

# “Efficacy of *Kushmandadi Yoga* in comparison with combination of *Tamsulosin&Dutasteride* in the Management of *Vatashthila* (Benign Prostatic Hyperplasia)”-An Ayurvedic Management Protocol

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## Abstract:

**Background** –BPH is a benign growth of the prostate that arises beyond the age of 50, commonly between the ages of 60 and 70.Both the glandular epithelium and the connective tissue stroma are affected by BPH. Involuntary hyperplasia occurs when the ratio and quantity of circulating Androgens and Oestrogens are disrupted. Testosterone levels decline with age, while Oestrogen levels do not diminish at the same rate. So Prostate enlarges through intermediate Peptide Growth factor.In contemporary sciences Benign Prostatic Hyperplasia has close resemblance with *Vatashthila*.**Objective-**The 3main objectives of present study is to study the efficacy of *Kushmandadi Yoga* on the objective parameters of *Vatashthila*.Also to study the efficacy of combination of *Tamsulosin&Dutasteride* on the objective parameters of *Vatashthila* and to compare the efficacy of *Kushmandadi Yoga* withcombination of *Tamsulosin&Dutasteride* on the objective parameters of *Vatashthila* (BPH).**Material & Method:** The study to be performed here is aSingle blind randomized parallel study in which 40 patients will be enrolled. In this regard Herbal drug *Kushmandadi Yoga* 2gm afterfood daily with lukewarm water is to be consumed in a day with *BalatailaMatrabastifor* 21days daily through rectum route only will be tried. The treatment will be performed for 60days and then assessed as per gradation adopted.**Results:**As per the symptoms of *Vatashthila* (BPH) the changes are expected to be observed in subjective parameters such as incomplete emptying, frequency, urgency, intermittency,weak stream, straining, nocturiaas well as with objective parameters such as Shape and size of the Prostate gland along with Post voidal volume of the urine in the bladder and Pressure & Velocity of Urine stream.**Conclusion:** The study is expecting the nonsurgical management which consist of both *Shodhana&Shamanachikitsa* to break the pathology of BPH (*Vatashthila*). The research is expecting to be baseline and benchmark of the prospective studies in BPH.

**Keywords:** *Vatashthila*, Benign prostatic hyperplasia, *Mutraghata*, *Kushmandadi Yoga*,*Bastichikitsa*,

## Introduction

In modern medicine, benign prostatic hyperplasia (BPH) is the most frequent lower urinary tract ailment. It is an abnormal hyperplasia due to disturbance of the ratio and quantity of circulating androgens and estrogens. It's an old age-related illness that affects men and causes major morbidity in older age groups, lowering quality of life<sup>1</sup>.From Hypothalamus there occurs pulsatile release of LHRH which in turn releases luteinizing hormone from Anterior Pituitary.This causes testicular Leydig cells to release testosterone (TS), which reaches the bloodstream. Then prostate Releases 5alpha reductase type 2 converts TS to DHT (dihydrotestosterone). DHT has a five-fold higher potency than TS. The testes produce 90% of the TS, while the adrenal cortex produces 10%. Dropping of Testosterone level slowly with advancing age but fall of estrogen level is not as same as that of TS, so enlargement of prostate occurs through intermediate peptide growth factor. Histological evidence of BPH is found in more than 50% of men in their fifties & nearly 90% of men in their nineties age.As the enlargement of prostate occurs, it causes the narrowing of urethra & subsequent partial emptying of bladder, resulting in many of the problems related to BPH.In BPH generally median and lateral lobes or one of them are involved. Sub mucous glands are more affected in adenomatous zone of prostate.Narrowing of lateral lobes of urethra leads to obstruction and median lobe enlarges into the bladder. Narrowing and elongation of urethra above the verumontanum happens. Because of pressure initially trabeculations and sacculations forms and then leads to the formation of diverticula. The prostatic venous plexus congestion happens due to compression of enlarged prostate called as vesical piles which causeshaematuria.

Major signs and symptoms include:

- Nocturia, Urgency, hesitancy, overflow and terminal dribbling of urine. Difficulty in micturition with weak stream and dribbling of urine.

