



Bipolar Plasma Vaporization Versus Transurethral Resection of Non-muscle Invasive Bladder Tumors (Intervention Study)

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Abstract: Introduction: Bladder cancer is the second most common genitourinary malignancy, about 75% of all bladder tumors are considered as non-muscle invasive bladder cancer (NMIBC). Transurethral resection of bladder tumors (TURBT) is considered the first and gold standard treatment option for patients with NMIBC. During the recent years, the bipolar vaporization technique provides significant improvement in hemostasis and obturator nerve stimulation with excellent safety profile. **Objectives:** To assess the bipolar plasma vaporization of bladder tumors (BPV-BT) as regarding effectiveness and safety profile and to compare it with the standard technique of the monopolar transurethral resection (TURBT) for management of patients with (NMIBC). **Patients and Methods:** 50 cases that fit the inclusion criteria that will be admitted in the period between August 2012 and August 2014 will be enrolled in the study [An intervention study (Randomized controlled clinical trial)]. Patients will be equally divided into 2 groups, Group A will undergo TURBT and group B will undergo BPV-BT. Results were compared as regarding intraoperative bleeding, obturator n. reflex, perforation, change in sodium and hemoglobin, catheter time, hospital stay as well as tumor recurrence and progression. **Results:** Comparing, BPV-BT approach improved results as regarding the mean hemoglobin decrease (0.10 g/dl) and the mean catheterization period (1.5 days), mean hospital stay (1.24 days), mean change in sodium (1.12 meq/dl), except for our mean operative time in the BPV-BT group which was 46.4 min. No cases required blood transfusion, no obturator n. reflex, perforation in the BPV-BT group while as regards tumor recurrence was numerically less in the BPV-BT than the TURBT group (8 to 15 recurrences respectively) but still statistically not significant. **Conclusion:** BVP seems to be a good and promising endoscopic alternative for management of patients with NMIBC, with higher efficacy and decreased morbidity especially in patients with large bladder tumors, also it gives the advantage of good visualization during surgery with minimal bleeding, but still requires more extensive trials with longer follow-up intervals.

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1. Introduction:

Bladder cancer is the second most common genitourinary malignancy, the fourth most common male cancer accounting for 7% of all cancers and the eighth highest cancer-related mortality rate [1].

About 75% to 80% of all bladder tumors are considered as a non-muscle invasive disease [2].

Transurethral resection enables eradication of all visible tumors and gives adequate tissue for histopathological analysis and also to detect the grade and depth of invasion [1].

Although, Transurethral resection of bladder tumors (TURBT) using a wire loop still remains the gold-standard treatment for non-muscle invasive bladder cancer (NMIBC), the unacceptably high early recurrence rates after first resection as well as the significant complications of standard monopolar resection, demanded the search for new alternatives [3].

The high efficacy and safety of the bipolar vaporization technique makes it widely used for treatment of benign prostatic enlargement, bladder outlet obstruction [4].

Although it's a logical next step for this technique, to include treatment and management of bladder tumors, it should be well evaluated so as not to compromise the oncologic principles [4].

2. Patients and Methods:

A total number of 50 cases that fit the inclusion criteria were admitted in the period between August 2012 and August 2014 & enrolled in the study (Randomized controlled clinical trial). Patients were equally divided into 2 groups, Group A will undergo TURBT and group B will undergo BPV-BT.

Preoperative

All patients signed a written informed consent and underwent a standard investigation protocol which

included general and local clinical examination, blood tests, urine culture, abdominal ultrasonography, intravenous pyelography or CT-scan if indicated.

Anticoagulants and antiplatelet agents should be stopped at the appropriate time before the procedure, usually 5-7 days prior to TURBT.

Intravenous antibiotics are given as close to 1 hour prior to instrumentation.

Inclusion criteria:	Exclusion criteria:
<ul style="list-style-type: none"> • Non muscle invasive, non-recurrent bl. tumor. • At least one bladder tumor >2.5 cm. • Normal upper tract function. 	<ul style="list-style-type: none"> • Invasive bladder cancer. • Tumor less than 2.5 cm. • Tumor in a diverticulum. • Abnormal upper tract. • Associated cancer prostate.

Intraoperative

Regarding BPV-BT

The procedures started with a comprehensive cystoscopy, determining the presence, size and location of all existing tumors.

Once a complete cystourethroscope is complete, tumor biopsy was performed with the bipolar resectoscope and a thin resection loop. These biopsies will ensure that one has adequate tumor pathological information (Grade).

