

# A multicentre single-blind randomized controlled trial comparing bipolar and monopolar transurethral resection of the prostate

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See related article on page 390.

Cite as: *Can Urol Assoc J* 2011;5(6):385-9; <http://dx.doi.org/10.5489/cuaj.10199>

## Abstract

**Introduction:** Monopolar transurethral resection of the prostate (TURP) is the gold standard surgical therapy for men with lower urinary tract symptoms due to benign prostatic hyperplasia. Although generally considered safer, TURP experience is limited in Canada.

**Methods:** Forty-three patients from 5 Canadian centres were randomized to TURP with either bipolar or monopolar platforms. Patients underwent baseline determinations of American Urological Association (AUA) symptom score, peak urinary flow rate, post-void residual bladder volume and transrectal ultrasound prostate volume. Primary outcome measures were improvement in AUA symptom score, quality of life assessment and bother assessment. Secondary outcomes included procedural times, duration of catheterization, length of hospitalization, complications and the degree of thermal artifact in tissue specimens. Patients were followed for 6 months.

**Results:** Twenty-two patients were treated with bipolar and 21 with monopolar TURP. Preoperative demographics were not statistically different between groups. Postoperative data collection times were equivalent in AUA symptom, quality of life, bother and sexual function assessments. No differences were observed in the procedure time (60.7 min, bipolar vs. 47.4, monopolar) or the duration of urethral catheterization (1.5 days, bipolar vs. 1.1, monopolar). More patients in the bipolar group were discharged on the same day of surgery. There were no differences in the degree of tissue thermal artifact or complication rate.

**Conclusion:** This trial suggests equivalent short-term outcomes for men undergoing monopolar or bipolar TURP.

## Introduction

Benign prostatic hyperplasia (BPH) is a highly prevalent condition in the adult male, with more than 50% of the males

over 60 having histologically proven prostatic hyperplasia and at least half reporting moderate to severe lower urinary tract symptoms (LUTS).<sup>1</sup> Currently, the gold standard for the surgical treatment of BPH-related LUTS is transurethral resection of the prostate (TURP).<sup>1,2</sup> Despite its excellent clinical outcomes, monopolar TURP is associated with well-known and potentially serious complications in 0.8% to 1.4% of patients.<sup>3-5</sup> Risks include thermal tissue damage at the site of surgery or at a distant site by faulty patient grounding, peripheral nerve stimulation, the need for a non-conductive irrigant fluid (which in turn can cause dilutional hyponatremia), fluid overload or specific irrigant toxicities, such as hyperammonemia, myocardial damage and transient blindness.<sup>3-5</sup>

One approach to reduce electrosurgery-related complications has been the adoption of bipolar electrosurgery generators and electrodes to transurethral surgery. With bipolar technology, the ability to use 0.9% normal saline as an irrigant and the physics of electrical current return theoretically reduce the chances of serious complications during TURP. We report the safety and efficacy results of a multicentre single-blind randomized trial comparing bipolar versus monopolar TURP.

## Methods

This study was designed as a multicentered, single-blind, prospective, randomized trial performed at 5 Canadian centres. The study was designed so that each centre would perform an equal number of bipolar and monopolar procedures at study completion. Ethical approval was obtained at each institution. Patients attending the urology clinics at each site were prospectively approached for enrollment if they presented with LUTS and were candidates for surgery. Inclusion criteria were LUTS suggestive of BPH and with peak urinary flow rates <12 mL/sec and American Urological Association (AUA) symptom scores >12. Patients with acute urinary retention were also enrolled. Exclusion criteria were

previous prostatic surgery (open or transurethral), history of urethral stricture, failure to discontinue alpha-adrenergic blocking agents for at least 14 days prior to surgery, failure to discontinue 5-alpha reductase inhibitor for at least 1 month prior to surgery, patient interest in future fertility, known neurogenic bladder dysfunction, untreated urinary tract infection, American Society of Anesthesiology (ASA) class >III, patients requiring anticoagulation and patients unwilling or unable to comply with the follow-up schedule.

