Prediction of the risk of surgical complications in patients undergoing monopolar transurethral resection of bladder tumour – a prospective multicentre observational study

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Abstract

Introduction: The aim of the study was to identify predictors of surgical complications of transurethral resection of bladder tumour (TURBT).
Material and methods: We prospectively recruited 983 consecutive patients undergoing TURBT within 7 months in six academic institutions. All patients were followed up from the surgery up to 30 days postoperatively with at least one telephone contact at the end of the observation. The primary study endpoint was any intra- or postoperative surgical complication. For the identification of predictors of complications, univariate and multivariate logistic regression models were used. Trial registration: ClinicalTrials.gov (NCT03029663). Registered 24 January 2017.
Results: Surgical complications were noticed in 228 (23.2%) patients, including 83 (8.4%) patients with more than one complication and 33 cases of Clavien-Dindo grade 3 complications (3.3%). The most common in-hospital complications were bleeding (n = 139, 14.1%) and bladder perforation (n = 46, 4.7%). In a multivariate analysis, nicotine use, high ASA score, and the presence of high-grade tumour were the most significant predictors of high-grade complications. The stage of the disease was the strongest predictor of bleeding, while the presence of muscle in the specimen and resident surgeon were the strongest predictors for bladder perforation.
Conclusions: TURBT poses a significant risk of surgical complications, the majority of which are of low grade.

Key words: bladder cancer, transurethral resection of bladder tumour, postoperative complications, intraoperative complications, residency.

Introduction

Transurethral resection of bladder tumour (TURBT) is one the most commonly performed urological procedure [1, 2]. Despite most bladder cancers being non-muscle invasive (NMIBC), TURBT can be a challenging operation due to high tumour burden, intraoperative bleeding, difficult tumour location, or other factors. Moreover, the experience of surgeon plays a key role in the oncological quality of TURBT [3]. The limited available data indicate that TURBT is a morbid procedure with a risk of surgical complications of 5–20% [4–9]. While these numbers are high in contemporary urology, profound discussion of surgical technique and possible complications is a mandatory part of patient counselling. Unfortunately, up to date, predictors of TURBT complications have not been not adequately identified. This precludes any individual calculation.

The aim of the study was to identify predictors of surgical complications of TURBT.

Material and methods

Patients

This prospective, multicentre, cross-sectional, observational study enrolled 983 consecutive patients undergoing TURBT in six academic institutions between January 2017 and July 2017. The mean age of the cohort was 68.8 years (range: 18–98), and the male-to-female ratio was 3 : 1. Inclusion criteria were as follows: age ≥ 18 years, resection of bladder tumour, sterile urine preoperatively or ongoing directed antibiotic therapy at the time of surgery, and signed, informed consent. The investigating urologists explained the purpose of the study to each patient, as well as the protection of participant confidentiality and the participants' freedom to drop out at any time. The study recruited patients with both primary and recurrent bladder tumours. Patients with primary tumours constituted 34.8% of the cohort. In 55% of cases a solitary tumour was resected. The size of the (largest) tumour was > 3 cm in 28.9% of cases and the detrusor muscle was infiltrated in 13.1% of cases. Preoperative micro- or macroscopic haematuria was noticed in 34.2% of patients. Detailed baseline patient characteristics are presented in Table I. The vast majority of patients underwent monopolar TURBT. Patients undergoing restaging resection, cold-cup biopsy, fulguration only, or cystoscopy only were excluded from the analysis.

Methods

The primary study endpoint was any intra- or postoperative surgical complication. A full list of clinical events defined as potentially related to TURBT in the study is presented in Table II. All patients were followed-up for 30 days postoperatively with at least one telephone contact at the end of the observation. The variables tested for prediction of complications were as follows: patient basic characteristics (sex, age, nicotine use, height, weight, body mass index – BMI, American Society of Anaesthesiologists score – ASA score, presence of haematuria and/or pyuria), oncological data (stage and grade of bladder cancer, presence of concomitant carcinoma *in situ*, number of previous TURBTs, recurrence rate, previous intravesical therapy), and surgical details (number and size of tumours, surgeon experience, surgery time, type of anaesthesia, postoperative catheterisation time, postoperative hospitalisation time, presence of muscularis propria in surgical specimen). All study data were collected by each study site in a dedicated uniform electronic form. Before the study initiation, the protocol was registered within ClinicalTrials.gov (NCT03029663) and was approved by the Institutional Review Board.

Statistical analysis

For binary outcomes, univariate and multivariate logistic regressions were applied. The statistical influence was expressed by a classical odds ratio (OR) together with a 95% confidence interval (95% CI) and a *p*-value. The computation was performed in the R platform [10].

