

## CLINICAL STUDY TO EVALUATE THE EFFICIENCY OF VARUNADI GANA KWATH BHAVITAM SHILAJATU RASAYANA AS ADJUVANT THERAPY IN THE MANAGEMENT OF VATASTHEELA W.S.R. TO PROSTATE CANCER

**Dr. Ashutosh K. Tripathi<sup>1\*</sup>, Dr. Deepak Kulshreshta<sup>2</sup>, Dr. J. K. Jain<sup>3</sup>, Dr. Shalini  
Tewari<sup>4</sup> and Dr. Swapnil Singhai<sup>5</sup>**

<sup>1</sup>Associate Professor, Department of Shalya Tantra, SDAC & DDH, Chandigarh.

<sup>2</sup>Professor & Principal, Department of Shalya Tantra, Government (Auto.) Ayurvedic  
College, Rewa.

<sup>3</sup>Associate Professor, Department of Panchakarma, Government (Auto.) Ayurvedic College,  
Rewa.

<sup>4</sup>Associate Professor, Department of Kaumarbhritya, SDAC & DDH, Chandigarh.

<sup>5</sup>Professor, Department of Kayachikitsa, Uttarakhand Ayurved University, Gurukul Campus,  
Haridwar.

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### \*Corresponding Author

**Dr. Ashutosh K. Tripathi**

Associate Professor,  
Department of Shalya  
Tantra, SDAC & DDH,  
Chandigarh.

### ABSTRACT

Prostate cancer shows that more than 95% of malignancies in prostate are adenocarcinomas. The typical adenocarcinoma of the prostate can be distinguished using PSA immunochemistry. A possible precursor of prostatic carcinoma is prostatic intraepithelial neoplasia. It involves the abnormal development of the epithelial cells which line the prostate glands. Prostate tumours are usually slow growing and symptoms may not occur for many years. In the early stages of prostate cancer, there are often no symptoms. However, due to its location surrounding the urethra, symptoms for the disease most commonly affect urination. Prostate cancer symptoms include frequent urination, increased

nocturia, difficulty in maintaining a steady stream of urine, hematuria and dysuria. Three standard treatments for localised prostate cancer exist; surgery, radiotherapy and active surveillance. In *Ayurveda* the *Vatastheela* have some similarity with Prostate cancer. According to *Charaka Samhita*, the vitiated *Vata* obstructed the passage of urinary bladder and anal canal with flatulence causes the formation of mobile, elevated structure, which is

associated with severe pain. 100 patients of *Vatastheela* were diagnosed on the basis of International Prostate symptom score along with PSA were included in this study. *Varunadi Gana Kwath Bhavitam Shilajatu Rasayana* was administered orally in dose of *Madhyama Matra* i.e. 24 gm upto 21 days. The overall result showed mild improvement in 94% patients in Group A and marked relief in 46% patients and moderate response in 54% patients in trial group B. There was improvement in quality of life of the patients and PSA level after completion of treatment in group B. No clinically adverse effect reported by the patients nor observed by the researcher during the study. The trial drug causes Srotoshodhana and mainly acts at level of Agni so improve the digestion and create excellence of Saptadhatu. It influences Oja, provides nourishment to the Dhatu and may induce Bala and Vyadhiksamatava or Immunity.

**KEYWORDS:** Prostate Cancer, *Vatastheela*, *Varunadi Gana Kwath Bhavitam Shilajatu Rasayana*.

## INTRODUCTION

In Ayurvedic classics Mutraghat gives the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria. Mutraghat is predominantly due to the Vata dosha. Ayurveda the *Vatastheela* may have some similarity with Prostate Cancer.

As per Acharya Sushruta vitiated vata when situated in guda (rectum) and vasti, it produces stone like (asthilavat), firm (ghana), elevated (unnata) growth (granthi). So that it causes obstruction to passage of faeces, urine and flatus and distension. It causes immense pain in bladder region. Acharya Sushruta, in chapter of vatavyadhi nidana mentioned *Vatastheela* as one of vatavyadhi. According to Charaka Samhita, the vitiated vata obstructed the passage of urinary bladder and anal canal with flatulence causes the formation of mobile, elevated structure, which is associated with severe pain.

This condition closely resembles with involvement of prostate gland and may be stage of carcinogenic changes in prostate.