- Suprapubic pain and in the loin due to cystitis and Water accumulation in nephrons of kidney respectively.
- From Acute as well as chronic retention can also occur in BPH.
- Overflow of urine along with retention. High pressure chronic retention along with functional obstruction.
- Impairment of emptying of bladder along with urethritis, cystitis, residual urine and stone formation
- Blood in Urine.
- Renal failure
- Prostatism – frequency raised during day and night, poor stream, delay and difficulty in micturition.
- Enlarged prostate is seen in per rectal examination. It is performed when the bladder is empty.
- Fever, chills, burning micturition and other features of urinary infection.
- International prostate symptom score can be checked for diagnostic purpose<sup>2</sup>.

“Decrease in voiding distance is an essential indicator of prostatic obstruction,” wrote Ballenger (1932) for the first time. Uroflowmetry and residual urine estimates are well-accepted and useful markers for diagnosis and treatment improvement.<sup>3</sup> Major differential diagnosis for BPH can be done from Stricture of urethra, bladder tumour, carcinoma of prostate, retention of urine due to neurological causes like diabetes, bladder neck hypertrophy, disseminated sclerosis, stenosis, Parkinson’s disease.

Investigations to rule out are-

- Urine routine for microscopy and Culture sensitivity
- Serum Creatinine test
- Blood urea
- Ultrasound abdomen - residual volume of urine
- Urodynamic including Urine flow rate > 15ml/sec is normal, 10-15ml is equivocal ; <10ml is low. Normal peak flow rate of urine is 20ml/sec. in obstruction it is less than 10ml/sec. Also Voiding pressure is checked <60 cm of water is normal; 60-80 is equivocal; >80 is high.
- Examination of bladder
- TRUS- transrectal ultrasonography - nodules/possibility of malignancy
- (PSA) Prostate specific antigen
- IVU- to check renal function
- Serum electrolytes.

Management-

Western science offers two treatment options: conservative pharmacological therapy (hormonal, etc.) or surgical intervention (open prostatectomy, Cryotherapy, (TURP),

- If acute retention of urine is the complaint of patient then Urethral catheterization. Suprapubic Cystostomy (SPC) if catheterization fails.
  - In case of uraemia, then catheterization of urethra is preferred because that allows the proper renal function and obstructive damages are prevented.
  - Correction of serum electrolytes.

Indications for surgery – Prostatism, acute retention of urine, chronic retention of urine with residual volume more than 200ml, complications like accumulation of water in nephrons or ureter etc.

Internal medication includes-  $\alpha$ -1 adrenergic blocking agents which are inhibitors of smooth muscle contraction of prostate. They decrease the resistance of neck of bladder hence improving the urine flow and 5-reductase inhibitors.

5 $\alpha$ -reductase inhibitor inhibits conversion of testosterone level to DHT. It is effective in enlarged and palpable prostate gland. Duration of this medicine is about 6-8 months.

When these medications are used for a year, the prostate gland shrinks by 20-25 percent. Furthermore, these medications are costly in contrast to their effectiveness, and they have some negative effects.<sup>4</sup>

The truth about these medicines is that a large percentage of men who try them will end up having surgery. Prostatectomy is the most common treatment for benign prostate hyperplasia. Even if the operation is performed, there is a substantial risk of early (hematoma, clot retention, bladder neck stenosis, erectile dysfunction, etc.) and late (secondary growth, urethral stricture, infection, etc.) consequences.

Regarding the likelihood, recurrence, and high expense of surgery, society must consider an alternative choice for this most common senile disease<sup>5</sup>.

Acharya Sushruta has mentioned Total, 12 types of *Mutraghata*, in which Vatashtila is one among them.

1. Vatakundalika
2. Ashthila
3. Vatabasti
4. Mutratita
5. Mutrajathara
6. Mutrotsanga
7. Mutragranthi
8. Mutrashukra
9. Ushnavata
10. 2 types of Mutrauksada

Whereas 13 types of BastiRoga is explained by Acharya Charaka in *Siddhi Sthana*<sup>6</sup>.

