

A CLINICAL STUDY ON SHILAJATU IN THE MANAGEMENT OF PUYA RETAS (PYOSPERMIA)

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ABSTRACT

Infertility is a burning problem globally today and has become a major issue. Genital tract infections are one among major causes of Male infertility. *Puyaretas* i.e. *Pyospermia* is the pathological state of the *Retas* (semen) caused by vitiated *Pitta Dosha* and *Rakta Dhatu* which resembles “*Puya*” (pus). Qualitative and quantitative abnormality of seminal plasma are brought about by either aerobic or anaerobic bacterial infections which may result in changes in both seminal and sexual parameters. It is estimated that about 250 million persons get infected annually. Moreover, unexplained infertility may be caused by aerobic and anaerobic infections which contribute 9.14% of all infertile couples of India. *Shilajatu* is the prime drug of choice in the management of *Puyaretas* as explained in Ayurveda classics. Clinical study on *Shilajatu* for therapeutic effect in the management of *Pyospermia* with sample size of 22 revealed that, *Shilajatu* eliminated micro-organisms responsible for the disease and retained the health of patients. It was administered to patients as a *Naimittika Rasayana*, with the dosage prescribed by *Acharya Charaka*. In spite of high dosage to present generation *Shilajatu* did not cause any untoward and side effects. Clinical study revealed statistically over all better improvement in patients of *Puyaretas*. Two patients conceived, 8 completely remitted from symptoms, 8 markedly improved with treatment, 2 improved and no change was observed in one patient.

Key words: Shilajatu, Rasayana, Puyaretas, Ayurveda, Pyospermia.

INTRODUCTION

Fertility is an existential necessity and as such has assumed overwhelming importance from the time immemorial. On the other hand, infertility is an inability to reproduce. It can cause great emotional anguish for people who want children. Infertility affects at least 20-25% of couples of reproductive age. Statistics vary but it would seem that around 35% of men are sub-fertile and at least 2% of men are totally

infertile. Reproductive tract infections are global problem and it is estimated that about 250 million new cases get infected annually. (JRH-1997). According to the WHO, each year around 499 million cases of curable sexually transmitted infections occur throughout the world in the age group of 15-49 years, of which 80% cases occur in developing countries and about 79 million cases occur in India annually¹.

The presence of pus cells or WBC's in

semen is known as Pyospermia and is generally indicative of an infective/inflammatory response of genitellium to bacterial invasion or nonbacterial conditions. Bacterial or nonbacterial inflammatory response of human male reproductive tract may contribute to infertility by adversely affecting sperm function causing anatomical obstruction or initiating leucocyte response i.e. Free radical induced cell injury causing Poor Semen Quality. i.e. Poor Semen Quality is responsible in about 50% of cases approaching to the physician complaining no issues. Ayurved describes this as shukradushti^{2,3}. Puyaretas is one among shukradushti. Puyaretas is the pathological state of the retas caused by vitiated Pitta dosha and Rakta dhatu which resembles "puya". Arunadatta commented that retas which resembles puya is called Puyaretas.⁴

Among the different Rasa Dravyas mentioned in Brihatrayees and Laghutrayees in the context of Rasayana and Vajikarana, no drug has been given so much of importance as Shilajatu⁵. The followers of Rasa Shastra support this view by considering that Shilajatu possess all the properties and actions of Maharasa, Uparasa, Ratna and Louha's⁶. These effects of Shilajatu have been attributed to humic substances called as Fulvic acids, Dibenzol-alpha Pyrones. Benzoic acid, Humic acid and other traced elements. The fulvic acids are bidirectional antioxidants. Recent researches have shown antioxidant, antistress and adaptogenic activities of Shilajatu. Shilajatu is a very potent bidirectional antioxidant possessing both Rasayana and Vajikarana property and is

believed to combat Shukradushti. Acharya Charaka in *Yonivyapat Chikitsa Adhyaya* mentions that Shilajatu effectively cures Retodosha⁷ (Cha.Chi.30/148). So this study was carried out to ascertain the efficacy of Shilajatu in the management of Puyaretas (Pyospermia).

MATERIALS AND METHODS:

Source of Data:

22 patients fulfilling the criteria were selected from SDM College of Ayurveda & Hospital, Udupi, Karnataka irrespective of caste, race and religion.

