

**A STUDY ON THE CORRELATION BETWEEN
CLINICAL OUTCOME AND RESIDUAL PROSTATIC
WEIGHT RATIO AFTER TRANSURETHRAL
RESECTION OF PROSTATE FOR BENIGN
PROSTATIC HYPERPLASIA**

Dissertation submitted to

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the award of the degree of*

M.Ch (UROLOGY) – BRANCH – IV



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DECLARATION

I solemnly declare that this dissertation titled “**A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia**” was prepared by me in the Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai under the guidance and able supervision of Prof. R. Jeyaraman MS, M.Ch., Professor & Head of the Department, Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai. This dissertation is submitted to the Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfillment of the university requirements for the award of the degree of M.Ch. Urology.

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CERTIFICATE

This is to certify that the dissertation titled “**A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia**” submitted by Dr.Senthil.D appearing for M.Ch. (Urology) degree examination in August 2012, is a bonafide record of work done by him under my guidance and supervision in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R.Medical University, Chennai. I forward this to the Tamil Nadu Dr.M.G.R.Medical University, Chennai.

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INTRODUCTION

Prostate is a major accessory sex gland of the male. It has exocrine function, but no major endocrine function has been discovered. 0.5ml of the volume of seminal fluid is from the prostatic secretions. The major secretory proteins from the prostate are Prostate Specific Antigen(PSA), Human Kallikrein 2(HK2), Human Kallikrein 1, Prostatic acid phosphatase(PAP), Prostate-specific transglutaminase, Seminogelins 1 and 2, Prostate-specific membrane antigen(PSMA), Prostate Stem cell antigen(PSCA), PSP-94, Immunoglobulins, C3 complement, Transferrin, etc¹. PSA is the most well known and most important of the prostatic secretions. Its main function is the liquefaction of the seminal coagulum.

The more important androgen is the prostate is Dihydrotestosterone (DHT), which is synthesised by conversion of testosterone by the enzyme 5-alpha reductase situated principally in the prostatic stromal cells. Prostate is a hormone responsive gland. Normal prostate weighs about 18 to 20 grams. After 40 years of age, prostate gland begins to enlarge in all men. Although androgens do not cause BPH, the development of BPH requires the presence of testicular androgens during prostate development, puberty, and aging². In contrast to other male reproductive organs like the penis, the prostate retains its ability to respond to androgens throughout

life³. The clinical importance of the prostate gland stems more due to its pathology than its physiology. The most important pathological conditions affecting the prostate are inflammation, hyperplasia and tumour. Of these the most common is the Benign Prostatic Hyperplasia (BPH). Histologic changes suggestive of BPH are found in 50% of men more than 50 years which rises to 75% in men in their 8th decade⁴. But not all prostatic enlargements cause symptoms. The symptom complex is multifactorial.

The classical term used for defining the symptoms due to prostatic enlargement was 'Prostatism' which comprised of a constellation of signs and symptoms⁵. But later it was found that such symptoms could be due to a wide variety of other disorders also, gradually the term prostatism was given up. The new term "Lower Urinary tract symptoms (LUTS)" is now being used to indicate the symptomatology of the typical patient. Of worth mentioning here is that LUTS is not only due to prostatic enlargement, there are a host of other conditions that cause LUTS. Hence, the evaluation of men with LUTS goes well beyond clinical evidence of enlarged prostate. Subjective assessment in the form of questionnaires and objective evidence of assessment of symptoms like the uroflowmetry and invasive pressure flow studies are used widely in patients with LUTS.

Once, the diagnosis of BPH as the cause of LUTS in men is established, the next logical step is the treatment of the condition. Medical and surgical management have been described for management of LUTS due to BPH. Although the safety and efficacy of medical management of BPH is well established, it may not produce adequate results in men with more symptoms and highly obstructed flow. Hence, still surgical treatment provides long term results in management of BPH. Traditionally surgical management for BPH was open prostatectomy, but with the invention of endoscopic instruments open prostatectomy is now almost obsolete. Many forms of minimally invasive surgery for BPH are available. But, Transurethral resection of Prostate (TURP) is considered the 'Gold Standard' care in surgical treatment of BPH. The indications for TURP are well established in literature. And the surgical procedure is also standardised. Improvements in technology and instrumentation have brought about great reductions in morbidity and mortality, yet the basic principles of TURP remain the same.

TURP consists of endoscopic resection of the prostate transurethrally. The prostate is not removed in toto as in open surgery, but rather in 'chips' Hence, entire gland is not removed, rather only a portion is removed. Since the bulk of the gland is responsible for the symptoms of LUTS, it is quite logical that all obstructing glandular tissues should be

resected for symptom improvement. But this is not possible in TURP due to anatomical factors. So, how much of glandular tissue should be resected to achieve maximum improvement in symptoms. This question is not satisfactorily answered in standard literature. The quantity of resection is highly surgeon dependent. Not many studies have investigated this aspect of the surgery. Most give conflicting reports on the adequacy of resection. Hence, our present study is aimed at analysing the adequacy of resection in TURP and its impact on patient symptoms.

AIM AND OBJECTIVE

The aim of the present study is to determine whether the residual prostatic weight ratio has an impact on the outcome following transurethral resection of prostate (TURP) for Benign Prostatic Hyperplasia (BPH). The outcome is to be measured in terms of subjective parameters like improvement in IPSS symptom score and Quality of Life (QOL) score and also objective parameters like Peak flow rate on non invasive Uroflowmetry.

REVIEW OF LITERATURE

The Prostate

The prostate gland is a major accessory male reproductive gland. It measures about 3cm in length, 4cm in width and 2cm in depth; and weighs about 18g in the normal adult male. It is anatomically situated in the base of the bladder and closely invests the most proximal part of the urethra, the prostatic urethra. It is enclosed by a capsule composed of collagen, elastin, and abundant smooth muscle. The prostate is wedged deep in the pelvis closely related to the rectum posteriorly and the external urethral sphincter caudally, and surrounds the urethra. The proximity to important structures makes any surgical procedure of the prostate challenging. Internally the prostate is composed of 70% of glandular structures and 30% of fibromuscular stroma. In general the glands of the prostate are of tubuloalveolar type. Structurally the prostatic glands are divided into zones⁶. The transitional zone, central zone, peripheral zone and the anterior fibromuscular stroma and the major divisions of the prostate. Classically the pathology of BPH is thought to arise from the transitional zone and prostatic malignancy and inflammation from the peripheral zone.

Benign Prostatic Hyperplasia (BPH)

Urinary obstruction resulting from benign prostatic disease was described in the earliest days of medicine. Initially formalized by Riolan in the 17th century, the relationship between BPH and urinary obstruction was further elucidated by Morgani in the mid-18th century; he provided one of the earliest descriptions of BPH and its sequelae⁷. More specific recognition of the pathologic process has been credited to Virchow in the last quarter of the 19th century. Despite a greater understanding of benign prostate growth, however, identification of its cause remains elusive.

BPH is the pathological process of the prostate that gives rise to symptoms of urinary obstruction, but is not the only cause for voiding symptoms. Histopathologically, it is a true hyperplastic process and not just hypertrophy⁸. It is characterised by an increase in the number of epithelial and stromal cells in the periurethral transition zone of the prostate. The exact molecular basis of this hyperplastic process still needs to be elucidated. There are many other potential causes of urinary symptoms in aging men, including diabetes mellitus, Parkinson's disease and stroke, which can lead to the same symptoms as seen in men with BPH. And the symptoms of BPH are non specific⁵. However, it is accepted that the most important cause of LUTS in aging men is due to bladder outlet obstruction caused by BPH⁵. Hence, it is important to rule out other causes of LUTS before subjecting the patients for management of BPH.

This needs thorough understanding of the patients' symptoms as well as the different investigational modalities.

As suggested by Barry and colleagues on the basis of autopsy studies, benign prostatic hyperplasia is generally a gradually progressive disease that commences in men who are around 40 years of age. Data from the Baltimore Longitudinal Study of Aging suggest that symptomatic benign prostatic hyperplasia also tends to progress with time in the majority of men. The average prostate volume increase is in the order of 0.6 ml per annum, and this is associated with a mean diminution of flow rate of 0.2 ml/s/year. Recent data confirm that men with larger prostates and higher PSA values suffer a faster rate of disease progression than those with smaller glands. The explanation for these findings lies in the progressive expansion of the transitional zone by the adenoma. This process reduces the distensibility of the urethra during voiding and produces gradually increasing bladder outlet obstruction. This increase in prostate volume is associated with a progressive risk of lower urinary tract symptoms, and a negative impact on quality of life. The increase in prostate volume is also associated with a rise in PSA value, which, in the absence of prostate cancer, can act as a useful surrogate for gland volume. Significantly, men with larger prostates and (since PSA provides a reflection of total prostate epithelial cell volume) higher PSA values are

more likely to develop complications of benign prostatic hyperplasia such as acute urinary retention or require benign prostatic hyperplasia-related surgery. Other risk factors for acute urinary retention include severe symptoms and markedly reduced maximum urinary flow rates.

The anatomical distribution of the adenoma is not always uniform. When the process affects mainly the proximal periurethral zone, so-called median or middle lobe enlargement occurs. In this situation, the adenoma is often stromal rather than glandular in nature, is not detectable by digital rectal examination (DRE) and is commonly associated with a disproportionate amount of bladder outlet obstruction.

Symptomatology

LUTS can be divided as obstructive and irritative. Symptoms like hesitancy, thin stream, intermittency, postvoid dribble, sense of incomplete emptying are obstructive symptoms. Whereas urgency, urge incontinence, frequency, nocturia are irritative symptoms. The other terminology used is voiding symptoms and storage symptoms respectively. In a non lethal condition like BPH, the patient symptoms should be the primary guidance to management, hence adequate evaluation and the subjective assessment of the symptoms cannot be over emphasized. But, this subjective estimation of patients' symptoms is caught with the worry regarding

tolerance level of the patients and bias on part of the examiner. To avoid these issues, various symptom scales have been devised and validated on large groups of populations and varied geographic regions. Although several questionnaires have been devised, the most useful and the most validated is the IPSS. The International Prostate Symptom Score (IPSS) is recommended as the symptom scoring instrument to be used for the baseline assessment of symptom severity in men presenting with LUTS⁹.

