Chapter - 4

Discussion

&

Conclusion
DISCUSSION

The title of the thesis is "A Critical Study over the effect of Shilajit (Asphaltum) and Kabab Chini (Piper cubeba, Linn) on the treatment of Mutragranthi (enlarged Prostate)." The title indicating the research work which is based on a Critical Study where effectiveness of Shilajit and Kabab Chini to be assessed on a specific Urinary disease named Mutragranthi of Ayurvedic system of medicine and enlarged prostate of modern medicine. Mutragranthi, a singular entity comprises of two words, 'Mutra' and 'granthi', Mutra means the watery substance which comes out through Upastha (Urinary passage) and granthi means a knot like elevated structure over any organ or channel. As per opinion of different Ayurvedic commentators of ancient era that "Mutragranthi" is a disease where obstruction towards Urination caused by formation of granthi (glandular swelling) over Urinary passage due to vitiation of doshas. Charak (1000 BC) of Samhita period first mentioned the disease Mutragranthi as a type of Mutraghata (obstructive Uropathy), later Susruta (600 BC), Vagbhatta (400-600 AD), Madhav Kar (900 AD), Sarangadhar (1300-1400 AD) and Bhavnishra (1600 AD) mentioned the disease Mutragranthi as a type of Mutraghata in their respective texts. Dr. Bhaskar Gobinda Ghanekar and Prof. K.R. Srikantha Murty like Ayurvedic Scholar of modern era mentioned 'Asthila granthi' or 'Pourush granthi' as an Ayurvedic Synonyms of 'Prostate gland' of western medicine. Mahamahopadhyay Kaviraj Gananath Sen Sharma Saraswati mentioned "Jwarakrita Mutrakrichhra" as an Ayurvedic Synonyms of the disease enlarged prostate of western medicine. Though this terminology is an appropriate one in relation to the
modern perspective yet there are no supportive references from Samhita and Siddhantas found to establish this terminology as a disease.

Eminent modern Ayurvedist Dr. R.R. Pathak has mentioned Mutragranthi as an Ayurvedic co-relation of the disease enlarged prostate of Western medicine in his reputed text 'Therapeutic guide to Ayurvedic Medicine'. Ancient Ayurvedic literatures have not mentioned any gland like prostate, but these literatures described the features of some Urinary diseases which are similar to the features of Prostatic hypertrophy. In this context it could be interpretate that the small prostate gland was out of their observation in the then time, but the features related to it's enlargement were under their consideration as because they named the disease in a separate way. So in this present study Mutragranthi has been considered as the Ayurvedic co-relation of the disease benign prostatic hypertrophy, giving maximum importance to the symptomatic similarities of both these ailments. Mutragranthi is a type of Mutraghata, where Mutravaha Srotadusti takes place in this ailment. Charaka has mentioned vasti (Urinary bladder) and vankhana (groin) as the Mula of this srota. Ancient Ayurvedic classics have not considered the role of Vrikkas (Kidneys) in connection with the formation of urine, and also don't mentioned the Gavinis (Ureters), curiously enough the word Gavini occurs in the Atharvaveda. It has now been established beyond any doubt that formation of Urine takes place in the two kidneys (vrikkas) and that the Ureters (Gavinis) are the channels through which urine flows into the Urinary bladder (vasti or Mutrasaya). As per Ayurveda Mutra (urine) is the drava mala of ahara (liquid waste of flood), vyana vayu...
is responsible for circulating of rashadhatu, samana vata is for separation and reabsorption of Jala and other kittaas in the vrikkas and apana vata for the function of excreting the mutra of the body.