Objective of the Study:

1. To assess the therapeutic effect of Triphala shodhit Shilajatu in Puyaretas
2. To document the changes in subjective, objective and seminal parameters after treatment

Inclusion criteria:

1. Patients complaining of primary and secondary infertility were incorporated for study after screening semen samples indicating Puyaretas (Pyospermia).
2. The patients who attended OPD of SDM Ayurveda Hospital, Udupi, directly with complaints of Puyaretas irrespective of marital status were also incorporated for study. The age of patients was restricted from 20 years to 45 years.

Diagnostic Criteria:

1. The semen sample which contain more than 5 pus cells/hpf, round cells more than 5/hpf, increased debris, amorphous matter were selected.
2. The semen samples with increased semen viscosity and decreased motility were selected.
3. Semen culture which showed micro-organism after isolation were also inducted

into the study.

4. Other necessary haematological, urine investigations were carried out to diagnose the disease as and when required.

Exclusion criteria:

1. Patients aged below 20 years and above 45 years were excluded.
2. Patients suffering from systemic disease like DM, KOCHS, IHD, STD, AIDS etc. were excluded.

Materials used for clinical study:

Swadistha Virechana Churna⁸: This formulation comprises of Shodhit Gandhaka (1 part), Yashthimadhu churna (1 part), Mishreya churna (1 part), Sonamukhi (3 parts), Sharkara (4 parts). The above drugs were thoroughly mixed and packed. This Swadistha Virechana Churna was prepared in SDM Ayurveda Pharmacy, Udupi.

Shilajatu Vati: This vati was prepared in SDM Ayurveda Pharmacy, Udupi after shodhana with Triphala Kashaya.

Research Design:

Patients were given Swadistha Virechana Churna 3 gm in the night for 3 days with water after food for Koshta Shodhana. After Koshta Shodhana, Shilajatu Vati 12gm in divided doses (4 gm⁹ thrice a day) with milk was administered before food for 7 weeks (Cha.Chi1:3:53-55).

Investigations:

1. Semen analysis.
2. Semen culture.
3. Other investigations if necessary.

Follow up study:

After completion of treatment also the patients were followed up for 3 months.

Ethical clearance:

Ethical clearance was obtained from the Ethical Committee of the Institution

Assessment criteria:

The criteria for assessment of effect of the treatment were made on the basis of changes in,

1. Subjective parameters: Saruja shukrapravritti, Sadaha shukrapravritti, Sakandu shukrapravritti and Mutrakricchrata were graded into following scoring pattern.

2. Objective parameters: Improvement in sexual health i.e. Sexual Desire, Erection, Rigidity (After intromission), Ejaculation and Orgasm were recorded and graded.

3. Semen analysis and semen culture parameters.

Overall effect of the treatment: The overall effect of the treatment was graded into:

1. Conceived: The partner's wife otherwise normal, conceived after male partner was treated.

2. Complete Remission: Patient attains normal range of pus cells, round cells (<5 Cells/hpf) Amorphous matter (<1+), Viscosity (<1+), Negative semen culture and complete relief in subjective manifestation.

3. Markedly improved: Marked reduction in round cells, amorphous matter, viscosity and subjective manifestations.

4. Improved: Relative reduction in round cells, amorphous matter, viscosity and subjective manifestations.

5. Unchanged: No improvement.

OBSERVATIONS

Totally 22 patients were registered in this clinical study, out of which 21 patients completed the study. Maximum number of patients registered were belonging to the age group of 36-40 yrs (9 pts) followed by 31-35

yrs (8 pts), 3 patients registered belonged to 26-30 yrs and 2 patients 41-45yrs age group.

Maximum number of patients i.e. 15 patients (68.17%) were complained of primary infertility followed by 5 patients (22.73%) of secondary infertility whereas 1 patient (4.55%) complained of sexual dysfunction and genital infection. Among 22 patients registered, 11 patients were having Mutrakricchra, 11 patients were having alpa shukra Pravritti as an associated complaint, 8 patients had premature ejaculation and Sadaha Shukra Pravritti, 6 patients Saruja Shukra Pravritti and 1 each patient complained of loss of libido and erectile dysfunction. Maximum of 95.45% patients were reported with negative family history of infertility in the study. Among 22 patients registered 7 patients were having habits of pan and tobacco chewing, 5 patients with

smoking, 2 patients each were having pan, tobacco chewing and consumption of alcohol, 1 patient presented with taking nasya.

