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Bladder Cancer

RESECT: A Randomised Controlled Trial of Audit and Feedback in Non–muscle-invasive Bladder Cancer Surgery

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Abstract

Background and objective: We aimed to determine whether audit, feedback, and education improves surgical performance after transurethral resection of bladder tumour surgery for non–muscle-invasive bladder cancer and as a secondary aim if it reduced recurrence rates.

Methods: This cluster randomised controlled trial compared audit and feedback plus peer comparison and education, with audit alone for four coprimary outcomes: (1) Single-instillation chemotherapy, (2) detrusor muscle sampling, (3) documentation of tumour features, and (4) resection completeness. Early recurrence was a secondary outcome.

Key findings and limitations: A total of 100 sites were randomised to intervention and 101 to control. In total, 14 915 patients were included. Intervention sites significantly improved documentation of tumour features (adjusted mean difference [95% confidence interval {CI}]: 6.0 [1.8, 10], $p = 0.005$) and of resection completeness (adjusted mean difference [95% CI]: 5.5 [1.5, 9.5], $p = 0.007$). There was no statistically significant difference in chemotherapy use (adjusted mean difference [95% CI]: 0.3 [–4.7, 5.3], $p = 0.9$) or detrusor muscle sampling (adjusted mean difference [95% CI]: 2.6 [–1.3, 6.4], $p = 0.2$). There was no statistically significant difference in early recurrence rate between arms (adjusted odds ratio [95% CI]: 1.02 [0.8, 1.4], $p = 0.9$); however, in the control arm, the early recurrence rate reduced compared with baseline (adjusted odds ratio [95% CI]: 0.7 [0.6, 0.9]).

Conclusions and clinical implications: Audit and feedback with education improved the documentation of important surgical findings that influence clinical management, but not the performance of detrusor muscle sampling, adjuvant chemotherapy use, or early recurrence rates. Improvements observed in the control arm may explain a lack of effect of the intervention in some outcomes.

ADVANCING PRACTICE

What does this study add?
This randomised study shows that in patients with non–muscle-invasive bladder cancer (NMIBC), audit of transurethral resection of bladder tumour (TURBT) outcomes, followed by feedback with peer comparison and education, leads to better documentation of TURBT surgery, but does not improve detrusor muscle sampling or adjuvant chemotherapy use. However, the control arm improved even without the feedback and education intervention, including a significant reduction in the early recurrence rate compared with baseline. Improvements in the control arm may explain a lack of effect of the intervention in some outcomes. This suggests that by simply being monitored, surgeons can reduce recurrence rates in NMIBC. We reinforce the idea that national audits are likely to improve bladder cancer surgery quality and propose that these should be implemented.

Clinical Relevance
This large, international randomized controlled trial provides the first high-level evidence that audit and feedback with education can improve documentation quality of procedural findings and outcomes in transurethral resection of non-muscle-invasive bladder tumours. While the intervention did not significantly impact detrusor muscle sampling, adjuvant chemotherapy use, or early recurrence rates, the study highlights the potential of structured auditing processes to

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standardize and elevate surgical practice across diverse healthcare provider settings. For the uro-oncology community, these findings underscore the importance of implementing systematic prospective programs to enhance surgery quality and potentially improve long-term outcomes of patients with cancer. Associate Editor: Gianluca Giannarini, MD.

Patient Summary

The quality of superficial bladder cancer surgery varies widely across hospitals. Quality includes whether the surgery was deep enough to remove all the tumour and whether additional bladder treatments were given, which can influence whether the cancer comes back, and, if full documentation of the tumour and operation was done, which informs best future cancer management. In this study, we looked at whether audit and feedback improve surgical quality for superficial bladder cancer. We asked hospitals to audit their bladder cancer cases, which were randomly divided in two groups. We gave one group feedback on their performance and education. The other group did not receive these feedback and education. We found that the feedback and education improved the documentation of the tumour and operation, but not how deep the resection was or of additional treatments. However, taking part in the study, regardless of getting feedback and education, appeared to reduce the number of cancer recurrences.

1. Introduction

The standard of care, primary treatment for suspected non–muscle-invasive bladder cancer (NMIBC) is surgical transurethral resection of bladder tumour (TURBT). NMIBC is a disease with poor clinical outcomes and high recurrence rate, progression rate, and health economic burden [1–3].

Compliance with evidence-based practice [4–10] for primary NMIBC treatment varies widely, which may lead to inequitable oncological outcomes [11–13]. A quality improvement initiative in Scotland demonstrated that a national audit and feedback programme for TURBT surgery was associated with improvement in surgical quality over time [14,15] and reduced recurrence and progression rates [16]. However, this study had no internal control or baseline performance, so it is difficult to disentangle the observations from secular trends or random variation.