In addition to IPSS scores, it is essential to measure and document the degree to which the BPH has physically restricted the urinary flow of the patient. This objective parameter, the reduced urinary flow rate, is measured by the non invasive Uroflowmetry. This non invasive test gives an indication about the peak flow, mean flow and voiding times of the patient. Although pressure flow studies as part of the urodynamic investigation are highly specific for the diagnosis of bladder outlet obstruction and is considered the gold standard¹⁰, Uroflowmetry gives a quick, cheap and reproducible measure of urinary flow.

International Prostate Symptom Score (IPSS)

The IPSS score (Appendix 1) was developed by the Measurement Committee of the AUA (Barry, 1992a)⁵. Such health questionnaires like the AUA/IPSS symptom score should have adequate reliability and

validity to be clinically useful. Several factors must be considered when using such questionnaires¹¹. First, internal consistency reliability must be ensured. That is, relatedness of different items in the scale, and this is evaluated by administering the questionnaire to a group of subjects. Second, the test-retest reliability of the questionnaire must be established. This can be accomplished by demonstrating that there is minimal change in the results when the test is given to the same patients after a short interval. Third, a questionnaire such as the AUA symptom score should have the same degree of accuracy as any other diagnostic test used to assess a disease process. To be valid, the symptom score results should accurately quantify the severity of BPH in the same manner that serum lipid levels reflect the disease status in patients with hypercholesterolemia. Finally, health measurement scales must be responsive to be useful in discriminating among patients who get better, get worse, or remain the same with or without treatment over time. Based on these criteria the AUA/IPSS questionnaire has been found to be highly reliable and valid in evaluating men with LUTS. Statistical measurements of internal consistency reliability and 1-wk test–retest correlation have been shown to be 0.86 and 0.92, respectively¹². Both of these measures highly support the reliability of the I-PSS in these areas.

The IPSS score consists of seven separate but related symptoms commonly seen in aging men with BPH. They are incomplete emptying, frequency, intermittency, urgency, weak stream and straining. Each is answered in numbers from 0 to 5 with respect to the frequency with which the patient experiences them over the last 3 months. 0 stands for not at all and 5 for almost always. The mark for each question is added and the final score is given which ranges from 0 to 35. Based on this score patients can be classified as follows⁵:

- 0-7 - Mild symptoms
- 8-19 - Moderate symptoms
- 20-35 - Severe symptoms

Obviously, application of these symptom scores alone does not confirm whether the given patient is suffering from BPH. Patients differ widely in their perception of symptoms and that would greatly influence the results of these questionnaires. However, overall, the IPSS has been shown to be reliable and valid through a variety of testing modalities¹¹.

Quality of Life (QOL) Index

The QoL index (Appendix 2) is actually a single question item added to the AUA symptom index and is a part of the IPSS score. It

measures the degree to which the LUTS is bothering the patient. It consists of a single question and patient marks their response from 0-6.

Uroflowmetry

Uroflowmetry is the electronic recording the urinary flow rate throughout the course of micturition. It is a non invasive urodynamic testing used in evaluation of men with LUTS. But, Uroflowmetry is a non specific test. It can only suggest that the patient is having a poor flow, the cause of which can be anywhere between stricture of the urethra to bladder myogenic failure¹³. The uroflowmeter apparatus consists of a pressure transducer which is placed near the outlet of a western style commode. Over the transducer, a beaker of volume 2 litres is placed which collects the urine. The transducer is connected to an analysing unit which send the output to a thermal or inkjet printer for printing. The machine can also be connected to a computer for data storage. The flowmeter in regular use is the Gravimetric flowmeters which operate by measuring the weight of the collected fluid or by measuring the hydrostatic pressure at the base of the collecting cylinder. The instrument measures the flow as millilitres/second (ml/s).

The AHCPR Guideline Panel reached the following conclusions regarding uroflowmetry¹⁴:

- Flow rate measurements are inaccurate if the voided volume is less than 125 to 150 mL
- Flow rate recording is the single best non invasive urodynamic test to detect lower urinary tract obstruction. Current evidence, however, is insufficient to recommend a given “cut-off” value to document the appropriateness of therapy
- The peak flow rate (PFR; Q_{max}) more specifically identifies patients with BPH than does the average flow rate (Q_{ave})
- Although Q_{max} decreases with advancing age and decreasing voided volume, no age or volume correction is currently recommended for clinical practice
- Although considerable uncertainty exists, patients with a Q_{max} greater than 15 mL/s appear to have somewhat poorer treatment outcomes after prostatectomy than patients with a Q_{max} of less than 15 mL/s
- A Q_{max} of less than 15 mL/s does not differentiate between obstruction and bladder decompensation

The Fourth International Consultation on BPH concluded that flow rate measurement represents a reproducible way to quantify the strength of the

urinary stream and, when used in combination with symptom scores for a small subset of patients (20%), has a high probability of correctly characterizing whether there is BOO¹⁵. In spite of its obvious lack of specificity, the uroflowmetry and specifically the QMax or Peak flow rate (PFR) show sensitivity in diagnosing BOO due to BPH in some studies. PFR is shown to predict response to surgery. Also it is a useful adjunct in follow up of patients treated for BPH. Nevertheless Peak flow rate of <15ml/s with a voided volume of more than 150ml has been traditionally taken as diagnostic of Bladder outlet obstruction.

Post void residual urine

Post void residual (PVR) is the quantity of urine that remains in the bladder immediately after the act of micturition. PVR can be measured by ultrasound measuring the bladder capacity usually and also by catheterisation and directly measuring the volume retained. Although catheterisation technique would be more accurate in calculating PVR, USG has been shown good correlation with the actual PVR¹⁶. Moreover difficulties of using catheterisation like discomfort, UTI, urethral injury could be avoided. The mean PVR in normal subjects is around 0.53ml¹⁷. However the test-retest reliability of PVR is poor. And many studies report that PVR correlates poorly with parameters like symptom assessment, flow rates and urodynamic measures of obstruction. Yet, some other investigators reported PVR as second best predictor after pressure flow studies about the improvement after surgery. PVR is more extensively studied in population who are on watchful waiting or conservative management as serial monitoring. The results of such series show that men with more PVR should be monitored more often for the appearance of complications of bladder outlet obstruction.

The AHCPR BPH Guideline Panel reached the following conclusions regarding PVR¹⁴:

- Residual urine volume measurement has significant intraindividual variability that limits its clinical usefulness
- Residual urine volume does not correlate well with other signs or symptoms of clinical BPH
- Large residual urine volumes may predict a slightly higher failure rate with a strategy of watchful waiting. However, the threshold volume defining a poorer outcome is uncertain
- It is uncertain whether residual urine volume predicts the outcome of surgical treatment
- It is uncertain whether residual urine volume indicates impending bladder or renal damage
- Residual urine volume can be measured with sufficient accuracy non invasively by transabdominal ultrasonography. The measurement variation caused by the method is less than the biologic range of PVR variation.

Ultrasound of the prostate

Ultrasound imaging of the prostate is done by either trans abdominal or trans rectal routes. The trans abdominal scanning is the most widely

available and widely used methodology. It typically used a 3.5 MHz probe. A full bladder is essential to adequately image the prostate as the clear urine in the bladder provides an acoustic window. Some studies have shown that prostate size as measured by USG depends on the bladder volume at that particular instance¹⁸. Transrectal ultrasound (TRUS) is an advance in prostate imaging where high frequency probe is used per rectally to image the prostate in sagittal and horizontal planes. Literature suggests that prostate weight measured by TRUS more significantly correlates with weight measured from prostate specimen after prostatectomy¹⁹. Prostate volume can be calculated from the measurements of the prostate gland from USG. Most formulas assume that the gland conforms to an ideal geometric shape: either an ellipse ($\pi/6 \times$ transverse diameter \times AP diameter \times longitudinal diameter), sphere ($\pi/6 \times$ transverse diameter³), or a prolate (egg-shaped) spheroid ($\pi/6 \times$ transverse diameter² \times AP diameter). Despite the inherent inaccuracies that arise from these geometric assumptions, all formulas reliably estimate gland volume and weight, with correlation coefficients greater than 0.90 with radical prostatectomy specimen weights, because 1 cm³ equals approximately 1 g of prostate tissue²⁰. But TRUS imaging is not widely available in developing countries in terms of both instrumentation and trained manpower. Also, TRUS is an invasive imaging technique which could

give the patient considerable discomfort. Hence, in cases of non availability of TRUS or limited resources, trans abdominal ultrasound could provide equal information to that provided by TRUS for prostate size, volume, etc. Studies have demonstrated that there was strong correlation between suprapubic and transrectal ultrasonography measurements of the prostate sizes, including both for volume or specific dimension measurements. Hence transabdominal ultrasound is as sensitive as transrectal ultrasound for measuring prostatic weight.

Management of BPH

As with any disease the management options for BPH are medical and surgical. Before the advent of drugs and endoscopy, open simple prostatectomy was the widely practiced surgical procedure. The advent of medical management of BPH significantly reduced the number of surgeries performed for BPH during the 90s. More than 55% reduction in number of prostatectomies was reported in European studies²¹.

The two classes of drugs used in the medical management of BPH are α -receptor blockers and 5- α reductase inhibitors. Alpha blocking drugs act by reducing the tone of the bladder neck and prostatic smooth muscle and thereby reducing the dynamic component of bladder outflow obstruction. The drugs in use are Prazosin, Doxazosin, Terazosin,

Tamsulosin and Alfuzosin. The clinical efficacy and safety profile of these drugs is well established. Newer agents like Silodosin and Naftopidil also show promise in management of LUTS. The second class of drugs, the 5 alpha reductase inhibitors act by blocking the conversion of testosterone to dihydrotestosterone in the prostatic stromal cells. The drugs are finasteride and dutasteride. Since DHT is the most important androgen involved in the growth of prostate, these drugs reduce the volume of the prostate in the long term. 20% reduction in gland volume has been documented by using finasteride alone²². The safety and efficacy of these drugs too are well established in literature.