Soft consistency of testes and tenderness were noticed in 6 patients whereas firm consistency noticed in 16 patients. 6 patients were having thickened spermatic cord. 6 patients had varicocele and 1 was operated for the same. Micro-organisms were isolated from Semen samples of 14 patients. Micro-organisms isolated were as follows- *E.coli* organism were isolated in 5 (35.71%) patients, *klebeselia* were isolated in 6(42.84%) patients. *Staphylococci +ve* and *-ve* were isolated each from 2 patients (14.28%) whereas each patient's semen culture revealed *Pseudomonas*, *Candida species* and *gram negative* organisms.

RESULTS

Effect of shilajatu on Subjective parameters:

There were significant improvement in Subjective parameters with more than 90% of decrease in complaints like Saruk Shukra

Pravritti, Sadaha shukra pravritti, sakandu shukra pravritti and mutrakricchrata after treatment.

Parameters	N	Mean		d	%	SD	SE	t	P
		BT	AT						
Saruk shukra pravritti	10	3.300 ±0.213	0.200 ±0.133	3.100	93.93	0.568	0.180	17.270	<0.001
Sadaha shukra pravritti	07	3.000 ±0.218	0.000 ±0.000	3.000	100	0.577	0.218	13.748	<0.001
sakandu shukra pravritti	08	2.625 ±0.183	0.250 ±0.164	2.375	90.47	0.518	0.183	12.979	<0.001
Mutrakricchra	10	3.300 ±0.260	0.000 ±0.000	3.300	100	0.823	0.20	12.676	<0.001

Effect of shilajatu on different Sexual health parameter (Objective parameters):

Shilajatu administration brought significant improvement in sexual health. Parameters like desire, erection, rigidity, ejaculation and orgasm were observed after the treatment.

Objective Parameters	N	Mean		d	%	SD	SE	t	P
		BT	AT						
Sexual Desire	20	3.700 ±0.164	3.750 ±0.160	0.050	1.35	0.224	0.050	1.000	0.330
Erection	20	3.900 ±0.261	4.100 ±0.240	0.200	5.12	0.410	0.0918	2.179	0.042
Penile rigidity (after intromission)	20	1.500 ±0.136	1.500 ±0.136	0.000	0	0.000	0.000	0.000	1.000
Ejaculation	20	3.350 ±0.221	3.550 ±0.211	0.200	5.97	0.410	0.0918	2.179	0.042
Orgasm	20	3.300 ±0.219	3.600 ±0.222	0.300	9.09	0.470	0.105	2.854	0.010

Shilajatu caused significant increase in penile erection period, improvement in ejaculation after satisfaction (both own and partner) and improved the attainment of

orgasm in every sexual act. No as such improvement was seen statistically in parameters like-sexual desire and penile rigidity (after intromission).

Changes in Seminal analysis and Semen culture parameters:

Shilajatu administration brought considerable improvement in quality of sperm.

Parameters	N	Mean		d	%	SD	SE	t	P
		BT	AT						
Total Sperm count	21	20.257 ±4.010	20.286 ±4.121	0.0286	0.14	8.657	1.889	0.0151	0.988
semen volume	21	2.243 ±0.217	2.333 ±0.293	0.0905	4.03	1.060	0.231	0.391	0.700
Liquefaction time	21	30.000 ±3.502	28.952 ±3.471	1.048	3.49	15.829	3.454	0.303	0.765
Active sperm Motility	21	23.571 ±3.655	30.143 ±3.716	6.571	27.88	9.569	2.088	3.147	0.005
Sluggish Motile	21	9.190 ±1.858	11.905 ±1.744	2.714	29.53	6.420	1.401	1.937	0.067
Immotile spermatozoa	21	67.238 ±4.292	57.952 ±4.278	9.286	13.81	9.865	2.153	4.314	<0.001
Pus cells	21	13.095 ±2.177	7.952 ±1.928	5.143	39.27	8.540	1.864	2.760	0.012
Epithelial cells	21	1.333 ±0.741	0.810 ±0.412	0.524	39.30	3.326	0.726	0.722	0.479
Normal	21	62.476	64.762	2.286	3.65	12.187	2.659	0.860	0.400

Morphology		±5.821	±5.072						
Abnormal Morphology	21	37.524	35.238	2.286	6.09	12.187	2.659	0.860	0.400
		±5.821	±5.072						

After administration of Shilajatu for 7 weeks, there was improvement in semen volume, increase in active motility of sperms, slight increase in the sluggish motility of sperms. There was marked decrease in immotile spermatozoa after treatment. There was moderate decrease in pus cells in semen, increase in sperm normal

morphology, slight decrease in abnormal morphology of sperm after treatment. In present study maximum numbers of patients were having normal liquefaction time hence the effect of shilajatu on liquefaction time could not be drawn from this data. There was no marked change in total sperm count and epithelial cells in semen after treatment.