Prostate cancer is found mainly in elder men. As men age, the prostate may get bigger and block the urethra or bladder. This may cause difficulty in urination or can interfere with sexual function. The condition is called benign prostatic hyperplasia, although it is not

cancer, surgery may be required to remove it. The symptoms of benign prostatic hyperplasia or of other problems in the prostate may be similar to symptoms for prostate cancer.

Several types of cells are found in the prostate, but almost all prostate cancers develop from the gland cells. Gland cells make the prostate fluid that is added to the semen. The medical term for a cancer that starts in gland cells is adenocarcinoma. Other types of cancer can also start in the prostate gland, including sarcomas, small cell carcinomas, and transitional cell carcinomas. But these types of prostate cancer are so rare that if you have prostate cancer it is almost certain to be an adenocarcinoma. Some prostate cancers can grow and spread quickly, but most grow slowly. In fact, autopsy studies show that many older men (and even some younger men) who died of other diseases also had prostate cancer that never affected them during their lives. In many cases neither they nor their doctors even knew they had it.

Most prostate cancers grow slowly. Some prostate cancers however can grow and spread quickly. Hence, the present study entitled 'Clinical study to evaluate the efficiency of Varunadi Gana Kwath Bhavitam Shilajatu Rasayana as Adjuvant therapy in the management of Vatastheela w.s.r. to Prostate Cancer' has been carried out to find the efficacy of Varunadi Gana Kwath Bhavitam Shilajatu Rasayana in patients of Vatastheela. The reason for choosing the study was to explore a combined efficacy of some herbal drugs with Shilajatu and their effects was evaluated with the help of clinical study. In view of increased prevalence rate of prostatic cancer patient without any efficient established management till date; present study with aim of evaluation of an ayurvedic formulation Varunadi gana Kwath Bhavitam shilajathu rasayana in the management of prostate cancer as adjuvant therapy.

## OBJECTIVES

- To study the aetiopathogenesis, symptomatology and progress of Vatastheela w.s.r. to Prostate Cancer as per diagnostic parameters of Ayurvedic & modern medical literature.
- To evaluate the efficacy of Varunadi gana Kwath Bhavitam shilajathu rasayana in the management of Vatastheela w.s.r. to Prostate Cancer.
- To reduce the severity of symptoms of patients of Vatastheela (Prostate cancer) with Ayurvedic medicine
- To improve the quality of life of prostate cancer patients.
- To evolve effective management in prostate cancer.

**CLINICAL STUDY** – The clinical study was carried out on 100 patients having classical picture of Vatastheela in two groups. The clinical study has been carried out on the basis of scientific methodology of the research. The data of patients obtained from different angles has been presented and statistically analyzed. The critical notes and comments on each and every observation have been made with the concerned parameters.

#### **Methods of collection of Data**

- A clinical study of patients attending the OPD of Government Ayurvedic College & Hospital, Rewa, Shri Dhanwantry Ayurvedic College & Hospital, Chandigarh and other referral hospitals was made and patients fulfilling the criteria of diagnosis as per the proforma were selected for the study.
- A clinical evaluation of patients was done by collection of data through information obtained by history, physical examination, and laboratory tests including radiological investigations.
- Review of literature was conducted from books, Authentic Research Journals, Websites and Digital Publications etc.
- The data which were obtained by the clinical trial will be summarized and analyzed through statistical measures.

#### **Inclusion Criteria**

- Patients with classical features of Vatastheela explained in classical texts.
- Patients of any socio-economic status, men and all ethnic origins.
- Men who were 45 years of age and over and able to provide informed consent.
- Malignant neoplasm of the prostate
- Both fresh and treated cases were selected.

#### **Exclusion Criteria**

- Patients with uncontrolled metabolic and other systemic disorders.
- Unconscious or severely ill
- Post surgical complicated patients
- Adults with dementia or with other psychological disorders.
- Patients with renal failure, HIV, STD, Tuberculosis, skin infection and open wounds.

### Criteria for Selection of Drug

Varunadi Kwath has been mentioned in the treatment of tumors and abscess inside the abdomen. Silajatu is very good effective in urinary disorder. Recent study shows that Shilajatu and its bio-activated compounds activated splenocyte of tumour bearing mice at an advanced stage of tumour growth. Also, the raw drugs are easily available and low cost compared to other therapy. Hence, these drugs were selected as an adjuvant therapy in the management of Prostate cancer.