General actiology of Mutravaha Srotadusti are the excessive intake of faulty ahar (diet) which are atidrava (very watery), kata (pungent) Tikshna (penetrating), amla (sour), Lavana (Salt), Atimadyapan (excessive alcohol in take), Trishna and mutranigrahan (supression of thirst and micturition), Agni and atapa Sevana (exposure to fire and sun), Ativyabaya (sexual excess) and some trauma like Salya (injury over Urinary organs), Krimi (bacteria or virus), Asmari (Calculus), Dhatukshaya (emaciation) and due to some diseases like Hridroga (heart disease), rakta (blood) and Jwara (fever) etc. The main cause of Pourush granthi Vriddhi is old age. As no such elaborate discussion regarding aetiopathogenesis of Mutragranthi has been found in ancient Ayurvedic literatures so in present study we tried to establish an appropriate pathogenesis, considering the actiology of Mutravaha Srotadusti, aetiopathogenesis of granthi, mutraghata, and Mutragranthi. As the old age is the natural Vataprakopakal of human life and if a man persists stress, strain, emotion, excessive journey and indulgence of vataprakopaka food like katu (pungent), Bukksha (rough), Suska (dry), Kasay (astringent), Tikta (bitter), Kshar (alkali), faulty habits like Ati vayam (excessive exercise), Ratrijagaran (waking in the night) etc then Prakristha vata vriddhi (huge provokation of vata) takes place. As kati (pelvis) is the root of all vata so that hugely provokated vata affects the organs of kati (vast!, Pourushgranthi etc). The site of Apana vaya is at kati and it's action mostly on excretion so aggravated
vayu causes obstruction towards excretion and leads to a condition of ati pravridh vata if the vata pravridh person again indulge to kapha prakopaka food like Guru (heavy), Hima (cold) and habits like exposure to cold etc. then production of Amarasha happens and this Amarasha mixing with rakta causes Mutravaha Srotadusti. Ati pravridh vata took these Kapha and rakta to vastimukh (opening of Urinary Bladder where Sthanasamsraya (localisation of dosha) followed by Doshadusya Sammarchhana occur and forms Siragranthi, like abarodha which causes Mutrabarodh (obstruction in Urination), Muhur mutranirgaman (frequent mictunition) vedana (pain) etc. From above discussion it is clear that main doshas involved in mutraganthis is vata and kapha, dusya are the rakta and Mangsa, adhisthan is vastimukh, involved srota is Mutravaha Srota and type of Srotadusti is Siragranthi or abarodha. Mutraganthis has been considered as a type of Mutraghata and Mutraghata is of 13 types as per all Ayurvedic classics, only Susrata mentioned 12 types. The medicines like chandraprabhagutika, Sarbeswarras and Swarnabanga panchak are being used in this problem from ancient era which contains Shilajit, Neembadikwath, Anantadya kwath and kiratadya kwath like medicines also contain kababchini which are useful in the treatment of Mutravaha Srotadusti, so the use of Shilajit and Kababchini in Urinary problem is evident from ancient era. From modern literature review it has been revealed that the prostate weighs only a few grams at birth; at Puberty, it undergoes androgen mediated growth and reaches the adult size about 20 grams by age 20. It remains stable in size for about 25 years and during the fifth decade a second growth spurt commences in the majority of men. The disease
affects men usually over the age of 45 and increases infrequency with age 80 that by eighth decade more than 90 percent of men usually suffer from prostatic hyperplasia. Though the actual pathogenesis of prostatic hypertrophy is unknown yet some theories like Hormonic theory and Neoplastic theory may be considered in this context. As age advances the male hormone diminishes while the quantity of the oestrogenic hormone is not decreases equally. According to this theory the Prostate enlarges because of predominance of the oestrogenic hormone. Prostatic enlargement can be regarded as involuntary hyperplasia akin to fibro adenosis of the breast; due to a disturbance of the ratio and quantity of the circulating androgens and oestrogens.

The Neoplastic theory postulates that the enlargement is benign neoplasm. As the prostate is composed essential of fibrous tissue, muscle tissue and glandular tissue, the neoplasm is fibr-myo-adenoma. As the prostate enlarges extravesically, it tends to displace seminal vesicles, so that instead of lying on the base of the bladder, these structures become a direct posterior relation of the upper limit of the prostate. When the hyperplasia affects the sub-cervical glands a 'middle' lobe develops which project up in to the bladder with in the internal sphincter. Sometimes both internal lobes also project in to the bladder, so that when view from with in, the sides and back of the internal urinary meatus are surrounded by an intravesical prostatic collar.

The most common clinical features are frequency of urination, usually first noted as nocturia, is a common early symptom. Difficulty
or delay in initiating urination, with variability and reduced forcefulness of the Urinary Stream and post void dribbling are often present. Suprapubic pain occurs if bladder bacteriuria is present. Acute retention of urine or retention with overflow incontinence may occur occasionally. Severe haematuria results from rupture of prostatic veins. Some patients may present with renal failure.