Although medical management of BPH is highly efficacious and safe, the clinical improvement is modest. Many patients with moderate to severe symptoms of BPH progress to have complications in spite of medical treatment. Hence, medical management is primarily used in the class of patients with mild symptoms on the IPSS score and small sized gland.

Surgical management

Surgical management in the form of TURP (Transurethral Resection of Prostate) is the Gold Standard in the management of symptoms of BPH. Various inventions over decades took surgical management away from

open simple prostatectomy to the minimally invasive TURP. They were the invention of incandescent lamp by Edison, the cystoscope by Nitze and Lieter, the development of fenestrated tube by Hugh Hampton-Young and the resection wire loop by McCarthy. The later inventions of the fibre optics and the rod lens system further improved the technicality of TURP. Hence, the TURP we know today is the results of decades of work by enthusiastic scientists to make it a safe and versatile surgery.

The most common indication for surgery in a patient is moderate to severe symptoms, bothersome and affect the quality of life of the patient. In addition there are some absolute indications like retention of urine, recurrent infection, recurrent haematuria and azotemia.

TURP is typically done under spinal anaesthesia. Pre operative patient evaluation should include cardiac work up. Any drugs like aspirin or clopidogrel should be stopped 7 days prior to the surgery. Patient is placed in the lithotomy position. Initially the urethra is calibrated with bougies till 28F. Preliminary cystourethroscopy should be done to know the condition of the urethra, prostate size, bladder neck, any bladder stones, mucosal trabeculations and to rule out bladder tumours. Either sterile water or glycine is used as the irrigant. In modern bipolar TURP normal saline can be used, and this is proved to reduce the symptoms of

Hyponatremia. Resection is usually done with 24 or 27F sheath resectoscope and cutting loops. The gland is not removed in toto as in open prostatectomy, but rather chips of the gland are cored out from the urethral surface of the prostate. The resection technique was first described and standardised by Nesbit in 1943²³ and later modified and fine tuned by many investigators. Yet, the basic principles of TURP remain the same. Controlled resection, limiting resection proximal to verumontanum, not violating the capsule and not undermining the bladder neck remains the most important tenets of TURP. Complications of TURP include bleeding, TUR syndrome, priapism, post operative incontinence, retention of urine, etc. Nevertheless, TURP is the most effective form of therapy for symptom alleviation in BPH and is still considered the Gold Standard.

Other minimally invasive procedures are also in vogue like Transurethral incision of prostate, microwave therapy, transurethral needle ablation, vapourisation of prostate, holmium LASER enucleation of prostate, prostatic stents, etc. Of these the holmium LASER enucleation has been recently shown to give results similar to that of TURP²⁴. Still, TURP remains the benchmark with which other methods are compared.

Adequacy of TURP

The methodology of TURP is standardised over the decades. And with the modern instrumentation and anaesthetic technologies, TURP is a safe surgery. Open surgery for BPH involves enucleation of the entire adenoma consisting predominantly the transitional zone²⁵. In this analogy it is imperative that we remove almost the whole of the transitional zone by TURP for adequate results. But, this complete resection cannot be achieved by the minimally invasive TURP due to anatomical and technical reasons. The anatomy of the bladder neck, ureteral orifices and the verumontanum dictate our resection protocol during TURP. Bladder neck is our proximal extent of resection. Care should be taken not to undermine the bladder neck and trigone, lest we may plough the resectoscope into a false passage posteriorly. This seriously limits further resection and necessitates cessation of the procedure and catheterisation. Likewise large median lobe with intra vesical protrusion may be surprisingly close to the ureteral orifices, hence utmost care should be taken. Lastly, probably the most important landmark is the verumontanum. The veru is the internal landmark for the external urethral sphincter. Just distal to the veru, the sphincter begins. So, any resection beyond the veru risks injury, direct or thermal, to the external sphincter. Once this happens, patient will end up with complete incontinence as the internal sphincter at the bladder neck is already destroyed by the TURP. These factors limit the extent of resection

of prostatic tissue by TURP. Yet, the chances of improvement in patient's symptoms are 70%-96% and the magnitude of reduction in symptoms was around 85%²⁶.

So, when it is not possible to remove the whole gland by TURP, how much should we resect? This question has never been sufficiently answered in literature. Individual surgeons have their own protocol for resection and have achieved good results from it. Prostate being hormone responsive continues to grow from the residual tissue even after TURP. This may theoretically give rise to symptoms of LUTS in long term. Re-resection rates mentioned in many studies is of the order on 8%. But, this may be an under reporting error. Aagaard et al. suggested that even after 10 years of follow-up, the functional results after minimal resection of the prostate are comparable with the conventional one²⁷. Hakenberg et al. analyzed the impact of residual prostatic weight (RPW) on outcomes after TURP and did not find a significant influence of this parameter on outcome²⁸. However Chen and associates in their study, reported a direct correlation between the residual prostatic weight and post operative outcomes. Their conclusion was, the less the residual prostatic weight at 16 weeks after surgery, the better the improvement in parameters like IPSS score and Qmax²⁹.

MATERIALS & METHODS

The following are the materials and methods employed for the present study titled “A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia”

Period of study:

The study is done between August 2011 and March 2012

Type:

This is a prospective study measuring improvement in clinical outcome after a surgical procedure

Place:

The study is conducted in the department of Urology, Rajiv Gandhi Government General Hospital & Madras Medical College, Chennai.

Inclusion criteria

All patients presenting to our department with Lower Urinary tract symptoms (LUTS) due to BPH and planned for surgical management in the form of Transurethral Resection of Prostate (TURP) were included in

the trial. Also patients presenting with retention of urine (AUR) due to BPH and planned for TURP were included.

Exclusion criteria

Patients presenting with LUTS which is not clear cut due to BPH were excluded. Likewise patients who had complications of BPH like raised renal parameters or vesical calculus were excluded. Malignancy patients were excluded. Also patients who developed some post operative complications were excluded. Summarising the exclusion criteria were:

- Patients having raised renal parameters
- Patients with known or suspected carcinoma prostate
- Patients having taken or now taking any medical treatment for BPH
- Patients with vesical calculus
- Patients with known or suspected cancer bladder
- Patients with neurogenic bladder
- Patients developing post operative complications like retention of urine, incontinence, stricture disease

Method of Study

Institutional Ethics Committee approval was obtained. Informed consent was taken from all patients. All details were recorded as per the proforma (Appendix-3). Surgery was done and all patients were followed up after one month of surgery.

Preoperative workup

Exhaustive clinical history was taken from all patients. Nature of LUTS, whether obstructive or irritative were noted. Patients with predominant Irritative symptoms or symptoms suggestive of neurogenic bladder were excluded. Comorbid conditions like Diabetes Mellitus were documented. Any history of urinary retention or any medical or surgical treatment of BPH was noted.

All basic blood and urine investigations were done in the pre operative period. Urine culture was done in all patients and appropriate antibiotics were started. Ultrasonogram of KUB region was done to assess upper tract dilatation, if any, bladder and prostate. Plain X-Ray of KUB was taken.

Prostate weight

Prostate imaging was done using transabdominal imaging technique with Aloka machine 3.5 MHz probe. Anteroposterior, transverse and craniocaudal measurements of the prostate gland was noted. Prostate volume was calculated from these measurements using the standard ellipsoid formula.

$$\text{Volume} = \pi/6 \times \text{AP diameter} \times \text{Transverse diameter} \times \text{Vertical diameter}$$

Since the specific gravity of the prostatic parenchyma is close to 1, the calculated volume in cu.cm. is equal to the weight in grams. This formula was used to calculate the prostatic weight and it was rounded to the nearest integer.

Subjective assessment

Subjective assessment or how the patient feels and perceives his symptoms are important in managing any disease. In BPH the most widely accepted and validated questionnaire, the IPSS (International Prostate Symptom Severity) index (Appendix-1) was used to assess patient symptoms. The adjunct to the IPSS score, the Quality of Life (QOL) score (Appendix-2) was also used to document preoperative patients symptom index. Based on the IPSS score, patients with mild symptoms alone were

offered medical management alone. Patients with moderate or severe symptoms were taken up for surgery, TURP.

Objective assessment

The reduction in urinary flow is to be proved objectively before management. The most widely available and useful measure in the office based non invasive Uroflowmetry. Uroflowmetry was done in all patients except those patients on catheter. Uroflow parameters like peak flow rate(PFR), mean flow rate (MFR) and post void residual urine (PVR) were recorded.

The Surgery

All patients after exclusion criteria were subjected to TURP. Spinal anaesthesia was used and patients were placed in the standard lithotomy position. Preliminary cystoscopy was done to assess the urethra, prostate gland, and to rule out co existing bladder stones or malignancy. With 24F sheath resectoscope and monopolar current, TURP was done using sterile water as irrigant in all patients. Resection time was noted. At the end of the procedure, 22F 3-way foley catheter was placed with traction. Irrigation with normal saline was continued for 12 hours. Catheter was removed after 4 days and patients were asked to void.

