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Efficacy and safety profile of TULA for recurrent non-muscle-invasive bladder cancer among urology outpatients at an NHS district general hospital

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ABSTRACT

Objectives: This case series aimed to evaluate the efficacy and safety of transurethral laser ablation (TULA) for recurrent non-muscle-invasive bladder cancer (NMIBC) at a UK district general hospital. The main objective was to investigate the burden of morbidity from TULA by recording bleeding, pain, and bladder perforation. Also, to determine the rate of recurrence and progression of NMIBC by the first follow-up cystoscopy. **Methods:** This was a retrospective study reviewing patients treated with TULA during the initial 11 months of implementation. Non-probability sampling was used to recruit patients who met the inclusion criteria. Recurrence was defined as a bladder tumour that reoccurred after the first TULA. Progression was defined as a bladder tumour that evolved into a higher grade, higher stage, or spread to other sites. The data was analysed using descriptive statistics, with results presented in tables and graphs. **Findings:** Twenty-six patients, with an average age of 77.63, underwent 30 procedures. Low-grade G2pTa was the most common previous histology. The average treatment lasted 64.73 seconds. Seven out of 14 patients had no recurrence. Six patients (42.86%) developed recurrence, and the most frequent location was off-site (4). Only one patient had progression confirmed with metastatic deposits in the small bowel and passed away seven weeks post-TULA. **Conclusions:** Tula is a safe outpatient intervention for treating recurrent NMIBC early and conveniently, avoiding the need for TURBT in high-risk patients and releasing theatre capacity.

KEYWORDS

Laser; bladder cancer; outpatient; recurrence; progression

1. INTRODUCTION

Bladder cancer (BC) is the tenth most common cancer worldwide [1]. The average age at diagnosis is 75 in the United Kingdom (UK), and 73 in the United States [2,3]. As the global population ages and with improved survival rates, people are living longer with BC [1,2]. Non-metastatic BC is classified as muscle-invasive (MIBC) or non-muscle-invasive (NMIBC) [4]. The latter has a high propensity for recurrence and disease prevalence [4]. The gold standard for treating NMIBC is transurethral resection of bladder tumour (TURBT). The outcome for many frail patients with multiple co-morbidities is increased surgical and anaesthetic risk from repeated TURBT. Additionally, healthcare providers face high resource and economic burdens in managing NMIBC [5]. Transurethral laser ablation (TULA) for recurrent NMIBC is emerging as a promising alternative treatment modality [4, 6,7]. Transurethral laser ablation involves passing a laser fibre via a flexible camera through the urethra into the bladder to destroy superficial cancer cells [6].

In 2015, the National Institute for Health and Care Excellence (NICE) defined the absolute criteria for consideration of fulguration without biopsy for people with recurrent NMIBC. Fulguration uses an electrical current to cauterise the bladder tumour. The criteria included: no previous intermediate or high-risk BC, a disease-free interval of at least six months, solitary papillary recurrence, and a tumour diameter of ≤3mm [8]. The European Association of Urology (EAU) developed this area further by acknowledging the safety of out-patient laser and diathermy in helping to reduce the therapeutic burden on recurrent NMIBC patients [4]. In 2015, Xu Y *et al.* conducted a prospective randomised study demonstrating that laser vaporisation with intravesical lidocaine in an outpatient setting is non-inferior to standard TURBT under general anaesthesia (GA) for the four-month recurrence rate [9]. These key publications, among others, have promoted TULA for urologists considering an alternative to TURBT for recurrent NMIBC. However, more high-quality data on the safety and efficacy of TULA is required.

Growing evidence suggests that TULA patients can continue taking anticoagulants or antiplatelets [10–12]. Yet not all major published studies recorded the use of blood thinners, thus preventing a definite conclusion.

The rates of BC recurrence and progression are crucial in assessing the effectiveness of TULA. These outcomes have been measured differently across major studies, which limits the ability to make robust comparisons. When discussed, the terminology used to describe the location of recurrence varies and lacks clear definitions [10,12,13]. Additionally, the variables employed to evaluate recurrence and/or progression differ; some studies prefer risk classification, others focus on location, while some consider relapse-free time [10–12,14].