If we considered the Pathogenesis of Benign Prostatic hypertrophy in Ayurvedic view, it will be found that any type of vriddhi (Growth or enlargement or hypertrophy) is caused by predominence of vata. If the growth is sthira (stable), achala (immobile) and causes gourava (heaviness) over the organ with alpa vedana (less pain) then the vriddhi (enlargement) would be called as Vataslaismika Vriddhi - so in the paralance of Modern and Ayurvedic Medicine BPH may be considered as Vataslaismika Vriddhi of Pourush granthi.

In review of the modern literatures it has been also revealed that finasteride is the drug of choice of this problem, but this 5 alpha reductase inhibitor have the hypotensive side effect and in longer onset of action produces adverse sexual effects. Other drugs like alpha-1 antagonists (alfuzosin), alpha1A Prostatic adrenoceptors (transulosin) and terazosin, doxazosin which are being used in this problem. These drugs are not so much active over large prostatic glands. The most popular surgical management in this problem is TURP (Transurethral resection of Prostate) but it has also reported in recent study that ventral penile deflection with severe sexual impairment (Kelami Syndrome) may appear after such operation.
From above discussion it is now clear that neither operative management nor medicinal measurement is safe and complete one.

So this project work is an attempt to contribute a safe, and effective Ayurvedic regimen to treat the said problem.

Shilajit and Kabab Chini these two Ayurvedic drugs has been choosen as the trial drug for the clinical study of this thesis work. Shilajit was variously described as an inorganic material, a bitumen, an asphalt, a mineral resin, a plant fossil exposed by the elevation of the Hialayas, a substance of mixed plants and animal origin but Dr. S.N. Ghosal and his co-workers have given some congenent evidence to remove such controversy. They stated that Shilajit is essentially constituted of fresh and modified remnants of humus (10-70%) of the water soluble fraction of Shilajit, admixed with plant and microbial metabolites occurring in the rocks rhizosphere of it's natural habitat.

Shilajit is of 4 varieties, Gold Shilajit, Silver Shilajit, Copper Shilajit and Iron Shilaji. From therapeutic point of view the fourth variety is considered to be active. Shilajit is of a bitter taste and of a smell resembling cow’s stale urine known as Gomuthra Shilajit; which is mostly use as Ayurvedic Medicine, after purifying it by certain processes. Purified Shilajit (Sodhita) is just like the concentrated watery extract of the crude stuff.

The organic constituents of Shilajit are moisture, Benzoic acid; Hippuric acid, Fatty acids, Resin and waxy matter, Gums, Albuminoids and vegetable matter, send etc. Mineral constituents
obtained from the ash by incineration of the substance, these are moisture, silica, Iron (Fe₂O₃), Alumina (Al₂O₃), Lime (CaO), Magnesia (MgO), Potash (K₂O), Sulphuric acid (SO₃), Chloride (NaCl), Phosphoric acid (P₂O₅) and Nitrogen. As these minerals are useful for the nutrition of the body. Shailajit used in Ayurveda as a rasayan (tonic), Charak (1000 BC) also mentioned “Silajit rasayan” specifically and praised it by such speech “There is hardly any curable disease which cannot be controlled or cured with the aid of Shilajit”. Prof. S.N. Ghosal and his co-workers established that Shilajit can notes non specific host resistance to diseases by augmentation of Cellular functions (rejuvenations). They have also established the immunomodulatory as well as anti oxidant effect of Shilajit through animal study.

Almost all the Ayurvedic texts mentioned that Shilajit has Katu and Tikta rasa, Usna and Laghu guna, Usna virya and Katu vipak. Shilajit has the doshic actions like vata and kapha nasak. By it’s Usna virya property pacifying vata and kapha it restricts and reduces the growth of Prostate. It’s actions as per Ayurvedic view are Chhedak, Yogabahi and Rasayoma. It is useful in the treatment of the diseases like Arsa, Meda, Sarkara, Pathuri, Mutrakrichhra, Kshay, Swas, Kustha, Udara, Krimi, Prameha and Sotha. Internally it’s actions are alternative, tonic, slightly laxative, cholagogue , respiratory stimulant, disinfectant, expectorant, antiseptic, anthelmintic, antocolic, anti inflammatory, analgesics, di-Uretic and lithontriptic. Externally it’s actions are antiseptic, anodyne, parasiticide and anti phlogistic.