Resected weight

The dry weight of the resected prostatic chips was measured by an electronic weighing machine with resolution of 0.1gram and maximum capacity of 200grams. The dry weight was measured and was rounded to the nearest integer. The residual prostatic weight was calculated from the following formula:

$$\text{Residual weight} = \text{Total prostatic weight} - \text{Resected weight}$$

The next parameter, the residual prostatic weight ratio (RPWR) was calculated from the following formula:

$$\text{RPWR (\%)} = (\text{Residual weight} / \text{Total weight}) \times 100$$

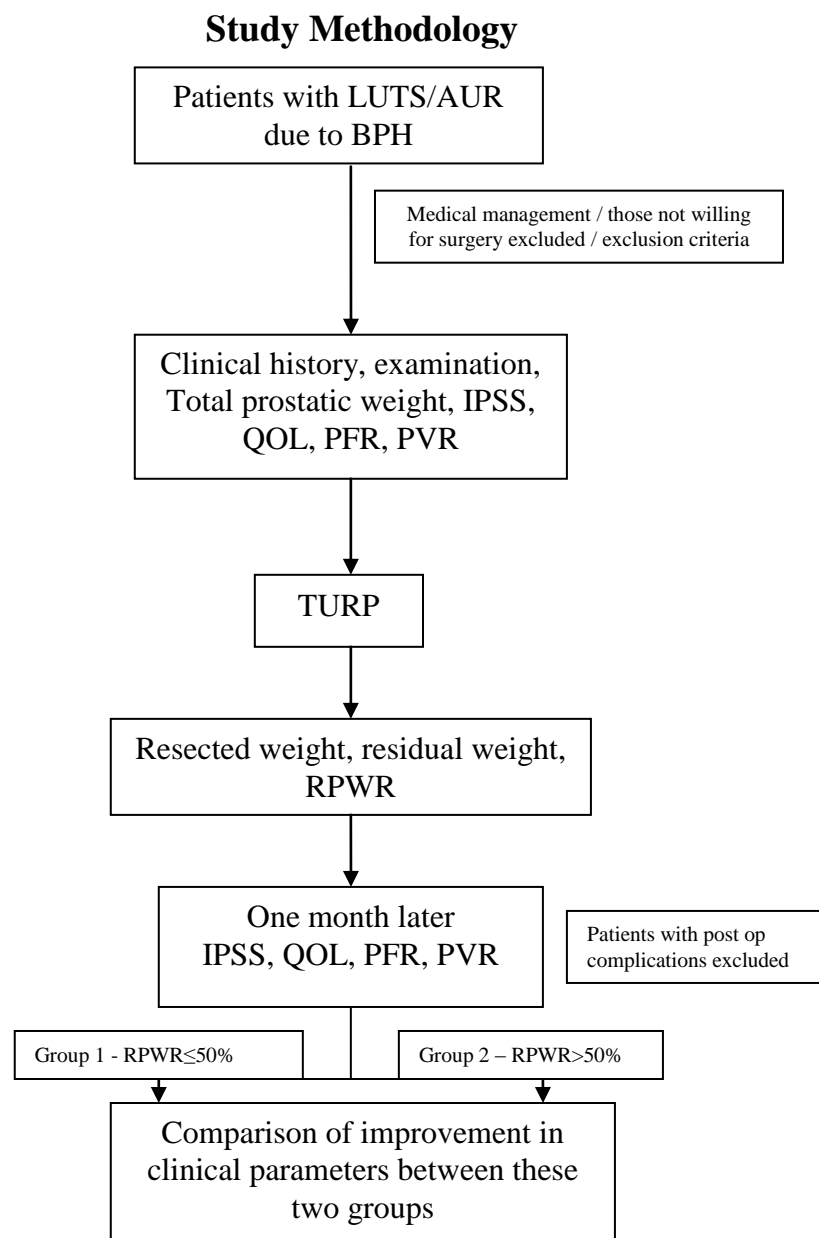
This value RPWR (Residual Prostatic Weight Ratio) was calculated for all patients and was rounded two decimal points.

Post operative follow up

All patients were followed up at 1 month. Patients who developed complications like retention of urine or incontinence in the post operative period were excluded from the study. The IPSS score index and QOL index was calculated for all patients in the post op period, and the non invasive Uroflowmetry was also done in the post op period.

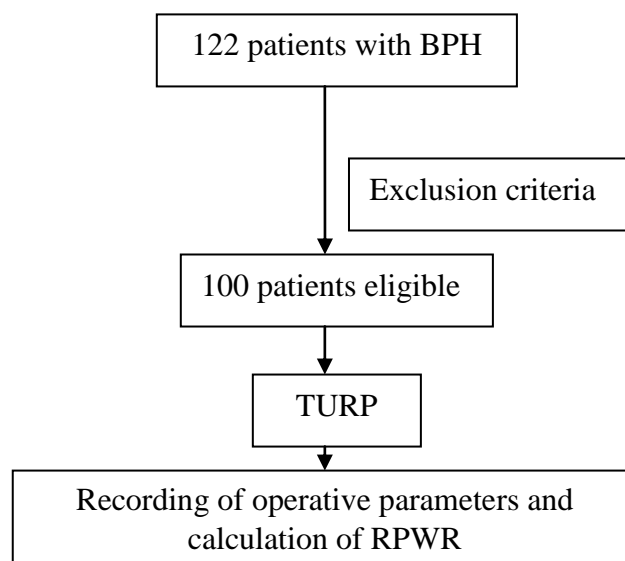
Statistical analysis

The patients were divided into two groups based on the value of the Residual Prostatic Weight Ratio (RPWR). Group 1 had a RPWR of $\leq 50\%$ and group 2 had a RPWR of $>50\%$. The improvements in the clinical parameters like IPSS score, QOL index, PFR and PVR were compared among the two groups.



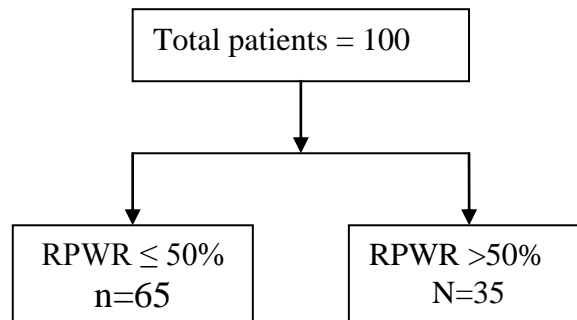
RESULTS

A total of 122 patients underwent TURP for benign hyperplasia of prostate during the study period. Of these 22 patients were excluded through the above mentioned exclusion criteria or excluded due to other reasons. 4 patients from the total 122 developed retention of urine in the post operative period and were excluded. 10 patients did not report for follow up after one month. Hence 100 patients were enrolled for evaluation and analysis. After careful pre operative evaluation, TURP was done for all these patients by the above said method. All histopathological results were benign. Intra operative parameters like operative time, resected weight and any intra operative complications were recorded. From the resected weight, residual prostatic weight and residual prostatic weight ratio (RPWR) were calculated.



Patient stratification

As said before, the patients were stratified into two groups based on the RPWR. Group 1 had a RPWR of $\leq 50\%$ and group 2 had a RPWR of $>50\%$. Analysis of various pre operative and post operative factors of these two groups were compared through analytical epidemiology methods. Of the total of 100 patients, 65 had a RPWR of $\leq 50\%$ and 35 patients had a RPWR of $>50\%$.



Pre operative parameters

Pre operative values of the various parameters studies are presented in the following table (Table 1)

Table 1

	Mean	SD	Variance
IPSS score	19.91	6.07	36.87
QOL index	4.39	0.76	0.58
Peak Flow Rate	9.28	3.9	3.59
PVR	47.29	24.28	327
Mean prostatic weight	38.97		

The mean total prostatic weight of the patients was 38.97 grams. The mean IPSS score was 19.91 with a standard deviation of 6.07. This is suggestive of almost severe symptoms in most of the patients operated. But the range varied from 9 to 31. Since, all patients with only mild symptoms of LUTS were offered only medical management, the mean IPSS score of the patients in this study is of the higher range. The mean QOL score was 4.39 with a range of 2 to 6. Only 5 patients reported a QOL score of 6 and post operatively only moderate improvement was seen in these 5 patients. The mean peak flow rate (PFR) or Qmax was 9.28 with a standard deviation of 3.9. So, most of these patients satisfied the criteria of $PFR < 12 \text{ ml/s}$ as the cut off point for defining bladder outlet obstruction. The other parameter, the post void residual urine had a mean value of 47.29ml.

Pre operative parameters among the two groups

The pre operative parameters just mentioned were compared among the two groups stratified after the surgery to see whether they are similar in all respects. The age, prostatic weight, IPSS score, QOL, PFR and PVR were compared among the two groups (Table 2).

Table 2

	<50%	>50%	p value
IPSS score	19.67	18.59	0.13
QOL index	4.33	4.49	0.35
Peak flow rate	9.49	8.90	0.08
PVR	47.55	46.83	0.48
Prostatic weight	38.21	40.27	0.08
Age	64.52	64.78	0.39

The mean age overall of all patients was 64.62. Group 1 (RPWR $\leq 50\%$) mean age was 64.53 and in group 2, it was 64.78. Student's T-test was used to study these two groups of people. And in the age analysis the p value was 0.39. Similarly, the prostatic weight among the two groups were 38.21 and 40.27 respectively with a p value 0.08. Likewise the IPSS score, QOL index, PFR and PVR measurements were also similar in the two groups' studies with p values of 0.13, 0.35, 0.08 and 0.48 respectively. Hence, the pre operatively the two groups were comparable and similar in all parameters studied and the variations were not statistically significant. This degree of similarity is essential for the comparative study of two groups.

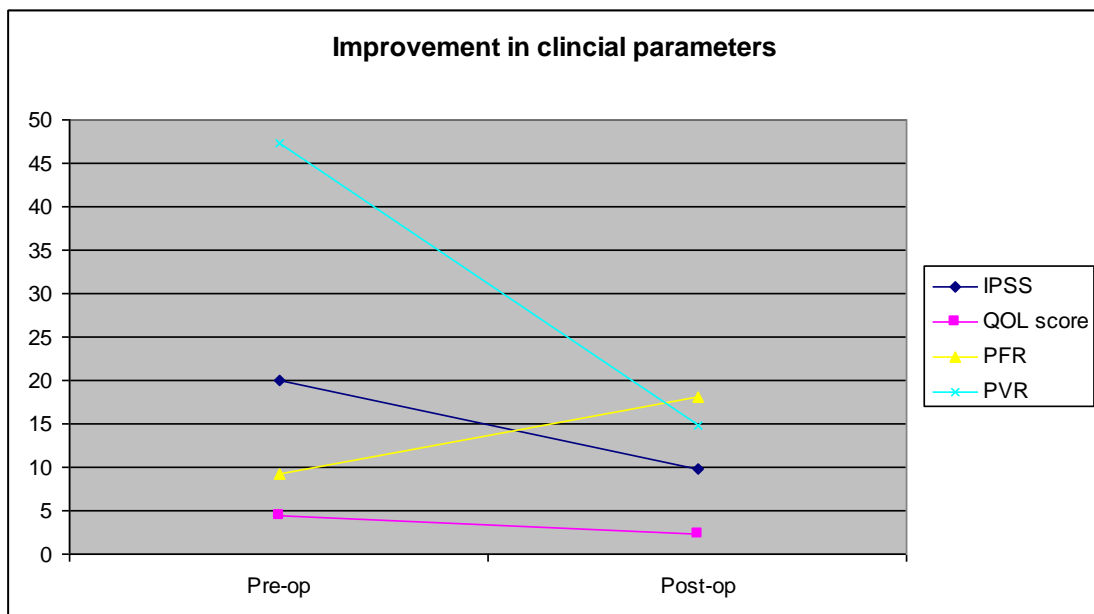
Overall improvement

The overall improvement in the parameters studied were compared between pre operative and post operative states and recorded (Table 3)

Table 3

	Pre-op	Post-op
IPSS	19.91	9.8
QOL score	4.39	2.37
PFR	9.28	18
PVR	47.29	14.83

All patients showed a significant improvement in clinical parameters post operatively. The IPSS score, QOL index showed a good reduction and there was a perceptible increase in flow rate. These figures are given in the table and further represented graphically below.



