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ORIGINAL RESEARCH ARTICLE

A CLINICAL STUDY TO EVALUATE THE ROLE OF SHIVAGUTIKA IN PELVIC INFLAMMATORY DISEASE

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Abstract:

Background: Pelvic Inflammatory Disease is an infective condition of genital tract with symptoms like lower abdominal pain and tenderness, abnormal vaginal discharge, chills, and fever. Various yonivyapaths (Diseases of the female reproductive system), presenting the above said symptoms like adhodara shoola (Lower abdominal pain), shoola in maithuna (dyspareunia), jwara (fever) and yonisrava (discharge per vagina) include vatala (endometriosis), paripluta (pelvic inflammatory disease), mahayoni (genital organ prolapse) and so on. **Aims and objectives:** To evaluate the effect of an shivagutika in PID subjects with an intention to maximize its clinical effectiveness and hasten its integration into wider clinical practice. **Materials and methods:** Shivagutika was administered twice daily with honey after food intake for 60 days. The signs and symptoms of PID were graded before and during the course of treatment. In most of the cases, there was a progressive reduction in the symptoms with time, indicating the efficacy of the formulation in PID. **Conclusion:** Shiva gutika efficiently decreases the symptoms of PID, clinically controls infection and can be recommended in the management of Pelvic Inflammatory Disease.

Keywords: Lower abdominal pain, Menstrual abnormalities, Pelvic Inflammatory Disease, Shivagutika, Vaginal discharge.

Introduction:

Pelvic inflammatory diseases are where fallopian tubes, ovaries, cervix or uterus are inflamed and infected[1]. PID can develop following a casual abortion that may cause the uterus to rupture. A weak uterus and adhesions may cause future miscarriages for the woman. PID may also be caused by sexually transmitted infection such as Chlamydia or Gonorrhea. If PID goes untreated, it causes scarring around the inflamed organs, which leads to infertility, chronic pelvic pain and blocked fallopian tubes – which make an ectopic pregnancy more likely[2].

Symptoms of various yonivyapadas specially udavarta, vatala, sanipatika, paripluta, pittala resembles with pelvic inflammatory diseases with main symptom of pelvic pain. This can be considered as tridoshaja vyādhi with vata predominance. In this especially there is derangement of apana and vyana vayu[3]. Anyhow sotha is produced in these conditions which

further aggravates the pain and suggests involvement of pitta dosa along with vata.

In modern system of medicine, antimicrobials, analgesics, NSAIDs are often prescribed in the treatment of Pelvic inflammatory diseases[4]. Gastrointestinal upsets which are increased by analgesics and anti-inflammatory drugs which also produce headache, dizziness, drowsiness. There is a great scope of research to find out management with long lasting effect, to treat the entire feature complex with single regimen. The aim of this study is to find out a safe, potent, cost effective nonsurgical management for Pelvic inflammatory diseases.

Materials and Methods:

The study employed a single arm before-after clinical trial design. Patients who met entry criteria with Pelvic Inflammatory Disease were assessed for signs and symptoms prior to and during the course of the treatment. The approval from the institutional ethical committee was taken and informed consent from each patient obtained.

Details of the drug:

Shivagutika which is explained in Rasayana adhyaya of chakradutta[5] served as the trial drug in this study. Shivagutika with shilajith as its main ingredient is indicated for various types of yoniroga, arbuda, pradara and considered as rasayana. The pharmacological activity of Shilajit shows good anti-inflammatory and analgesic properties which is recommended in PID. Hence it was selected as the trial drug in this study. The trial drug in this study, shivagutika was purchased from the market.

Ingredients of Shivagutika :

The ingredients of Shivagutika are explained in Table 1.