### Research Design

It is an observational clinical study. Patients was assigned in two groups consisting of 50 patients each excluding dropouts with pre, mid and post test study design.

### Intervention

**Group A:** 50 prostate cancer patients on placebo treatment mimicking trial drug as adjuvant with allopathic cancer treatment.

**Group B:** 50 prostate cancer patient on Trial drug as adjuvant with allopathic cancer treatment.

- *Snehana* - Patients was given Gugguluthikthakam ghritham 50gm OD for 3 days.
- *Swedanam* – Abhyanga and mild sweda in the form of hot bath for 1 day.
- *Virechana* - Virechana with Trivritt leha.
- *Rasayana therapy* - Varunadi Gana kwath Bhavitam shilajatu rasayana (madhyama matra) 24 gm daily up to 21 days. The trial drug was given in empty stomach early morning (6am). After it got digested patient was asked to have pathyahara. Pathya kala was followed for a period of 42 days.

### Criteria for Assessment

The assessment was made before, during and after the treatment on symptoms as International Prostate Symptom Score (I-PSS).

**International Prostate Symptom Score (I-PSS)**

Symptom	Not at All	Less than 1 in 5 times	Less than Half the time	About Half the time	More than Half the time	Almost always
Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5
Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5
Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak Stream How often have you had a weak urinary stream?	0	1	2	3	4	5
Straining How often have you had to strain to start urination?	0	1	2	3	4	5
	None	1 Time	2 Times	3 Times	4 Times	5 Times
Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5

The seven questions of the I-PSS are identical to the questions appearing on the American Urological Association (AUA) symptom Index which currently categorizes symptoms as –  
 Mild (symptoms score less than or equal to 7)  
 Moderate (symptom score range 8-19)  
 Severe (symptom score range 20-35)

The International Scientific Committee (SCI), under the patronage of the World Health Organization (WHO) and the International Union against Cancer (UICC), recommends the use of only a single question to assess the quality of life. The answers to this question range from ‘delighted’ to ‘terrible’ or 0 to 6.

Quality of life Due to Urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

**Assessment of total effect:** The total effect of therapy was assessed as;

Assessment	Score
Complete cure	100%
Marked Relief	> 50% to 99%
Moderate Response	> 25 to 50%
Mild Improvement	< 25%
No response	0%

## OBSERVATIONS

**Group A–** The placebo treatment with allopathic cancer treatment provided a significant relief ( $P < 0.001$ ) on the symptoms; incomplete emptying (19.28%), increased frequency of micturation (12.92%), intermittency (12.83%), urgency (15.38%), weak stream (13.45%), straining (12.72%) and nocturia (10.08%). Effect of treatment on quality of life improved was 7.98%.

Symptoms	Mean		Difference In Mean	Relief %	SD	SE	T	P
	BT	AT						
Incomplete Emptying	3.94	3.18	0.76	19.28	0.43	0.06	7.08	<0.001
Frequency	3.56	3.10	0.46	12.92	0.54	0.08	5.25	<0.001
Intermittency	2.96	2.58	0.38	12.83	0.6	0.09	3.22	0.017
Urgency	4.16	3.52	0.64	15.38	0.48	0.07	4.71	<0.001
Weak Stream	3.42	2.96	0.46	13.45	0.5	0.07	4.84	<0.001
Straining	4.40	3.84	0.56	12.72	0.5	0.07	6.41	<0.001
Nocturia	4.76	4.28	0.48	10.08	0.54	0.08	4.93	<0.001

## Assessment criteria for Quality of Life

Assessment criteria	Mean		Difference In Mean	Relief %	SD	SE	T	P
	BT	AT						
Quality of Life	4.76	4.38	0.38	7.98	0.53	0.07	2.87	0.005

**Group B**– The trial drug Varunadi gana kwath Bhavitam Shilajatu rasayana with allopathic cancer treatment provided a highly significant relief ( $P < 0.001$ ) on the symptoms; incomplete emptying (53.23%), increased frequency of micturation (54.91%), intermittency (47.71%), urgency (55.66%), weak stream (60.22%), straining (54.062%) and nocturia (60%). Effect of treatment on quality of life improved was 50.21%.