The term '*Mutraghata*' is made up of two words: '*Mutra*' and '*Aghata*,' means reduced urine flow due to blockage in the urinary stream<sup>7</sup>. *Mutraghata* and Benign Prostatic Hyperplasia (BPH) have same signs and symptoms<sup>8</sup>. *Mutraghata* is caused by a malfunction of *ApanaVayu*, as well as vitiation of the *Kapha* and *Pitta Doshas*, according to Ayurveda. The affected Dosha are created in the body as a result of faulty *Ahara* and *Vihara* (food habits and exercise of routine), parivartan of *ritu* (seasonal changes), and *Vaya*. Finally, they pass via *SukshmaSrotasa* and arrive at *KhaVaigunya* state, i.e. Basti Pradesh (urinary bladder), where the clinical entity *Mutraghata* is established and has symptoms such as urine retention, incomplete voiding, and so on.<sup>9</sup>

The *hetusamprati* of *Vatashthila* explained in *SushrutaUttartantra* is *Vayu* located in the region between rectum and urinary bladder produces dense, fixed and raised stone-like glandular swelling which in turn, causes retention of feces, urine and flatus, distention and excruciating pain in the urinary bladder. This is known as *Vatashthila*. Acharya *Sushruta* has mentioned the Lakshanas of *Vatashthila* like *Adhmana*, *Mala Baddhata*, *Mutra* and *Apanavayu*, *Chala*, *UnnataGranthi*, *Vinmutra*, *Anilasanga*, *Vedana* in *Basti*<sup>10</sup>

Acharya *Vagbhata* mentioned *Vatashthila* is explained as a condition where the mass or swelling appears in between urinary bladder and rectum leading to obstruction to passage of urine.

In *Vatashthila*, *VataDosha* is more prominent, so Acharya *Sushruta* mentioned in *ChikitsaSthana* the Basti is Pradhan Chikitsa for *VatajaDosha* and Charaka also mentioned in *SidhiSthana* Basti is ArdhaChikitsa among all Chikitsa<sup>11</sup>

In the treatment of retention of urine mentioned in *SushrutaSamhita*, the wise should apply decoctions, pastes, ghrita, edibles, electuaries, milks, alkalies, wine, asavas, sudation, urethral douches and other procedures which remove calculus.

In all types of retention of urine, generally *Vayu* is the causative factor and *Pitta & Kapha* collaborate as covering agents. Because of this, here general treatment is mentioned which should be applied after considering *dosa*, drugs and disease carefully<sup>12</sup>.

Hence medications with *Vata-Kapha* pacifying characteristics, such as *Srotoshodhana* (channel cleaning), *Lekhana* (scraping), *Shophahara* (anti-inflammatory), *Mutrala* (diuretic), and digestive characteristics, might help break the *MutraghataSamprapti* (BPH)<sup>13</sup>.

#### Methodology:

**Trial design:** Randomized Clinical Controlled, Single blind  
Interventional study.

**Study setting:** Diagnosed Patients of BPH will be selected from *Shalyatantra* OPD & IPD of M.G.A.C.H. and R.C. Wardha  
**Single blind Randomised, Controlled Study in 40 patients**