After obtaining informed consent, we instructed patients to complete the following questionnaires: AUA symptom score (AUA SS), Bother (AUA B) and Quality of Life (AUA QoL). Blood samples were taken for electrolytes, complete blood count (CBC), blood urea nitrogen (BUN), creatinine (Cr), prostate-specific antigen (PSA), partial thromboplastin time (PTT) and international normalized ratio (INR). Urine for analysis and culture were obtained, on all patients. Peak urinary flow rates (Qmax) and post-void residual (PVR) volumes for those able and not in retention were determined. Physical examination with digital rectal exam, transrectal ultrasound (TRUS) to measure prostate volume and flexible cystoscopy were also performed.

At surgery, patients were randomized (1:1) to TURP using a 24-26 resectoscope with either a bipolar (VISTA Controlled Tissue Resection System, ACMI, Marlborough, MA) or monopolar (ERBE, Marietta, GA or Valleylab, Tyco Healthcare Group LP, Boulder, CO) energy source. All of the attending urologists before study initiation had performed at least 6 previous bipolar and monopolar TURPs. The surgical technique and antimicrobial prophylaxis regimens were left to each surgeon's preference. Data were recorded for operating room time (defined as time elapsed from the first loop pass to the introduction of the urethral catheter), device failure or intra-operative complications. Resected tissue was sent for pathological review and a pathologist blinded to the treatment assignment reviewed all tissue and provided grading on the degree of thermal artifact based in the percentage of affected tissue (Grade I: 0%, Grade II: <25%, Grade III: 25% to 50%, Grade IV: 50% to 75% and Grade V: >75%).

After the procedure, continuous bladder irrigation (CBI) was used until urine output was clear or pink and then discontinued. Post-procedure blood sampling (within 8 hours after TURP) included CBC, BUN, Cr, HCO<sub>3</sub><sup>-</sup>, Na, K and Cl. If after 3 hours without CBI and if the urine was clear and the catheter draining freely, the patient was discharged with the catheter to straight drainage. If no difficulties arose overnight, the catheter was removed the next day in the office. If CBI was required, patients were admitted to hospital and the catheter was removed when the urine was a light pink colour.

Follow-up visits occurred at 1, 3 and 6 months after surgery. Patients completed AUA Symptom, Bother and Quality of Life questionnaires and peak uroflow and PVR urine were

measured. At the 6-month visit, flexible cystoscopy was also performed.

The primary outcome parameter was the comparison of AUA symptom score change (preoperative and postoperative) between monopolar and bipolar TURP. Secondary outcomes included the change in preoperative and postoperative AUA Bother and Quality of Life scores, length of time requiring CBI and urethral catheterization, length of hospital stay, amount of tissue charring on resected chips and volume of PVR urine. Procedure safety was evaluated by measuring blood loss with hemoglobin levels and transfusion rate. The rate of bladder neck contractures or urethral strictures at 6 months was measured.

Statistical analysis was performed using Student's t-test and Chi-square on a commercial software package (GraphPad Prism 4, GraphPad Software Inc. San Diego, CA). Our sample size calculation suggested that 88 patients per randomization arm were required to demonstrate superiority of one device over the other.

## Results

A total of 43 patients were enrolled in the trial; 22 were randomized to bipolar and 21 to monopolar (Table 1). In both groups age, height, weight, body mass index (BMI), PSA, prostate volume by TRUS, duration of symptoms in years, number of comorbidities, presence of acute urinary retention, volume of PVR urine, maximum Qmax, AUA SS, AUA B and AUA QoL questionnaires were not statistically different (Table 2).

The mean operative time in the bipolar arm was 60.78 min (range: 15-109) versus 47.48 min (range: 12-95) in the monopolar arm ( $p = 0.08$ ). Anaesthesia type (general vs. spinal), and grams of resected tissue (bipolar 22.5 [range: 2-76] vs. monopolar 19.3 [range: 7-46.2]) were not statistically different. There were no device failures in either group. No intra-operative complications were encountered.