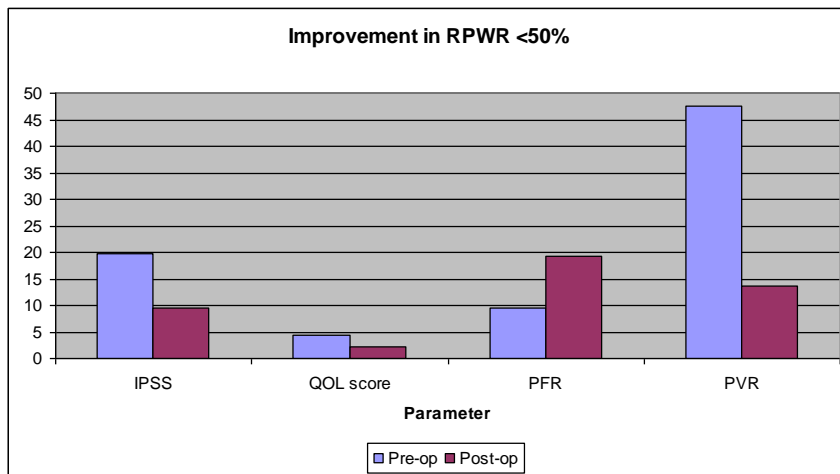
However, these results were of the one month follow up data. Further late follow up all these patients were not done. Yet, some patients were again reviewed at 6 months post operatively and showed maintenance of these clinical parameter values. This was equal among the two groups.

Follow up in patients with RPWR $\leq 50\%$ (Group1)

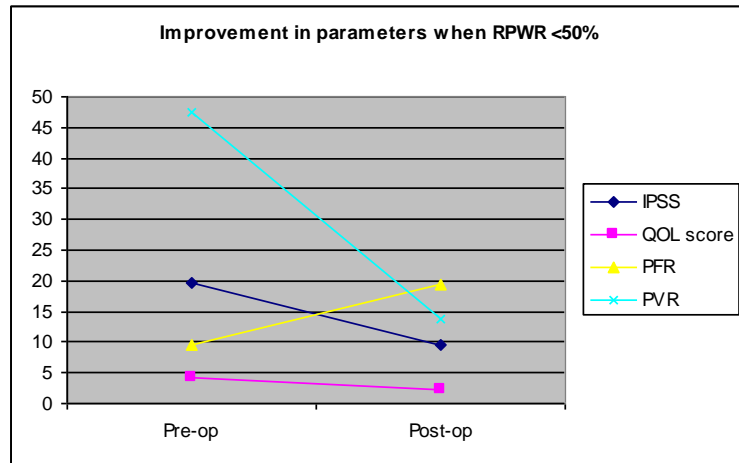
The results of group-1 patients are tabulated as follows (Table 4):

Table 4

	Pre-op	Post-op	Improvement
IPSS	19.67	9.6	10.07
QOL score	4.33	2.29	2.04
PFR	9.49	19.29	9.8
PVR	47.55	13.73	33.82



The patients with RPWR <50% showed good improvement in clinical parameters post operatively as given in the table. It is further graphically represented below

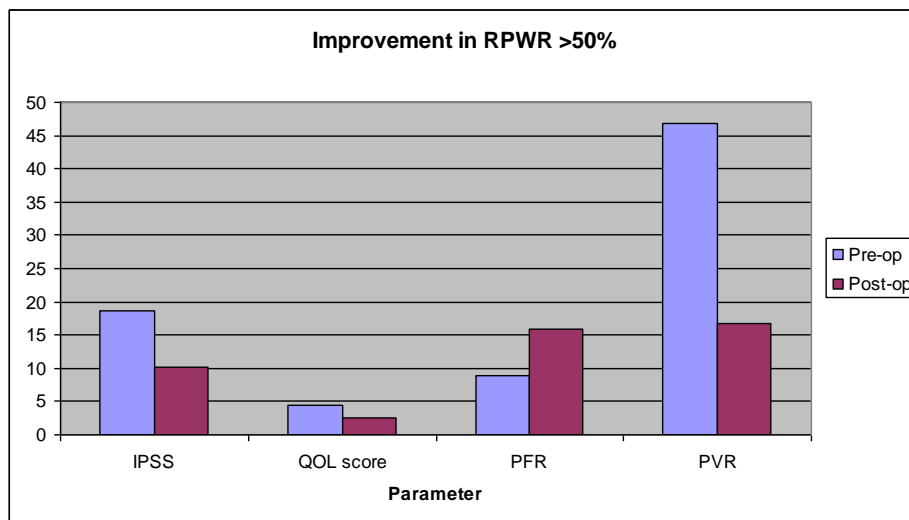


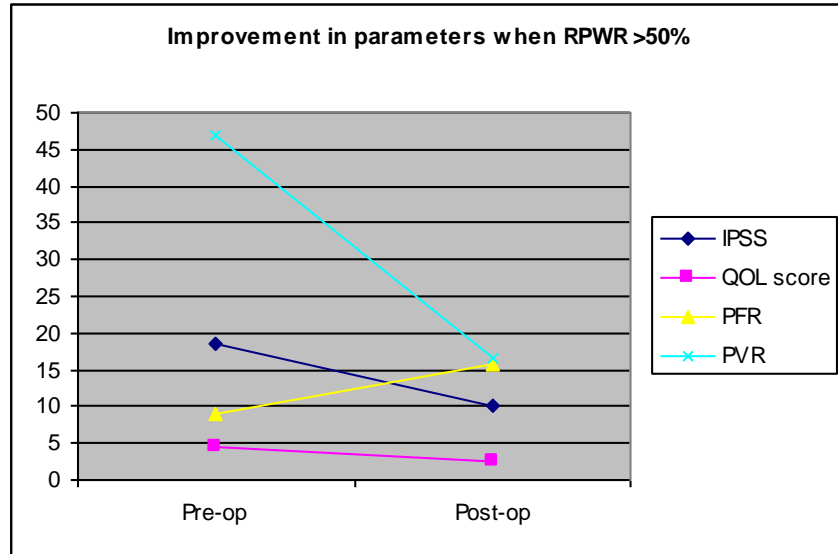
Follow up in patients with RPWR >50% (Group2)

The results in this group are tabulated below (Table 5) and also a graphical representation is given. This group also showed significant improvement with surgery.

Table 5

	Pre-op	Post-op	Improvement
IPSS	18.59	10.14	8.45
QOL score	4.49	2.51	1.98
PFR	8.9	15.81	6.91
PVR	46.83	16.7	30.13

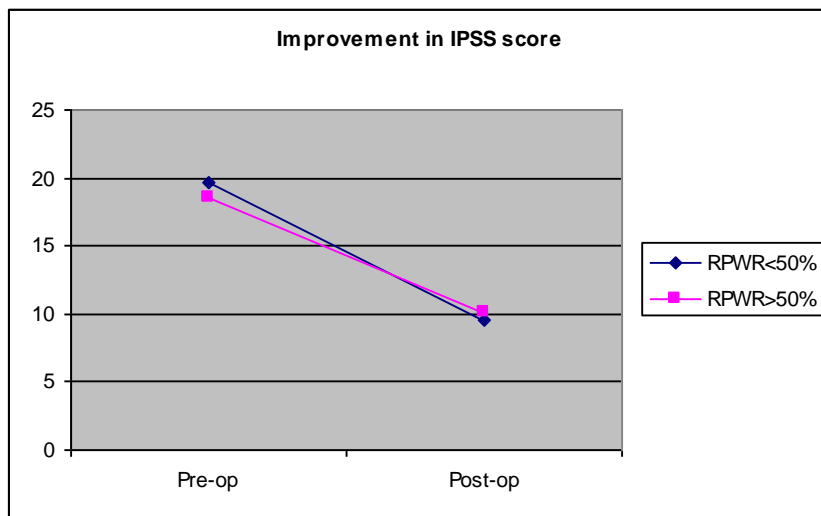




Comparative analysis of Groups 1 & 2

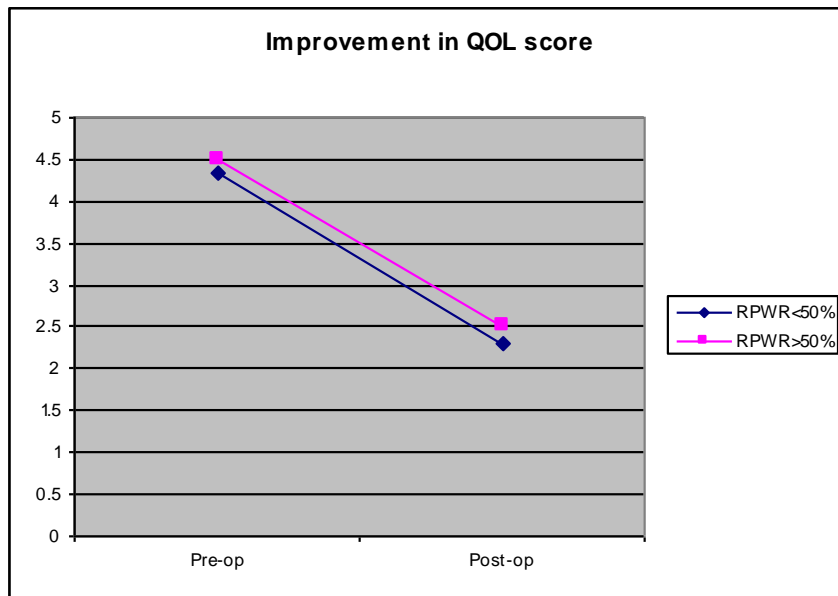
The comparative analysis of both groups was done by the Student's T-test. The improvement in the clinical parameters (Like difference in preoperative and post operative values of IPSS, QOL, PFR and PVR) were compared between the two groups. The mean and standard deviation of these values were calculated and statistical significance studied by the T-test. The various parameters are now analysed separately.

