

**SAFETY AND EFFICACY OF BIPOLAR ENERGY FOR
TRANSURETHRAL RESECTION OF BLADDER TUMOURS**

Dissertation submitted to

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the award of the degree of

M.Ch (UROLOGY) – BRANCH – IV



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CHENNAI

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DECLARATION

I solemnly declare that this dissertation titled “**SAFETY AND EFFICACY OF BIPOLAR ENERGY FOR TRANSURETHRAL RESECTION OF BLADDER TUMOURS**” 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 fulfilment of the university requirements for the award of the degree of M.Ch. Urology.

Place: Chennai

Date:

Dr.Vasudevan T.

CERTIFICATE

This is to certify that the dissertation titled “**SAFETY AND EFFICACY OF BIPOLAR ENERGY FOR TRANSURETHRAL RESECTION OF BLADDER TUMOURS**” submitted by **Dr.Vasudevan T.** appearing for M.Ch. (Urology) degree examination in August 2013 is a bonafide record of work done by him under my guidance and supervision in partial fulfilment 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.

Prof.R.Jeyaraman MS, MCh

Professor & HOD

Department of Urology,

Madras Medical College & Rajiv

Gandhi Government General

Hospital,

Chennai - 600003

The Dean

Madras Medical College & Rajiv

Gandhi Government General

Hospital,

Chennai - 600003

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INTRODUCTION

Bladder cancer is one of the commonest malignancies and worldwide it is the fourth most common malignancy in males and eighth in females¹. About 70% of patients with Bladder cancer have disease limited to the mucosa or sub-mucosa. This group forms the main bulk of the disease and is termed as non-muscle invasive or superficial bladder cancer². The success of therapy in non-muscle-invasive bladder cancer (NMIBC) relies upon the biologic nature of the tumour and on the treatment chosen. Endoscopic surgery is considered the main treatment of non-muscle invasive tumours (Ta and T1)³.

In 1910, Edwin Beer, changed the paradigm of managing bladder tumours from Open surgery to Endoscopic management⁴. In 1931, the first cutting loop resectoscope was introduced by Stern and McCarthy which gave a boost for transurethral surgeries. Several modifications in technology and technique have evolved, but loop resection remains the gold standard⁵.

Endoscopic resection of the growth (TURBT) is the most important and a crucial step in the management of non-muscle-invasive tumours. The objective of TURBT is to (1) Know the histology of the tumour (2) Stage the tumour (3) Grade the tumour and 4) possibly achieve cure⁶.

The most common energy source used in TURBT is conventional Monopolar electrosurgery. But Monopolar electrosurgery has its own drawbacks. First, the patient's body forms a part of the electrical circuit. Second, for irrigation non-conducting solutions like Sterile water, Glycine are used, which increases the incidence of TUR syndrome. Third, the incidence of obturator jerk is more with Monopolar TURBT. So, in order to overcome these drawbacks there has been lots of advances in the surgical technique and technology. One of the improvements in technology is Bipolar energy source, which is well proven for its efficacy and is in common use for TURP (Transurethral resection of prostate)⁷.

The quoted reason for the benefit of Bipolar over Monopolar is decreased incidence transurethral resection syndrome (TUR syndrome) as it uses saline for irrigation which is proven beyond doubt in TURP. But the incidence of transurethral resection syndrome is as such rare in bladder tumour resection even with Monopolar electrosurgery. This may be the reason for non-popularity of Bipolar TURBT⁸.

There are only few studies in published literature comparing the Monopolar and Bipolar resection of bladder tumours. This study aims to elucidate the safety and efficacy of Bipolar TURBT in comparison to Monopolar transurethral resection (TURBT) in bladder tumours.

AIM AND OBJECTIVE

The primary aim and objective of the present study is to evaluate the Safety and efficacy of Bipolar energy in resecting bladder tumors and with a secondary objective to study the histological changes (Thermal artefacts) noted in the resected specimens between the Monopolar and Bipolar energy.

REVIEW OF LITERATURE

The Bladder

Bladder functions as a reservoir and varies in size, morphology, position and relations as per its content and the nature of surrounding viscera. It lies entirely in the pelvis when empty and extends antero-superiorly into the peritoneal cavity when full. It is approximately tetrahedral in shape when empty and has two inferolateral surfaces, superior surface, base and neck⁹.

The base or the Trigone is triangular and lies postero-inferiorly. The base is closely related to the anterior vaginal wall in females and to the rectum in males. The Seminal Vesicle and Vas deferens lie on each side in close approximation to the bladder. The fascia separating the bladder and rectum is referred to as the Rectovesical fascia, which is also known as Denonvillier's fascia¹⁰.

The Neck of the bladder is the lowest and the most fixed part. It lies about 3-4 cm posterior to the symphysis pubis. The bladder neck changes little in position with bladder filling. In males, the bladder neck lies in close proximity to the base of the prostate^{9, 10}.

Bladder Mucosa¹¹

The bladder mucosa is loosely attached to the underlying muscle in most parts of the bladder except Trigone where it is firmly adherent. Thus when the bladder is empty mucosa is thrown into folds and the folds disappear when bladder gets filled. But in Trigone the mucosa changes little with filling and emptying of the bladder.

Trigone of the bladder is bound by three anatomical land marks, namely, the Ureteric orifices and the internal urethral meatus. The interureteric region is thickened due to the continuation of inner longitudinal muscle from the ureters and is called the Inter-ureteric crest or Mercier's bar. During cystoscopy the Mercier's bar appears pale and is an important landmark in tracing the Ureteric orifices as they are located at its extremity.

Bladder mucosa is made up of specialised cells called the Transitional cells, which are 5-7 layers thick all around except at the trigone where it is only 3 layers thick. This is also called as the Urothelium. Subjacent to the urothelium lies the lamina propria which contains the blood vessels and lymphatics. The Lamina propria contains a discrete layer of discontinuous smooth muscle layer called the muscularis mucosae, which has a significance in that it creates confusion in histopathological sections and sometimes while staging the tumour this can be confused for detrusor and staged as muscle invasive.

Detrusor^{9, 11}

The smooth muscle of the bladder is called as the Detrusor and is indistinctly arranged into three layers namely inner and outer longitudinal and middle circular. But near the Trigone and bladder neck the three layers are clearly appreciable. The inner longitudinal layer is continuous with inner smooth muscle of urethra. The middle circular layer forms the pre-prostatic sphincter and the outer posterior layer is thickest and provides backing for Trigone.

The muscular layer of the Trigone has three distinct layers: (1) a Superficial layer which is continuation of the longitudinal muscle of the Ureter (2) a Deep layer, from the Waldeyer sheath and (3) a Detrusor layer proper

URETERIC ORIFICES AND URETERO-VESICAL JUNCTION¹²

The Ureteric orifices are slit-like apertures, present at the extremities of inter-ureteric crest. They are 2.5 cm apart in empty bladder and 2.5 cm from internal urethral meatus and when bladder gets full these dimensions double. The uretero-vesical junction forms an important part of the urinary tract in that it not only allows antegrade flow of urine, but also prevents retrograde flow of urine from the bladder thereby preventing reflux and its effect on the kidneys. The importance of this is that in the presence of reflux there is high likelihood of seedling of urothelial tumours from the lower tract.

BLOOD SUPPLY AND LYMPHATIC DRAINAGE⁹

ARTERIES

The main arterial supply to the bladder is derived from the superior and inferior vesical arteries, which in turn are branches of the anterior division of the internal iliac artery. Additional supply is provided by the obturator and inferior gluteal arteries in both sexes and few branches from the uterine and vaginal arteries in females.

VEINS

The veins from the bladder form a plexus near the inferolateral surfaces and finally empty into the internal iliac veins.

LYMPHATIC DRAINAGE

Lymphatics from the bladder mainly drain into the external iliac nodes. Also lymphatics from the Trigone and inferolateral wall drain additionally into obturator, internal iliac and rarely into common iliac nodes.

Innervation¹³

Bladder is richly innervated by autonomic nerves from the pelvic plexus. The bladder wall is mainly supplied by Cholinergic nerves and the Trigone and bladder neck are rich in Sympathetic supply.

Bladder and the Obturator nerve

The Obturator nerve runs over the Obturator internus muscle within the pelvis and lies in close relation to the lateral walls of the distended bladder. The surgical importance of this anatomy is that during endoscopic resection, particularly TURBT, there is a chance for direct Galvanic stimulation during activation of the loop which can lead to hazardous outcome. The Obturator nerve supplies the adductor compartment of the thigh and activation of the nerve during TURBT with consequent adduction of the limb can lead to bladder injury by the active loop¹⁴.

Bladder Cancer

Bladder malignancy is the fourth and eighth common tumour in men and women respectively. Also it is the 9th most common cancer worldwide¹. It accounts for 145,000 deaths worldwide. There has been upsurge in the frequency of Bladder cancer in Asia because increased prevalence of smoking. Most common histological subtype Worldwide is Urothelial carcinoma except

for Egypt where there is higher incidence of Squamous Cell Carcinoma due to the endemicity of Schistosomiasis. Age and environmental factors like smoking are related to the development of Bladder cancer. The incidence is more common in males than in females with a ratio of 3:1. Bladder cancer is less frequent in younger age group (<40yrs) and tends to be low grade and non-aggressive. Mean age of presentation is 70yrs in both the sexes and there is a progressive increase in the incidence and death with advancing age¹⁵.

It is a well known fact that genetic abnormalities and external risk factors play a major role in the development of bladder cancer. Smoking is considered as the most common associated risk factor for the development of bladder cancer. A diet which includes green leafy vegetables and fruits are considered to offer some protection against bladder cancer¹⁶. The presence of low-penetrance genes (NAT-2 and the GSTM1 polymorphisms) increases the susceptibility to carcinogens and subsequent formation of bladder cancer. In endemic areas infested with Schistosomiasis there is increased prevalence of Squamous Cell Carcinoma in those areas, probably due to chronic inflammation as is same for chronic catheterisation, long standing calculus and chronic inflammation.

Histologically, Urothelial carcinomas constitute about 90% of bladder cancers, remainder 5% by Squamous cell carcinomas, and less than 2% by Adenocarcinoma. Overall Urothelial carcinoma is the commonest cancer of the urinary tract and stands second in position next only to Renal cell carcinoma

leading to death in genitourinary tumors. About 80% of Urothelial tumors are diagnosed early in patients when still the tumour is superficial and non-muscle invasive¹⁵.

When cystoscopy is performed for bladder cancer, it is prudent to record the location, size, number, and nature of the tumors. Urinary cytology is considered as a basic outpatient test and obtained as a tool to identify the likelihood of high-grade disease and aid in the follow-up of patients after definitive management. Contrast imaging is done to stage the disease and to survey the upper tracts since one of the theories behind the pathology of Urothelial carcinoma is “Field change cancerisation”¹⁷.

Management of Bladder Cancer

The primary treatment for visible lesion is transurethral resection of the bladder tumor (TURBT) under anesthesia with the aim to (1) resect all visible growth and (2) obtain adequate specimens for histopathological grading and staging. Bimanual examination of the bladder is most important step an Urologist should do under anaesthesia prior and after resection and persistence of a palpable mass after the surgery denotes peri-vesical spread^{17, 18}.

Historical milestones of Electrosurgery and the Resectoscope

Prehistoric man had the idea of using heated pebbles to control haemorrhage and the idea of cautery is not new. It was in the beginning of the eighteenth century that the use of electrical energy came into use in the field of surgery. It was Goldwyn who classified the invention and development of electrosurgery into three recognizable eras. First is the period indistinctly etched in the history with the use of static current. No one knows when it began and who invented it. Next period in the historical progression of electrosurgery is credited to Luigi Galvani's who in 1786 in fact accidentally found that current could stimulate muscle contractions. This period better known as "Galvanization era" is considered as the birth of electrophysics. The last period which dates back to 1831 with the invention by Faraday and Henry that an electric current can be produced by a fast moving magnet within a coil of wire¹⁹.

The fact that current at high frequency could pass through a patient's body without producing pain or burn was shown by Morton way back in 1881. It was d'Arsonval who is considered as the "Father of Electrosurgery" in 1891 showed when the frequency is set at 10 kHz, there was heating up of the tissue with increasing proportion to the square of the density of current¹⁹.