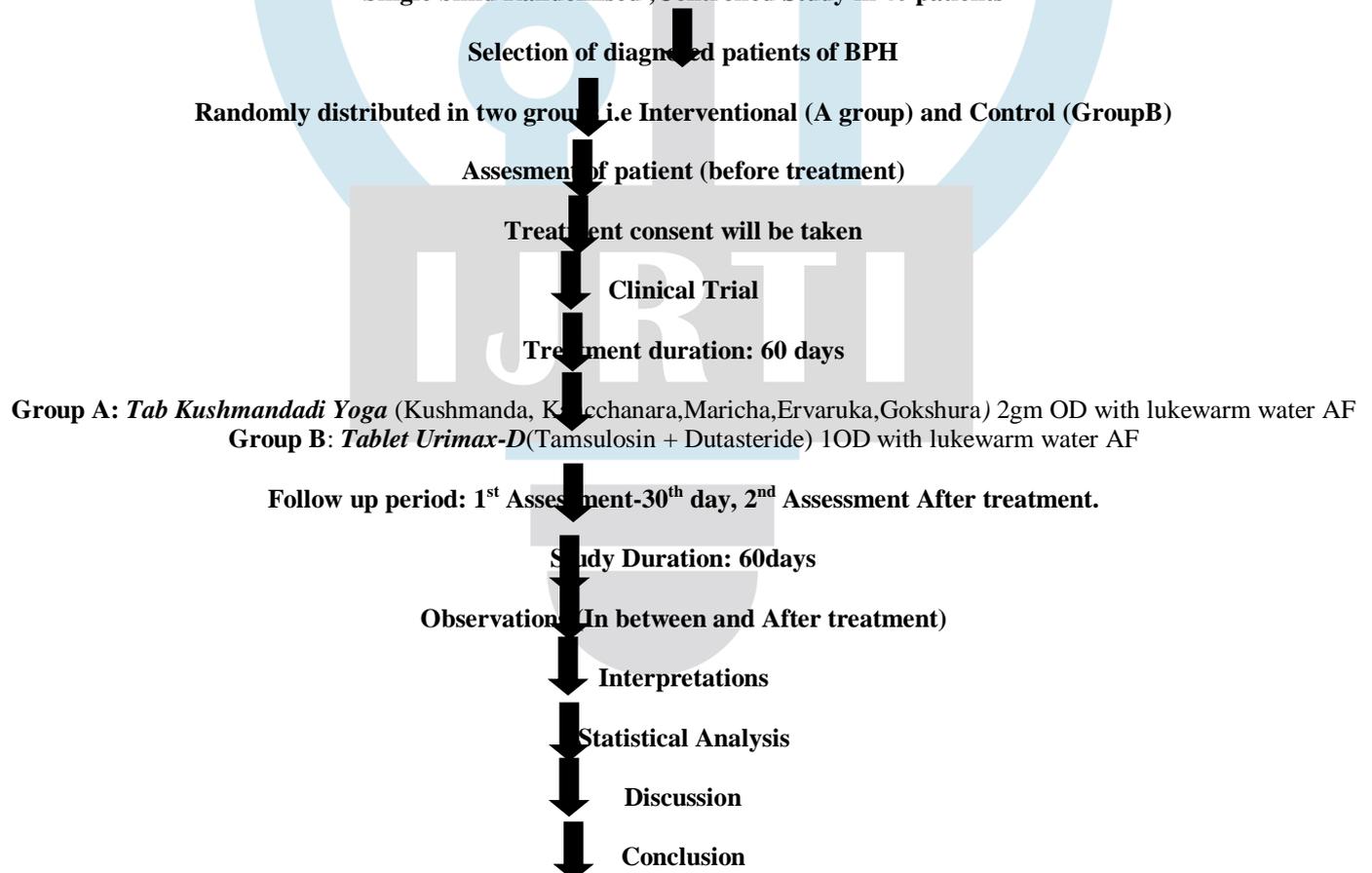


Figure 1 Flow diagram of the study procedure

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IEC No-MGACHRC/IEC/July-2021/338

**Inclusion Criteria:**

- Patients willing with Written informed Consent for will be taken.
- Patient in the age group between 35-75years.
- Patients with having mild to moderate BPH having Prostate size up to 50gm (Grade- 2) will be included after screening.
- Patients with Controlled Type-2 Diabetes mellitus.
- Patients who are indicated for Matrabasti<sup>14</sup>.

**Exclusion Criterion:**

- Patients of Grade 3 and Grade 4 BPH.
- Patient suffering from Systemic disorders like uncontrolled Diabetes mellitus, Tuberculosis, Hypertension.
- Urethral Stricture
- Functional BOO (Bladder Outflow Obstruction) due to neurological conditions like CVA, TabesDorsalis, Parkinsonism, Disseminated Sclerosis, Loss of Neuro vesicle co-ordination, Syringomyelia, Alzheimers disease.
- Carcinoma of Prostate
- Diverticulum of the bladder
- Trigone Hyperplasia
- Disability due to old age and serious systemic illness
- Acute and chronic Retention of urine

**Criteria for discontinuing or modifying allocated interventions:**

1. If the patient becomes non cooperative.
2. The patient is not willing to continue the treatment or to follow the assessment schedule.
3. Death of the patient due to any cause.

**Follow up period during and after treatment:** 1<sup>st</sup> follow up-30<sup>th</sup> day.e when the Course of Matrabasti finishes and 2<sup>nd</sup> follow up- After 60<sup>th</sup> day

**Primary Outcomes :**To see improvement in Incomplete emptying, changes in frequency of urination ,intermittency of urine, weak stream, straining while urination, urgency and nocturia.

**Secondary Outcomes:**To assess size of the prostate gland by seeing the post voidal volume of urine from USG and also by checking the pressure & velocity of urine stream through Uroflowmetry. Along with this to find out improvement in the Quality of life of patient due to Urinary disturbance.