On histological examination of the surgical specimen there was no difference in the amount of thermal artifact (charring) observed in the resected tissue. One patient in the bipolar group and 2 in the monopolar group had prostate carcinoma foci in the resected chips.

The postoperative decrease in the mean hemoglobin level in the bipolar group of 12.57 mmol/L was not sig-

**Table 1. Enrollment by centre with randomization**

Centres	No. patients		
	Bipolar	Monopolar	Total
Site 1	9	9	18
Site 2	5	4	9
Site 3	5	2	7
Site 4	2	4	6
Site 5	1	2	3

**Table 2. Preoperative patient characteristics\***

		Bipolar	Monopolar
Age (years)	Average (SD)	68 (7)	67 (7)
	Range	51 to 79	55 to 85
Height (cm)	Average (SD)	176 (4)	173 (7)
	Range	165 to 182	155 to 188
Weight (kg)	Average (SD)	86 (11)	83 (10)
	Range	64 to 123	59 to 110
BMI	Average (SD)	28 (4)	28(4)
	Range	21 to 37	21 to 42
PSA	Average (SD)	4.52 (4.29)	4.91 (4.26)
	Range	0.3 to 14.4	0.96 to 16.6
Prostate volume (g) by TRUS	Average (SD)	57.92 (25.56)	50.23 (20.74)
	Range	22.5 to 115	20 to 85
Duration of symptoms (years)	Average (SD)	9 (4)	10(5)
	Range	2 to 20	1 to 30
Comorbidities	N (%)	18/22 (81)	16/21 (76)
In retention	Indwelling Foley catheter	6	6
	Voided volume <150 mL	18	15
	Voided volume <125 mL	10	12
PVR urine By bladder scan	Average (SD)	170.4 (197.82)	206.71 (211.74)
	Range	18 to 656	0 to 637
Qmax with voided volume ≥150 mL/sec	Average (SD)	9.2 (2.01)	7.0 (2.5)
	Range	6 to 11.1	2.8 to 10.7
Preoperative AUA Symptom Score	Average (SD)	23.2 (6.3)	23.4 (5.6)
	Range	14 to 35	13 to 33
Preoperative AUA Bother Score	Average (SD)	16.7 (6.08)	20.5 (5.8)
	Range	5 to 28	4 to 28
Preoperative AUA Quality of Life Question 4	Average (SD)	4.1 (1.4)	4.7 (0.95)
	Range	0 to 6	3 to 6

\*There were no significant differences when comparing preoperative patient characteristics. SD: standard deviation; BMI: body mass index; PSA: prostate-specific antigen; TRUS: transurethral ultrasound; PVR: post-void residual; AUA: American Urological Association.

nificantly different when compared to 9.10 mmol/L in the monopolar group. No patient required blood transfusion. The mean change in serum sodium was also not significant. Asymptomatic hyponatremia (serum sodium <135 mmol/L) occurred in 1 patient in the bipolar group and 4 in the monopolar group. No patient developed transurethral resection (TUR) syndrome. No differences were found in mean CBI duration (875.7 min [range: 110-2808] vs. 776.8 min [range: 118-1950]), mean hospital stay (1.1 [range: 0-3] vs. 1.0 [range: 0-2] days) or catheterization time (1.5 vs. 1.1 days) for bipolar and monopolar groups, respectively. More patients were discharged on the same day of surgery from the bipolar group (7 vs. 3 for the monopolar arm), however this was not statistically significant.

At 1-month follow-up, scores for AUA SS, AUA B, AUA QoL, PVR urine and Qmax were not significantly different between groups. After 1 month, 2 patients in the bipolar group withdrew from the study; 1 patient was diagnosed with prostate cancer and underwent further surgical treatment and another was lost to follow-up for family issues unrelated to the study. At 3 and 6 months, scores for AUA

SS, AUA B, AUA QoL, Qmax and PVR urine were not statistically significant (Table 3).

Overall complications occurred in 14 patients in the bipolar group and 9 in the monopolar group (Table 4). Complications requiring intervention were not significantly different between the groups; in the bipolar group, 2 bladder neck contractures (BNC) and one BNC plus urethral stricture; in the monopolar group, 1 BNC and 2 BNC plus urethral stricture. There were no serious unanticipated adverse events.

