Monopolar Versus Bipolar Transurethral Resection of Bladder Tumors: A Single Center, Parallel Arm, Randomized, Controlled Trial

Vivek Venkatramani,* Arabind Panda, Ramani Manojkumar and Nitin S. Kekre

From the Departments of Urology and Pathology (AP), Christian Medical College, Vellore, India

Purpose: We compared the safety and efficacy of bipolar transurethral resection and monopolar resection for bladder tumors.

Materials and Methods: A single center, parallel arm, randomized, controlled trial was performed from May 2011 to August 2012. All patients with suspected bladder tumors were eligible for study inclusion. Those who refused consent and those undergoing routine restaging transurethral resection of bladder tumor were excluded from analysis. The primary end point was the incidence of obturator jerk. Secondary study outcomes included the decrease in hematocrit, rates of recoagulation and transfusion, bladder perforation, decrease in sodium, resection syndrome and resection time. Pathological quality was assessed by comparing deep muscle and the degree of severe cautery artifact in the 2 arms.

Results: A total of 257 transurethral resections were performed during the study period. After exclusion 147 patients were randomized, including 75 in the monopolar arm and 72 in the bipolar arm. There were 6 and 4 protocol violations in the monopolar and bipolar arms, respectively. Intent to treat and per protocol analyses were performed. The incidence of obturator jerk was greater in the bipolar arm (60% vs 49.2%, $p = 0.27$). There was no significant difference between secondary outcomes. The only significant difference was a significantly lower incidence of severe cautery artifact in the bipolar arm (25% vs 46.7%, $p = 0.0096$).

Conclusions: Bipolar transurethral resection of bladder tumor was not superior to monopolar resection with respect to obturator jerk, bladder perforation and hemostasis. There was a significantly lower incidence of severe cautery artifact after bipolar resection.

Key Words: urinary bladder neoplasms, cautery, artifacts, obturator nerve, intraoperative complications

Abbreviations and Acronyms

CONSORT = Consolidated Standards of Reporting Trials

TUR = transurethral resection

TURBT = bladder tumor TUR

Accepted for publication December 3, 2013.

Study received institutional review board and ethics committee approval.

* Correspondence: Department of Urology, Christian Medical College, Vellore 632004, India (telephone: 91-7639831979 or 91-416-2282111; FAX: 91-4162282055; e-mail: docvivek@gmail.com).

See Editorial on page 1646.

SINCE its inception, TURBT has been performed with monopolar cautery.[1] Bipolar resection has now been proved to be a safe, effective alternative for prostate TUR.[2–4] Initial studies of bipolar TURBT were promising with fewer fluid and electrolyte abnormalities, and a decreased incidence of obturator jerk.[5–7] However, no high level evidence exists and the exact role of bipolar TURBT remains undefined.

In this prospective, randomized, controlled trial we compared the safety and efficacy of bipolar TURBT and monopolar resection.

0022-5347/14/1916-1703/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2013.12.004
Vol. 191, 1703-1707, June 2014
Printed in U.S.A.

MATERIALS AND METHODS

Study

Design. We designed and performed a single center, parallel arm, randomized, controlled trial at our institution from May 2011 to August 2012. The allocation ratio was 1:1. Approval of the institutional review board and ethics committee was obtained, and the trial was registered with the Clinical Trials Registry of India (No. CTRI/2011/06/001785, www.ctri.nic.in). CONSORT guidelines[8] were used to report all aspects of the trial.

Inclusion and exclusion criteria. All consecutive patients undergoing TURBT for suspected bladder tumors were eligible for study. Diagnosis was based on imaging and/or cystoscopy. Exclusion criteria included restaging TURBT for high grade bladder cancer, refusal to participate and unfitness for spinal anesthesia.

Outcomes. The primary outcome was the incidence of obturator jerk between the 2 arms. A single central pathologist compared specimen quality in each arm by determining the presence of deep muscle in the sample and comparing the degree of cautery artifact. Severe artifact was defined as more than 50% cautery artifact in most chips.[9] Secondary outcomes included bladder perforation, decrease in hematocrit, need for blood transfusion, clot retention and need for recoagulation, decrease in serum sodium, TUR syndrome and resection time.