**Statistical analysis:** Wilcoxon rank sum test.

**Time duration till follow up:** Follow up days is 30<sup>th</sup> and 60<sup>th</sup> day.

**Time of enrolment, interventions:** Patients of Benign Prostatic Hyperplasiaafter diagnosis be taken in thisstudy who so ever fulfills the inclusion criteria.

**Interventions-** 2gm Tablet to be consumed in a day after food with lukewarm water for 60days, during the treatment period.

**Groups -** Two groups with 20 patients in each Group A (Interventional group) Group B (Controlled group).

Group	Sample Size	Internal Medication
Group A	20	<i>Kushmandadi Yoga- 2gm</i> afterfood with lukewarm water, to be consumed in a day
Group B	20	Tablet Urimax- D (Tamsulosin 0.4mg + Dutasteride 0.5mg )- 1tab afterfood, once in a day

**Recruitment:** Patient will be recruited by single arm study

**Implementation:** Principal invigilator will register subject.

**Data collection methods:** Randomized Computerized Table method

**Assessment criteria:**

**A. Subjective criteria-** American Urology Association Symptom Index (AUA-SI) or International Prostate System (IPSS) for BPH

IPSS	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score (BT)	Value
<b>Partial emptying</b> past months, how much you had a sensation of unemptying your bladder completely after you finish urinating?	0	1	2	3	4	5		
<b>Frequency</b> How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5		
<b>Intermittent urination</b> Over the last months, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5		
<b>Urgent urine flow</b> Over the last month, how difficult have you faced it to postpone urination?	0	1	2	3	4	5		
<b>Urine Weak stream</b> Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5		
<b>Pressure urination</b> Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5		
<b>Night urination</b> Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5		
IPSS score after evaluation								

0 to 7	Mild symptoms of disease
8 to 19	Moderate Symptoms
20 to 35	Severe Symptoms
Complete Cure	100% Relief
Maximum Improvement in symptom	76 to <100% Relief.

Moderate Improvement in symptom	51 to 75% Relief
Mild Improvement in symptom	26 to 50% Relief
Unchanged	Up to 25 % Relief

QOL because of urinary problem	Delighted	Pleased	Mostly satisfied	Mixed – about equally satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible	BT	AT
If you spend the rest of the life with urinary condition the way it is now, how would you feel ?	0	1	2	3	4	5	6		

**Total Score- Min-0, Max-5**  
 But it should be remembered that there is no direct relation between the degree of enlargement and the occurrence of symptoms<sup>15</sup>.

Reference-

- 0 to 7 minimally symptomatic
- 8to 19 moderately symptomatic
- 20 to 35 severely symptomatic

**B. Objective criteria :**

- USG-Abdomen and Pelvis- for size of prostate gland and Post Voidal Volume of Urine
- Uroflowmetry- for Pressure and Velocity of urine

**Data management:** Principal investigator will do coding of data.

**Ethics and dissemination:** Permission for research has been taken from Institutional Ethical Committee ref no. IEC No:MGACHRC/IEC/July-2021/338

**Consent :** Informed written consent from the selected patient will be obtained.

**Dissemination policy:** For future research results will be disseminated and research will be published in reputed journal.

**Informed consent materials:** All the research related document and consent form will be given to the patients.

**Discussion:**

*Vata* is the fundamental cause of all *Mutraghata* (including *Vatashthila*) according to Ayurvedic literature. In Ayurvedic texts, *basti* is described as the treatment of choice for *Vata*-dominant disorders.

Acharya Charaka described Bastias"Chikitsa-ardhamiti" means "half of the treatment of all ailments" and "half of the therapy of all diseases."

Hence for *Vata*-dominant disorders, *Basti* is said to be the most effective treatment. *BastiChikitsa*, as well as *UttaraBasti*, are the greatest treatments for geriatric. *Mutraghata* is best treated using Ayurvedic formulations like as those found in classics<sup>16</sup>.

- Also due to restrictions and negative consequences of pharmacological and surgical treatments in modern parlance. Because of Long-term usage of alpha adrenergic blockers and 5-alpha reductase inhibitors is likely to cause a variety of health problems.

**In Immune system major disorders** are (Hypersensitivity reactions, including rash, urticarial etc.

**In Reproductive system** it may cause- (gynecomastia&Priapism)

**In Cardio Vascular system:** Palpitation, arrhythmia, and tachycardia etc.

**Skin** it may cause desquamation, including Stevens-Johnson syndrome.

**It may cause-** Constipation, vomiting.

Hence there is a need for reduced side-effect therapy in the treatment of BPH, which Ayurveda can provide.