It’s doses mentioned in different texts 500 mg to 1½ gm.
From above discussion it is revealed that as the Shilajit has the actions like Rasayana (tonic) and immunomodulation so it could be useful in the treatment of aging problem like enlargement of Prostate. As Shilajit has vatanasak and kaphanasak actions and mutragranthi also a disease of vata and kapha predominance so Shilajit could treat this problem by pacifying the vata and kapha. By anti inflammatory, analgesic, antiseptic and anthelmintic actions it could help the patients keeping free from secondary hazards of enlarged prostate like U.T.I., prostitis and dysuria etc.

Another plant drug Kabab Chini is the trial drug of this project. It is of piperaceae family and it's Sanskrit Synonyms are Surapriya, Vrittaphalam and Sugandha Maricha. In English it is known as Cubeb, Tailed Pepper, Tailed Cubeb. The unripe dried berries are the useful part in medicine. Chemically it contains Cubebin, Cubebol, Cubeb-Camphor, Cubebic acid and other sesquiterpenes. The most characteristic constituent of Cubeb is the essential oil (oil of Cubeb).

As per modern view, it's therapeutic actions are acrid, bitter, thermogenic, aromatic, stimulant, anodyne, dendifice, anti inflammatory, anthelmintic, deobstruent, vulnerary appetising, carminative, digestive, stomachic, cardiotonic, expectorant, rejuvinative, emmenagogue, di-uretic, sedative and anti septic.

The properties of Kabab Chini achieved in different Ayurvedic texts are, It's rasa is Katu and Tikta, Guna is Laghu, Ruksha and Tikshna, Vipak is katu and virya is Usna. It's dosic actions are Kapha and vata samak.
As per Ayurvedic point of view it’s actions are deepen, pachan, ruchikarak, Sugandhi, hriddya, Mukhajaratanasak, Kriminasak, hridroghanasak, vrisya, Trishnanasak and amanasa.

It’s doses are, powder – 1-3 gms., oils – 1-3 drops and Infusion 1-2 oz.

From above discussion it could be said that by it’s kapha and vatanasak activity it may be helpful as like as Shilajit in the treatment of vata and kapha pradhan disease Mutragranthi. It’s Rasayan (tonic), anti-inflammatory, anthelmintic and anti-infectant effect could also prevent the patients from secondary hazards of BPH in the way of action of Shilajit. It has special deepan and pachan properties and action like pachak which helps paka (digestion) of Ama, as a result amarasa formation will be restricted and patient will get relief from abarodha (obstruction).

From the most important work Clinical Study of this project performed at out patient department and Indoor patient department of Institute of Post graduate Ayurvedic Education and research at S.V.S.P. Hospital, 294/3/1, A.P.C. Road, Kolkata – 700 009. 56 male patients above 50 years of age have been selected for clinical study after proper screening. Certain subjective as well as objective criteria have been followed to select such patients. The complaints like frequency of micturition (specially nocturia), difficulty in Urination, variability and reduced forcefulness of Urination, suprapubic pain,
post void dribbling and the history of occasional retention of urine, these all have been considered as subjective criteria. The evidence of BPH in ultrasonography, prostatic glandular hypertrophy in per rectal examination, PSA level below 4 ng / ml and serum acid phosphatase level below 3 KA units / 100 ml. all these evidences considered as objective parameter. In this study some cases of BPH have been eliminated where there were the evidence of malignancy, tumur in pelvic organs, stricture urethra, calculus in Kieney, Üreter and Bladder, Diabetes melitus, C.R.F., Low G.C., Bed ridden and Unconcious or Semiconcious patients. These 56 (after screening) male patients have been randomly categorized in 4 main groups e.g. A, B, C and D having the number of patients 26, 10, 14 and 6 respectively.

Group – A Patients treated with the mixture of Suddha (Purified) Shilajit and Kabab Chini in equal ratio named ‘M’ capsule (1 cap = 500 mg), so Group – A patients treated with 2 ‘M’ capsule twice daily. Group – B patients treated with Kabab Chini powder named as 'OK' capsule (1 cap = 500 mg) in the dose of 1 capsule twice daily. Group – C patients treated with the powder of suddha shilajit named ‘OS’ capsule (1 cap = 500 mg), in the dose of 1 cap twice daily Group-D patients treated with placebo with powder of rice named as ‘P’ capsule (1 cap = 500 mg) in the dose of 1 cap twice daily. All these patients contined their medicines before meal for 3 months with their normal diet.