IPSS scores:



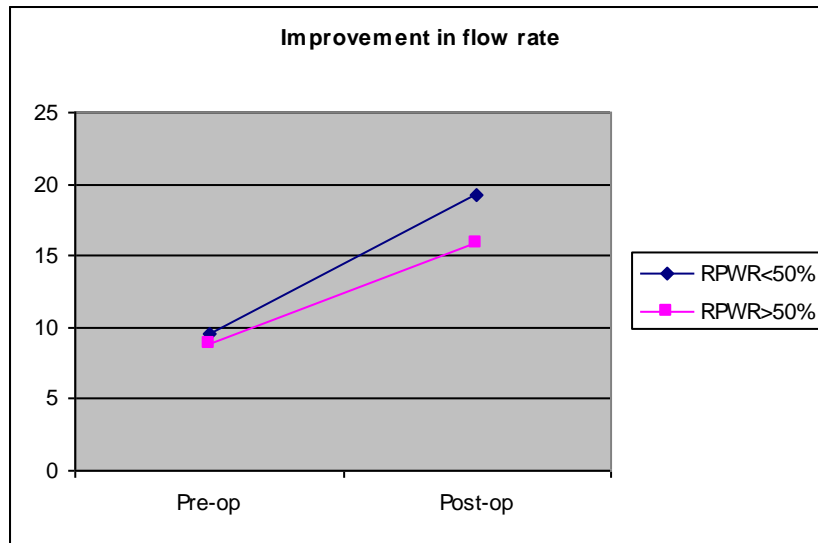
The mean improvement of IPSS score was of the value of 10.07 points in group-1 and 8.45 points in group-2. The improvement was apparent in both groups and the improvement was both clinically and statistically significant. Yet, the improvement in group-1 appeared to be more than group-2 by around 1.5 points. Whether this difference is significant was to be answered by the t-test.

QOL scores



The improvement in the subjective QOL score is presented by the above graph. The mean improvement in group-1 was 2.04 point and of group-2 was 1.98 points. The apparent increase in the first group was only 0.06 points.

Peak Flow Rate



The improvement in both groups was 9.80ml/s and 6.91ml/s respectively. There was a good difference in this clinical parameter between the two groups, the statistical significance of which is to be determined.

Post void residual (PVR)

The post void residual values too showed significant decrease in both groups but the difference between the two was not apparent. The reduction in PVR in group-1 was 33 ml and that of group-2 was 30 ml.

T-Test

Student's T-Test is a statistical tool to compare two similar populations and give the probability (p) value. If the p value is <0.05 , the result is considered statistically significant. It takes into consideration the mean and standard deviation of the values. p value of <0.05 signifies that there is less than 5% probability that the result might have been occurred by chance. In other terms, the value in concern lies outside mean $\pm 2SD$.

T-test was used in our study to measure the statistical significance between the two groups. Regarding the IPSS score, the mean and SD of group-1 was 10.07 and 4.29 respectively. The mean and SD of group-2 was 8.45 and 4.26 respectively. The p value of this variable was found to be 0.04. Hence the reduction in the IPSS score in group-1 was statistically significant than group-2

Next, in the QOL index the mean of the two groups was almost similar and the p value was only 0.14, not significant.

Comparing the peak flow rates, the p value from the t-test was found to be <0.001 , highly significant statistically. And the p value for PVR comparison was 0.41, not significant. The test results are tabulated as follows (Table 6):

Table 6

	RPWR <50%		RPWR >50%		p value
	Mean	SD	Mean	SD	
Δ IPSS	10.07	4.29	8.45	4.26	0.04
Δ QOL	2.04	1.08	1.98	0.90	0.14
Δ PFR	9.80	4.53	6.91	3.51	<0.001
Δ PVR	33.20	20.60	30.13	21.57	0.41

Complications

No major complication was seen in the study population. As said before patients who developed retention of urine or incontinence in the post operative period were excluded. Since the aim of the study was only to determine the effect of RPWR on outcome, complications of surgery were not taken into account. No patient required blood transfusion or developed TUR syndrome.

DISCUSSION

TURP is highly efficacious as a surgical procedure in the management of LUTS due to BPH. It is still considered the gold standard of therapy for this group of people against which all other methods should be compared. In the present study too the efficacy of TURP overall is evident. There had been a significant improvement in subjective parameters like IPSS score and QOL index and also increase in Qmax or PVR which is considered one of the best indicators of bladder outlet obstruction. In spite of TURP being the gold standard management for many decades there is still no consensus regarding the quantity of tissue to be resected during a typical TURP procedure. In the original MaCarthy's series in 1931, he recommended that prostatic tissue from lateral and median lobes be resected till a free unobstructed view of the bladder was established. But, in 1978, Blandy stated that total resection of the adenoma within the surgical capsule between the bladder neck and verumontanum was necessary³⁰. Even in Nesbit's original description of TURP, all adenoma tissue has to be resected for completion of surgery³¹. Historically the amount of tissue resected at TURP has been decreasing over time. Due to concern regarding potential complications of resecting for more time, surgeons limit the resection time to less than 30 minutes and are satisfied with creation of channel.

In our study, though the improvement in parameters has been significant in both groups, the difference in the group-1 (RPWR \leq 50%) has been more than group-2 (RPWR $>$ 50%). In terms of IPSS improvement, it the most widely used questionnaire across the globe in various languages and is accurate and validated in representing patient symptoms. And it has been accepted by all Urologists as an assessment tool in symptoms analysis of LUTS. The improvement in IPSS score of the order of 10.07 and 8.45 is seen in the two groups respectively. Though in these two groups individually this improvement is statistically significant, the improvement in group-1 is evidently more marked than in group-2. The p value on comparative analysis was also found to be significant. Hence, the more tissue being resected during surgery gives better patient realisation of his LUTS symptoms.

The QOL score in an independent measure of the patient satisfaction. Across both the groups the improvement in QOL score is around 2 points. Most of the patients were satisfied by their symptom improvement after TURP. The QOL score after surgery was most commonly 2 points meaning that the patients were 'mostly satisfied' by their present state of symptoms. And there was no statistically significant difference in this parameter between the two groups.

Next, the most important parameter defining obstruction in BPH, the peak flow rate or the Qmax of PFR. Although it is well documented that a low PFR may mean anatomical obstruction as well as myogenic failure, a low PFR of <15ml/s is taken as an indicator of bladder outlet obstruction in clinically BPH patients, other causes like neurogenic bladder being excluded. This objective parameter if improvement was shown to improve significantly in both groups. The mean PFR improved from 9.28 ml/s preoperatively to 18 ml/s post operatively in the whole group. This was a significant improvement and validated the efficiency of TURP. And, this improvement was seen in both the groups. The increase was 9.8 ml/s in group-1 and 6.91 ml/s in group-2. The difference in the two groups is again striking. The difference is almost 3 ml/s more in the group with $RPWR \leq 50\%$, p value of this variable being <0.001 . Hence, when more than 50% of the adenoma is resected, the improvement in urinary flow rates is more apparent. This improvement if flow rate is not apparent in other studies of similar nature and most standard textbooks do not agree to the notion that resecting more adenoma tissue results in better outcome. But still the Peak flow rate or Qmax is considered the single best indicator of reduction in flow. Hence, the results of our study are taken as significant. And, since the Qmax has increased compared to the pre operative values in most of the patients, it could be inferred that the

reduction in the flow rate is due to bladder outlet obstruction due to BPH and not due to detrusor failure.

The other parameter studied, the post void residual also showed good improvement among the two groups, but in comparative analysis, no statistically significant difference was noted. The p value was only 0.41 indicating no significance. In literature, the PVR value is not taken as a measure to quantify success or failure of a procedure. Nor does it indicate the aetiology of obstruction. It has also been found that more PVR did not correlate with increase in UTI. When PVR > 300ml, myogenic failure causes should be suspected for LUTS rather than BOO. Yet, PVR is primarily defined for use in patients who are under conservative management or watchful waiting. It gives us an indication that the patients with more PVR should be followed up more frequently to monitor for upper tract changes. Hence, our study finding of no significant difference in PVR improvement in the two groups does not affect the result.

Various authors have studied the impact of residual weight on symptoms previously. Chen²⁹ and associated reported their study in 2000 published in BJU. Their study showed a correlation of improvement in IPSS, PFR, mean flow rate with residual prostatic weight. In this study

patients were followed up at 16 weeks and the residual prostatic weight was measured by ultrasound analysis. This residual weight was found to correlate negatively with clinical improvement. That is, less the residual weight more the clinical improvement. Songra et al³² in 2004 from India reported their study. They reported more improvement in clinical outcome parameters like PFR, MFR and IPSS score with more of tissue resected. The clinical outcome correlated well with RPWR. This author too advocated resection of more tissue to improve clinical outcome.

An exactly opposite result was given by Aagaard and associates²⁷ in 1993. Their study showed no statistically significant difference based on the quantity of tissue removed. Hackenberg et al²⁸ in 2001 did a similar study and found that the difference in clinical improvement was not significant. More recently a study in Lithuania was reported by Daimantas Milonas in 2010 showed improvement in symptoms score with increase in resected weight.

Hence, all these studies gave only contradictory and inconclusive answers to the question how much of tissue should be resected at TURP. Our present study aimed to answer these questions. It was found that quantity of resection did play a role in outcome. Residual Prostatic Weight Ratio of $\leq 50\%$ gave better symptomatic improvement subjectively and

also improved flow rates significantly when compared to RPWR < 50%. The other parameters like QOL improvement and reduction in PVR showed no significant difference between the two groups.