The follow-up for most studies was at least 12 months; notwithstanding, a lack of uniformity in the follow-up process remains. Wong *et al.* (2013) performed a follow-up telephone consultation at three days, three months and 12 months [11]. One study conducted a control cystoscopy at three months [12]. In one major study, eight patients were lost to follow-up without explanation [11].

There is growing evidence in favour of TULA as an alternative to TURBT, especially for frail comorbid patients and for healthcare providers facing rising healthcare costs and limited resources. Nonetheless, data from the major studies are heterogeneous and require greater quality and uniformity in assessing the effectiveness and safety of TULA.

The aim of this paper is to evaluate the efficacy and safety of TULA in the initial implementation phase at a district general hospital in the UK. The objectives are: to investigate the burden of morbidity from TULA by recording bleeding, pain, and bladder perforation; to determine the recurrence rate of NMIBC by the first follow-up cystoscopy; to determine the progression rate of NMIBC by the first follow-up cystoscopy.

2. METHODS

2.1. Study Design

This was a retrospective observational study. Data was compiled from a series of cases with a similar background and exposure to TULA.

2.2. Population

The subjects were conveniently sampled from consented patients who underwent TULA as part of their standard National Health Service (NHS) management pathway. The study consisted of a single group and is classed as non-probability sampling. These subjects represent a subset of the wider population of recurrent NMIBC patients. The projected sample size was 20-30 patients and covers the first 11 months of implementing TULA in the Urology department.

2.3. Setting

The hospital data was gathered from the department's records and patient medical records between 27th November and 15th December 2023.

2.4. Data Collection

The data was entered into a modified NICE data collection TULA template. Patient-identifiable details were excluded at data extraction, anonymising the Microsoft Excel dataset, thereby eliminating the need for a legend. The extracted data included demographics, consent, and baseline data about the tumour, including whether a biopsy was taken. The site and number of bladder tumours at TULA were captured, along with outcome measures of benefit, such as tumour recurrence and progression. Adverse outcomes, including pain, bladder perforation and Emergency department (ED) presentation/hospital admission, were also included. Previous BC histology and intravesical therapy were incorporated, along with alternative treatments.

The 1973 and 2004 WHO classification systems were used to grade BC. Recurrence was defined as a tumour that reoccurred at any point after the first TULA. It was predicted that the timing of follow-up cystoscopy would vary among patients. Therefore, the first cystoscopy post-TULA was defined as the follow-up for each patient. Local recurrence was defined as a bladder tumour in the same anatomical region of the bladder as the previously resected tumour(s). Due to the small sample size, patients were divided into the following groups: left lateral, right lateral, anterior wall, posterior wall, and trigone. Progression, based on histology or imaging, was defined as a bladder tumour that evolved into a higher grade, higher stage, or spread to other sites.

2.5. Inclusion and Exclusion Criteria

The inclusion criteria were as follows: previous histological diagnosis of NMIBC; low or intermediate risk of progression, or patients at high risk of progression but with a high surgical risk (American Society of Anesthesiologists (ASA) 4); recurrence of bladder tumour confirmed on surveillance cystoscopy; and patient consent for TULA.

Participants were excluded based on the following: previous histological diagnosis of MIBC; high risk of BC progression; active urinary tract infection confirmed by urine dipstick; clinically unwell to undergo TULA; and refusal/absence, or withdrawal of consent.

2.6. Ethics Approval

The Anglia Ruskin University Faculty Research Ethics Panel for Health, Medicine and Social Care approved the study on 1st November 2023. Also, the hospital's Clinical Audit department granted ethics approval.

2.7. Data Analysis

The data was cleaned and analysed using descriptive statistics. IBM SPSS Statistics (version 29) software was employed to interrogate the data. Due to the weakness of the data, inferential statistics

were not performed. The results have been presented in frequency tables and graphs, highlighting trends and outliers.

3. RESULTS

3.1. Study Subject Characteristics

From 5th January 2023 to 15th November 2023, 30 procedures were performed on 26 patients. The average age followed a Gaussian distribution; 68.2% of patients fell within 67.91 and 87.35 years. Four patients were in their nineties. These basic demographics are presented in **Table 1**.