The main stage was represented by the actual plasma vaporization, during which the wedge-like electrode displaying a plasma corona on its surface was gradually moved in direct contact with the tumoral tissue.

The coagulation of the majority of the bleeding sources was performed in the same time as the vaporization process, which was applied until the muscular layer of the bladder wall was clearly exposed.

Subsequently, the bipolar resection of the center and margins of the tumoral bed was performed, ensuring inclusion of muscle in the specimen for adequate pathological information (Stage).

BPV-BT was done using a Storz 26 Fr continuous flow resectoscope with plasmakinetic wedge-like electrode using the bipolar current. Power was maintained at the default settings with the coagulation setting at 60 W and the cutting current at 120 W generated from an ERBE VIO 300 D machine.

Irrigation was done using isotonic 0.9% sodium chloride solution at room temp.

Regarding TURBT

Conventional monopolar transurethral resection of the bladder tumors was done using Storz 26 Fr continuous flow resectoscope with the hot loop electrode. Power was maintained at the default settings.

Intraoperative difficulties as inadequate visualization, bleeding, as well as complications like perforation were noted.

For very large tumors (> 50% of bladder mucosa) or high grade T1 tumors, we will perform a repeat transurethral resection 2 to 4 weeks after the initial resection.

Postoperative

All patients received continuous bladder irrigation postoperatively, and the irrigation volume and bladder washouts required were recorded.

Duration of catheterization was recorded as well as any postoperative complications. The length of hospital stay was estimated. Details of adverse events were noted, including any pyrexia greater than 38C, hypotension episodes, and hematuria, blood transfusion or clot retention episodes and TUR syndrome.

Serum HGB, sodium and potassium were measured on day 1 postoperatively.

Single immediate postoperative Intravesical chemotherapy was given to all cases according to the EAU Guidelines while Immunotherapy when indicated.

Follow up

Follow up of the patients was done at 1, 3, 6, 9, 12 and 18 months and it includes tumor recurrence and progression by pelviabdominal U/S, cytology & cystoscopy.

3. Results:

There was no statistically significant difference between both groups as regarding the mean age of the patients ($p = 0.171$) or the sex of the patients ($p = 0.5$).

The sizes of the tumors was ranging from 2.5 to 5.5 cm with a mean size of 3.5 ± 0.87 cm for the TURBT group, whereas the BPV-BT group tumors sizes ranged from 2.5 to 5.3 cm with a mean of 3.7 ± 0.83 cm.

Intraoperative obturator n. reflex occurred in 4 (16%) cases of the TURBT group while the BPV-BT group passed without experiencing such complication (0%).

As regards the TURBT group, Intraoperative blood transfusion was ranging from 0 to 2 units of

packed RBCs, and was required only in 3 cases (12%), while no cases (0%) required bl. transfusion in the BPV-BT group.

Regarding Intraoperative perforation, it happened in 5 Cases (20%) of the TURBT group (A), 4 cases

(16%) were extra peritoneal managed conservatively, 2 of them (50%) were due to intraoperative obturator n. reflex and 1 case (4%) was intraperitoneal and managed surgically.

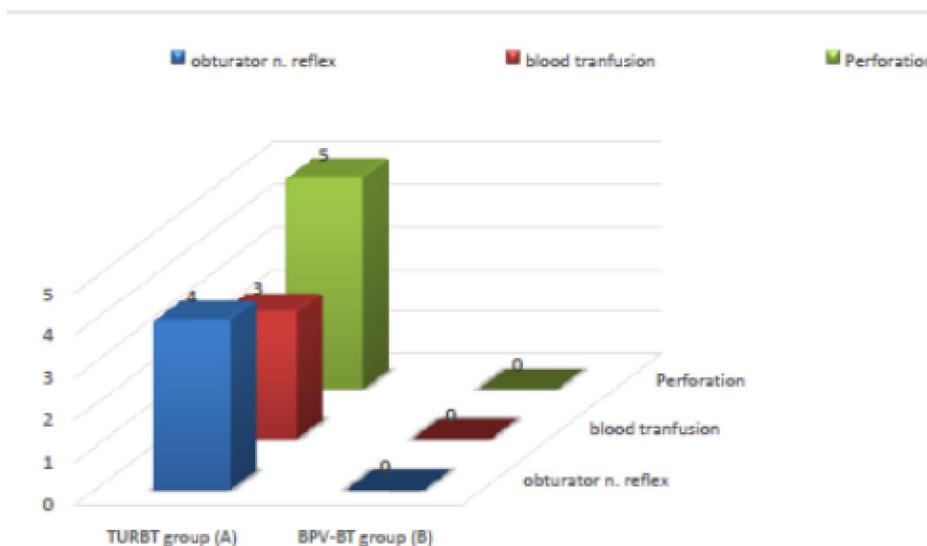


Figure 1: comparing both groups as regards intraoperative complications

Whereas the BPV-BT group (B) had no cases (0%) of intraoperative perforation.