The drawback in this study is the short follow up interval. Patients were followed up for only one month after surgery. The Chen et al study followed up patients after 16 weeks and reported their findings. In our study, about 30-40 patients were reviewed 4 months after surgery, they showed maintenance of the improvement achieved at one month. Since, this was not done for all 100 patients, this was not documented. Nevertheless, the improvement thus studied was significant. Another aspect is that trans abdominal sonography was used rather than TRUS as in many other studies. Although nowadays TRUS is commonly used, many trials failed to show much difference in calculating prostatic weight between the two methods. Most authors advocate TRUS for accurate volume measurement, but this is more employed in the setting of minimally invasive therapy for prostate cancer and for biopsy purposes. When the aim is to measure only the dimensions of the prostate, there is no much difference between trans abdominal and trans rectal scans. So the perceived difference in weight may not be significant. PSA levels were found in many reports to drastically reduce by around 40-60% following TURP. That was not measured in our study.

CONCLUSION

TURP is a safe and effective procedure for the management of LUTS due to BPH. The improvement in subjective and objective parameters is significant across the patient group studied. The amount of tissue resected did have a positive correlation with the clinical outcome. When the residual weight ratio is less than 50% the improvement in IPSS scores and PFR, the most important subjective and objective measures of outcome, is significant. Hence, 50% of tissue removal during TURP should be achieved in all patients for optimal symptom improvement with no increase in the incidence of adverse effects.

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Appendix-1

International prostate symptom score (IPSS)

Name: _____

Date: _____

	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	Year score
Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	

	None	1 time	2 times	3 times	4 times	5 times or more	Year score
Nocturia 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	

Total IPSS score	
-------------------------	--

Appendix-2

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

Appendix-3 - Proforma

A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia

SL No.			Date
Name		Age	IP No
DOS			
Diabetes			Neurogenic
h/o retention			Prior treatment

Pre-operative:

IPSS score		QOL score	
PFR	MFR	V.Vol	PVR

Pre-op weight

Procedure	Op time
-----------	---------

Resected weight	<u>RPWR</u>
-----------------	-------------

HPE

1 month follow-up:

IPSS score		QOL score	
PFR	MFR	V.Vol	PVR

**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3**

Telephone No: 04425305301
Fax : 04425363970

CERTIFICATE OF APPROVAL

To
Dr. Senthil .D
PG in MCh Urology
Madras Medical College, Chennai -3.

Dear Dr. Senthil D

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled "A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia " No. 20082011.

The following members of Ethics Committee were present in the meeting held on 16.08.2011 conducted at Madras Medical College, Chennai -3.

- | | |
|--|---------------------|
| 1. Prof. S.K. Rajan, MD | -- Chairperson |
| 2. Prof. V. Kanagasabai, MD
Dean, Madras Medical College, Chennai-3, | -- Deputy Chairman |
| 3. Prof. A. Sundaram, MD
Vice Principal , Madras Medical College, Chennai -3 | -- Member Secretary |
| 4. Prof R. Sathianathan , MD | -- Member |
| 5. Prof R. Nandhini, MD
Director, Institute of Pharmacology, MMC, Ch-3 | -- Member |
| 6. Prof. C. Rajendiran, MD
Director , Institute of Internal Medicine, MMC, Ch-3 | -- Member |
| 7. Thiru. A. Ulaganathan
Administrative Officer, MMC, Chennai -3 | -- Layperson |
| 8. Thiru. S. Govindasamy . BA.BL | -- Lawyer |
| 9 . Tmt. Arnold Soulina MA | -- Social Scientist |

We approve the proposal to be conducted in its presented form

Sd / . Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report


Member Secretary, Ethics Committee

ஆராய்ச்சி ஒப்புதல் கடிதம்

பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை முடிவு குறித்த விவரங்களை சேகரிக்கும் ஆராய்ச்சி

பெயர் :

தேதி :

வயது :

உள்ளோயாளி எண் :

பால் :

ஆராய்ச்சி சேர்க்கை எண் :

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கம் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு எனது சம்மதத்தை தெரிவிக்கிறேன்.

எனது பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை முடிவுகள் மற்றும் ஆராய்ச்சிக்கு தேவையான அணைத்து விவரங்களையும் தெரியபடுத்துவதற்கு முழு சம்மதம் தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் தான் பங்குபெறுகிறேன் மற்றும் இந்த ஆராய்ச்சியில் இருந்து எந்நேரமும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை குறித்த இந்த ஆராய்ச்சியின் விவரங்களை கொண்ட தகவல் தாளை பெற்றுக்கொண்டேன்.

நான் என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதிக்கிறேன்.

இந்த ஆராய்ச்சியின் தகவல்களையும் முடிவுகளையும் அறிவியல் நோக்கத்திற்காக பயன்படுத்துவதற்கு நான் அனுமதிக்கிறேன். நான் இந்த ஆராய்ச்சியில் பங்கு பெற சம்மதிக்கிறேன்.

பங்கேற்பவர் பெயர் :

பங்கேற்பவர் கையொப்பம்

(அ) இடது கட்டைவிரல் ரேகை

ஆய்வாளர் பெயர் :

ஆய்வாளர் கையொப்பம்

இடம் :

தேதி :

ஆராய்ச்சி தகவல் தாள்

பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை முடிவு குறித்த விவரங்களை சேகரிக்கும் ஆராய்ச்சி

தங்களின் பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை குறித்த விவரங்கள் பெற்றுக்கொள்ளப்பட்டது.

ராஜீவ் காந்தி அரசு பொது மருத்துவமனையில் நடைபெறும் பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை பற்றிய ஒரு ஆராய்ச்சி நடைபெற்று வருகிறது.

பராஸ்டேட் சுரப்பி அறுவை சிகிச்சை முடிவுகள் குறித்த விவரங்களை சேகரிப்பது இந்த ஆராய்ச்சியின் நோக்கமாகும்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களிடம் கேள்விகள் கேட்கப்பட்டு அதன் தகவல்களையும் அறுவை சிகிச்சையின் முடிவுகளையும் ஆராய்வோம். அதனால் தங்களது சிகிச்சைக்கு எந்த பாதிப்பும் ஏற்படாது என்பதை தெரிவித்து கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்து கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின் வாங்கலாம் என்பதையும் தெரிவித்து கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி

INFORMED CONSENT FORM

Title of the study: "A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia"

Name of the Participant:

Name of the Principal (Co-Investigator): Dr.Senthil D

Name of the Institution: Rajiv Gandhi Govt General Hospital, Chennai – 3

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in "A study on the correlation between clinical outcome and residual prostatic weight ratio after transurethral resection of prostate for benign prostatic hyperplasia"

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I have been informed the investigator of all the treatments I am taking or have taken in the past 3 months including any native (alternative) treatment.
6. I have been advised about the risks associated with my participation in this study.
7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
8. I have not participated in any research study within the past 6 month(s)
10. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.
11. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.
12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.
13. I have understand that my identity will be kept confidential if my data are publicly presented
14. I have had my questions answered to my satisfaction.
15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature _____ Date _____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature _____ Date _____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature _____ Date _____

For Children being enrolled in research:

Whether child's assent was asked: Yes / No (Tick one)

[If the answer to be above question is yes, write the following phrase:

You agree with the manner in which assent was asked for from your child and given by your child. You agree to have your child take part in this study].

[If answer to be above question No, give reason (s)

:_____.

Although your child did not or could not give his or her assent, you agree to your child's participation in this study.

Name and Signature of / thumb impression of the participant's parent(s) (or legal representative)

Name _____ Signature _____ Date _____

Name _____ Signature _____ Date _____

Name and Signature of impartial witness (required for parents of participant child illiterate):

Name _____ Signature _____ Date _____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent :

Name _____ Signature _____ Date _____

MASTER CHART

Sl. No.	Patient characteristics		History		Pre-op			Operative parameters						One month follow up				
	Name	Age	Diabetes	h/o retendion	IPSS score	QOL score	PFR	PVR	Pre-op weight (g)	Procedure	Operation time (min)	Resected weight (g)	Residual weight	RPWR (%)	IPSS score	QOL score	PFR	PVR
1	Adalakanathan	69	No	No	17	4	9	20	34	TURP	45	18	16	47.06	9	2	20	10
2	Adhil	61	No	No	25	5	6	50	26	TURP	45	13	13	50.00	6	3	16	15
3	Adhinoolem	60	No	No	24	5	8	70	34	TURP	45	18	16	47.06	14	4	20	5
4	Alexander	65	No	Yes	13	5	NA	NA	50	TURP	40	19	31	62.00	6	4	15	15
5	Anbeagan	60	No	No	27	5	8	65	46	TURP	45	15	31	67.99	12	3	15	5
6	Anbu	62	No	No	18	4	8	35	36	TURP	45	19	17	47.22	8	2	19	15
7	Andi	64	No	No	29	4	8	70	40	TURP	55	23	17	42.50	11	3	20	15
8	Angamuthu	65	No	No	15	5	11	60	40	TURP	65	24	16	40.00	5	2	21	10
9	Arokiaj	59	No	No	17	5	7	40	26	TURP	50	14	12	46.15	9	2	22	5
10	Basthavaithalam	70	No	Yes	14	6	NA	NA	48	TURP	60	18	30	62.50	12	5	15	50
11	Beesubramanian	67	No	Yes	10	4	NA	NA	38	TURP	60	21	17	44.74	6	2	15	10
12	Beesundaram	72	No	No	27	5	12	60	28	TURP	40	17	11	39.29	12	3	22	10
13	Bekaran	68	No	Yes	13	6	NA	NA	38	TURP	55	20	18	47.37	4	2	18	10
14	Bose	60	No	No	31	5	7	80	42	TURP	60	25	17	40.48	13	3	23	40
15	Chandrasekaran	64	No	No	25	3	13	55	36	TURP	65	23	13	36.11	7	2	21	10
16	Chidambaram	70	Yes	No	28	5	10	55	32	TURP	35	19	13	40.63	12	2	23	15
17	Chiranjeevi	62	Yes	No	21	4	9	35	45	TURP	55	23	22	48.89	11	2	21	10
18	Dhanapal	67	No	No	22	3	13	15	36	TURP	50	22	14	38.89	12	2	22	30
19	Dhandapani	59	No	No	10	4	6	70	28	TURP	40	14	14	50.00	6	1	20	10
20	Eisayan	68	No	No	12	4	9	55	36	TURP	40	18	18	50.00	6	1	17	40
21	Gandhi	68	No	Yes	20	4	NA	NA	40	TURP	45	24	16	40.00	8	3	15	20
22	Gunasekaran	60	No	No	19	4	12	60	42	TURP	60	15	27	64.29	10	3	20	20
23	Ibrahim	61	Yes	No	26	4	7	40	40	TURP	60	22	18	45.00	17	3	21	25
24	Iliyas	75	No	Yes	20	4	NA	NA	36	TURP	35	22	14	38.89	8	4	12	10
25	Ismail	68	No	No	24	5	12	50	56	TURP	60	39	17	30.36	12	2	20	5