Assessment of results done depending on the value of subjective and objective parameters before treatment and after treatment. 5 major symptoms have been taken into consideration as subjective
parameter. The scoring system of Carolyn – M Hicks 1999 have followed in case of these symptoms. The length, breadth, thickness, weight of prostate and post void residual Urine of Bladder from the Ultrasonography findings have been considered as objective parameters.

Hb%, ESR value measured before treatment and after treatment to know the effect of our trial drugs over anaemia and degenerative process of BPH patients. The value of Serum Urea, Creatinine, Bilirubin, S.G.O.T. & S.G.P.T. in BPH patients measured before treatment and after treatment to know the nephrotoxicity as well as hepatotoxicity of our trial drugs.

In our clinical study the data on incidence of religion, income status, occupation, residence, educational status and addiction have been taken but not so significant interpretation could be made on these data. Only in income status incidence of 56 BPH patients it has been observed that poor and very poor persons are maximum in number, probably due to lower standard of living or food of poor patients than the rich one. In addiction incidence it has been found that maximum number of patients are addicted to Tea and tobacco, which may be a cause of aggravation of vata. In the incidence of prakriti it has been observed that Vataja, Vata kaphaja, kaphaja and vata pittaja persons mainly affected by it, this incidence has been supported the ayurvedic pathogenesis of the disease.
The major symptoms like frequent micturition (specially nocturia), difficulty in micturition, reduced forcefulness of Urination, post void dribbling and suprapubic pain like symptoms were present in about 98%, 95%, 87.5%, 82% and 75% patients among 56 BPH patients. This incidence proved that from lower to upper the features are common to commoner to the patients of Benign Prostatic hypertrophy.

Mean scoring of Before treatment, changed after treatment with different therapy. Incase of Group – A patients mean scoring reduced (relieved ) after treatment, 71%, 54%, 66%, 65% and 63% respectively, incase of Group B patients these scoring reduced to about 22%, 14%, 21%, 32% and 24% respectively. Whereas in group C patients these scoring reduced– to about 50%, 57%, 50%, 54% and 58% respectively. But whereas in case of placebo group – Group D patients these 'after treatment' scoring increased significantly than the scoring of Before treatment.

From this result it could be said that Group-A patients got maximum relieve, Group – B patients got minimum relief...and Group – C patients got average relief. So in subjective parameter 'M' capsule i.e. mixture of Shilajit and Kabab Chini showed excellent effect in the dose of 1 gm twice daily by relieving the symptoms. Group – B patients showed not so good effect with only Kabab Chini- 500 mg twice daily, where as Group – C, which patients have been treated with only Shilajit in the dose of 500 mg twice daily showed average effect and incase of placebo group there is no relief of symptoms happened and intensity of these symptoms became raised. All these scoring statistically showed significant change in before treatment and after treatment.
In objective parameter the value of Length, Breadth, thickness weight of prostate and post void residual urine measured before treatment and after treatment in all groups. It has been found that incase of Group – A patients reduction of these value were about 15%, 13%, 17%, 9% & 31%, in group – B patients 3%, 4%, 4%, 3% & 10%, in Group – C patients 11%, 9%, 9%, 7% & 23% respectively. So form this result”, it is again proved through objective parameter that length, breadth, thickness and weight of prostate as well as post void residual urine volume reduced maximum in Group – A, minimum in Group – B and average in Group-C patients. In Group-D patients it has been observed that these value increased about 4%, 4%, 6%, 1% and 10%. As the Group – D patients treated with placebo so it may be said that if treatment not continued with 'M', 'OK' or 'OS' capsule mean size and weight of prostate will increase along with post void residual urine.

From above discussion it is clear that Shilajit has the much more symptoms relieving effects as well as growth reducing activity than Kabab Chini. If Kabab Chini use as an Anupan (vehicle) the effectiveness of Shilajit will increase significantly.

