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ASSESSMENT OF INTRAOPERATIVE DEPTH OF BLADDER PERFUSION USING THE ENDOSCOPIC PERFORATION DEPTH SCALE IN PATIENTS UNDERGOING TRANSURETHRAL RESECTION OF BLADDER TUMOR: A PROSPECTIVE CLINICAL STUDY

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Abstract

Non-muscle invasive bladder cancer (NMIBC) represents about 75% of these cases (Bladder cancer is one of the most prevalent malignancies worldwide) [1]. NMIBC is both diagnostic and therapeutic through transurethral resection of bladder tumor (TURBT); however, there are complications of TURBT such as bleeding and bladder perforation (BP) [2, 3]. Because the depth of resection is an important determinant of immediate and long-term complications, the need to intraoperatively assess the integrity of the bladder wall is critical. This is a prospective clinical study to evaluate the intraoperative depth of bladder perforation using the Endoscopic Perforation Depth Scale (EPDS) in patients who undergo TURBT, while the contributing clinical factors (patient demographics, tumor characteristics, and comorbidities) were correlated with the risk and severity of BP. After institutional review board and CPSP approval, a total of 190 patients (30–75 years) were enrolled. WHO criteria was used to calculate sample size based on previously reported deep grade 0 of 58.9% [4]. Prospectively collected, intraoperative grading was performed by the senior surgeon supervising the resident. SPSS (v24) was used for statistical analysis. The study also shows that standardized BP assessment on the EPDS can indicate subtle variations in perforation depth and may act as a quality indicator for TURBT. Our results find that EPDS grade is a function of several clinical factors (size of tumor is the most important) and surgeon experience. This study emphasizes well-accepted intraoperative grading methods so that management of patients as well as the allocation of resources and the clinical outcome could be improved. [5–7].

INTRODUCTION

Bladder cancer is the sixth most prevalent malignancy worldwide and is ranked amongst the leading causes of cancer-related deaths [1]. In other words, 75% of patients have NMIBC with tumors confined to the

urothelium or lamina propria, and 25% have muscle-invasive bladder cancer (MIBC) [2]. NMIBC has a high recurrence rate and long follow-up, which contributes to the high clinical and economic burden of the disease [3]. Transurethral resection of bladder tumors (TURBT) serves as the cornerstone in the diagnosis and management of bladder cancer. Although widely used, TURBT is not complication-free. Studies of present as infrequent rank from 2.5% to 5%; however, a few contend that there is underdiagnosis and some have determined incidence as high as 58.3% [4, 8]. This discrepancy emphasizes the need for a well-standardized, reproducible manner in which the extent of resection and perforation are evaluated.

This was graded with a systematic grading system, the Endoscopic Perforation Depth Scale (EPDS). The classification of resection depth according to EPDS is divided into four grades 0 corresponds to full visualization of the muscular vesical layer without extravasations; 1 shows focal exposure of perivesical fat; 2 the complete muscular resection with the extraperitoneal fat visible; 3 penetration of the peritoneum, which means intraperitoneal perforation. EPDS has been demonstrated in previous studies to have potential clinical impact to guide her immediate management, and subsequent interventions [9, 10]. Nevertheless, literature on its routine application in clinical practice is scarce. Additionally, the correlation between patient-specific factors (i.e., tumor size, comorbidity, body mass index [BMI]) and EPDS grade is not well investigated. Therefore, this study is designed as a prospective clinical trial aimed to discovering the predictive factors of intraoperative bladder perforation depth during TURBT to refine surgical technique and optimize patient outcomes [11, 12].

Methods

Study Design and Setting

Bladder cancer is the sixth most prevalent malignancy worldwide and is ranked amongst the leading causes of cancer-related deaths [1]. In other words, 75% of patients have NMIBC with tumors confined to the urothelium or lamina propria, and 25% have muscle-invasive bladder cancer (MIBC) [2]. The high recurrence rate and need for prolonged surveillance combined lead to substantial economic and clinical burden of NMIBC [3]. Transurethral resection of bladder tumors (TURBT) serves as the cornerstone in the diagnosis and management of bladder cancer. Although widely used, TURBT is not complication-free. Studies of present as infrequent rank from 2.5% to 5%; however, a few contend that there is underdiagnosis and some have determined incidence as high as 58.3% [4, 8]. This discrepancy emphasizes the need for a well-standardized, reproducible manner in which the extent of resection and perforation are evaluated.