Symptoms	Mean		Difference In Mean	Relief %	SD	SE	T	P
	BT	AT						
Incomplete Emptying	4.02	1.88	2.14	53.23	0.35	0.05	17.59	<0.001
Frequency	3.46	1.56	1.9	54.91	0.36	0.05	17.54	<0.001
Intermittency	3.06	1.60	1.46	47.71	0.5	0.07	13.46	<0.001
Urgency	4.06	1.80	2.26	55.66	0.49	0.05	21.6	<0.001
Weak Stream	3.52	1.40	2.12	60.22	0.39	0.06	20.39	<0.001
Straining	4.18	1.92	2.26	54.06	0.44	0.05	20.75	<0.001
Nocturia	4.80	1.92	2.88	60.00	0.33	0.05	33.9	<0.001

#### Assessment criteria for Quality of Life

Assessment criteria	Mean		Difference In Mean	Relief %	SD	SE	T	P
	BT	AT						
Quality of Life	4.74	2.36	2.38	50.21	0.49	0.07	15.86	<0.001

#### Effect of drugs on Prostate Specific Antigen (PSA) Test

Group	Mean		Difference In Mean	Relief %	SD	SE	T	P
	BT	AT						
Group A	11.01	10.23	0.78	7.08	0.61	0.09	0.97	0.34
Group B	10.22	6.11	4.11	40.22	1.95	0.28	6.94	<0.001

#### Comparison of Overall Effect of Therapy

Group A provided mild improvement in 47 (94%) patients and 3 (6%) patients were showed no response after completion of treatment. In trial drug Group B provided marked relief in 23 (46%) patients, 27 (54%) patients showed moderate response and no patient found unchanged. No patient got complete cure in both the groups. There was improvement in quality of life of the patients and PSA level after completion of treatment in group B. No clinically adverse effect reported by the patients nor observed by the researcher during the study.

#### DISCUSSION

A probable mode of action of Varunadi Gana Kwath Bhavitam Shilajatu rasayana has been drawn on the basis of its properties and discussion on the whole study.



**Mode of Action of Varunadi Gana Kwath Bhavitam Shilajatu Rasayana** - The present drug formulation Varunadi Gana Kwath contains drugs like Varuna (*Crataeva nurvala*), the two Sairyaka (*Barleria prionitis*), Shatavari (*Asparagus racemosus*), Dahana (*Plumbago zeylanica*), Morata (*Chenomorpha fragrans*), Bilva (*Aegle marmelos*), Visanika (*Pistacia intergerrima*), the two Brihati (*Solanum indicum*) Kantakari (*Solanum surattense*), the two Karanji- pootikaranja (*Pongamia pinnata*), Latakaranja (*Casealpania crista*), the two Jaya, Agnimantha (*Premna integrifolia*), Pathya (*Terminalia chebula*), Bahalapallava (*Moringa olifera*), Darbha (*Desmostachya bipinnata*) and Rujakara (*Semicarpus anacardium*). Varuna is Tikta, Kashaya in Rasa, Laghu, Ruksha in guna, Katu in Vipaka and Ushna in Veerya and Kaphavatahara in nature. It is useful in Vidradhihara and gulmahara. By observing the above mentioned drugs and their property, it gives the Kaphavatahara and medoghna effects. The Rasayana drugs possessing the Ushna, Laghu, Ruksha and Katu, Tikta, Kashaya Rasa may be acting at level of Agni, Vitalizing the organic metabolism leading to an improved structural and function pattern of Dhatus and Production of the Rasayana effects. Shilajatu having Katu, Tikta, Kashaya Rasa, Vishada, Ruksha, Laghu Guna, Ushana Veerya and Katu Vipaka may cause Srotoshodhana and mainly acts at level of Agni so improve the digestion and create excellence of Saptadhatu. Rasayana drugs which influence oja are supposed to induce Bala and Vyadhiksamatava or Immunity.

## CONCLUSION

The present research can be summarized as

- All the drugs chosen for the study are having Kaphavatahara and medoghna properties in nature. So by their virtue, they help in treatment of Vatastheela. The drugs are easily available, economical and with no side and adverse effect.
- Varunadi gana kwath bhavitam Shilajatu rasayana provides nourishment to the dhatu and may induce bala and vyadhiksamatava or Immunity.
- Varunadi gana kwath bhavitam Shilajatu rasayana provided better relief in the amelioration of signs and symptoms of Vatastheela (Prostate cancer).
- Groups B have shown statistically significant results.
- Varunadi gana kwath bhavitam Shilajatu rasayana might be contributing in the overall improvement of quality of life of the patients.