Table 1. Patient characteristics

Patient (n)		26
Procedure (n)		30
Age	Mean (±SD)	77.63 (± 9.72)
	Range	54 - 96
Sex	Male	23 (76.7 %)
	Female	7 (23.3 %)
ASA (mean)		3
Blood thinners (n)		5 (19.2 %)

3.2. Original Bladder Cancer Histology

The modal diagnosis for previous BC was low-grade (LG) G2pTa **Fig. 1**. Though one patient had carcinoma in-situ (Cis), they were unfit for surgery and so underwent TULA.

3.3. TULA Procedure

TULA treatments ranged from 3 to 246 seconds (s). Two cases lasted 3s and involved ablating a single tumour each. Conversely, two bladder lesions were treated in the longest case. These lesions were estimated at 0.75mm and 3.00mm in diameter and located on the anterior bladder wall. This patient received a subsequent TULA session that lasted 64s and closely approximates the average for this case series, 64.73s.

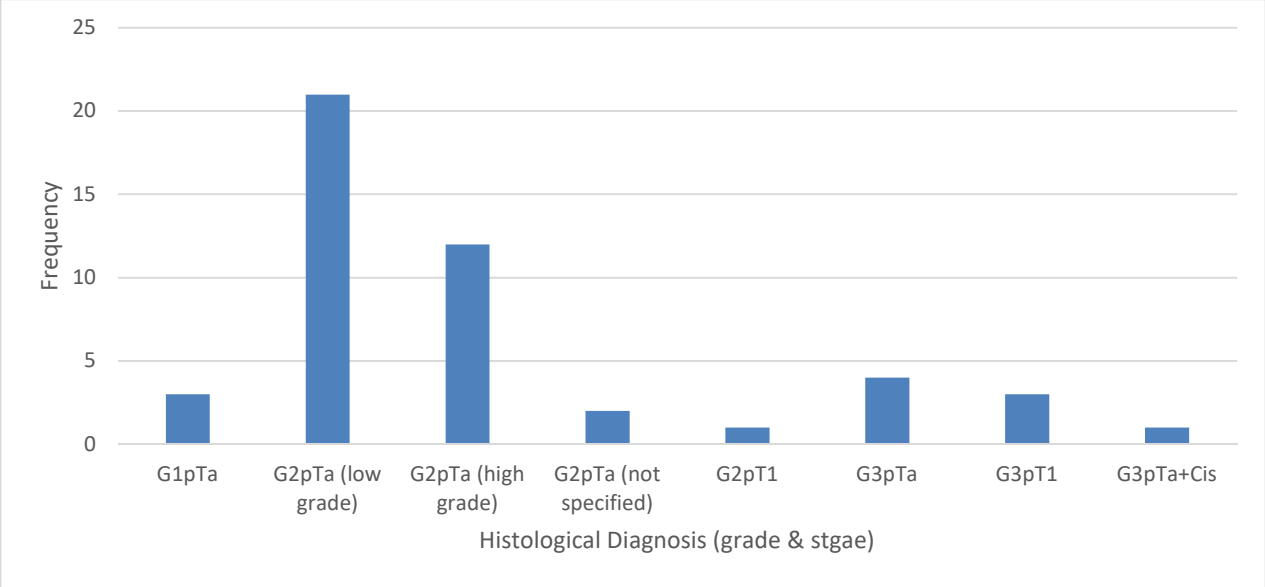

Figure 1. Frequency of previous bladder cancer histology

3.4. Recurrence of Bladder Tumour Post First TULA

Four patients underwent a second TULA procedure. Thus, 53.85% (14 out of 26) of subjects received their first follow-up cystoscopy within 10 weeks after the last recorded TULA procedure **Fig. 2**. The most common finding was no recurrence (50.00%). Six patients (42.86%) had recurrent bladder tumours, and off-site (4) was the most frequent location. Unfortunately, one patient died from metastatic BC before their first cystoscopy. Hence, they are included in the calculations and represented as N/A (not applicable).