- The drugs used in this present study are easily available throughout the year in all seasons.
- Most of the herbal drugs are formed by adulteration. So there is a need for Standardisation.
- There are a lot of single herbal and traditional medications, as well as compounds, that are being tested all over the world to see whether they can help with BPH.
- To derive a standard and easily accessible drug throughout the year which is not only cost effective for this disorder in order to reduce the signs and symptoms but furthermore Increases the Quality Of Life of patient is the main area for discussion.
- On extensive review of Research work in Ayurveda regarding BPH it is found that many clinical study showing the efficacy of Basti in the management of BPH has been published but less clinical trials has been carried out as to embark its role in BPH.
- Also major studies have been carried out in *Shamanachikitsa*. So there is requirement for *Shodhanachikitsa* along with *Shamanachikitsa* to break the *SampraptiVighatana* of the disease.
- Considering the importance of Matrabasti for BPH the present work will become a milestone simultaneously the current study will also prove the collaborative efficacy of Matrabasti along with the Novel Herbal preparation i.e. *Kushmandadi Yoga*..
- If the present study proves the significant role of combination of both above said intervention then it will be the greater achievement in the clinical practice of Urology in Ayurveda.
- It will also offer an alternative options for the patients of BPH who are contraindicated for combination of Tamsulosin&Dutasteride i.e. patients who are suffering from Kidney, Liver disorders, or are allergic to the ingredients.
- So the present study is to see efficacy of those drugs mentioned in the texts as single formulations, if used in compound form for the treatment of *Mutraghata*.

#### Expected result and conclusion:

The drugs chosen in the intervention group includes Kanchhanara which possess *Shothahara*<sup>18</sup>, *Tridosahara*, *Grahi*, *Dipana*, *Gandavridhahara*, *Anulomana* property. *Gokshura* has *Mutrala*<sup>19</sup>. *Vrisya*, *Vastishodhana*, *Shularoga* property. *Maricha* contains *Chedana*, *dipana* *Sleshmahara* property. *Ervaruka* is *Mutradoshahara*, *Ashamarinasha*, *Athtilavridhahara*<sup>20</sup>. *Kushmanda* possess *Bastishodhaka*, *Mutrala* property. Apart from this all these drugs alter in the hormonal pathology of the disease by inhibiting 5alpha reductase agent<sup>21</sup>.

When it comes to conservative management Matrabasti, BalaTaila which contains Atibala (*Abutilon indicum*) and TilaTaila (*Sesamum indicum* Linn.) Taila as *SnehaDravya* in the forms of *Pana*, *Abhyanga*, and *Basti* is specifically mentioned in the administration of *Mootraghata*. The active element in Atibala has been discovered as betasitosterol (*Abutilon indicum*). Beta sitosterol has been scientifically proven to have anti-inflammatory (by interfering with prostaglandin metabolism) and antiandrogenic (or anti-estrogenic) properties. The active chemical component beta sitosterol found in all herbs has been shown to be particularly beneficial in the treatment of BPH<sup>22</sup>.

The therapy choices are as diverse as the BPH symptom spectrum. Although BPH is rarely fatal, most doctors agree that proper management can help patients improve their quality of life. The goal of BPH therapy is to improve quality of life by minimising disease progression and the development of new morbidities while also relieving symptoms and raising maximal flow rate. The predicted outcome of this analysis is that patients in intervention group is more effective than controlled. It is more efficacious in minimizing the subjective as well as objective parameters of BPH.

**Figure no. 1 Gantt Chart (Quarterly based)**

Scholar	Dr. Shreya Soni						
Title	“Efficacy of <i>Kushmandadi Yoga</i> in comparison with combination of <i>Tamsulosin&amp;Dutasteride</i> in the Management of <i>Vatashthila</i> (Benign Prostatic Hyperplasia)”						
Steps	Q1	Q2	Q3	Q4	Q5	Q6	
IEC Clearance and CTRI approval							

Enrolment of Patients						
Drug Collection and preparation						
Collection of Data						
Writing thesis parts up to Methods						
Analysis of Data						
Writing rest of thesis						
Submission						

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