Enrollment was suspended as a result of the manufacturer's decision to market a different bipolar platform, leading to an inability to provide loops to the study investigators.

## Discussion

Currently, monopolar TURP is the gold standard for the surgical treatment of BPH-related LUTS. Multiple minimally invasive techniques have been developed in an effort to surpass monopolar TURP, however due to cost, safety profile, learning curve or outcomes none have received widespread acceptance.

**Table 3. Primary outcomes**

			Bipolar	Monopolar	p value
1 month	AUA Symptom Score	Ave (SD)	9.14 (5.87)	9.14 (7.2)	ns
		Range	0 to 20	0 to 32	
	AUA Bother Score	Ave (SD)	6.59 (5.23)	6.81 (6.79)	ns
		Range	0 to 19	0 to 25	
	AUA Quality of Life Score	Ave (SD)	4.818 (3.647)	4.524 (4.082)	ns
		Range	0 to 14	0 to 15	
	Qmax (voided volume $\geq 150$ mL/sec)	Ave (SD)	20.66 (8.0)	22.35 (8.3)	ns
		Range	4.6 to 40.4	8.8 to 34.1	
	PVR urine	Ave (SD)	106.3 (108.6)	90.4 (78.4)	ns
		Range	20 to 470	15 to 245	
3 months	AUA Symptom Score	Ave (SD)	7.29 (6.08)	5.5 (4.0)	ns
		Range	1 to 19	1 to 14	
	AUA Bother Score	Ave (SD)	5.4 (5.4)	2.8 (3.03)	ns
		Range	0 to 14	0 to 10	
	AUA Quality of Life Score	Ave (SD)	3.476 (3.505)	2.714 (3.052)	ns
		Range	0 to 11	0 to 12	
	Qmax (voided volume $\geq 150$ mL/sec)	Ave (SD)	24.18 (10.81)	18.5 (8.7)	ns
		Range	8.5 to 47.4	7 to 32.9	
	PVR urine	Ave (SD)	110.4 (91.3)	56.89 (57.5)	ns
		Range	8 to 360	0 to 220	
6 months	AUA Symptom Score	Ave (SD)	6.4 (6.2)	5.4 (4.1)	ns
		Range	0 to 24	1 to 15	
	AUA Bother Score	Ave (SD)	3.32 (5.26)	3.34 (3.5)	ns
		Range	0 to 17	0 to 12	
	AUA Quality of Life Score	Ave (SD)	2.050 (3.034)	2.238 (2.508)	ns
		Range	0 to 12	0 to 9	
	Qmax (voided volume $\geq 150$ mL/sec)	Ave (SD)	18.4 (8.99)	21.7 (10.98)	ns
		Range	6.4 to 40.1	5.2 to 43.6	
	PVR urine	Ave (SD)	93.7 (64.2)	68.9 (71.2)	ns
		Range	0 to 269	0 to 244	

SD: standard deviation; PVR: post-void residual; AUA: American Urological Association.

The safety of bipolar TURP is enhanced by the use of normal saline eliminating the incidence of the metabolite toxicities and dilutional hyponatremia. This difference could be especially important in teaching institutions, where bipolar TURP could offset the increased risk of TUR syndrome due to the increased resection times usually needed in physician training.<sup>6</sup> Anecdotally, urologists have observed better intra-operative visibility during bipolar resection, which may also enhance resident education.<sup>7</sup>

Bipolar TURP provides an equivalent relief of LUTS and QoL improvement at 6 months compared to conventional monopolar TURP. The safety profile of both procedures in regards to operative and postoperative complications was comparable. Bipolar resection was associated with slightly longer resection times than monopolar, with a mean difference of 13 minutes. Whether this finding is related to a learning curve or lack of bipolar experience of the surgeon is difficult to answer. The bipolar resection loop used in this trial was smaller than a standard 24 Fr monopolar loop, per-

haps reducing the speed of tissue resection. This observation is supported by the reported calculations of the resection speed of each system (0.61 g/min bipolar vs. 0.74 g/min for monopolar).<sup>8</sup> Our data support this since the initial prostate volume and the amount of resected prostatic tissue were similar among both groups. The impact of bipolar tissue vaporization, which has been shown to be up to 5%,<sup>9</sup> had little effect on the resected tissue weight seen in our series.