Bovie is considered as the "Father of Modern electrosurgery" by contributing a diathermy unit capable of delivering high-frequency current. He also showed

that this high frequency current could be used in surgery with the help of Dr. Harvey Cushing on 1 October 1926 which is considered as an important milestone in the history of electrosurgery¹⁹.

The Monopolar electrosurgical unit, called commonly as “Bovie”, is a routine instrument in the modern day surgical armamentarium. The electrophysics of Monopolar is well known.

The credit for the invention of a Bipolar unit goes to Dr. Malis in 1955. The Malis bipolar unit worked at 1 MHz wavelength and required only 140V rather than 2500V required by Monopolar system¹⁹.

The historical milestone in the technological inventions in the endoscopic management of bladder tumours was the invention of Cystoscope by Maximillian Nitze in 1877 which allowed Urologists to look into the bladder. The ever first attempt at electroresection of the bladder was by Beer in 1910. In 1926, Stern was the one who introduced resectoscope subsequent to which there have been many modifications in the resectoscope design²⁰.

The resectoscope designed by Stern-McCarthy was a rack and pinion model instrument which was operated by both the hands and a tungsten loop slid front and back to make the resection. It had an outer sheath which allowed irrigation, passage of telescope and working element. With the Stern resectoscope sheath a tubular cylinder of tissue was resected using high frequency current. Although

effective in resecting the prostatic mass, it was difficult to engage the bladder tumours with this instrument²⁰.

It was the efforts of McCarthy who modified the Stern resectoscope by incorporating Bakelite to the tip of the sheath and thereby making it possible to work when the current was applied and also prevented the risk of electric burns to the operating surgeon^{21, 22}.

Nesbit is regarded for his unique contribution of single handed spring action working element which permitted safe resection²³.

Even though the model proposed by Iglesias way back in 1979 is very much similar to Nesbit, he is credited for the introduction of continuous flow resectoscope sheath which speeded up the resection at the compromise of larger sheath size. The Iglesias sheath essentially had two sheaths, of which the larger outer sheath was meant for drainage and smaller inner sheath for irrigation. There are many advantages for this design in that it is operated by single hand, loop is inside the sheath in resting position and moreover important advantage is its unique continuous flow design which enabled it to keep the bladder pressure low and a buy in the resection time²⁰. Thus the incidence of TUR syndrome should be theoretically low.

Monopolar TURBT

TURBT can be performed under spinal or general anaesthesia. Whatever anaesthesia is used, it should ensure adequate relaxation of the bladder and abdominal wall⁵.

Before proceeding with the resection a thorough inspection of urethra, entire bladder and both Ureteric orifices is done. The nature of the lesion, its location, number, size (approximately comparable to loop diameter) and velvety-tan areas suggestive of CIS are recorded. It is better to represent the tumour in a pictorial fashion^{24, 25}.

The technique of resection depends on the size of the lesion. Tumours less than 1cm can be resected in toto along with a good part of underlying muscle. Tumours more than 1cm is usually resected piece meal starting from the exophytic part to the base and then taking a separate specimen from the underlying muscle. Deep resection specimen is sent for pathological analysis in a separate container. It is shown in studies that there is high probability of understaging in T1 tumours and most surgeons re-resect within 3weeks of primary resection^{24, 25}.

B-TURBT

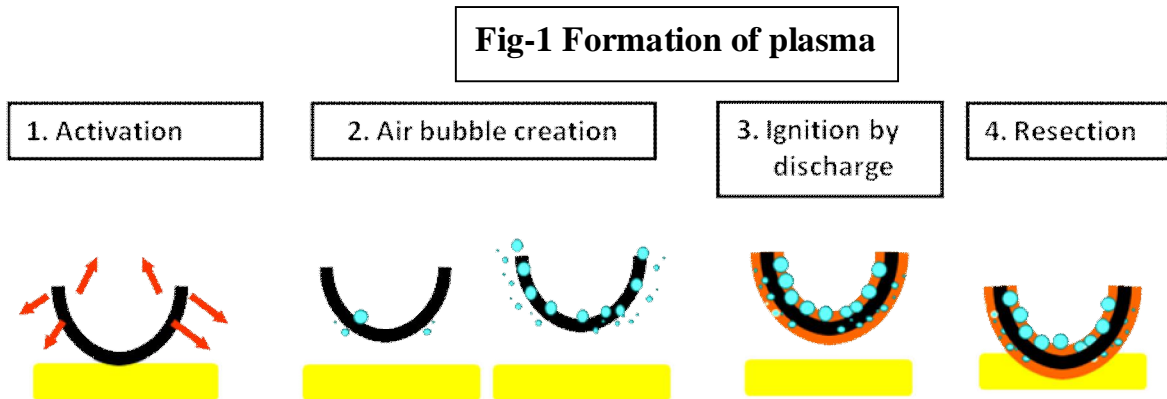
The surgical technique is essentially the same as in Monopolar. In Monopolar electrosurgery the path of the electric current is from the active loop, then through the tissues (patient), through the indifferent electrode placed abutting the patient's skin and back to the electro-surgical unit to complete the circuit. The heat generated at the loop-tissue interface is used for resection.

In Bipolar electrosurgery, the large return electrode of the Monopolar mode is replaced with a second small electrode. The path of the electric current is from the active loop, through the conducting irrigant, through the patient's tissue, to the second indifferent electrode which is placed very close within the same loop and then back to the electrosurgical generator. Two electrodes are combined in the instrument. Current passes between tips and not through the patient. Hence, there is no current flowing through the patient's body.

Creation of plasma

In Bipolar resection, Current flows through the saline because impedance is lower in saline than in body tissue. Air bubbles are created around the loop by the heat caused from current flow. The whole loop is covered by small bubbles. Finally the loop is coated by an insulation layer. At this point Sodium ions are

excited. Current is discharged to the air surrounding the electrode, similar to lightning. Then the electrode is covered by plasma. Resection is made by the heat of the plasma created around the electrode (Fig-1).



The colour of plasma formed due to saline is orange in colour and depends on ion present in the irrigation fluid (Fig-3). The path of the current in resection loop is from active electrode, through the saline, through the tissue and back to the indifferent electrode close to active loop (Fig-2).

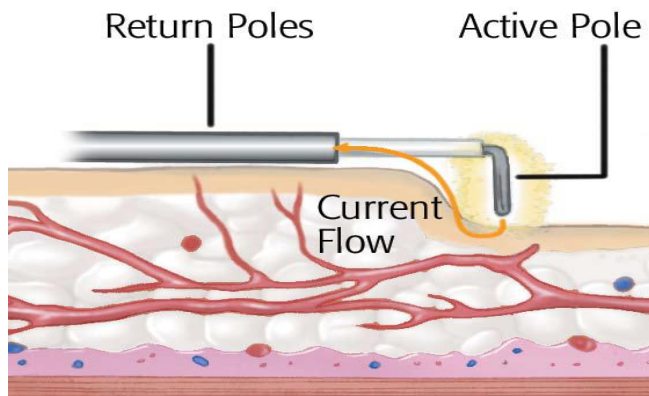


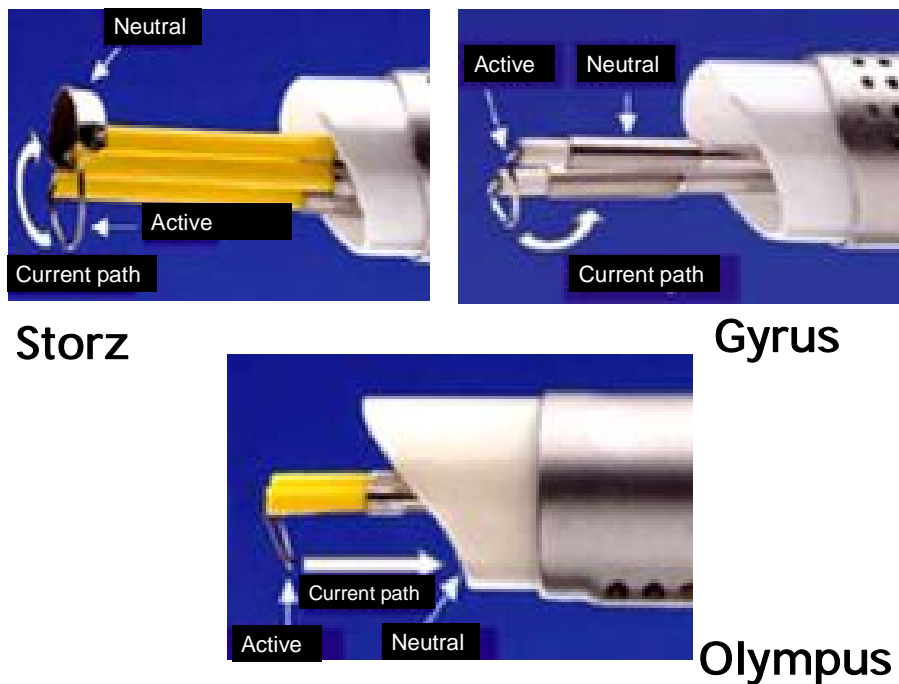
Fig-2 Path of current



Fig-3 Orange Plasma Of Saline

A number of Bipolar loop designs are available in the market depending on the manufacturer (Fig-4).

Fig-4 Various Bipolar Designs



The loops are designed so that both the electrodes are placed closely. The Olympus system used the resectoscope sheath as the neutral electrode. The Gyrus loops are so designed that the neutral electrode is incorporated into the stem of the loop and active and neutral electrodes are separated by insulation. In the Karl Storz model the indifferent loop is placed just opposite the active loop and is much thicker than the active loop.

Complications

The incidence of complication after TURBT is reported to be around 5–6%. The factors which are considered to lead to higher incidence of complications are the size, number and location of the tumours. Bulkier, multifocal and tumours in inaccessible regions like dome have higher rate of complication during TURBT. Hemorrhage is the most common complication occurring in 2–3% of cases. Hemostasis achieved during TURBT and maintaining an empty bladder reduces the incidence of bleeding postoperatively^{26,27}.

A more dreadful complication of TURBT is bladder perforation occurring in about 1.3–3.5% of patients. Clinically insignificant micro-perforations go unnoticed. Extraperitoneal perforations are common and are usually managed by continuous catheter drainage. Less frequent are intraperitoneal perforations requiring open exploration and suture closure of the defect. The perforation can occur as a result of obturator nerve stimulation, sudden muscle contraction and rapid jerky movement of the lower extremity. This obturator stimulation can be prevented by obturator block, using GA with good muscle relaxants or replacing energy source to bipolar electrocautery^{5, 28}. It goes without saying that over-distended bladder comes in proximity to obturator nerve and therefore the surgeon should have tendency to resect with partially filled bladder.

In M-TURBT, the high voltage is required to push the current from the active electrode to the indifferent electrode as the distance between the two is greater. In contrast to Monopolar systems, the energy and the voltage required by a bipolar systems is much less because both active and indifferent electrode are placed close to each other and current traverses only a small amount of tissue^{28,29}.

Theoretically no current should pass through the obturator nerve. But the initial formation of plasma on activation of a bipolar loop requires high current. It is often noticed that obturator jerks in bipolar resection occur during the initial parts of resection, more so over when the tumour is located on the lateral wall. Then further maintenance of plasma needs only a lower voltage. As there is less charring and blackening of the tissue, vision is excellent allowing controlled resection and subsequent avoidance of complications²⁹.

The incidence of TUR syndrome is not noted with increased frequency in TURBT as noted in TURP. But there have been reports quoting to have documented higher incidence of TUR syndrome in few cases. Nevertheless, it is likely that during resection of large tumours some amount of fluid is likely to get absorbed and can lead to dilutional hyponatremia. This incidence is less when using Bipolar energy as saline is used as an irrigant instead of water or glycine⁸.

In monopolar systems, since the electrical energy is carried through the tissue, resistance offered by the tissue elevates temperature to as high as 400°C which leads to tissue damage and desiccation making difficulty in interpreting pathological specimens^{30, 31}.

But in bipolar energy, the radiofrequency current converts the conducting irrigant into plasma which is at a higher temperature which dissociates the bonds between the tissues reducing it into elementary molecules.

Since the current is not completely running through the tissues and is circuited through the closely placed indifferent electrode temperature rise in the tissues resected is only modest (40 to 70°C) than during monopolar surgery and the collateral spread is less^{30, 31}. The depth of penetration is more in monopolar resection when compared to bipolar resection.