Effect of Shilajatu on different microorganism:

Shilajatu administration in patients with Seminal culture positive patients caused semen culture completely sterile after 7 weeks. The details were as follows.

S.N	Microorganisms isolated in seminal culture	No of Pts	Before Treatment	After Treatment		%
				+ve	-ve	
1	<i>E-coli</i>	5	+ve	3	2	40%
2	<i>Klebsiella</i>	6	+ve	-	6	100%
3	<i>Staphylococci +ve</i>	2	+ve	-	2	100%
4	<i>Staphylococci -ve</i>	2	+ve	-	2	100%
5	<i>Pseudomonas aeruginosa</i>	1	+ve	-	1	100%
6	<i>Candida species</i>	1	+ve	1	-	0%
7	<i>Gram -ve bacterias</i>	1	+ve	-	1	100%

Overall effect of therapy of Shilajatu in 21 patients of Puyaretas:

S.N	Parameters	No of pts.	%
1	Conceived	2	9.52
2	Complete Remission	8	38.10
3	Markedly Improved	8	38.10
4	Improved	2	9.52
5	No change	1	4.76

DISCUSSION

In this study, main complaints were primary infertility, secondary infertility; sexual dysfunction and genital infection by the specific symptomatology of Puyaretas. The association of Mutrakricchra showed long standing sexually acquired urinary tract

infection caused by more prevalent organisms like *E.Coli*, *Klebsiella*, *Chlamydia*, *Staphylococcus* and *Pseudomonas aeruginosa*. These were also found in semen culture. Dahet Shukra pravritti i.e. burning ejaculation and sakandu Shukra pravritti were specific subjective

manifestations of Puya Retas indicative of associated acute inflammatory diseases like Acute Bacterial prostatitis, urethritis etc. Tender epididymus was found in 3% of the patients indicates epididymitis which caused poor sperm motility. Chronic non-specific genital infection causes unexplained male infertility disorders. Cystic spermatic cord may be due to inflammatory disorders. Varicocele may contribute to male infertility. Abnormal semenogram with Astheno-zoospermia and Teratozoospermia were found in sub-fertile patients with Pyobacteriospermia. The most frequent findings between Leucocytospermia samples was Asthenospermia i.e. those samples with leucocytospermia associated with low sperm quality, low sperm morphology and low value of seminal fructose. Granulocytes are related with low sperm quality. It was also observed that poor sperm viability was found when the microorganisms were present in the semen.

After completion of study, 17 patients revealed that administration of Shilajatu caused improvement in liquefaction time, motility, decrease in immotile sperms, marked decrease in pus cells and epithelial cells but not so significant results in total sperm count, semen volume and morphology. However the patient completely relieved from subjective symptoms like pain, burning, itching sensation during ejaculation, burning micturition.

The Shilajatu acted upon sexual functions as it caused significant changes in penile erection, ejaculation and orgasm. Shilajatu administration caused complete sterile culture in those patients from which the

Klebsiella, staphylococci “+”ve *staphylococci* “-”ve, *Pseudomonas aeruginosa* and gram “-”ve bacteria were isolated. Out of 5 patients from which *E.Coli* was isolated, 2 patients showed complete improvement, in 3 patients no change was observed. However there was no action of Shilajatu noticed on *Candida species*.

The overall effect of treatment with Shilajatu was good in patients with Pyobacteriospermia. This study justified the quotation of Acharya Charaka “Girijasya prayogaccha Retodoshanapohati”.

CONCLUSION

Clinical study of Shilajatu for therapeutic effect in Pyospermia with sample size of 22 revealed that Shilajatu eliminated disease caused micro-organisms and retained the health of the patients. It was administered to patients as a Naimittika Rasayana with the dosage prescribed by Acharya Charaka. In spite of high dosage to present generation, Shilajatu did not cause any untoward and side effects. Clinical study revealed statistically overall better improvement in patients of Puya Retas. Keeping all these factors together it can be concluded that Shilajatu is a humus rich blackish-brown substance rich in antioxidant properties, which is useful in many diseases and serves as a potent Rasayana, Vajeekara when administered with an appropriate dose, anupana and at appropriate time.

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