Results

Surgical complications were observed in 228 (23.2%) patients, including 83 (8.4%) patients with more than one complication. When comparing baseline data between patients without and with complications, the latter had larger tumours (2.6 vs. 1.8 cm, $p < 0.01$), longer surgery time (36.2 vs. 26.4 min, $p < 0.01$), longer postoperative catheterisation time (64.0 vs. 25.1 h, $p < 0.01$), and longer postoperative hospitalisation time (1.9 vs. 1.3 days, $p < 0.01$).

Table III presents a detailed list of complications noticed within the study. The most common in-hospital complications were postoperative bleeding defined subjectively as presence of the blood in the urine in the postoperative period ($n = 139$, 14.1%) and intraoperative bladder perforation ($n = 46$, 4.7%). There were 33 cases of Clavien-Dindo grade ≥ 3 complications in 32 patients (3.3%), namely: re-interventions due to bleeding ($n = 17$, 1.7%), bladder perforation ($n = 10$, 1.0%), or urinary retention ($n = 3$, 0.3%); acute coronary syndrome ($n = 1$, 1.0%); deaths due to pulmonary embolism ($n = 1$, 1.0%); and myocardial infarction ($n = 1$, 1.0%). After discharge, the most common complications were lower urinary tract

Table I. Baseline characteristics of the study cohort

Clinical characteristic	Prevalence
Gender:	
Male	737 (75%)
Female	246 (25%)
Age [years]:	
< 65	320 (32.6%)
65–70	226 (23%)
70–75	175 (17.8%)
> 75	262 (26.6%)
ASA:	
1	146 (14.9%)
2	605 (61.5%)
3	219 (22.2%)
4	3 (0.3%)
Missing	10 (1%)
BMI [kg/m^2]:	
≤ 25	307 (31.2%)
25.1–30	424 (43.2%)
30.1–35	184 (18.7%)
> 35	55 (5.6%)
Missing	13 (1.3%)
Nicotine use:	
Yes	395 (40.2%)
No	578 (58.8%)
Missing	10 (1%)
Prior TURBT:	
0	342 (34.8%)
1	276 (28.1%)
2	146 (14.7%)
≥ 3	215 (22%)
Missing	4 (0.4%)
Recurrence rate [rec/year]:	
0 (primary tumour)	342 (34.8%)
≤ 1	535 (54.4%)
> 1	102 (10.4%)
Missing	4 (0.4%)
Previous intravesical chemotherapy:	
Yes	39 (4%)
No	943 (95.9%)
Missing	1 (0.1%)
Previous intravesical BCG immunotherapy:	
Yes	103 (10.5%)
No	878 (89.3%)
Missing	2 (0.2%)
Preoperative haematuria:	
Yes	337 (34.2%)
No	646 (67.7%)

Clinical characteristic	Prevalence
Preoperative pyuria:	
Yes	299 (30.4%)
No	684 (69.6%)
Missing	3 (0.3%)
Level of training of primary surgeon:	
Specialist	547 (55.6%)
Resident	436 (44.4%)
Number of tumours:	
1	542 (55.1%)
2	166 (16.9%)
≥ 3	258 (26.2%)
Missing	17 (1.7%)
Type of anaesthesia:	
Spinal	712 (72.4%)
Intratracheal general	132 (13.4%)
Totally intravenous general	94 (9.6%)
Missing	45 (4.6%)
Tumour size [cm]:	
< 1	238 (24.2%)
1–3	431 (43.8%)
> 3	284 (28.9%)
Missing	30 (3.1%)
Length of hospitalisation [days]:	
≤ 1	752 (76.5%)
2	91 (9.3%)
> 2	135 (13.7%)
Missing	5 (0.5%)
Length of catheterisation [h]:	
≤ 24	767 (78.1%)
25–48	74 (7.5%)
> 48	132 (13.4%)
Missing	10 (1%)
Tumour stage (T):	
0	130 (13.2%)
a	472 (48%)
1	206 (21.1%)
2	129 (13.1%)
PUNLMP	8 (0.8%)
Cis	11 (1.1%)
Missing	27 (2.7%)
High-grade tumour:	
Yes	360 (36.6%)
No	588 (59.8%)
Missing	35 (3.6%)
Concomitant Cis:	
Yes	62 (6.3%)
No	890 (90.5%)
Missing	31 (3.2%)

ASA – American Society of Anaesthesiologists score, BCG – Bacillus-Calmette Guerin, BMI – body mass index, Cis – carcinoma in situ, TURBT – transurethral resection of the bladder tumour.