Fig-5 MONOPOLAR

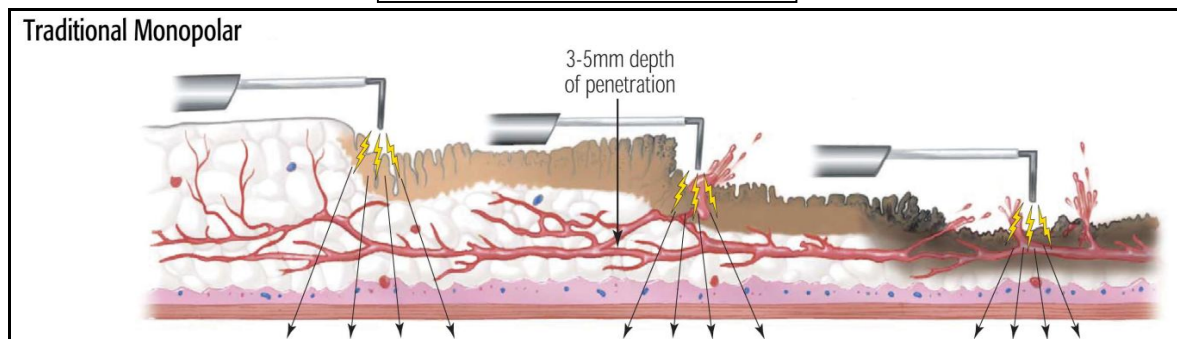
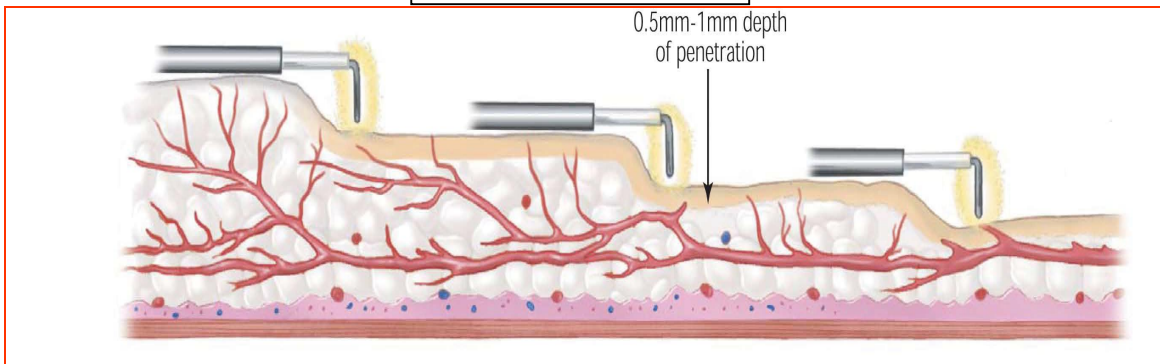


Fig-6 BIPOLAR



In reviewing the literature, one study conducted by Geavlete B et al³² comparing Bipolar energy and Monopolar energy for large non-invasive bladder tumours have shown that the Bipolar resection was superior in that the operation time, obturator nerve stimulation, hospital stay, bladder injury, hemolysis and post-operative bleeding was significantly lesser than the Monopolar resection.

Another study conducted by Meneghini A et al³³ noted that in Bipolar resections there were no thermal artefacts in resected specimens which substantially improved pathological interpretation through better evaluation of depth of muscle penetration, angiolymphatic invasion and adjacent mucosa.

In another study conducted by Gupta et al²⁹ comparing the Monopolar and Bipolar resection of Bladder tumours under low power setting have shown that there is reduction of complications like obturator jerks, bladder perforation and TUR syndrome.

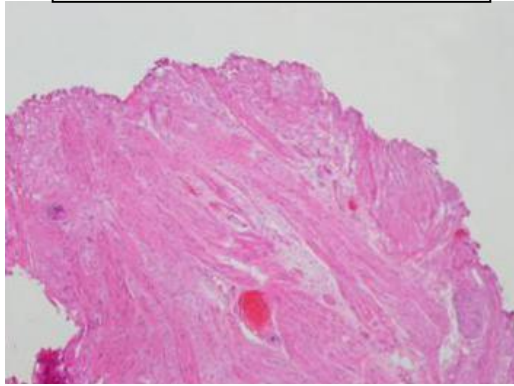
Yang SJ et al⁶ have shown that the complications are less with Bipolar resection of Bladder tumours in their study comparing the both. Also they noticed that there was no difficulty in histopathological evaluation of specimens resected using Bipolar energy. Bach T et al³⁴ in their study on Bipolar resection showed a decrease in resection time, decreased carbonisation of tissues and non-stickiness of the tissues to the loops.

Kihl et al¹⁴ reported in their study of 160 Monopolar TURBTs noted 10.6% incidence of adductor contraction. While McKiernan et al³⁵ in their series noted 11% incidence of adductor response during Monopolar resections. But in case of Bipolar resection of bladder tumours Wang et al⁷ in their series of 11 patients did not notice any obturator reflex during TURBT. Likewise Brunken et al³⁶ also did not notice any obturator nerve stimulation during their surgery.

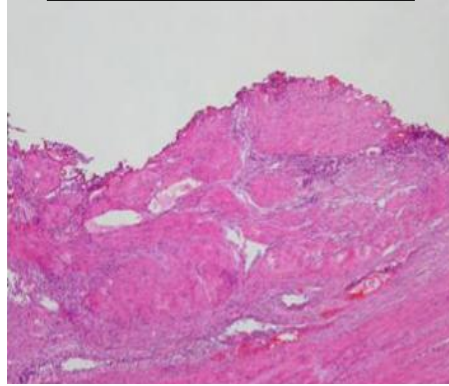
Thermal damage produced by the electrosurgery has been graded using the WHO Grading^{7, 44} system (Appendix-3). It has been graded into four grades according to the difficulty in identifying the cellular architecture and as the grade increases the more is the difficulty in identifying the tissue architecture.

WHO THERMAL DAMAGE GRADE

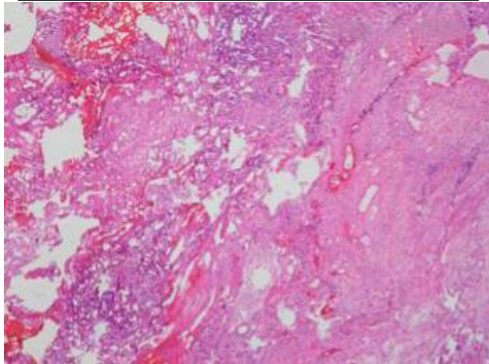
MONOPOLAR GRADE-1



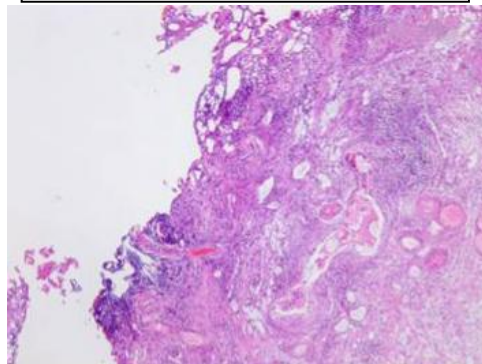
BIPOLAR GRADE-1



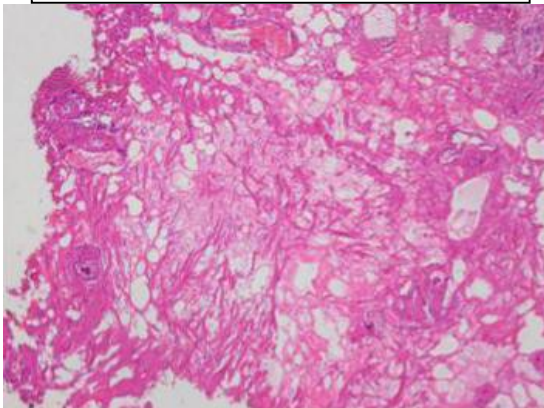
MONOPOLAR GRADE-2



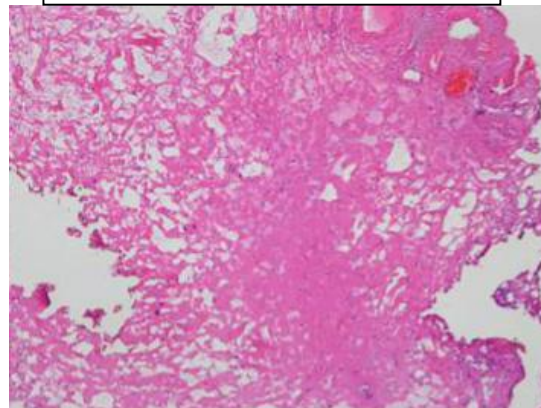
BIPOLAR GRADE-2



MONOPOLAR GRADE-3



BIPOLAR GRADE-3



So, with all these added benefits of the Bipolar energy, a study was conducted to evaluate the Safety and Efficacy of Bipolar energy source in TURBT in comparison to Monopolar TURBT and also to study the thermal artefacts produced by both the energy sources on resected specimens.

MATERIALS & METHODS

The following are the materials and methods employed for the present study titled “SAFETY AND EFFICACY OF BIPOLAR ENERGY FOR TRANSURETHRAL RESECTION OF BLADDER TUMORS”

Period of study:

The study is done between March 2012 and Feb 2013

Type:

This is a prospective study evaluating the safety and efficacy of bipolar energy in TURBT

Place:

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

Inclusion criteria

All patients diagnosed to have Bladder tumour by Ultrasonography, CECT and Cystoscopy

Exclusion criteria

- Patients with coagulopathy
- Seriously ill patients
- Tumours with perivesical extension and metastases
- Patients with elevated renal parameters

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-1). Patients were randomized into two groups of 50 each to undergo TURBT either Monopolar (Group 1) or Bipolar (Group 2). Patients either underwent Monopolar or Bipolar TURBT in Glycine and Saline respectively.

We used the Gyrus ACMI PK system and used PK thin loop for resection. The settings we employed were 160W cutting and 80W coagulation respectively for Bipolar resection. Martin ME MB2 monopolar system was used for Monopolar resection at the setting of 120W cutting and 60W coagulation.

The setup of instruments for Monopolar TUR resection is well known. But the setup for Bipolar TUR resection is essentially the same with certain modifications.

The working element is modified and has no shaft. There is a modified slot for engaging the Bipolar loop. The working element is provided with an adaptor so that it can fit into the regular resectoscope sheath. The Bipolar loop is also modified from the conventional Monopolar loop. It is much sturdier to compensate for the shaft which is absent in working element. The high frequency cable is integrated into the loop. So loop cannot be separated from the cable. There is also a leak proof wiser present in the shaft of the loop. The basic setup for bipolar resection is given in the figure below.