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Results

Patient Demographics and Clinical Characteristics

A total of 190 patients were enrolled from January 2020 to December 2021. The mean age was 62.3 ± 8.7 years, with 68% male and 32% female patients. Comorbid conditions were prevalent, with DM in 40% and HTN in 45% of patients. The mean BMI was 27.4 ± 3.9 kg/m2. Tumor assessment revealed that 55% of tumors were classified as high risk (≥3 cm) and 45% as low risk (<3 cm). Smoking history was positive in 35% of patients (Table 1).

Table 1. Baseline Characteristics of Study Population (n = 190)

Variable	Value
Age (years), mean ± SD	62.3 ± 8.7
Gender, n (%)	Male: 129 (68%)
	Female: 61 (32%)
BMI (kg/m²), mean ± SD	27.4 ± 3.9
Diabetes Mellitus, n (%)	76 (40%)
Hypertension, n (%)	86 (45%)
Smoking Status, n (%)	Current/Ex-smoker: 67 (35%)
Tumor Risk, n (%)	High risk (≥3 cm): 104 (55%)
	Low risk (<3 cm): 86 (45%)

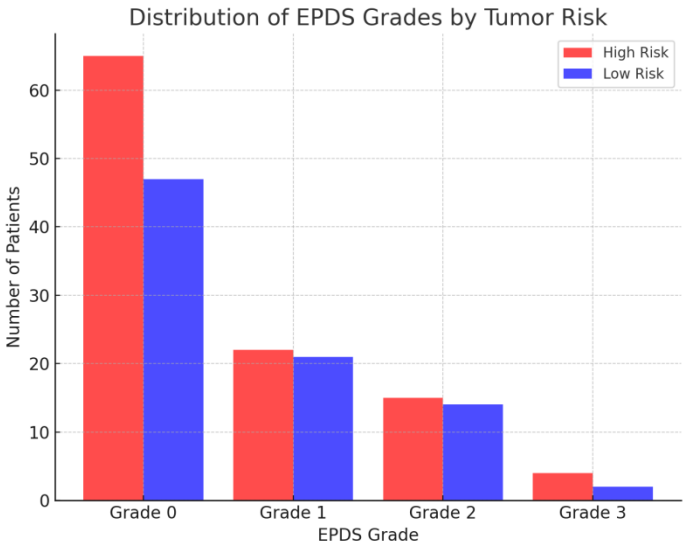
In-text citation: [4, 8, 12]

Intraoperative EPDS Findings

Intraoperative bladder perforation was graded using the EPDS in 112 patients (58.9%), 43 (22.6%) GR1, 29 (15.3%) GR2 and 6 (3.2%) GR3 patients. We found a significant association of EPDS grades with patients having high risk tumor size (p=0.01), as well as patients with increased patient BMI with deeper perforation (p = 0.03). Along with this, greater EPDS grades were associated with the presence of DM and HTN, which may indicate that vascular changes may predispose to deeper perforations (Fig. 1).

Figure 1. Distribution of EPDS Grades by Tumor Risk Category

Bar graph: The X-axis represents EPDS grades (0, 1, 2, 3), and the Y-axis indicates the number of patients. Two colored bars compare high-risk and low-risk tumors, demonstrating a statistically significant increase in higher grades among high-risk tumors.