After 3 months treatment with 'M' capsule the Group – A patients showed excellent effect by reducing before treatment scoring of features and value of objective parameter. Again Group A patients subdivided in to 3 groups i.e. A₁, A₂ & A₃, A₁ subgroup of patients treated with 'M' capsule – 2 cap once daily, A₂ subgroup of patients treated with M capsule, 1 cap twice daily and A₃ subgroup of patients treated with P capsule, 1 cap twice daily. All these patients treated for 1½ months. It has been observed that if M capsule continued to the
patients in divided dose, 1 cap twice day, it will show better effect than single dose i.e. 2 capsule once a day. Through result of placebo it has been proved that if treatment stopped to the patients then there is chance of again aggravation of symptoms and increase of size and weight of prostate.

It is being observed in this clinical study that the Hb% level also increased in Group-A, Group – C and Group – B patients respectively. Perhaps this enhancement of Hb% happened in Group-C and Group-A patients due to the presence of Iron and other minerals in Shilajit. In Group – B patients mild enhancement of Hb% probably due to deepan & pachan effect of Kabab Chini, where it helped iron to absorb in the system by increasing the digestive power.

ESR level became decreased in Group – A, B & C patients probably due to anti-inflammatory anti infectant and rasayana (tonic) effect of Shilajit and Kabab Chini both.

As no such significant change found in the level of Serum urea, Creatinine, Bilirubin, S.G.O.T. and S.G.P.T. so it could be said that these two drugs have no nephrotoxicity or hepatotoxicity in the prolong use of the same. Beside these other systemic toxicity of both these drugs has not been proved in this study but clinically nothing has been detected yet as adverse effect of these drugs.
So from above discussion it could be said that Shilajit have a significant anti-hypertrophied role) in the treatment of BPH (Mutragranthi) Kabab Chini itself have some minor role over cure of this disease but if it use along with Shilajit then it will exert a very effective role in the treatment of Mutragranthi or Benign Prostatic hypertrophy. Clinically both these drugs have no such side effect found in this study.

After this discussion it is now could be said that Mutragranthi is Vata and Kapha Predominence disease found in old age at the phase of degeneration of men. It could be treated safely with Shilajit in the dose of 500 mg. twice daily along with the Kabab Chini in same proportion. In this therapy Kabab Chini embance the power of Shilajit, so it could be stated as an Anupana (vehicle).
CONCLUSION

Through review of the Ayurvedic literatures in relation to the disease Mutragranthi, review of the modern literatures on the problem enlarged prostate, review of the drugs, clinical study and discussion of thesis all the following points may be concluded:

1. Mutragranthi may be considered as an Ayurvedic terminology of Benign Prostatic hypertrophy (BPH) of modern medicine.

2. The aetiology of BPH is still unknown in modern medicine.

3. In old age Prakristha Vataprakopa (hugely provoked Vayu) mixing ith Kapha, enlarges the size of Pourush granthi and produces the abarodha (obstruction) in Vastimukha (orifice of urinary bladder).

4. Medicinal treatment as well as Surgical Management of BPH are not always safe and Unique in Western medicine.

5. Shilajit itself has a great role in the treatment of Mutragranthi in a dose of 500 mg twice daily.

6. Kabab Chini has little effect over this problem in single use of the same.
7. Combined mixture of Shilajit and Kabab Chini in equal proportion, in a dose of 1 gm. twice daily for 3 months, followed by continuation of 500 mg. twice daily will exert the excellent effect over this problem.

8. Kabab Chini may be called as Anupan (vehicle) of Shilajit in the treatment of this problem.

9. If the said regimen of treatment stopped to the patients of Mutragranthi (BPH), further aggravation of symptoms may be found.

10. Shilajit and Kabab Chini could cure the patients of Mutragranthi (BPH) by their Usna Virya properties. Vata and Kapha nasak activity of these two drugs decreasing the Vriddhi (growth or enlargement of Pourush granthi (Prostate).

11. Shilajit itself and Shilajit along with Kabab Chini could also enhance the Hb% and decrease the ESR level, means restrict chronic inflammation and degeneration.

12. No such adverse effect found over Renal functions and Hepatic function in prolong use of these two drugs.

13. Clinically no such side effects observed over other system during the therapy.

14. General condition may be improved with Shilajit and Kabab Chini, which have been found in present study.