There was a statistically significant difference between both groups as regarding the mean change in sodium levels ($p = 0.005$).

And there was also a highly statistically significant difference between both groups as regarding the mean change in the hemoglobin levels between the postoperative and the preoperative data in both groups ($p = 0.000$).

Postoperative hospital stay in the TURBT group (A), ranged from 1 to 6 days with a mean of $1.88 \pm$

1.16 days, whereas ranged from 1 to 3 days with a mean of 1.24 ± 0.52 days in the BPV-BT group (B).

The catheter time was ranging from 1 to 14 days with a mean of 3.4 ± 3.8 days in the TURBT group (A), while ranged from 1 to 10 days with a mean of 1.5 ± 1.8 days in the BPV-BT group (B).

The overall tumor recurrence, although numerically, whether at same site or another site was higher in the TURBT group (A) 15 recurrences to 8 recurrences in the BPV-BT group (B), still not yet statistically significant difference, and this may be attributed to the small sample size ($p = 0.586$).

Table 1: Comparison between TURBT and BPV-BT as regard site of tumor recurrence

			Groups		Total	P value
			TURBT	BPVBT		
Site	Recurrence at other site	Count	3	2	5	0.586
	Recurrence at the same site	Count	12	6		
Total		Count	15	8	23	

4. Discussion:

Visualization was excellent all through the operation due to minimal or even no bleeding. The vaporized sites show a smooth surface with sharp edges, with no irregularities or cellular debris [5].

By comparing this technique with the data available in literature seems to confirm the advantages

provided by BPV-BT over the standard method (TURBT).

As regarding intra- and postoperative data, a study involving 480 patients who underwent bipolar resection using the same TURis generator showed a mean operative time of 27 minutes, a mean decrease in HGB of 0.7 g/dl and a mean catheterization of 3 days [6].

By comparison, our technique showed improved results as regarding the mean hemoglobin decrease (0.10 g/dl) and the mean catheterization period (1.5 days), mean hospital stay (1.24 days) except for our mean operative time in the BPV-BT group which was 46.4 min.

Bl. perforation is a common complication, especially tumors on the lateral wall [7].

Mostly occurs following obturator nerve stimulation during the standard monopolar resection. The literature data showed a bladder wall perforation rate of 1.3%, while our experience did not include such a complication with the BPV-BT group, and an even higher perforation rate in the TURBT group (5 cases, 2 of them due to obturator reflex) [8].

As regarding bleeding, a study determined 3.4% of cases who showed significant bleeding that needed blood transfusions [8].

In our study, no such cases were recorded in the BPV-BT group, but even a higher rate of blood transfusion in the TURBT group as we were aiming for complete resection and dealing with large tumors.

Another advantage in the bipolar plasma vaporization system, is that the electric current passes from the active to the return pole of the electrode skipping the body of the patient, unlike the monopolar resection, thus minimizing the hazards of nerve reflex [9].

In our study, no cases of obturator n. reflex was recorded with the BPV-BT group whereas 4 cases recorded in the TURBT group.

One of the most important benefits of the bipolar system, is the use of saline as an irrigation fluid that avoids the major complications of TUR syndrome and dilutional hyponatremia [9].

No cases of TUR syndrome recorded in our study, and the mean change in sodium in the BPV-BT group was 1.12 mEq/L and 2.16 mEq/L in the TURBT group.

Regarding tumor recurrence, our results showed that there is no statistically significant difference between both groups, Although numerically, the overall tumor recurrences whether at same or another site was higher in the TURBT group (A) 15 recurrences to 8 recurrences in the BPV-BT group (B), and this may be attributed to the small sample size ($p = 0.586$).

Conclusion:

The bipolar plasma vaporization seems to be a good and promising endoscopic alternative for management of patients with NMIBC, with higher efficacy and decreased morbidity especially inpatients with large bladder tumors, also it gives the advantage of good visualization during surgery with minimal bleeding, but still requires more extensive trials with longer follow-up intervals.

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