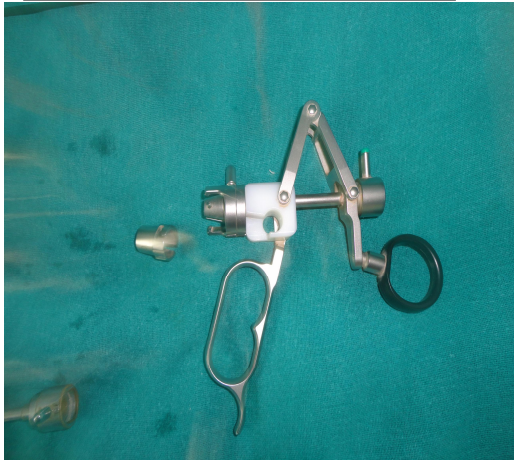
GYRUS ACMI PK SYSTEM



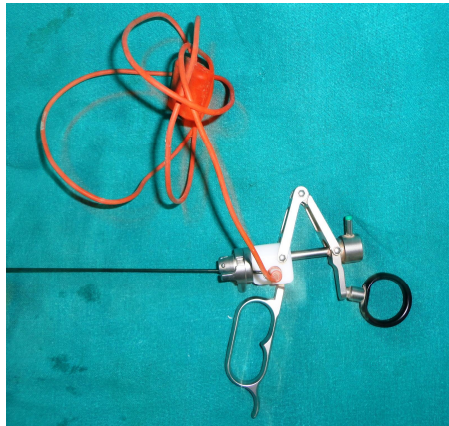
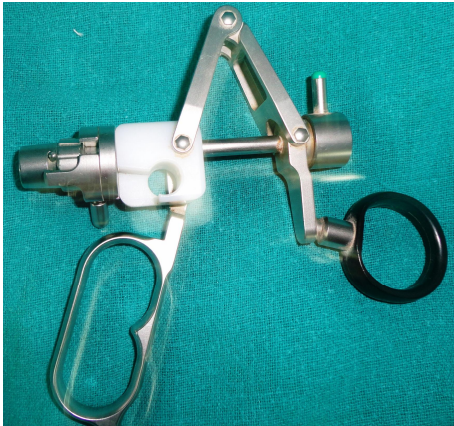
BASIC SET-UP



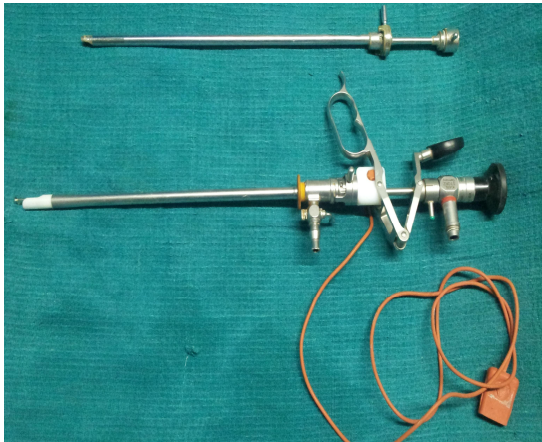
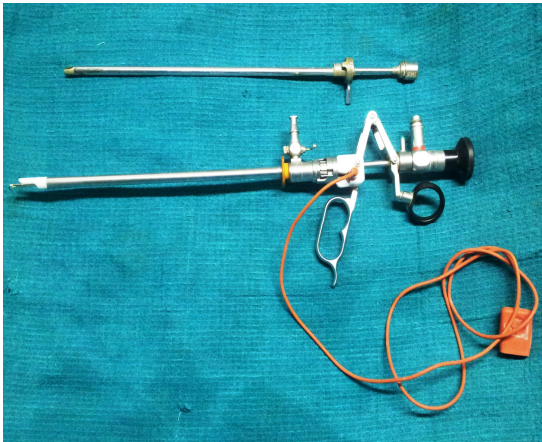
MODIFIED WORKING ELEMENT



TECHNIQUE TO ENGAGE THE LOOP



Fully Assembled Sheath



Preoperative workup

Exhaustive clinical history was taken from all patients. Co-morbid conditions like Hypertension and Diabetes Mellitus were documented.

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 the site, number, nature, size and to survey upper tracts. CECT KUB was done in all patients to note extravesical presence of urothelial tumours and to assess the loco-regional extent (Staging).

Procedure

All the resections were performed by our Senior Professor who was very experienced in performing TURBT. A 24-F Karl Storz non-continuous flow resectoscope was used with either glycine or saline irrigation for Monopolar TURBT (Group 1) and for Bipolar TURBT (Group 2).

All patients after exclusion criteria were subjected to either Monopolar or Bipolar TURBT. Spinal anaesthesia without any nerve block was used and patients underwent the procedure in Lithotomy position. Preliminary cystoscopy was done to assess the urethra, prostate gland, and the nature, size, location and multiplicity of bladder tumours. Using 24F non-continuous Karl Storz

resectoscope sheath and Baumrucker type active working element TURBT was performed in both groups.

Tumour resection was done in a step by step manner starting from the summit of the tumour so as to deflorate reaching the stalk or the base. Once the base was resected, the underlying muscle was resected separately. The two specimens superficial and deep were put in separate containers and sent for histopathological examination. After completion of the procedure all the bleeding points were coagulated and hemostasis secured. We routinely used a 22Fr three way Foley catheter for drainage and irrigation. Irrigation with saline was given for first 12hours or till clear urinary drainage was seen.

The resection time was calculated from the period of initiation of resection to the removal of resectoscope sheath. For every patient, resection time, volume of irrigation, obturator jerks, perforation, TUR syndrome, Post-operative Hemoglobin, sodium, dry specimen weight and catheterization period were recorded. Patients were discharged on the day of catheter removal.

We sent the specimens to our pathology department in two separate containers labelled as Superficial and Deep on the containers. It was processed and examined by a Senior professor in pathology. Tumours were examined for histology, invasion of Lamina or Detrusor. Additionally specimens were

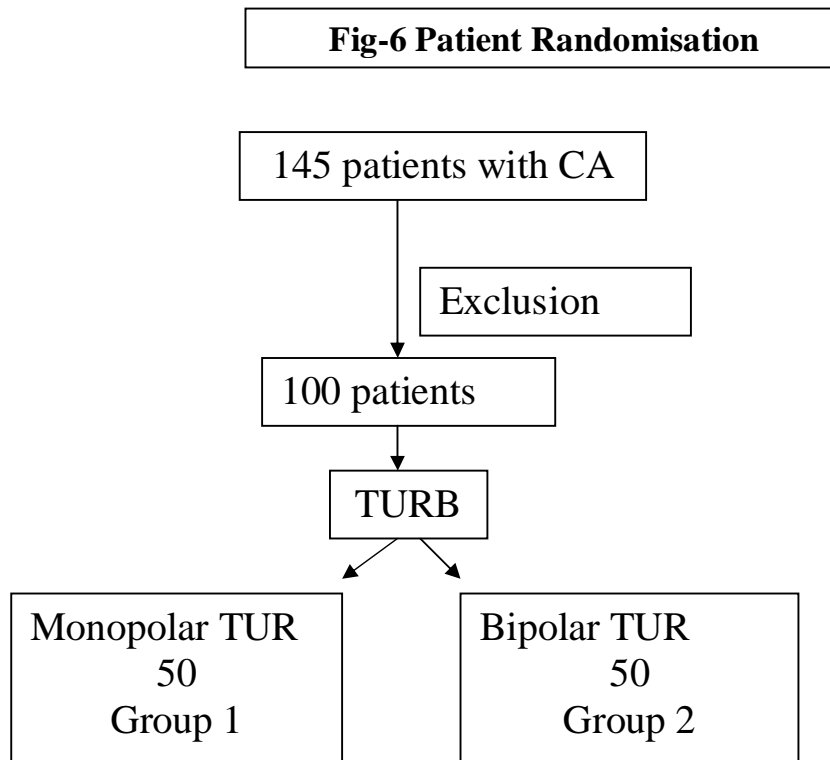
assessed for thermal artefacts produced by both Monopolar and Bipolar energy sources as per WHO grading .

WHO Thermal Injury Grading

Degree of thermal damage	Characterization
0	No thermal damage
1	Lowest grade of thermal artifacts. The cellular structure is identifiable and not impaired
2	Medium grade. Cellular structure and nuclei are impaired, but still identifiable
3	High grade artifacts. Complete loss of the cellular structure. No differentiation of the cellular parts

OBSERVATION AND RESULTS

As a whole 145 patients underwent TURBT for bladder tumour during the study period. Out of these 145 patients, 45 patients were excluded from the study due to various reasons like locally advanced disease as detected by CECT, elevated renal parameters and anticoagulants use which could not be withdrawn for medical reasons. So, after excluding these 45 patients, rest underwent TURBT either with Monopolar or Bipolar energy (Fig-6).



Pre-operative parameters of both Group 1 and Group 2 are presented in Table 1 and 2 respectively.

Table-1 Patient and Tumour Demography (M-TURBT)

Variable	Value
Total number of patients, n	50
Male	45(90%)
Female	05(10%)
Age(years)	
Mean± SD	58.2± 8.45
Range	40-76
Smoking, n(%)	37(74%)
Comorbidities, n	
Diabetes	14(28%)
Hypertension	17(34%)
Tumour number, n	50
Single	46(92%)
Multiple	04(8%)
Location, n	
Lateral Wall	29(58%)
Posterior wall	02(4%)
Anterior Wall	01(2%)
Trigone	14(28%)
Dome	07(14%)

Table-2 Patient and Tumour Demography (B-TURBT)

Variable	Value
Total number of patients, n	50
Male	44(88%)
Female	06(12%)
Age(years)	
Mean± SD	56.5± 10.4
Range	32-80
Smoking, n(%)	35(70%)
Comorbidities, n	
Diabetes	15(30%)
Hypertension	18(36%)
Tumour number, n	50
Single	45(90%)
Multiple	05(10%)
Location, n	
Lateral Wall	39(78%)
Posterior wall	03(6%)
Anterior Wall	02(4%)
Trigone	10(20%)
Dome	04(8%)

Group 1(M-TURBT)

In whole, 50 patients with Bladder tumours were subjected to Monopolar resection. There were tumours in 45 men and 5 women. Age range of the patients was between 40 and 76yrs with a mean of 58.2 ± 8.45 yrs. History of tobacco abuse in the form of smoking/chewing was present in 37(74%) patients. Comorbidities were present either in the form of Diabetes in 14(28%) or Hypertension in 17(34%). When the tumour multiplicity was considered, 4(8%) patients had multifocal disease and remainder 46 (92%) patients had solitary lesions. The distribution of the tumour was 31 in the lateral wall, 1 in anterior wall, 14 in trigone and 7 in dome.

Mean \pm SD tumour size was 20.6 ± 7.5 mm. The Mean drop in PCV after the procedure was 2.38 ± 0.83 . The Mean drop in sodium after the procedure was 3.2 ± 1.76 mEq/L with no patient developing TUR syndrome. The mean time to resect the tumours was 24.84 ± 4.75 mins. Perforation of the bladder was noted in 3 cases. There were totally 10 patients having Obturator jerks in all of 50 patients, either occurring singly or multiple times in a same patient (20%) with a mean of 0.32. The mean specimen weight was 1.52 ± 0.47 gms. We discharged the patient once the hematuria via Foley settled and on the day of catheter removal. So the mean hospitalization after the procedure was 2.56 ± 1.88 days. When the thermal artefact grade was analysed the mean grade was 1.42 (Table 3).

Table-3 Intraoperative and Post-operative parameters (M-TURBT)

Monopolar	N	Mean	Std. Dev	Min	Max	1st Quartile	Median	3rd Quartile
Difference in PCV(%)	50	2.38	0.83	1.0	4.0	2.0	2.0	3.0
HEMOGLOBIN DEFICIT(gms%)	50	0.42	0.23	0.1	1.2	0.2	0.4	0.6
SODIUM DEFICIT(meq/l)	50	3.20	1.76	1.0	8.0	2.0	3.0	4.0
RESECTION TIME(mins)	50	24.84	4.75	14.0	38.0	21.8	25.0	26.3
OBTURATOR JERK	50	0.32	0.71	0.0	3.0	0.0	0.0	0.0
SPECIMEN WEIGHT (gms)	50	1.52	0.47	1.0	3.0	1.0	1.5	2.0
THERMAL ARTEFACT GRADE	50	1.42	0.70	0.0	2.0	1.0	2.0	2.0

The Histopathological examination of the tissue specimens yielded a diagnosis of Transitional Cell Carcinoma in 48 patients. Out of this 48 transitional cell carcinoma Papillary histology was found in 17, Low-grade T1 in 16, High-grade T1 in 12 and Muscle invasive in 3 specimens. The histopathology of two specimens turned out to be Adenocarcinoma and Squamous Cell Carcinoma one in each respectively. All the specimens were examined and reported without any difficulty.

Forty eight patients received post operative instillation of Mitomycin-c within 6hours. Twelve patients received induction dose of intravesical BCG and five patients were subjected to Radical Cystectomy. Out of this five patients, 3 had

detrusor invasion, 1 had Squamous Cell Carcinoma and 1 had Adenocarcinoma (Table-4)

Table-4 Histopathology (M-TURBT)

Variable	N
Stage	50
Ta	17(34%)
T1 Low grade	16(32%)
T1 High grade	12(24%)
T2	03(6%)
Histopathology	
TCC	48(96%)
Adenocarcinoma	01(2%)
SCC	01(2%)
Intravesical Therapy	
Mitomycin-c	48
BCG	12
Radical Cystectomy	05

Group 2(B-TURBT)

In whole, 50 patients with Bladder tumours were subjected to Bipolar resection. There were tumours in 44 men and 6 women. Age range of the patients was between 32 and 80yrs with a mean of 56.5±10. History of tobacco abuse in the form of smoking/chewing was present in 35 (70%) patients. Co-morbidities were present either in the form of Diabetes in 15 (30%) or

Hypertension in 18 (36%). When the tumour multiplicity was considered 5(10%) patients had multifocal disease and remainder 46 (92%) patients had solitary lesions. The distribution of the tumour was 42 in the lateral wall, 2 in anterior wall, 10 in Trigone and 4 in dome.