26	Jacob	61	No	No	Yes	15	5	NA	NA	38	TURP	65	24	14	36.84	5	1	16	5
27	Jeyaraman	59	Yes	No	No	19	5	8	55	40	TURP	60	16	24	60.00	8	3	18	35
28	John Joseph	61	Yes	No	No	26	4	9	45	28	TURP	40	13	15	53.57	6	1	19	25
29	Joseph	60	No	No	No	14	4	7	15	58	TURP	70	40	18	31.03	11	2	17	10
30	Kandavel	69	No	No	No	21	5	13	35	30	TURP	40	16	14	45.57	12	2	22	5
31	Kannan	59	No	No	No	15	3	13	20	44	TURP	55	29	15	34.09	6	1	21	20
32	Karunanidhi	65	No	No	No	14	4	10	45	30	TURP	45	10	20	65.57	10	3	23	10
33	Kesirajan	70	No	No	No	22	5	8	60	42	TURP	35	16	26	61.50	9	3	14	10
34	Kesavamocthy	61	Yes	No	No	18	4	9	40	50	TURP	45	15	35	70.00	13	2	15	5
35	Kesavan	65	No	No	No	19	4	10	45	38	TURP	45	21	17	44.74	6	2	22	20
36	Krishnapillai	66	Yes	No	No	27	4	9	80	36	TURP	40	21	15	41.57	9	1	19	20
37	Kumaran	71	No	No	No	21	4	6	30	32	TURP	35	19	13	40.83	10	3	19	10
38	Loganathan	65	Yes	No	No	12	3	11	20	28	TURP	40	13	15	53.57	5	2	17	20
39	Maduraiimuthu	65	No	No	No	15	4	7	45	24	TURP	65	14	10	41.57	6	1	21	25
40	Mannankatti	69	No	No	No	23	3	11	60	28	TURP	55	16	12	42.86	15	3	21	10
41	Mariam Pichai	71	No	No	No	13	4	8	55	30	TURP	50	16	14	45.57	5	2	20	15
42	Mohammed Khan	56	Yes	No	No	26	4	12	25	44	TURP	55	27	17	38.54	6	4	20	10
43	Murthy	69	No	No	No	28	3	11	20	36	TURP	75	17	19	52.78	21	3	21	20
44	Murugesan	70	Yes	No	No	15	5	9	50	28	TURP	35	12	16	57.14	6	2	14	5
45	Muthu	62	Yes	No	No	16	5	13	40	26	TURP	45	13	13	50.00	4	2	23	5
46	Muthu Reddy	63	No	No	Yes	18	5	NA	NA	40	TURP	45	23	17	42.50	10	1	17	5
47	Muthukumar	68	No	No	No	13	4	10	80	32	TURP	50	16	16	50.00	8	2	18	15
48	Muthuraman	64	No	No	No	18	4	9	60	48	TURP	65	30	18	37.50	10	1	19	10
49	Nachiappan	71	No	No	No	23	4	10	35	58	TURP	75	20	38	63.32	19	3	18	40
50	Nagarajan	70	No	No	Yes	17	4	NA	NA	36	TURP	30	14	22	61.11	8	2	12	15
51	Pechaleppan	67	No	No	No	15	4	10	15	34	TURP	30	12	22	64.71	7	2	15	5
52	Pelani	58	No	No	No	30	5	8	40	42	TURP	60	26	16	38.10	12	2	14	35
53	Pelani	69	No	No	No	14	4	8	45	34	TURP	40	16	18	52.94	7	2	20	20
54	Pandian	71	No	No	No	11	5	13	20	42	TURP	60	32	10	23.81	7	1	20	25

55	Pandiarajan	56	No	No	25	4	10	65	46	TURP	75	29	17	36.96	12	2	17	5
56	Perumal	58	No	Yes	25	6	NA	NA	36	TURP	45	18	18	50.00	15	2	14	5
57	Pichandi	58	No	No	19	4	10	35	46	TURP	75	21	25	54.35	9	2	16	8
58	Raja	59	No	No	25	4	10	50	36	TURP	55	12	24	66.67	11	3	18	15
59	Rajamanickam	64	Yes	No	15	5	7	60	36	TURP	45	14	22	61.11	6	2	15	15
60	Ramachandran	69	No	No	10	4	9	35	44	TURP	30	15	29	65.91	5	3	15	60
61	Ramalingam	62	Yes	No	20	5	9	75	66	TURP	60	27	39	59.09	12	2	14	20
62	Rathinavelu	66	No	No	28	5	8	30	32	TURP	35	16	16	50.00	10	1	14	10
63	Raviendran	58	Yes	No	10	5	9	55	44	TURP	50	13	31	70.45	9	3	14	10
64	Robert	70	No	No	19	2	10	65	44	TURP	45	27	17	38.64	9	1	22	10
65	Sambandhan	63	No	No	17	5	10	75	42	TURP	70	20	22	52.38	10	2	17	15
66	Samikannu	65	No	No	18	5	7	55	28	TURP	45	13	15	53.57	10	3	12	10
67	Saminathan	70	No	No	18	5	11	55	40	TURP	60	22	18	45.00	7	2	21	5
68	Sampath	59	No	No	20	4	10	50	56	TURP	75	42	14	25.00	15	3	20	15
69	Sampath	58	No	No	20	5	8	45	40	TURP	60	18	22	55.00	15	2	15	5
70	Sangli	69	No	No	29	5	10	20	38	TURP	45	23	15	39.47	11	5	22	25
71	Sankaralingam	65	No	No	24	5	6	55	34	TURP	60	14	20	58.82	14	3	12	15
72	Sankarapandian	63	Yes	No	17	5	10	50	26	TURP	40	13	13	50.00	7	3	22	10
73	Santhanam	62	No	No	14	5	10	70	40	TURP	60	17	23	57.50	12	3	16	15
74	Santhosam	57	Yes	No	27	4	9	75	42	TURP	55	23	19	45.24	7	2	20	15
75	Sekar	72	No	No	23	4	8	75	40	TURP	55	23	17	42.50	15	3	20	35
76	Senguttuvan	64	No	No	30	5	8	55	38	TURP	55	26	12	31.58	24	2	18	10
77	Sheriff	62	Yes	No	23	4	9	45	34	TURP	30	18	16	47.06	13	3	16	5
78	Singaravelu	58	Yes	No	9	4	8	30	34	TURP	60	19	15	44.12	7	2	15	5
79	Sivakadacham	58	No	Yes	15	4	NA	NA	40	TURP	50	17	23	57.50	9	2	18	5
80	Sivalingam	57	No	No	24	4	10	55	40	TURP	50	26	14	35.00	6	3	21	20
81	Sivanandam	67	No	No	10	4	8	60	34	TURP	35	22	12	35.29	5	3	22	15
82	Soundarapandian	67	No	Yes	30	5	NA	NA	58	TURP	55	35	23	39.66	10	3	20	5
83	Srinivasan	66	No	No	20	4	10	50	40	TURP	45	23	17	42.50	8	2	19	5

84	Stephen Raj	65	Yes	Yes	30	6	NA	NA	60	TURP	65	33	27	45.00	20	4	15	15
85	Subramaniam	59	Yes	Yes	15	5	8	75	56	TURP	80	37	19	33.93	6	1	21	5
86	Subramanian	59	No	No	18	4	10	60	28	TURP	55	17	11	39.29	11	1	19	25
87	Suruivel	70	No	Yes	25	6	NA	NA	36	TURP	40	20	16	44.44	10	3	13	5
88	Swaminathan	65	No	Yes	27	4	NA	NA	40	TURP	45	17	23	57.50	13	3	14	25
89	Thandamuthu	63	No	No	28	5	8	55	34	TURP	45	19	15	44.12	13	3	22	5
90	Thirumoorthy	62	No	Yes	17	5	NA	NA	42	TURP	50	20	22	52.38	10	3	16	35
91	Tirupathi	70	No	No	10	4	7	55	24	TURP	35	14	10	41.67	3	2	14	15
92	Ulaganathan	67	No	No	14	4	9	30	56	TURP	55	25	31	55.36	9	2	15	15
93	Vedivel	72	No	No	29	3	15	45	36	TURP	40	22	14	38.89	11	2	22	10
94	Venchesappan	69	No	No	11	5	8	45	38	TURP	65	17	21	55.26	8	1	20	10
95	Veerasathran	65	No	Yes	27	5	NA	NA	38	TURP	60	25	13	34.21	9	3	14	10
96	Veersiah	59	No	No	24	3	11	20	56	TURP	75	41	15	25.59	12	2	21	10
97	Velmurugan	59	No	No	24	5	9	10	30	TURP	45	16	14	46.67	16	3	22	15
98	Vetrivel	65	No	No	10	5	8	40	36	TURP	55	16	20	55.56	7	5	15	10
99	Vijayarajan	58	No	No	26	3	9	20	46	TURP	65	17	29	63.04	13	1	13	5
100	Wasim	64	Yes	No	27	4	7	75	38	TURP	45	17	21	55.36	9	2	11	10