Table II. Clinical events defined as potentially related to TURBT in the study

Clinical events
Intraoperative events (alphabetic order):
Bladder perforation, extraperitoneal
Bladder perforation, intraperitoneal
Intravesical gas explosion
Injury to bladder mucosa (not related to resection)
Injury to ureteral orifice
Injury to urethra (including "false" passage)
Obturator nerve reflex
Others
Postoperative events (alphabetic order):
Acute urinary retention (after catheter removal)
Bleeding, requiring blood transfusion
Bleeding, requiring conservative treatment
Bleeding, requiring surgical intervention
Cardiac arrhythmia
Death
Deep venous thrombosis
Electrolyte imbalance
Fever
Lower urinary tract symptoms
Myocardial infarction
Orchitis/epididymitis
Pain
Post-TUR syndrome
Prostatitis
Pulmonary embolism
Renal colic
Renal function deterioration
Respiratory tract infection
Stroke
Others
Urinary incontinence
Urinary tract infection

Table III. Detailed list of complications noted within the study

Complication	Number of patients ()
Intraoperative complications:	
Bladder perforation	46 (4.7)
Significant obturator nerve reflex	20 (2.0)
Gas explosion	4 (0.4)
Urethral injury and/or false passage	4 (0.4)
Postoperative complications during hospitalization:	
Haematuria	139 (14.1)
Lower urinary tract symptoms	24 (2.4)
Bleeding requiring re-interventions	17 (1.7)
Urinary retention	10 (1.0)
Bleeding requiring transfusion	7 (0.7)
Bladder tamponade	6 (0.6)
Urinary tract infection	4 (0.4)
Fever	3 (0.3)
Acute coronary syndrome	1 (0.1)
Death due to pulmonary embolism	1 (0.1)
Death due to myocardial infarction	1 (0.1)
Heart failure acute exacerbation	1 (0.1)
Patient catheter self-extraction	1 (0.1)
Renal colic	1 (0.1)
Postoperative complications after discharge:	
Lower urinary tract symptoms not related to infection	68 (6.9)
Urinary tract infection	61 (6.2)
Haematuria	53 (5.4)
Urinary retention	6 (0.6)
Urinary incontinence	3 (0.3)
Impotence	2 (0.2)
Retrograde ejaculation	1 (0.1)
Bleeding requiring re-interventions	1 (0.1)
Bladder perforation requiring re-interventions	1 (0.1)
Walking problems	1 (0.1)
Bladder tamponade	1 (0.1)

symptoms not related to infection (n = 68, 6.9%), symptomatic urinary tract infections (n = 61, 6.2%), haematuria (n = 53, 5.4%), and urinary retention (n = 6, 0.6%), with 6 (0.6%) patients requiring reintervention and no Clavien-Dindo grade ≥ 4 complications.

In a multivariate analysis, high ASA score, nicotine use and the presence of high-grade tumour were the most significant predictors of high-grade complications. The stage of the disease was the strongest predictor of bleeding, while the presence of muscle in the specimen and the resident surgeon were the strongest predictors for bladder perforation. Detailed results of the uni- and multivariate logistic regression analyses between clinical factors and endpoints are presented in Tables IV and V, respectively. Only statistically significant correlations are presented.

Discussion

While TURBT is one the most commonly performed urological procedure, literature data on its safety is scarce. The few studies published in the past enrolled limited numbers of patients, had a retrospective nature, or did not lead to any practical conclusions. We prospectively analysed complications of TURBT, finding that the surgery was associated with a relatively high risk of com-

plications. However, the clear majority of them were of low grade and required only conservative management. For the most common high-grade complications, the most important predictors were high ASA score, nicotine use, high cancer stage and grade, presence of muscularis propria in a specimen, and the resident surgeon. Based on our findings, we believe the rate of complications can be further reduced by proper preoperative identification of high-risk patients, who should be operated on with extra caution by an experienced surgeon.