Mean \pm SD tumour size was 21.68 ± 7.64 mm. The Mean drop in PCV after the procedure was 1.22 ± 0.46 . The Mean drop in sodium after the procedure was 3.02 ± 1.67 mEq/L with no patients developing TUR syndrome. No Perforation of the bladder was noted. The mean resection time was 33.72 ± 2.36 mins.

There were totally 4 patients having Obturator jerks in all the 50 patients (8%) with a mean of 0.08. The mean weight of the resected specimen was 1.69 ± 0.60 gms. When we analysed the thermal artefacts the mean approached 0.54. We discharged the patient once the hematuria via Foley settled and on the day of catheter removal. So the mean hospitalization after the procedure was 2.1 ± 0.36 days (Table 5).

Table-5 Intraoperative and Post-operative parameters (B-TURBT)

Bipolar	N	Mean	Std. Dev	Min	Max	1st Quartile	Median	3rd Quartile
Difference in PCV(%)	50	1.22	0.46	1.0	3.0	1.0	1.0	1.0
HEMOGLOBIN DEFICIT(gms%)	50	0.37	0.20	0.1	0.8	0.2	0.4	0.6
SODIUM DEFICIT(meq/l)	50	3.02	1.67	1.0	7.0	2.0	2.0	4.0
RESECTION TIME(mins)	50	33.72	2.36	30.0	40.0	32.0	34.0	35.0
OBTURATOR JERK	50	0.08	0.27	0.0	1.0	0.0	0.0	0.0
SPECIMEN WEIGHT (gms)	50	1.69	0.60	1.0	3.0	1.1	1.5	2.0
THERMAL ARTEFACT GRADE	50	0.54	0.68	0.0	2.0	0.0	0.0	1.0

The Histopathological examination of the tissue specimen yielded a diagnosis of Transitional Cell Carcinoma in 49 patients. Out of this 49 transitional cell carcinoma Papillary histology was found in 23, Low-grade T1 in 16, High-grade T1 in 08 and Muscle invasive in 2 specimens. The histopathology of one specimen turned out to be Squamous Cell Carcinoma. All the specimens were examined and reported without any difficulty.

Forty nine patients received post operative instillation of Mitomycin-c within 6hours. Eight patients received induction dose of intravesical BCG and three

patients were subjected to radical Cystectomy. Out of this three, 2 had detrusor invasion and 1 had Squamous Cell Carcinoma.

Table-6 Histopathology(B-TURBT)

Variable	N
Stage	50
Ta	23(46%)
T1 Low grade	16(32%)
T1 High grade	08(16%)
T2	02(4)%
Histopathology	
TCC	49(98%)
Adenocarcinoma	00
SCC	01(2%)
Intravesical Therapy	
Mitomycin-c	49
BCG	08
Radical Cystectomy	03

Thermal Artefact

Thermal artefacts were graded according to WHO grading system (Appendix 3). There was no difficulty noticed during histopathological examination of resected specimens.

In Monopolar group, there were 27(54%) grade 2 thermal damage, 17(34%) grade 1 thermal damage and no grade-3 thermal damage in examined specimen.

In Bipolar group, there were 07(14%) grade 2 thermal damage, 12(24%) grade 1 thermal damage and no grade 3 thermal damage in examined specimen

Table-7 WHO Thermal Damage Grading³⁹

	M-TURBT	B-TURBT
Grade 0 (%)	6(12%)	31(62%)
Grade 1 (%)	17(34%)	12(24%)
Grade 2 (%)	27(54%)	07(14%)
Grade 3 (%)	0	0

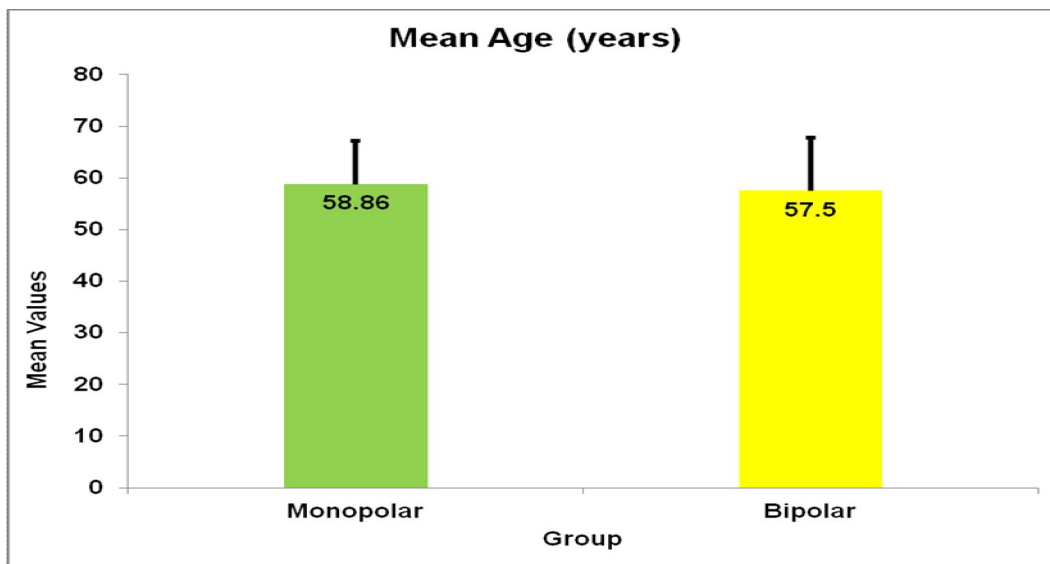
Complications

Three patients in Monopolar group had bladder perforation. Two of them were extraperitoneal and were managed by prolonged catheter drainage. One patient underwent exploratory laparotomy and closure of the perforation. None of the patients in the bipolar group had perforation and no patient in either group required blood transfusion or developed TUR syndrome.

Comparative Statistical analysis of M-TURBT & B-TURBT

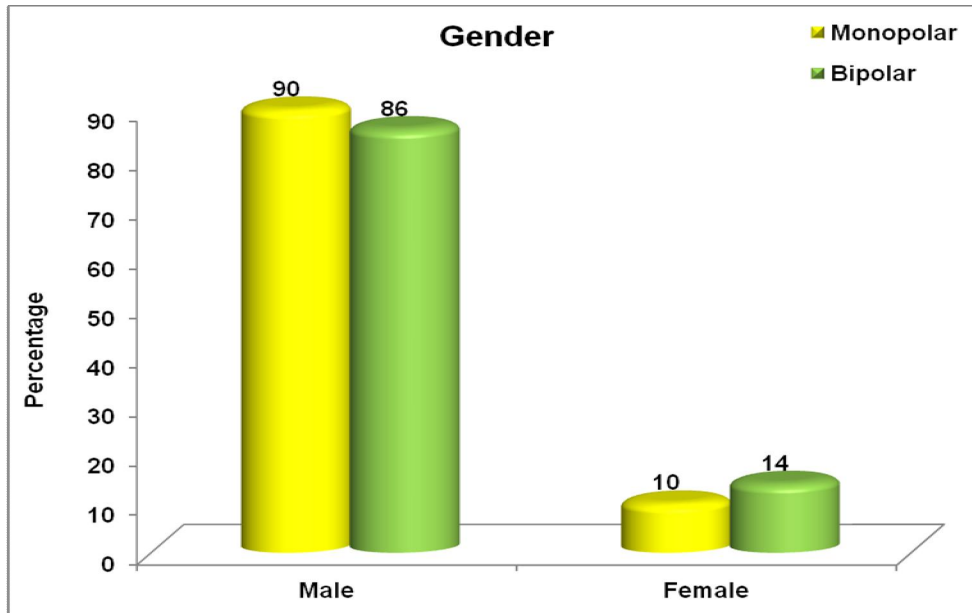
The comparison of mean values of continuous and categorical variables was done using the Student's t-test and the chi-square test respectively. If the p value is <0.05, the result is considered statistically significant.

The mean age of the patients in both M-TURBT and B-TURBT was comparable and when analysed statistically did not reach significance (p=0474).



Variable	Group	N	Mean	Std. Deviation	P-Values
Age (years)	Monopolar	50	58.86	8.45	0.474
	Bipolar	50	57.50	10.38	

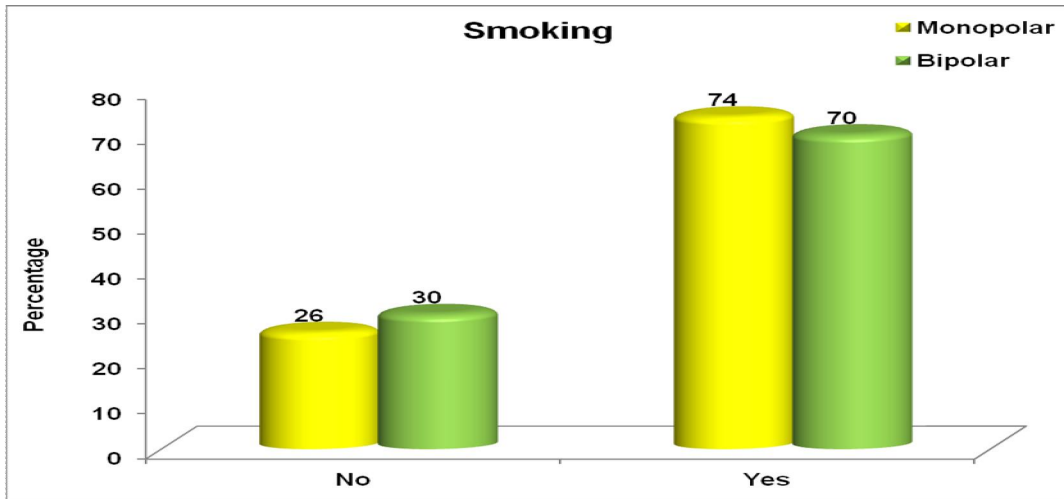
The both the groups were comparable in the distribution of sexes and analysis did not reveal any statistical difference($p=0.538$).



Gender	Group				Total	
	Monopolar		Bipolar		N	%
	N	%	N	%		
Male	45	90.0	43	86.0	88	88.0
Female	5	10.0	7	14.0	12	12.0
Total	50	100.0	50	100.0	100	100.0

Chi-Square Tests	P-Value
Pearson Chi-Square	0.538

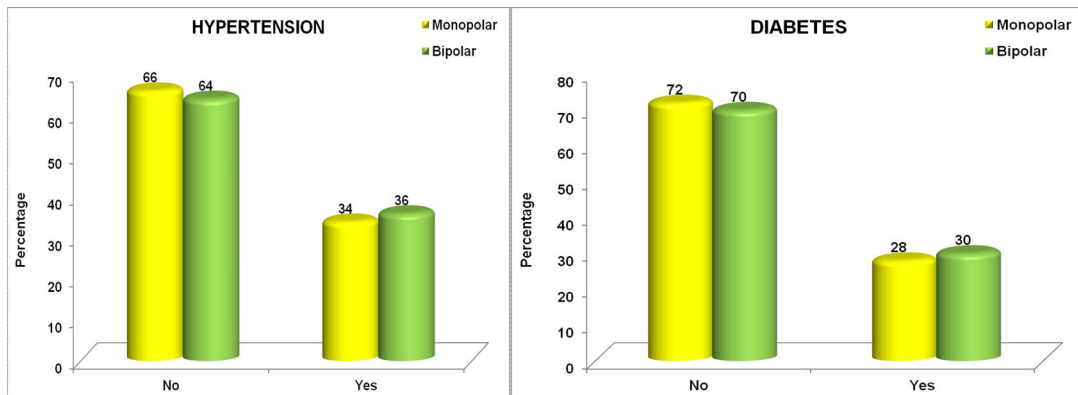
The association of smoking with bladder cancer was also assessed. Eventhough there was high incidence of tobacco abuse within each group there was no statistically significant difference between the two groups($p=0.656$).