Table 1: Ingredients of Shivagutika

Sl. No.	Name	Latin name	Quantity
1.	Shilajith	Bitumen	640 gms
2.	Shunti	*Zingiber officinale*	80 gms
3.	Pippali	*Piper longum*	80 gms
4.	Katuka	*Picrorhiza kurroa*	80 gms
5.	Karkatashringi	*Pistacia integerrima*	80 gms
6.	Maricha	*Piper nigrum*	80 gms
7.	Vidarikanda	*Pueraria tuberose*	40 gms
8.	Talisapatra	*Abies webbiana*	160 gms
9.	Vamshalochana	*Bambusa arundinacea*	20 gms
10.	Patra	*Cinnamomum zeylanicum (leaves)*	20 gms
11.	Twak	*Cinnamomum zeylanicum (bark)*	20 gms
12.	Nagakesara	*Mesua ferra*	20 gms
13.	Ela	*Eletharia cardamomum*	20 gms
14.	Sesamum oil		80 ml
15.	Sugar		640 gms

16.	Ghee	160 gms
17.	Honey	320 gms

Setting and Sample:

The study population consisted of 15 subjects with PID. The OPD of Prasuti Tantra, S.S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi, served as settings for the study.

Inclusion and exclusion criteria:

Inclusion criteria :

Patients of active reproductive/child bearing age, with symptoms of PID such as lower abdominal pain, abnormal vaginal discharge, low backache, menstrual abnormalities and dyspareunia, who have been diagnosed to have PID in the last 6-12 months and are ready to undergo relevant investigations and hospital admission.

Exclusion criteria:

Pregnant or unmarried women, patients suffering from any systemic disease like tuberculosis, hypertension, diabetes etc ,with history of drug allergy and psychological disorders, patients having specific pathology of genital tract i.e. benign or malignant tumor, erosion of cervix etc, subjects with history of recent delivery or abortion and patients with acute PID who require hospitalization.

Method of administration of the drug:

Shivagutika (500mg) was administered twice daily with honey after food intake for sixty days.

Study Variables:

The primary study variables were the following:

1) Clinical signs and symptoms of PID.
2) USG Findings.

A clinical signs and symptoms checklist was developed to measure the presence or absence of signs and symptoms of PID. (Pain abdomen, per vaginal discharge, Low back ache, dysmenorrhea, dyspareunia and tenderness in fornices). Ultrasonography of Pelvic organs was carried out for the presence of fluid collection in pouch of Douglas and to know the condition of adnexal uteri. High vaginal swab culture and sensitivity test was done for identification of specific organism. The symptoms were noted before the treatment began.(F1) The patients were then subjected to treatment, which included internal administration of Shivagutika (500mg) twice daily with honey after food for sixty days. 3 assessments were done in all the patients and the presence (mild / moderate) or absence of each of the above mentioned signs and symptoms were assessed during the course of treatment. First two follow up were at the interval of 15 days (F2 and F3) and last at the interval 30 days (F4). Thus total period of follow up was of 2 months. After stopping the administration of the drugs under trial patients were advised to report after 30 days for last follow up (F5). During the follow up study, further improvement or deterioration of the signs & symptoms were recorded.

Observations:

Among the 15 patients registered in the study, the incidence of PID was more in the age group 31-35 yrs(32%), majority ones being house wives (85%), with larger percentage having irregular bowel habits (71%). Utmost percentage of patients were with gravidity 3 (32%), parity 2 (39%) and no history of abortion (53%).The age of menarche was 13-14yrs in 82% of patients, duration of menstrual bleeding 3-4 days in 60% of patients, amount of menstrual bleeding average in 64%. 35% of patients used barrier or safe period method for contraception. Frequency of sexual intercourse was 2-3 times/ week in 75% of patients.

Pain in lower abdomen was absent in 14%, mild in 57% and moderate in 29% of

patients. Incidence of abnormal per vaginal discharge reported mild discharge in 29% of patients and moderate in 71%. Low backache score reported absent in 36%, mild in 57% and moderate in 7%of patients. Pain during menstruation was absent in 36%, mild in 36% and moderate in 28% of patients. 50% of the study subjects reported with Dyspareunia whereas it was absent in the other 50%. Tenderness in fornices was absent in 50% and present in the other 50%. The presence of positive finding of PID in USG was present in 57% and not present in the other 43%.