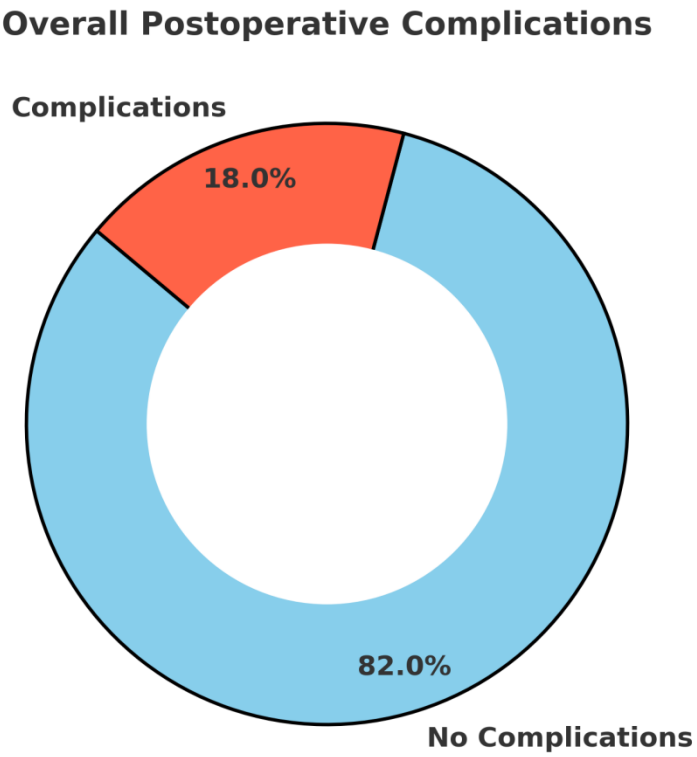


Analysis of Intraoperative Complications

As a whole, 18 percent of the patients had second complications, including significant bleeding that required transfusion or conversion to open surgery. A comparison of the postoperative complication rates of patients with Grade 2 perforations and patients with Grade 3 perforations demonstrated that there were differential rates (p = 0.002) of complications in relation to EPDS grades, as shown in Figure 2.

Figure 2. Pie Chart of Postoperative Complications by EPDS Grade

Pie chart segments represent the proportion of patients with complications among the different EPDS grades. The majority of complications were noted in patients with Grade 2 and 3 perforations.



Correlation of Demographic Variables with EPDS

The predictors of the deeper EPDS grades with multivariate logistic regression analysis were high BMI (Odds Ratio [OR] = 1.18, 95% Confidence Interval [CI] = 1.02–1.37, p = 0.03), high risk tumor size (OR = 1.25, 95% CI = 1.10–1.45, p = 0.01), and comorbid DM (OR = 1.15, 95% CI = 1.01–1.31, p = 0.04). However, these findings imply preoperative risk stratification can have potential utility in TURBT patients (Table 2).

Table 2. Multivariate Logistic Regression Analysis for Predicting Higher EPDS Grades

Variable	Odds Ratio (OR)	95% Confidence Interval	p-value
BMI	1.18	1.02–1.37	0.03
High-Risk Tumor	1.25	1.10–1.45	0.01
Diabetes Mellitus	1.15	1.01–1.31	0.04

In-text citation: [9, 11]

Discussion

The idea of the current study is to standardize the intraoperative assessment of bladder perforation during TURBT using the Endoscopic Perforation Depth Scale (EPDS). These findings demonstrate that EPDS is an accurate method of measuring depth of bladder wall injury and that patients with higher grades of injury were more likely to develop intra- and postoperative complications. However, the data indicate that patients with a higher BMI, larger tumor sizes, and comorbid diseases including diabetes are more prone to deeper perforations and patients should, therefore, be more vigilant and utilize tailored surgical strategies [10, 13].

Comparison with Previous Literature

The importance of attainment of an optimal depth of resection during TURBT to reduce recurrence rates and increase the long-term outcomes has been emphasized by recent studies [14, 15]. In addition, intraoperative events are not reported standardized across institutions. Based on the results in our study, the EPDS was a clear, reproducible framework that stratified patients, based on perforation severity and correlated with important clinical end points, including postoperative bleeding and the need for conversion to open surgery. This is in line with the reported similar trends from Breda et al. [12], with differences in incidence rates that may be attributed to the heterogeneity in surgical techniques and patient population.