Bladder perforation is probably the most important complication from a clinical point of view. First, it may require laparotomy and cystorrhaphy in cases of intraperitoneal perforation, while all patients usually require prolonged bladder catheterisation and antibiotic prophylaxis, which have their consequences [11]. Second, bladder perforation influences the oncological outcomes by precluding immediate postoperative intravesical chemotherapy instillation and increasing the risk of extravesical cancer spread [12–14]. In our study, we found that resident surgeon and the presence of muscle in a specimen were factors independently associated with over three-fold higher risk of bladder perforation. For this reason, we strongly believe that complex cases should be faced only by experienced endourologists. Moreover, experienced surgeons are more likely to perform a complete TURBT with a muscle in a spec-

Table IV. Univariate logistic regressions analysis (statistically significant results only)

Clinical event	Predictive factor	OR	95% CI	*P*-value
Complication during hospital stay	Recurrence rate	0.75	0.58–0.96	0.021
	Preoperative haematuria	2.02	1.49–2.73	< 0.001
	Preoperative pyuria	1.46	1.07–1.99	0.018
	ASA score	1.5	1.18–1.92	0.001
	Tumour size	1.32	1.22–1.43	< 0.001
	Surgery time	1.03	1.03–1.04	< 0.001
	High-grade tumour	1.81	1.33–2.45	< 0.001
Any Clavien-Dindo ≥ 3 complication	Nicotine use	2.15	1.07–4.31	0.031
	BMI > 30 kg/m^2	1.06	1.01–1.12	0.023
	Preoperative haematuria	2.22	1.12–4.42	0.023
	ASA score	2.36	1.33–4.2	0.003
	Number of tumours	1.12	1.04–1.21	0.002
	Tumour size	1.29	1.11–1.49	< 0.001
	Surgery time	1.02	1.01–1.04	< 0.001
	High-grade tumour	2.74	1.35–5.54	0.005
Complication during 30-day postoperative period	ASA score	1.44	1.1–1.87	0.007
	Number of tumours	1.07	1.01–1.13	0.015
	Tumour size	1.12	1.03–1.22	0.009
	Surgery time	1.0099	1.0021–1.0177	0.012
Bleeding	Gender	1.65	1.05–2.59	0.03
	Preoperative BCG immunotherapy	0.48	0.23–1.01	0.054
	Preoperative haematuria	1.91	1.33–2.75	< 0.001
	ASA score	1.66	1.23–2.23	< 0.001
	Tumour size	1.4	1.28–1.53	< 0.001
	Surgery time	1.03	1.02–1.04	< 0.001
	Tumour stage	1.91	1.54–2.39	< 0.001
	Muscle in specimen	2.14	1.39–3.31	< 0.001
Bladder perforation	Nicotine use	1.89	1.03–3.44	0.039
	Resident operator	2.23	1.21–4.11	0.01
	Tumour size	1.16	1.01–1.33	0.04
	Surgery time	1.03	1.02–1.04	< 0.001
	Muscle in specimen	3.53	1.48–8.44	0.005

OR – odds ratio, 95% CI – 95% confidence interval, ASA – American Society of Anaesthesiologists score, BCG – Bacillus-Calmette Guerin, BMI – body mass index.

Table V. Multivariate logistic regressions analysis (statistically significant results only)

Clinical event	Predictive factor	OR	95% CI	*P*-value
Complication during hospital stay	Preoperative haematuria	1.5	1.07–2.08	0.017
	ASA score	1.34	1.03–1.74	0.03
	Surgery time	1.03	1.02–1.04	< 0.001
	High grade tumour	1.53	1.11–2.12	0.01
Any Clavien-Dindo grade ≥ 3 complication	Nicotine use	2.26	1.07–4.81	0.034
	BMI > 30 kg/m^2	1.07	1.01–1.13	0.032
	ASA score	2.64	1.38–5.04	0.003
	Number of tumours	1.15	1.06–1.24	< 0.001
	Surgery time	1.02	1–1.03	0.007
	High grade tumour	2.88	1.3–6.37	0.009
Complication during 30-day postoperative period	ASA score	1.48	1.12–1.95	0.005
	Number of tumours	1.07	1.02–1.14	0.012
	Tumour size	1.11	1.01–1.2	0.022
Bleeding	Preoperative BCG immunotherapy	1.2	1.11–1.31	0.008
	Tumour stage	1.83	1.32–2.54	< 0.001
Bladder perforation	Resident operator	3.19	1.39–7.29	0.006
	Tumour size	0.78	0.62–0.97	0.029
	Surgery time	1.02	1–1.03	0.015
	Muscle in specimen	3.4	1.11–10.38	0.032

OR – odds ratio, 95% CI – 95% confidence interval, ASA – American Society of Anaesthesiologists score, BCG – Bacillus-Calmette Guerin, BMI – body mass index.