**BIBLIOGRAPHY**

1. Ayur Annie M.R.; Lee, Grant's atlas of anatomy, Lipincott Williamns and Wilkin's, 10<sup>th</sup> edition- 1999.
2. Bhava Mishra, "Bhava prakash", translation by prof. K.R. Srikantha Murthy, 1<sup>st</sup> edition, Varanasi, Krishnadas Academy, Oriental Publishers and distributors, 1998.
3. Campbell's Urology, London, New York, W.B. Saunders Co. Ltd. 8<sup>th</sup> edition, 2001.
4. Chaurasia B.D., Human Anatomy regional and applied CBC publishers and Distributors, New Delhi, 3<sup>rd</sup> Edition, 1995.
5. Goodman Alfred et al., Goodman and Gillman's, the Pharmacological basis of therapeutics Pergamen press, New York, Oxford Beijing Franfurt Sao Paulom, Sydney, 8<sup>th</sup> Edition, 2.
6. Govinda Das, Bhaishajya ratnavali, Hindivyakhya, Shastri Ambika Dutta, Ed. Shastri Rajeshwar datt, Virechana, Chowkhambha Sanskrit Samsthana, 13<sup>th</sup> edition, 1997.
7. Guyton Arthur C, Guyton Book of Physiology, W.B. Saunders Company, 8<sup>th</sup> edition.
8. Hamilton Baily's Physical Signs demonstration of physical signs in clinical surgery, Butter worst Heinmann Internation edition, 18<sup>th</sup> reprint, 2000.
9. Kasture Vaidya Haridas Sridhar, Ayurvedic panchakarma Vigyan, Sri, Baidyanath Ayurveda Bhawan Ltd. Nagpur, 6<sup>th</sup> edition, 1999.
10. Madhavakar Madhava Nidanam, commented by Vallabha Sharma, Mumbai, kshemaraja, Srikrishna das Shresthi, 1984.
11. Mohan harsh, text book of Pathology, Jaypee brothers medical publisher, New Delhi, 2<sup>nd</sup> edition.
12. Parashar Acharya Sri Radhakrishna, Ayurvedacharya, Sarangadhara Samhita, Sri Baidnath Ayurveda Bhawan Ltd. Nagpur, Calcutta, Patana, 3<sup>rd</sup> edition, 1984.
13. Pharmacopoeial Standards for Ayurvedic formulations CCRAS, New Delhi, revised edition, 1987.
14. Rosette J., de la et al., Guidelines on benign Prostatic Hyperplasia, European Association of urology, 2002.
15. Sharma P.V., Dravyaguna Vigyana, Chaukhambha Bharati Academy, Varanasi, reprint, 2001.
16. Shastri Kashinath, Chaturvedi Gorakhanath, Charaka Samhita Chaukhambha Bharti Academy, Varanasi.
17. Singh Ramharsh, Kayachikitsa part-2, Chaukhambha Sanskrit Samsthana.
18. Snell Richards; Clinical. Anatomy for medical students little, Brown and company

Bostan, Toronto, London, 4<sup>th</sup> edition.

19. Sushruta Samhita – Nibandha Sangraha Vyakhya and Nyayachandrika – Chaukhamba Orientalia.
20. Sushruta Samhita – Shareera Sthana- Dr. B.G. Ghanekar - Meharchand Lachhmandas Publication, 12<sup>th</sup> Edition, 1995.
21. Sushruta Samhita–I & II, Hindi Commentary by Kaviraja Ambikadutta Shashtri – Chaukhamba Sanskrit Samsthan, 6<sup>th</sup> Edition-1987.
22. Sushruta Samhita Nidana Sthana– Dr. B.G. Ghanekar- Meharchand Lachhmandas Publication, 1977.
23. Vagbhata, Astanga Hridayam: Murthy Srikanth Prof. K.R., Krishndas Academy Vol. I, II, II Varanasi, 4<sup>th</sup> edition, 2000.