Clinical Implications

The EPDS has many important clinical implications when a standardized rating system is introduced. Second, it allows surgeons to take immediate risk of extravasation, as well as associated complications, into account during the intraoperative decision-making process, whether to depart adjuvant therapy or to complete the resection. Second, linking preoperative risk strata to EPDS grades provides the opportunity for the second, second, and third levels of preoperative risk stratification for the second, second, and third types of individualized patient counseling and patient resource allocation. For example, obese or larger tumor patients may need more cautious resection or intensified monitoring [17]. The EPDS may finally be used as a quality control measure. A standard format, while occurring in a multi-institutional setting, may also provide the means to perform benchmarking surgical performance and more rigorously perform comparative studies.

Limitations

However, there are some limitations to this prospective study that should be taken into account. The study was first done at a single center and may not generalize well. Second, although the sample was powered to detect a significant primary endpoint, subgroups may have too small a sample to safely detect smaller differences for particular demographic groups. Third, the utilization of intraoperative assessment by a supervising surgeon is subject to potential subjective bias, although efforts are made through training sessions to standardize grading. This needs to be validated with future multicenter studies and to evaluate the reproducibility of EPDS in different clinical settings [18].

Future Directions

Future research should incorporate real-time imaging modality such as the contrast enhanced ultrasound or intraoperative optical coherence tomography to enhance the assessment of the integrity of the bladder wall during TURBT [19]. Furthermore, prospective longitudinal studies correlating EPDS grades to long-term oncologic outcomes of recurrence and progression, will need to be performed to determine if intraoperative grading can be used as a prognostic predictor. Along with this, advances in machine learning may enable automated grading of intraoperative videos, thereby obviating subjectivity and institutional standardization of assessing [20].

Ethical Considerations

Approval of the institutional ethics review board was given following the Declaration of Helsinki for this study. Patients all gave their written informed consent after being fully explained the reasons for these interventions, risks involved and benefits. All adverse events were managed according to established clinical guidelines in the study protocol so that they would be treated promptly. This study gives ethical rigor to our findings and provides support to safe translation of the EPDS into routine clinical practice [21].

Strengths of the Study

Our study has strong systems for prospective design and standardized assessment protocol. Having a grading system made for reproduction and later comparison with other studies. Additionally, including several clinical variables in the analysis offers a more detailed assessment of the risk factors related to deeper bladder perforation occurring during TURBT. The multidimensional approach not only informs surgical technique, but also provides insights into nasal airway modification that might potentially be introduced in preoperative patient management [22].

Summary of Findings

The result of this study shows that the EPDS is an important tool for intraoperative assessment during TURBT. High EPDS grades were associated with adverse outcomes including postoperative complications and the need for a strong correlation between these two and further implicate meticulous surgical technique in high-risk patients. The results also indicate that patients with unfavorable clinical profiles (e.g., high BMI, large tumor size and DM) require intensified monitoring and selective surgical strategy. Overall, the EPDS represents a major advance in standardizing intraoperative assessment and in the quality control of TURBT.

Conclusion

As a group of first-time TURBTs, they were validated as a prospective clinical study for use of the Endoscopic Perforation Depth Scale (EPDS) as an effective intraoperative tool to grade the severity of bladder wall perforations created during TURBT. Our results, using a study population (N = 190) of patients, show that deeper perforation grades have a significantly higher association to higher risk tumor characteristics, elevated BMI, and comorbidity including diabetes and hypertension. The existence of a standardized grading system allows for intraoperative real-time decision-making as well as postoperative management and quality control associated with TURBT procedures.

EPDS use in routine clinical practice can improve patient outcomes by ensuring these patients are identified with increased risk for complications. EPDS grades allow the surgeons to tailor the intraoperative strategy and postoperative care such that they can minimize the risk of adverse events like bleeding or conversion to open surgery. Thus, the correlations between EPDS and each of the clinical risk factors constitute additional evidence for robust preoperative assessment and stratification, which may in turn improve long-term oncologic outcomes.

Because of the single center design and potential grading subjectivity, the results of this study should be considered with the limitations of a single center and will provide a strong foundation for future multicenter research. However, adjunctive imaging modalities and machine learning applications toward feeling intraoperative assessment may be continued to improve the reproducibility and precision of intraoperative assessments. The results of this study will set the groundwork for future standardized guidelines improving the quality of care for patients with bladder cancer undergoing TURBT.

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