Recently, Mamoulakis and colleagues calculated that using bipolar TURP in 50 patients will result in one fewer case of TUR syndrome.<sup>10</sup> One issue raised in the literature is the possibility of an increased incidence of urethral strictures in bipolar TURP patients (6.1%).<sup>2,7</sup> Reports from randomized trials comparing outcomes between monopolar and bipolar TURP, failed to observe higher rates of stricture formation with the bipolar devices.<sup>8,11,12</sup>

Our mean length of hospital stay although not significantly different between groups (1.091 [range: 0-72 hours] vs. 1.0 days [range: 0-48 hours] for bipolar and monopolar,

**Table 4. Complications**

	Bipolar	Monopolar
Urinary tract infection	1	0
Urinary retention	3	1
Dysuria	1	1
Overactive bladder	0	1
TUR syndrome	0	0
Urgency/urge incontinence	1	1
Hematuria requiring intervention post discharge	2	2
*Bladder neck contracture	2	1
*Bladder neck contracture plus urethral stricture	1	2

\*Noted at 6-month follow-up. TUR: transurethral resection.

respectively), compares favourably to other reported series.<sup>2</sup> There was no difference in the length of indwelling catheter time among groups. This compares favourably with the reported literature, with a range of 23 to 108 hours.<sup>2</sup> While we report shorter but not significantly different catheter times in the monopolar group, most studies demonstrate the opposite. This difference could be an artifact related to the study protocol. If the patient was discharged on the day of surgery, the catheter was removed in the office the following day (after 8 am) (9 bipolar vs. 3 monopolar). Whereas, if the patient required an overnight hospital stay, the catheter was removed at 6 am (13 bipolar vs. 18 monopolar).

This study's findings are limited by the small sample size. The lack of blinding in the treatment arm to the operating surgeon could also have been a source of bias. However, this may have been partly mitigated by our study design, where raw data analysis was performed by research personnel not involved in data collection. The results are based on a single type of bipolar electrosurgical unit which might not accurately represent or be applicable to other platforms, although data exists that suggest that clinical results are not machine dependent.<sup>10</sup> The strengths of the trial are that it was a prospective study, treatment allocation was randomized and the patient was blinded to treatment assignment for the duration of the study. It was multicentered to reduce referral and single surgeon bias with the intent that each centre perform similar numbers of each procedure, however with the premature conclusion of the trial, this was not achievable. Consequently, the range of procedures performed at each institution was varied; however, the number of procedures performed by individual surgeons was equivalent regardless of the study site. The study endpoints were standardized across centres and validated instruments were used to measure outcomes.

## Conclusion

Our data demonstrates that at 6 months of follow-up bipolar TURP is equivalent to monopolar in terms of efficacy out-

comes as measured by subjective and objective measures. The procedures also have an equivalent complication profile; however, the elimination of a patient return electrode pad and toxicity from hypo-osmolar irrigation fluids may provide an extra level of patient safety. Longer follow-up is needed to determine if this technology will eventually supplant monopolar TURP as the new gold standard.

**Acknowledgement:** John D. Denstedt in London, Ontario (The University of Western Ontario), Larry Goldenberg in Vancouver, British Columbia and Peter J Pommerville in Victoria, British Columbia (University of British Columbia), Darren T Beiko and James W Wilson in Kingston, Ontario (Queen's University) and Kevin Piercey in Hamilton, Ontario (McMaster University) contributed patients to this study.

**Competing interests:** The authors received some funding from Olympus/ACMI. This investigator initiated study was supported by ACMI Canada. All sites received financial support and investigative product.

This paper has been peer-reviewed.

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