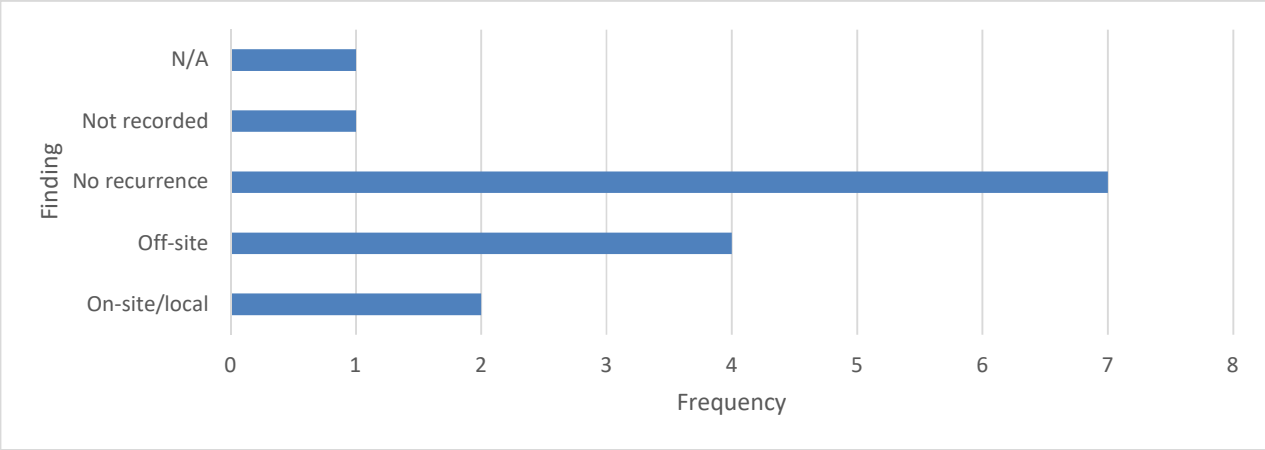

Figure 2. First follow-up cystoscopy outcomes by the site of recurrence post-TULA

3.5. Bladder Cancer Progression

No biopsies were taken of the recurrent bladder tumours post-TULA. The patient with BC progression post-TULA had metastatic deposits in the small bowel and passed away seven weeks post-TULA.

3.6. Safety of TULA

In addition to the above, two patients presented to the ED, were managed in the department, and were sent home.

One patient graded their pain three out of 10 using the Visual Analogue Scale (VAS). No procedure was stopped due to pain, and there was no report of bladder perforation. All patients voided without a urethral catheter immediately post-TULA, and no patient presented to the hospital ED with difficulty voiding.

4. DISCUSSION

4.1. TULA Safety Profile

4.1.1. Bleeding

There was no record of intraoperative or immediate post-TULA haematuria. Standard flexible cystoscopy can cause bleeding in at least one in 10 patients [15]. One patient presented to the ED, five days post-TULA, complaining of severe haematuria that morning. They were discharged home as their urine was light rose. This patient was also on edoxaban for atrial fibrillation, which they administered the day of their procedure. One could infer that patients without anticoagulation/antiplatelet therapy have a lower risk of haematuria. At a minimum, TULA poses a low risk of intra-procedure and immediate post-procedure haematuria.

4.1.2. Pain

A systematic review by Malde in 2022 calculated the TULA mean VAS for pain as one [16]. It is unclear whether the patient who scored 3/10 for pain was referring to the whole procedure or just laser ablation. Hence, more specific responses are required to highlight trends. Nevertheless, no procedure was abandoned due to pain, and this was without the use of analgesia [9,14].

4.1.3. Bladder Perforation

There was no record of bladder perforation. The patient with the most pre-TULA bladder procedures had four TURBTs at varied sites, four cold cup biopsies and two cystodiathermy procedures. Eight of these GA procedures resulted in the diagnosis of BC. According to some authors, despite safe guidelines, such a patient would be classed as heavily pretreated and therefore at risk of bladder perforation [17]. Interestingly, this patient had two TULA sessions. The first lasted 246s, treating two bladder tumours; the longest duration in this study. The second, 64s. Protective factors in this case series may have been the lack of over-distension, thereby maintaining bladder wall thickness [18].