Smoking	Group				Total	
	Monopolar		Bipolar		N	%
	N	%	N	%		
No	13	26.0	15	30.0	28	28.0
Yes	37	74.0	35	70.0	72	72.0
Total	50	100.0	50	100.0	100	100.0

Chi-Square Tests	P-Value
Pearson Chi-Square	0.656

The co-morbidities associated with bladder cancer were also studied and both the groups were comparably matched without any statistical difference.



HYPERTENSION	Group				Total	
	Monopolar		Bipolar		N	%
	N	%	N	%		
No	33	66.0	32	64.0	65	65.0
Yes	17	34.0	18	36.0	35	35.0
Total	50	100.0	50	100.0	100	100.0

Chi-Square Tests	P-Value
Pearson Chi-Square	0.834

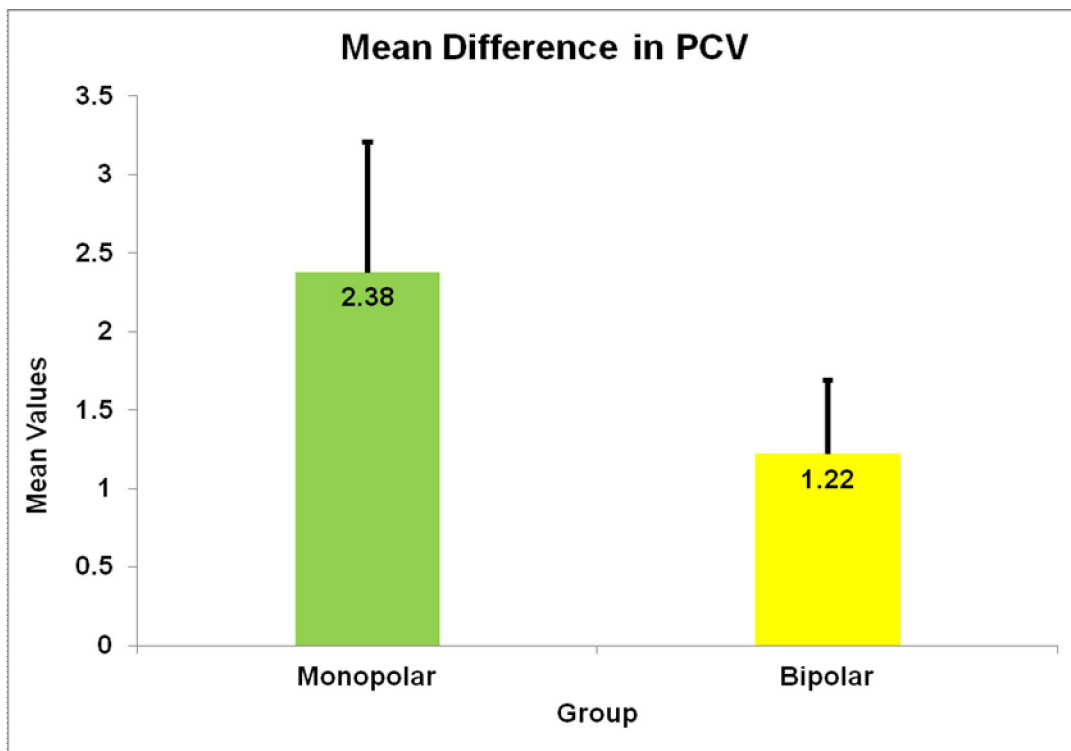
DIABETES	Group				Total	
	Monopolar		Bipolar		N	%
	N	%	N	%		
No	36	72.0	35	70.0	71	71.0
Yes	14	28.0	15	30.0	29	29.0
Total	50	100.0	50	100.0	100	100.0

Chi-Square Tests	P-Value
Pearson Chi-Square	0.826

Most important of all, the means of variables were compared between the two energy sources to know the difference between them and its significance. The results of the t-test are given below. The packed cell volume (PCV), resection time, obturator jerks and thermal artefact grades had significant values.

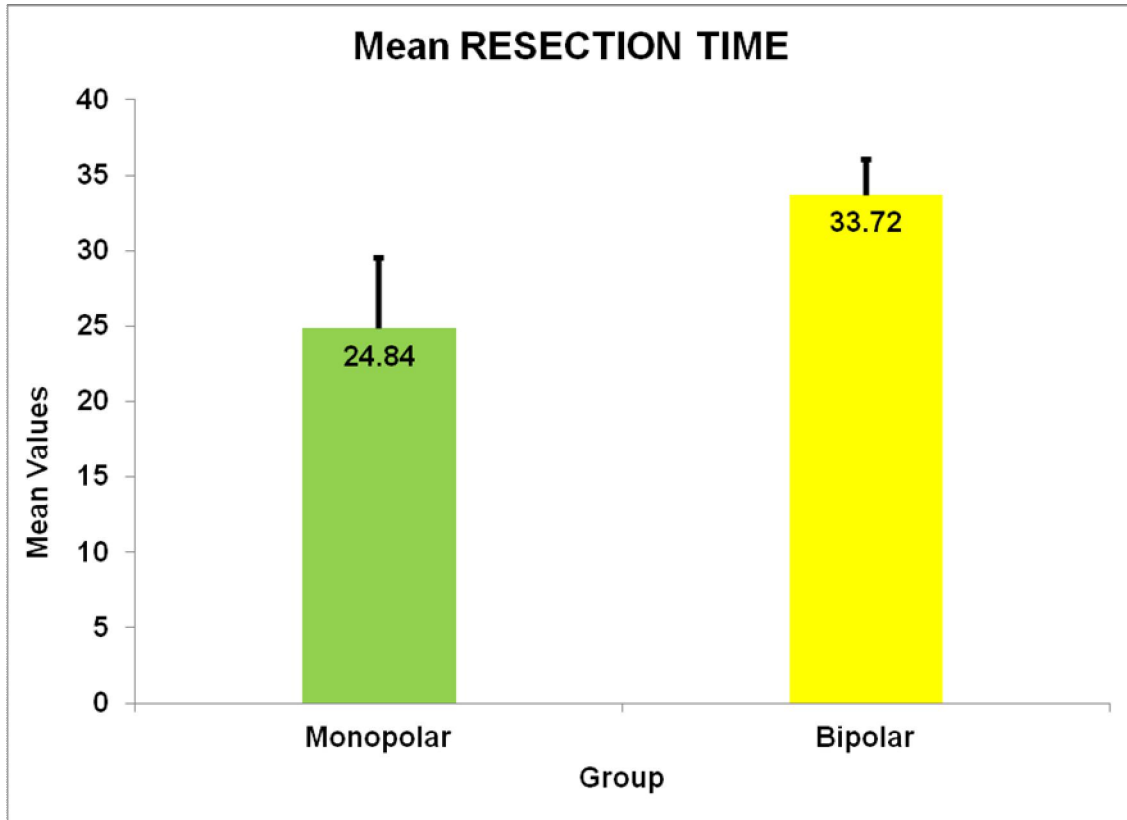
The difference in PCV was much lesser in Bipolar group than Monopolar (p=0.001).

Variable	Group	N	Mean	Std. Deviation	P-Values
Difference in PCV	Monopolar	50	2.38	0.83	0.001
	Bipolar	50	1.22	0.47	



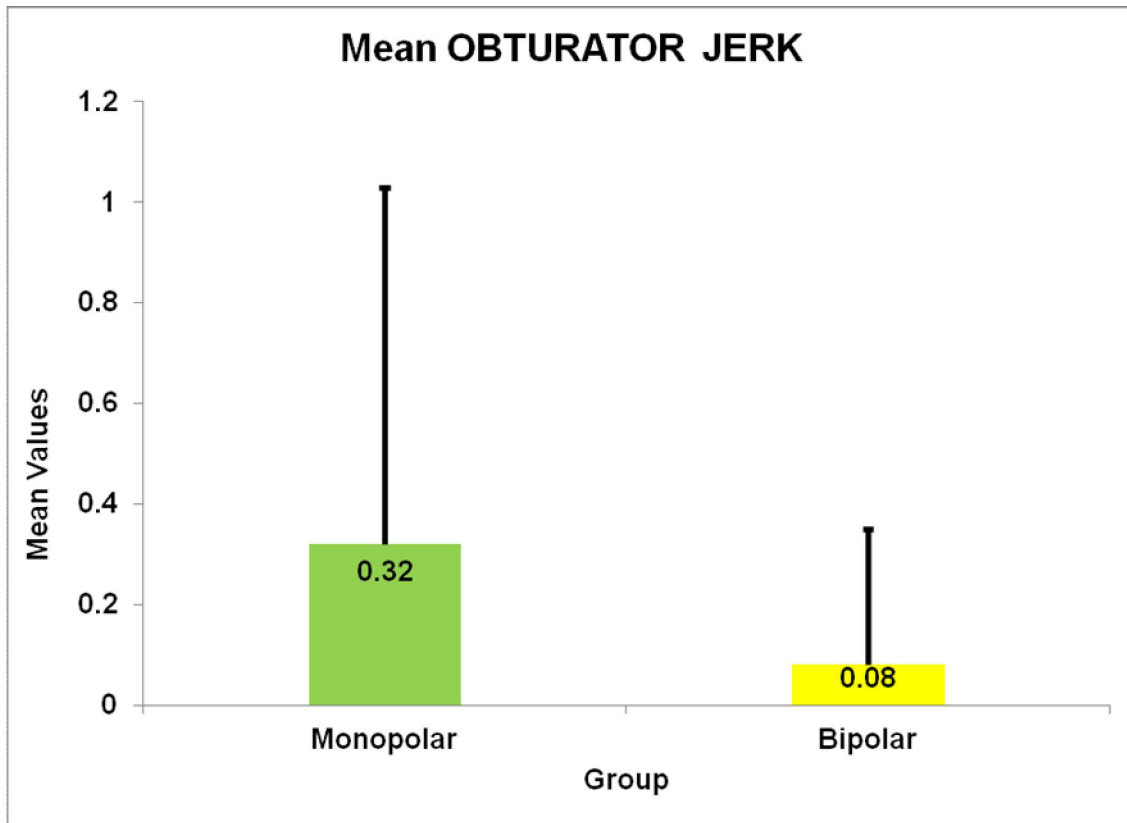
The resection time between groups also reached significance with prolonged time in Bipolar (p=0.001).

Variable	Group	N	Mean	Std. Deviation	P-Values
RESECTION TIME	Monopolar	50	24.84	4.75	0.001
	Bipolar	50	33.72	2.36	



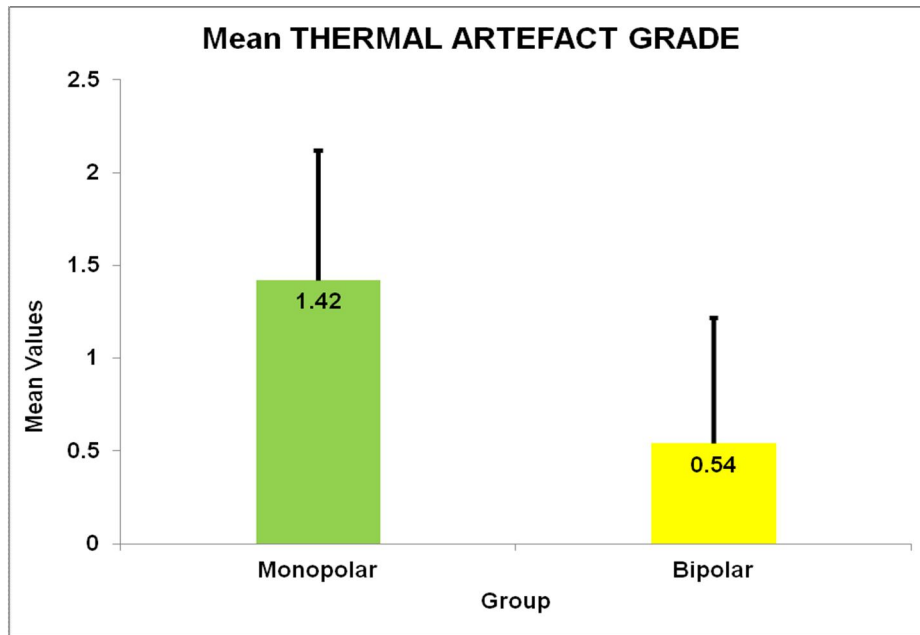
The obturator jerks were more in Monopolar group with statistically significant values ($p=0.029$)

Variable	Group	N	Mean	Std. Deviation	P-Values
OBTURATOR JERK	Monopolar	50	0.32	0.71	0.029
	Bipolar	50	0.08	0.27	