Protocol. Spinal anesthesia was applied in all cases. No obturator block was used. This was done to overcome the potential confounding effect of anesthesia on our primary end point, obturator jerk.

Bipolar resection was done using the PlasmaKinetic™ SuperPulse Generator with a thin PlasmaKinetic SuperLoop. Settings were 100 W for cutting and 80 W for coagulation. Normal saline was used as irrigant.

Monopolar resection was performed with a 4 mm VaporCut® resection loop with 1.5% glycine used as irrigant. Settings were 90 W for cutting and 70 W for coagulation.

All resection was performed in standard fashion. Tumors were resected from periphery to center with the stalk resected last. An additional sample of deep muscle was obtained from the tumor base. Postoperative irrigation was done as indicated. The catheter was removed at 24 to 48 hours in uncomplicated cases.

Consultants and urology residents under their supervision were involved in performing the operations. Surgeons were classified as residents, consultants with up to 3 years of experience or consultants with more than 3 years of experience.

Sample Size Calculation

Sample size (n) was calculated using 80% power and a 95% significance level for obturator jerk, assuming a 25% incidence for the monopolar system and a 5% incidence for the bipolar system. These values were arrived at after a comprehensive literature review. We used the equation, $n = 2(p^{-})(1 - p^{-})(Z_{\beta} + Z_{\alpha/2})^2/(p_1 - p_2)^2$, where $p_1 = 0.25$ and $p_2 = 0.05$. A sample size of 49 events was calculated. To achieve this we estimated that we would need to recruit 75 patients per arm.

Techniques

Randomization. Randomization was performed using the block randomization technique with 10 cases allocated to a block.

Allocation concealment and blinding. Allocation was concealed in sealed envelopes and implemented by the operating room technician. Patients were blinded to the allocated arm. A single central pathologist blinded to allocation analyzed all samples. The statistician was also blinded.

Statistical Analysis

Statistical analysis was performed using SPSS®, version 16. The mean ± SD is shown for normally distributed data. Significance was determined using the independent sample t-test for quantitative variables and the chi-square test for qualitative data. We performed intent to treat analysis of all randomized patients. Per protocol analysis of the 2 groups was done after excluding patients in whom there were protocol violations, including general anesthesia or additional procedures such as ureteroscopy. No interim analysis was performed.

RESULTS

Figure 1 shows the study CONSORT diagram. A total of 257 TURBTs were performed during the study period and 147 patients were randomized, including 75 and 72 in the monopolar and bipolar arms, respectively. Protocol violations occurred in 10 cases, including 8 of lateral wall tumors when the anesthetist inadvertently administered general anesthesia. One patient underwent simultaneous ureteroscopy. In another patient with a small tumor a laryngeal mask airway was used.

The 2 study arms were well matched with respect to baseline patient variables and tumor morphology

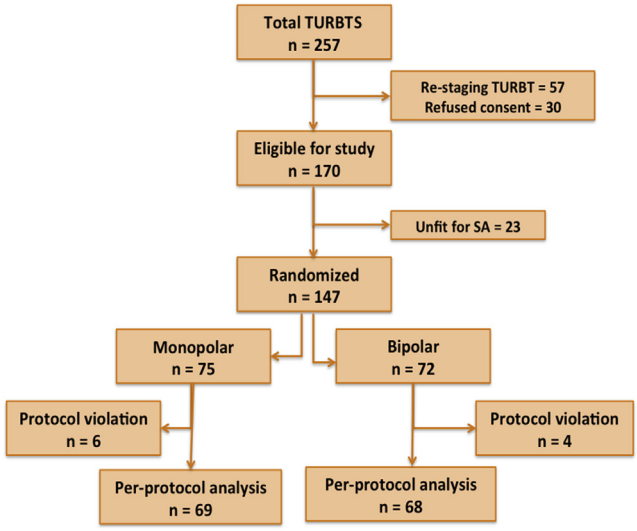

Figure 1. CONSORT diagram