4.1.4. Laser en-bloc Resection

One patient underwent en-bloc laser resection of a single papillary urothelial bladder tumour, which is a different technique compared to laser ablation. This technique is recorded in the literature for primary cancers and used in clinical practice. The rate of recurrence is comparable to that of standard TURBT; however, the certainty of evidence on recurrence is low [19,20]. In the context of this study, en-bloc laser resection aligns with the principle of reducing the therapeutic burden for elderly, frail, and comorbid patients with recurrent MNIBC.

4.2. Efficacy of TULA

4.2.1. TULA-Related Bladder Tumour Recurrence

Six out of 14 patients had recurrence of bladder tumour at their first surveillance cystoscopy. There was no record for one patient. Based entirely on the findings reported at the first surveillance cystoscopy, the recurrence rate was 42.86%. The patient who died from metastatic BC seven weeks post-TULA may have developed a recurrent bladder tumour, raising the recurrence rate to 46.67%. Despite the low follow-up, 42.86% is comparable to the overall rate of recurrence (47%) in the literature [16]. Most major studies performed their first follow-up cystoscopy at three or six months. Also, 42.86% was recorded after a shorter follow-up, 14 versus 22 months (range 0 – 74). Furthermore, on-site/local recurrence of 33.33% closely follows the literature at 32% [16]. A larger sample should reduce variability in sampling distribution, thereby more accurately reflecting this subset of recurrent NMIBC patients.

4.2.2. Progression

The only histologically proven case of post-TULA progression was a male in his seventies with a 20-pack-years history of smoking cigarettes. He presented to the ED complaining of abdominal symptoms and was provisionally diagnosed with adhesional small bowel obstruction. He was managed conservatively but later required surgery. The patient continued to deteriorate post-operatively and was subsequently palliated. They passed away two days later. Histology of the resected bowel demonstrated urothelial cells infiltrating the bowel wall. More data is required to discuss progression post-TULA.

4.2.3. Probability Calculator

The European Organisation for Research and Treatment of Cancer (EORTC) calculator, recommended by EAU [4] and provided by Omni [21], was used to generate probabilities of recurrence

and progression. The average values from this study were used. The one-year recurrence for this study (46.67%) was higher than the EORTC calculator (38%). The EORTC one-year predicted progression for this study is 5%. As only one patient had histology, the strength of the data on progression is weak. However, if accurate, 3.85% would compare better than the calculated probability.

4.2.4. Limitations

A major limitation of this study is that retrospective data is inferior to prospective data [22]. Unknown confounding factors can influence the results of retrospective studies. Also, it is not possible to establish a relationship between risk factors and outcomes. With better recruitment and a longer study window, a prospective study would be feasible.

The small sample size is another limitation. Notwithstanding, for a busy district general hospital serving a population of around 331,000, it reflects activity in the first 11 months of implementation. A larger sample size would help to generate more accurate results, identify outliers and better represent the larger subset of recurrent NMIBC patients unsuitable for TURBT. Hence, hypotheses could be generated for future research.

A further limitation was the lack of bladder biopsies, which prevents assessment of histological progression. Some clinicians argue that taking biopsies causes bleeding, which hampers visibility as the single working channel is occupied with the laser fibre instead of irrigation fluid. It has also been established that skilled urologists can distinguish between recurrent NMIBC and MIBC; thereby reducing the need for biopsies [23].

The most common laser used in major studies is the Holmium-doped Yttrium Aluminum Garnet (Ho:YAG), compared with the Leanardo Mini used in this study. As the type of laser used may influence outcomes, comparing the results of this study with other studies requires caution.

Another limitation is the documentation of the duration of TULA treatment. It is unclear whether cystoscopy and TULA treatment were timed together or laser treatment alone. Based on the wide spectrum of values, both categories may be represented. For example, 246s is a relatively long time to ablate a tumour.

5. CONCLUSIONS

This case series confirms that TULA is a safe and convenient intervention for the outpatient management of recurrent NMIBC. Despite the small sample size, the rate of bladder tumour recurrence was higher than the EORTC probability calculator. If patients are selected appropriately, this can help reduce the therapeutic burden for the ageing population cared for by the hospital and save costs.

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AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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