Likewise when analysing the thermal damage it was seen that there were more artefacts in Monopolar group($p=0.001$)

Variable	Group	N	Mean	Std. Deviation	P-Values
THERMAL ARTEFACT GRADE	Monopolar	50	1.42	0.70	0.001
	Bipolar	50	0.54	0.68	



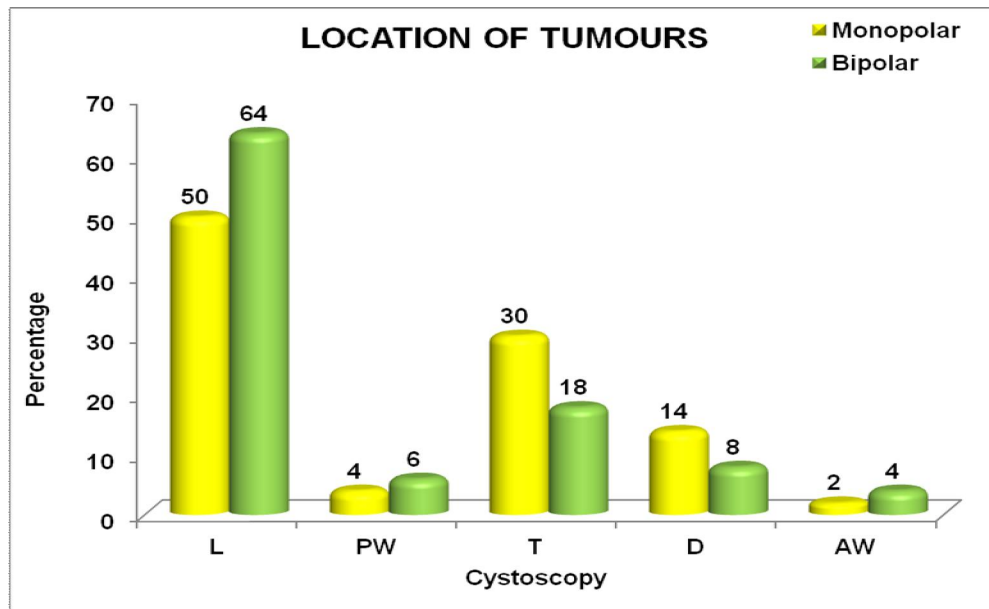
The haemoglobin deficit, sodium deficit and resection specimen weight between the groups did not reach statistical significance even though there was difference in the values.

Variable	Group	N	Mean	Std. Deviation	P-Values
HEMOGLOBIN DEFICIT	Monopolar	50	0.42	0.23	0.248
	Bipolar	50	0.37	0.20	
SODIUM DEFICIT	Monopolar	50	3.20	1.76	0.601
	Bipolar	50	3.02	1.67	
SPECIMEN WEIGHT (gms)	Monopolar	50	1.52	0.47	0.107
	Bipolar	50	1.69	0.60	

When the location of the tumours were compared between the two groups there was no difference ($p=0.435$).

LOCATION OF TUMOURS	Group				Total	
	Monopolar		Bipolar			
	N	%	N	%	N	%
L	25	50.0	32	64.0	57	57.0
PW	2	4.0	3	6.0	5	5.0
T	15	30.0	9	18.0	24	24.0
D	7	14.0	4	8.0	11	11.0
AW	1	2.0	2	4.0	3	3.0
Total	50	100.0	50	100.0	100	100.0

Chi-Square Tests	P-Value
Fisher's Exact Test	0.435



DISCUSSION

Bladder malignancy is the fourth and eighth common tumour in men and women respectively¹. It accounts for 145,000 deaths worldwide. There has been an upsurge in the frequency of bladder cancer in Asia because of increased prevalence of smoking. Most common histological subtype worldwide is Urothelial carcinoma except for Egypt where there is higher incidence of Squamous cell carcinoma due to the endemicity of Schistosomiasis. Mean age of presentation is 70yrs in both the sexes and there is a progressive increase in the incidence and death with advancing age¹⁵.

Overall Urothelial carcinoma is the commonest cancer of the urinary tract and stands second in position next only to Renal cell carcinoma leading to death in genitourinary tumors. About 80% of Urothelial tumors are diagnosed early in patients when still the tumour is superficial and non-muscle invasive¹⁵.

The most important fact when dealing with Bladder tumours is that they tend to recur and progress. The important variables that should be considered in the risk stratification of the patients should include tumour multifocality, size, grade, stage, CIS and history of previous recurrence¹⁸.

It is proven that Grade of the tumour is more important in predicting the prognosis rather than stage in Urothelial cancers. The size of the tumour,

multifocality, nature of the tumour (Sessile vs Pedunculated) and the presence or absence of angiolymphatic permeation also determines the prognosis³⁷.

Worldwide there are cultural and environmental differences in the nature of food, degree of exposure and the presence or absence of susceptibility genes for carcinogenesis and this factor could contribute to recurrence¹⁶.

The TNM system which is commonly used for most tumours is also used for Bladder cancer staging. Elsewhere, TNM staging includes size and multiple natures of the tumours for staging. But in Urothelial tumours of the Bladder the 'T' stage is determined by the depth of penetration rather than size and multifocality. Tumor size and multiplicity are not included in the TNM staging of bladder cancer. But without question size and multifocality are important prognosticators³⁸.

When cystoscopy is performed for Bladder cancer, it is prudent to record the location, size, number, and nature of the tumors. Contrast imaging is done to stage the disease and to survey the upper tracts since one of the theories behind the pathology of Urothelial carcinoma is "Field change cancerisation"¹⁷. The primary treatment for visible lesion is transurethral resection of bladder tumor (TURBT).

In 1910 Beer was the first to do an endoscopic resection of bladder tumour. Since then TURBT has remained the basic diagnostic and often therapeutic tool

for Bladder tumours⁸. Conventionally, Monopolar loop resection of the Bladder tumours have been and are being done using non-conducting irrigation solutions such as sterile water, 1.5% glycine and other alternative fluids. Sterile water has many advantages for an optimal irrigant such as better field of vision, cheap and non-conducting. But there is some amount of water intravasation into blood circulation which can lead to osmotic lysis of red cells and dilutional hyponatraemia³⁹. So to reduce this effect but not exclude non-hemolytic solutions are being used. But even these irrigants are not isotonic, so the incidence of hyponatremia still exists. But these irrigants for monopolar comes at a cost.

Saline is safer than water in many ways in it, that it is physiological, has equivalent visibility comparable to water, less expensive, isosmotic with plasma and is considered as the irrigant of choice for endoscopic procedures. But this irrigant cannot be used in Monopolar resections as the current will be carried by the saline without any tissue effect⁴⁰. With technological advance, invention of Bipolar electrosurgery, it became possible to use physiological solution such as Saline for resection.

Bipolar electroresection in Saline for the above mentioned reasons avoids the risk of TUR syndrome. This is mainly because even if large amounts of Saline is absorbed, it is isotonic and does not lead to dilutional Hyponatremia⁴¹.

Whenever transurethral resection is being done, the tissue venous and lymphatic channels are opened up and since the irrigation is done under positive pressure it is understood that irrigant is bound to enter into these channels, thereby leading to aforementioned complications. The degree of absorption of fluid is dependent upon many factors. The height of the irrigant, surface area of resected area, resection time, type of the irrigant used and of course the number of venous channel opened.

In a study conducted by Hahn et al regarding endoscopic resection of Bladder tumours, using Monopolar energy (M-TURBT) first reported the incidence of TUR syndrome in four patients. Subsequently, there are few literatures in published literature reporting the syndrome with an average incidence of 2% Monopolar TURBT⁴². But when it comes to Bipolar TURBT there is even lesser number of studies reporting the incidence of TUR syndrome.

In our study if we take the incidence of TUR syndrome, even though there was a biochemical evidence of minor drop in the level of sodium in M-TURBT, none of the patients had symptoms of Dilutional Hyponatremia. Moreover the statistical analysis of the difference in the sodium levels did not reach significance ($p=0.30$). When we consider the incidence in B-TURBT, even though there were minor alterations in the sodium levels, none of the patients developed symptomatic TUR syndrome. When we compared the mean sodium

drop between Monopolar and Bipolar TURBT, it did not reach statistical significance ($p=0.601$). This seems to be due to the less venous channels opened during resection in comparison to TURP and the resection time is much shorter than for TURP. So whatever energy source is used the incidence of TUR syndrome seems to be negligible.

When it comes to the incidence of obturator jerks, it is much lesser in Bipolar resections compared to Monopolar resections. In a study comprising of 160 resections, Kihl et al reported obturator jerks in 10.6% of cases employing Monopolar energy¹⁴. Another similar study by McKiernan et al. notified obturator reflex in 11% of their patients using Monopolar energy³⁵.

In our study, the incidence of obturator jerks in Monopolar TURBT was 20% and the incidence of jerk in Bipolar TURBT was 8%. But the number of jerks was more in Monopolar group and occurred more number of times in some patients. All the jerks noted in Bipolar group were single. When we analyzed the two group there was a statistically higher incidence of jerks in M-TURBT ($p=0.029$).

In a study conducted by Wuand et al using Bipolar TURBT at a power setting of 160watts for cutting and 80watts for coagulation mode employing 121 patients reported an overall complication rate of 13.2%, with 2.5% patients

developing significant haematuria mandating blood transfusion, 1.7% incidence of bladder perforation and 4.9% incidence of obturator jerks⁴³.

If we consider our study, we also used the same settings none of our patients needed transfusion for, none had bladder perforation and we noticed obturator jerks in 8%. We noticed that the jerks were common when the tumour was located in the lateral walls and all of them occurred during the initial activation of the loop. None of the jerks occurred during the actual resection. Similarly, a study conducted by Gupta et al using low power settings, have noticed a decrease number of jerks and also the jerks were noticed during the activation of the loop²⁹.

One of the quoted advantages in literature is that, there is lesser degree of carbonisation and darkening while resecting bladder tumours employing Bipolar energy which allows excellent visualization of the residual tumour tissue after resection allowing complete resection²⁹.

The specimen after resection from B-TURBT is comparable from a histological point of view to that obtained using M-TURBT, with few advantages of the Bipolar resection specimens showing lesser thermal damage. Yang SJ et al have done a study to assess the deep tissue damage comparing Monopolar and Bipolar TURBT and did not find any difficulty in histopathological diagnosis between both energy sources⁶. When we examined our specimens, there was

increased number and degree of artefacts noticed in Monopolar resections than bipolar resections when graded using WHO grading (Appendix 3). But grade-3 thermal artefact was not noticed in both M-TURBT and B-TURBT. All the artefacts noticed in the B-TURBT were Grade-1 and most of the M-TURBT specimens showed grade-2 artefacts. On statistical analysis it was shown that Bipolar is superior in preserving the cytoarchitecture ($p=0.001$)

When operating on high risk group like patients with pacemakers, cardiac diseases, unstable angina and patients with decreased pulmonary reserve it is shown that bipolar resection is much safer than Monopolar resection²⁹.

When the resection time was considered, the mean resection time was more with the use of Bipolar energy($p=0.001$) which was statistically significant. This may be explained from the fact that the formation of plasma on activation of the loop has a lag period of few milliseconds, which is experienced by the surgeon in reality. Secondly, slower the loop is moved, better is the hemostasis. To gain on the hemostatic effect of the bipolar energy, it is accepted to lose time during resection. Third factor is that, the surgeon has the tendency to go easy during resection since he is already aware that saline is being used.

CONCLUSION

The conclusions that can be drawn from this study are

- Bipolar resection of Bladder tumours have lower incidence of complications especially bleeding, TUR syndrome, obturator jerks and bladder perforation.
- The degree of thermal damage is much lesser in histological sections and interpretation of the grade which is one of the most important prognosticators especially in bladder tumours since high grade lesions are proven beyond doubt to progress and recur.
- Bipolar TURBT is safe and efficacious in managing bladder tumours.