imen [15–17]. This leads to reduced recurrence rate at first follow-up cystoscopy in NMIBC cases and shorter time to cystectomy in MIBC cases [15, 16, 18]. On the other hand, in stage Ta tumours, the muscularis propria is not mandatory for completeness of TURBT and proper staging, which was confirmed by Shoshany *et al*. [19]. These cases seem more appropriate for residents at their learning curve. Finally, we discussed only clinically significant perforations, while radiological signs of perforation can be present in as many as 58% of asymptomatic patients after TURBT [20]. Bleeding was the most common complication observed in our analysis. It affected almost one sixth of patients in the early postoperative period or after discharge. However, the severity of symptoms ranged from patients treated conservatively to others who needed bladder irrigation, blood transfusion, or surgical reintervention. In contrast to our findings, Hollenbeck *et al*. observed haematuria only in 2.1% of cases in a group of 21,515 TURBTs. At the same time, 30-day mortality of 1.3% was reported [21]. We suppose these differences resulted from the retrospective design of the Hollenbeck study, which hampered precise and adequate data collection on the postoperative course. In the recent observational study by Bansal *et al*., transient haematuria was observed in 26% of patients, and another 6% of patients required blood transfusion or reintervention due to bleeding after TURBT [5]. A modifiable risk factor of perioperative bleeding is coagulopathy. However, according to available data, it is not justified to discontinue antiplatelet monotherapy with acetylsalicylic acid in patients scheduled for TURBT because it does not reduce the bleeding risk significantly but may increase the cardiovascular risk [22]. Carmignani *et al*. showed that TURBT is feasible and relatively safe also in patients receiving dual antiplatelet therapy [23]. However, the risk of bleeding and clot retention may be increased in patients receiving anticoagulation therapy [24].

In our study, significant obturator nerve reflex was observed in 2% of cases. There are many possible methods to decrease this risk under debate [25]. One of them is the use of bipolar resection instead of monopolar. In 2016, Cui *et al*. and Zhao *et al*. published two independent meta-analyses on the efficacy and safety of monopolar and bipolar TURBT. Both research groups analysed data from eight trials, concluding that bipolar resection is associated with fewer complications compared to monopolar TURBT. However, this conclusion is not universal and differs in detail even between these two meta-analyses. While surgery time, catheterisation time, and blood loss are reduced with bipolar resection, data on the risk of obturator nerve reflex, bladder perforation, or transfu-

sion rate are heterogenous [26, 27]. Moreover, in recent studies published by Balci *et al*. and Ozer *et al*. the risk of obturator nerve reflex and bladder perforation is even higher during bipolar than monopolar TURBT [28, 29], while the difference in overall safety was not noticed. In our study, the choice between monopolar and bipolar resection was made by the surgeon. Yet, because of the fact that the majority of procedures were monopolar, the issue was not analysed as a risk factor of complications. Another method to reduce the risk of obturator nerve reflex and bladder perforation in cases of tumours located on later bladder wall is obturator nerve block. While this method is effective [30], its routine implementation in all cases does not seem feasible. In the present study, obturator nerve block was performed only upon request of the operating urologist.

The most important limitation of our study is a short-term follow-up, aimed only at the identification of surgical complications. Because TURBT is an oncological procedure, one can be interested also in the impact of complications on recurrence-free survival, which was not assessed within the study. Another issue is no information regarding surgical technique, especially concerning the use of mono- and bipolar resection or en-bloc and in-fractions resection. While the first issue was discussed before, the latter should also be interpreted with caution because Zhang *et al*. recently observed no advantage of en bloc resection over conventional TURBT in terms of safety [4]. For grading of complications, we adopted the Clavien-Dindo classification, which is now the most accurate one. However, this classification was developed for postoperative complications only, while there is no analogous classification for intraoperative complications. Additionally, catheterisation time and hospitalisation time can be considered both as predictors and outcomes in this study. While they can increase as a result of intraoperative complications (i.e. bladder perforation), they can also influence the risk of postoperative complications (i.e. urinary tract infection, pneumonia, embolism, etc.). Finally, due to the large number of analyses, bias resulting from accidental observations might appear.

In conclusion, TURBT poses a significant risk of surgical complications, the majority of which are of low grade. The most significant, clinically sound predictors of TURBT complications are high ASA score, history of nicotine abuse, high-grade tumour, high-stage tumour, presence of muscularis propria in the specimen, and the resident surgeon. Proper preoperative identification of patients at high risk of complication may further reduce this risk if the surgery is performed carefully by an experienced surgeon.

Acknowledgments

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants. The protocol was registered within ClinicalTrials.gov (NCT03029663) and was approved by the Institutional Review Board of Warsaw Medical University.

Informed consent was obtained from all individual participants.

The data used to support the findings of this study are available from the corresponding author upon request.

Conflict of interest

The authors declare no conflict of interest.

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