of Vridha Jeevaka: Chaukhambha Viswa Bharati; 2004;348.*
9. Mishra Siddhinandana, editor. *Bhaishajya Ratnavali of Govinda Dasa Sen, Chikitsasthana, :Chaukhambha Samskrita Sanstana; 2011;547.*
10. Krishnan Vaidyan, editor. *Sahasrayogam: Choorna Yogangal: vaiswanara choornam: Vidyarambham Publishers; 2009:191.*