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APPENDIX-1

PROFORMA

Safety and efficacy of bipolar energy in Transurethral resection of bladder tumours

Name
Age
Sex
Hospital NO

Smoking/Tobacco
DM/HTN/TB
Previous Surgery

Ultrasound KUB

	Right	Left
Kidney		
Bladder		
Prostate		

Pre-op haemoglobin
Post-op haemoglobin
Difference in hemoglobin

Pre-op electrolytes

Na⁺

K⁺

Cl⁻

Post-op electrolytes

Na⁺

K⁺

Cl⁻

CECT KUB

Site

Size

Number

Sessile/ Pedunculated

Lymphnode

Upper Tracts

Cystoscopy

Site

Size

Number

Sessile/ Pedunculated

TURBT

Monopolar/bipolar

Resection time

Resected specimen weight

Obturator reflex

Irrigant Glycine/saline

Irrigation volume

TUR syndrome

Bladder perforation

HPE

APPENDIX-2

INFORMED CONSENT FORM

Title of the study: “ **Safety and efficacy of bipolar energy in Transurethral resection of bladder tumours**”

Name of the Participant:

Name of the Principal (Co-Investigator): Dr. Vasudevan T

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 **the study on “Safety and efficacy of bipolar energy in Transurethral resection of bladder tumours”**

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 _____

ஆராய்ச்சி ஒப்புதல் கடிதம்

சிறுநீரகப்பை புற்றுநோய் அறுவை சிகிச்சை முடிவு குறித்த விவரங்களை சேகரிக்கும் ஆராய்ச்சி

பெயர் :

தேதி :

வயது :

உள்நோயாளி எண் :

பால் :

ஆராய்ச்சி சேர்க்கை எண் :

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கம் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு எனது சம்மதத்தை தெரிவிக்கிறேன்.

எனது சிறுநீரகப்பை புற்றுநோய் அறுவை சிகிச்சை முடிவுகள் மற்றும் ஆராய்ச்சிக்கு தேவையான அணைத்து விவரங்களையும் தெரியபடுத்துவதற்கு முழு சம்மதம் தெரிவிக்கிறேன்.

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

சிறுநீரகப்பை புற்றுநோய் 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

சிறுநீரகப்பை புற்றுநோய் அறுவை சிகிச்சை முடிவு குறித்த விவரங்களை சேகரிக்கும் ஆராய்ச்சி

தங்களின் சிறுநீரகப்பை புற்றுநோய் அறுவை சிகிச்சை குறித்த விவரங்கள் பெற்றுகொள்ளப்பட்டது.

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

சிறுநீரகப்பை புற்றுநோய் 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

Appendix-3

WHO THERMAL DAMAGE GRADE

Degree of thermal damage	Characterization
0	No thermal damage
1	Lowest grade of thermal artifacts. The cellular structure is identifiable and not impaired
2	Medium grade. Cellular structure and nuclei are impaired, but still identifiable
3	High grade artifacts. Complete loss of the cellular structure. No differentiation of the cellular parts

APPENDIX-4

ETHICAL COMMITTEE APPROVAL FORM

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. T. Vasudevan
PG in MCH Urology
Madras Medical College, Chennai -3

Dear Dr. T. Vasudevan

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled " Safety and efficacy of bipolar energy for transurethral resection of bladder tumours" No.19032012.

The following members of Ethics Committee were present in the meeting held on 22.03.2012 conducted at Madras Medical College, Chennai -3.

- | | |
|--|---------------------|
| 1. Prof. S.K. Rajan. MD | -- Chairperson |
| 2. Prof. Pregna B. Dolia MD
Vice Principal, Madras Medical College, Chennai -3
(Director , Institute of Biochemistry, MMC, Ch-3) | -- Member Secretary |
| 3. Prof. B. Kalaiselvi. MD
Prof of Pharmacology ,MMC, Ch-3 | -- Member |
| 4. Prof. C. Rajendiran, MD
Director , Inst. Of Internal Medicine, MMC, Ch-3 | -- Member |
| 5. Thiru. S. Govindsamy. BA BL | -- Lawyer |
| 6. Tmt. Arnold Soulina MA MSW | -- 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, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.


Member Secretary, Ethics Committee

41	KUPPAN	60	M	YES	YES	NO	9.6	28	134	9.2	26	2	0.4	133	1	LL	13	1	Ped	N	NO	LL	1	Ped	Gly	2000	22	0	2	NIL	NIL	2	HGT-T1	1
42	MARY	65	F	NO	NO	NO	10.4	29	134	10.2	25	4	0.2	133	1	T	14	1	Ped	N	NO	T	1	Ped	Gly	2000	23	0	1.5	NIL	NIL	2	LGT-Ta	2
43	SIVAKUMAR	40	M	NO	NO	YES	10.4	33	136	10	30	3	0.4	134	2	T	13	1	Ped	N	NO	T	1	Ped	Gly	2000	25	0	2	NIL	NIL	2	LGT-T1	0
44	EZHUMALAI	47	M	NO	NO	NO	9.6	31	134	9.4	28	3	0.2	132	2	T	12	1	Ped	N	NO	T	1	Ped	Gly	2500	25	0	1	NIL	NIL	2	LGT-T1	0
45	RAMASAMY	65	M	YES	NO	NO	9.5	32	133	9.4	30	2	0.1	131	2	LL	26	1	Ped	N	NO	LL	1	Ped	Gly	2500	32	2	1.4	NIL	NIL	2	LGT-T1	2
46	JAYAMMAL	55	F	NO	YES	NO	9.4	30	140	9.2	28	2	0.2	138	2	RL	16	1	Ped	N	NO	RL	1	Ped	Gly	2000	26	0	1.5	NIL	NIL	2	HGT-T1	2
47	SOLAPPAN	60	M	YES	NO	YES	9.8	28	142	9.4	26	2	0.4	140	2	T	14	1	Ped	N	NO	T	1	Ped	Gly	2000	18	0	1	NIL	NIL	2	LGT-Ta	2
48	ARUNAN	58	M	YES	NO	NO	10.2	31	142	9.8	29	2	0.4	140	2	RL	32	1	SES	N	NO	RL	1	SES	Gly	3000	34	1	2	NIL	NIL	3	HGT-T2	2
49	BOOTHALINGAM	72	M	YES	YES	NO	11	32	138	10.8	30	2	0.2	136	2	LL	33	1	Ped	N	NO	LL	1	Ped	Gly	3200	32	1	1	NIL	NIL	2	LGT-T1	1
50	KHADARBASHA	76	M	YES	NO	YES	11	33	148	10.6	30	3	0.4	142	6	AW	24	1	Ped	N	NO	AW	1	Ped	Gly	3000	38	0	1.2	NIL	NIL	2	HGT-T1	1

HTN HYPERTENSION

DM DIABETES

Hb HEMOGLOBIN

Na SODIUM

K POTASSIUM

HbD HEMOGLOBIN DEFICIT

NaD SODIUM DEFICIT

L LOCATION

S SIZE

N NUMBER

M MORPHOLOGY

UT UPPER TRACTS

LN LYMPH NODE

IR IRRIGANT

RT RESECTION TIME

OJ OBTURATOR JERK

SW SPECIMEN WEIGHT

USG ULTRASONOGRAPHY

TURBT TUR OF BLADDER TUMOURS

PCV PACKED CELL VOLUME

LL LEFT LATERAL WALL

RL RIGHT LATERAL WALL

T TRIGONE

D DOME

AW ANTERIOR WALL

PW POSTERIOR WALL

PED PEDUNCULATED

SES SESSILE

GLY GLYCINE

D DAY

HGT HIGH GRADE TUMOUR

LGT LOW GRADE TUMOUR

SAL SALINE

HPE HISTOPATHOLOGICAL EXAMINATION

PERF PERFORATION

TAG THERMAL ARTEFACT GRADE

TURS TUR SYNDROME

CECT CONTRAST ENHANCED CT

CP CATHETERISATION PERIOD

PCVD DIFFERENCE IN PCV

41	GOVINDASAMY	67	M	YES	NO	YES	9.4	26	136	9.2	25	1	0.2	132	4	LL	28	1	PED	N	NO	LL	1	PED	SAL	2200	34	0	1.8	NIL	NIL	2	LGT-T1	0
42	DURAI	58	M	YES	NO	YES	9.8	25	140	9.6	24	1	0.2	136	4	RL	32	1	SES	N	NO	RL	1	SES	SAL	1800	35	0	2	NIL	NIL	2	HFT-T2	1
43	GANESA NADAR	63	M	YES	YES	NO	11	32	134	10.8	31	1	0.2	132	2	T	14	2	PED	N	NO	T	2	PED	SAL	2200	36	0	1.1	NIL	NIL	2	LGT-Ta	0
44	MATHEW	80	M	YES	NO	NO	9.6	26	132	9.4	24	2	0.2	130	2	LL	35	1	PED	N	NO	LL	1	PED	SAL	2000	35	0	2.3	NIL	NIL	2	LGT-T1	1
45	KRISHNIAH	56	M	NO	NO	YES	9.6	27	128	9.2	26	1	0.4	126	2	LL	26	1	PED	N	NO	LL	1	PED	SAL	2000	32	0	1.5	NIL	NIL	2	LGT-T1	0
46	MARKADEYAN	51	M	YES	NO	NO	9.8	28	138	9.6	27	1	0.2	132	6	D	23	1	PED	N	NO	T	1	PED	SAL	1800	35	0	1.4	NIL	NIL	3	LGT-Ta	0
47	PEETHAMBARAM	54	M	YES	YES	NO	10.2	32	134	9.4	31	1	0.8	133	1	RL	25	1	SES	N	NO	RL	1	SES	SAL	2000	35	0	1.2	NIL	NIL	2	LGT-T1	1
48	MARUTHU	67	M	YES	NO	YES	9.6	27	138	9.2	25	2	0.4	136	2	LL	32	1	SES	N	NO	LL	1	SES	SAL	2000	36	0	2.4	NIL	NIL	2	HGT-T2	0
49	MARIAMMA	60	F	YES	NO	NO	9.8	27	138	9.4	26	1	0.4	134	4	LL	15	1	PED	N	NO	PW	1	PED	SAL	1500	34	0	1	NIL	NIL	2	LGT-Ta	1
50	MOHAN	66	M	NO	NO	NO	9.4	26	138	9.2	25	1	0.2	136	2	T	23	1	PED	N	NO	T	1	PED	SAL	2500	35	0	1.5	NIL	NIL	2	LGT-Ta	0

HTN	HYPERTENSION	LL	LEFT LATERAL WALL
DM	DIABETES	RL	RIGHT LATERAL WALL
Hb	HEMOGLOBIN	T	TRIGONE
Na	SODIUM	D	DOME
K	POTASSIUM	AW	ANTERIOR WALL
HbD	HEMOGLOBIN DEFICIT	PW	POSTERIOR WALL
NaD	SODIUM DEFICIT	PED	PEDUNCULATED
L	LOCATION	SES	SESSILE
S	SIZE IN MM	GLY	GLYCINE
N	NUMBER	D	DAY
M	MORPHOLOGY	HGT	HIGH GRADE TUMOUR
UT	UPPER TRACTS	LGT	LOW GRADE TUMOUR
LN	LYMPH NODE	SAL	SALINE
IR	IRRIGANT	HPE	HISTOPATHOLOGICAL EXAMINATION
RT	RESECTION TIME	PERF	PERFORATION
OJ	OBTURATOR JERK	TAG	THERMAL ARTEFACT GRADE
SW	SPECIMEN WEIGHT IN GRAMS	TURS	TUR SYNDROME
USG	ULTRASONOGRAPHY	CECT	CONTRAST ENHANCED CT
TURBT	TUR OF BLADDER TUMOURS	CP	CATHETERISATION PERIOD
PCV	PACKED CELL VOLUME	PCVD	DIFFERENCE IN PCV

APPENDIX-6

TURNITIN ORIGINALITY REPORT

SAFETY AND EFFICACY OF BIPOLAR ENERGY FOR TRANSURETHRAL RESECTION OF BLADDER TUMOURS

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INTRODUCTION Bladder cancer is one of the commonest malignancies and worldwide it is the fourth most common malignancy in males and eighth in females 1. About 70% of patients with Bladder cancer have disease limited to the mucosa or sub-mucosa . This group forms the main bulk of the disease and is termed as non-muscle invasive or superficial bladder cancer2. The success of therapy in non-muscle-invasive bladder cancer (NMIBC) relies upon the biologic nature of the tumour and on the treatment chosen. Endoscopic surgery is considered the main treatment of non-muscle invasive tumours (Ta and T1)3. In 1910, Edwin Beer, changed the paradigm of managing papillary bladder tumours from Open surgery...