Results:

Effect of therapy on Clinical signs and symptoms of PID:

Pain abdomen, Per vaginal discharge, Low back ache, Dysmenorrhea, Dyspareunia and Tenderness in fornices showed statistically significant reduction following treatment. The details of these are given in table no.2. During the follow up, there was one dropout and hence the statistical analysis was done for only 14 subjects.

Table 2: Effect of therapy on Clinical signs and symptoms of PID

Criteria		BT%	AT%	BT Mean ±SD	AT Mean ±SD	%of relief	t	p
Pain abdomen Score	Score .0	14.28	78.57	1.141	0.214	75	t-5.643	p<0.001 H.S
	Score .1	57.14	21.42	0.66	0.425			
	Score .2	28.57	0					
Vaginal discharge	Score .0	0	42.85	1.71	0.57	42	t-6.450	p<0.001 H.S
	Score .1	28.57	57.14	0.46	0.51			
	Score .2	71.42	0					
Low back ache	Score .0	35.71	64.28	0.714	0.357	44	t-2.687	p<0.02 H.S
	Score .1	57.14	35.71	0.611	0.497			
	Score .2	7.14	0					
Pain in Menstruation	Score .0	35.71	50	0.928	0.500	22	t-3.122	p<0.01.H.S
	Score .1	35.71	50	0.828	0.518			
	Score .2	28.57	0					
Dyspareunia	Absent	50	78.57	57	-	-	Z-2.00.	p<0.05 .Sig
	Present	50	21.42					
Tender Fornices	Absent	14.28	78.57	75	-	-	t-10.67	p<0.02 H.S
	Present	85.71	21.42					

Effect of therapy on USG Findings:

The presence of positive finding of PID in USG was noticed in 8 patients at first visit (57%). In 4th follow up however it was present only in 2 patients (14%). Comparison of USG finding

between initial and last follow up showed significant values ($p<0.05$.S) as stated in table 3.

Table 3: Effect of therapy on USG Findings

USG findings	BT %	AT %	% Relief Change	t	p
Absent	42.85	85.71	75	Z-2.44	p<0.05 .Sig.
Present	57.14	14.28			

Discussion: Women with symptomatic PID commonly have lower abdominal pain and tenderness (especially during coitus), abnormal vaginal discharge, chills, and fever. Therapeutic goals for treating PID are elimination of reproductive tract infection and inflammation, improvement of symptoms and physical findings, prevention or minimization of long-term squeal[6].

Shilajatu, the main ingredient of shiva gutika has kashaya (astringent), amla rasa (sour taste), katu vipaka (pungent in biotransformation), anushnasheeta veerya (not to cold in potency)[7]. It is useful in alleviating tridoshas (three humours). It possess rasayana (rejuvenation), vrishya properties (aphrodisiac)[8]. It is useful in the treatment of prameha (diabetis mellitus), pandu (anemia), gulma (tumour), pleeharoga (splenic disordes), sthaulya (obesity), shotha (swelling), jvara (fever) etc. It is said that there is no such disease which cannot be cured with shilajatu[9]. Shilajatu is also used as yogavaha as it increases efficacy of many drugs. Apart from this the other drugs in shivagutika have kaphavata shamaka property. Shilajatu has significant anti-inflammatory, analgesic, immuno modulatory, antiviral and antioxidant activity[10]. Antimicrobial activities against staphylococcus aureus, escherichia coli and candida albicans and S. aureus and antifungal activity against alternaria cajani were identified[11].

The above observations it is clear that shivagutika is a good drug of choice in the treatment of pelvic inflammatory disease.

Conclusion: From the above clarifications it can be concluded that Shiva gutika efficiently decreases the symptoms of PID, clinically controls infection and can be recommended in the management of Pelvic Inflammatory Disease.

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