This study is the first randomised controlled trial (RCT) of audit and feedback in TURBT surgery, aiming to determine whether "audit, feedback, and education" improves achievement of TURBT performance indicators at the cluster level. A key secondary aim is to determine whether audit, feedback, and education reduce the early NMIBC recurrence rates at the case level.

2. Patients and methods

2.1. Design

The protocol has been published (Supplementary material) [17].

This pragmatic, parallel, cluster RCT with 1:1 allocation ratio between arms was embedded in an international multicentre observational study. Any global health care organisation performing TURBT surgery for NMIBC was eligible and was defined as a cluster. The intervention was delivered at the cluster level.

The study had four phases: (1) site registration and evaluation of usual practice; (2) collection of baseline performance data for at least 20 consecutive patients at each site who underwent TURBT surgery prior to the study commencement; (3) randomisation of sites; and (4) prospective data collection: sites submitted data for at least 20 consecutive TURBT cases performed after randomisation.

2.2. Site inclusion and exclusion criteria

The inclusion criteria were at least 20 consecutive baseline cases. All consecutive cases performed by all surgeons in each site were included. Sites were excluded if these did not submit a further $\geq$20 eligible cases after randomisation.

2.3. Case inclusion and exclusion criteria

Consecutive cases at each site were included if they underwent elective *primary* TURBT for presumed NMIBC. Concurrent upper tract urothelial carcinoma cases were excluded.

2.4. Intervention and control

The intervention was administered via a web-based feedback and education dashboard (Supplementary Fig. 1) at the cluster level and was informed by the Theoretical Domains Framework [18]. Intervention development is reported in the protocol. Barriers and facilitators to optimal TURBT were understood from our previous qualitative study [19] and systematic reviews, and were then mapped to behaviour change techniques with behavioural theory underpinnings and empirical evidence of performance improvement [20,21].

Following randomisation, sites in the intervention arm were fed back their baseline achievement of the four perioperative TURBT quality indicators, compared with other participating anonymised site's achievement and a target achievement level. Quality indicators and targets were derived from the literature, NMIBC guidelines [8,10], and expert steering group consensus after an external peer review [17]. These were chosen either because of high-certainty evidence supporting their efficacy in reducing NMIBC recurrence rates (single instillations and detrusor muscle sampling) or due to strong guideline recommendation stating that specific practices are associated with better NMIBC outcomes (tumour feature and resection completeness documentation). Investigators could stratify their feedback by tumour grade and at the individual anonymised

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surgeon level. Education was provided via expert operative videos on how to obtain detrusor muscle, proformas for documentation of TURBT outcomes, recorded educational videos, evidence summaries, and links to the evidence base [17].

Principal investigators were asked to disseminate the performance data to their department. A postrandomisation site evaluation was done to determine compliance and whether practice had changed.

The control group participated with data collection but had no feedback peer comparison or education. Control sites were informed that they would not receive feedback until the end of the prospective phase of the study and were asked to continue collecting data until that time. They were not aware of what the intervention arm would specifically involve and were not given access to training materials or comparison of their performance in relation to peers.

2.5. Primary outcomes

Four coprimary outcomes were measured at the cluster level as the baseline-adjusted average of proportional achievement of each outcome at each site in each arm. Cases were excluded from specific outcomes where relevant data were investigator missing.

The coprimary outcomes were the proportions of eligible cases:

1. With tumours >5 mm where detrusor muscle was present in the surgical specimen.
2. Where single-instillation intravesical chemotherapy (SI-IVC) was administered within 24 h of TURBT. Sites where insurmountable local or national service, supply, or economic constraints preventing SI-IVC use were reported at study enrolment were excluded from this outcome a priori.
3. Where resection completeness is documented in the operation record.
4. Where all of the tumour number, size, and location are documented in the operation record.

2.6. Secondary outcomes

The key secondary outcome was recurrence at first check cystoscopy performed within 12 mo of complete TURBT, assessed at the patient level (early recurrence rate). Cases were excluded if a check cystoscopy was not performed within 12 mo, had missing data, or muscle-invasive bladder cancer was identified pathologically at TURBT. A sensitivity analysis to impute recurrence status where data about a check cystoscopy performed within 12 mo were missing was also undertaken, and a second sensitivity analysis was conducted, restricting the allowable time for first check to 6 mo.

Other secondary outcomes included (1) the proportion of eligible cases in whom all applicable primary outcomes were achieved, assessed at the site, and (2) the grade $\geq$3 complication rate within 30 d of surgery according to the Clavien-Dindo classification [22].

2.7. Sample size

Based on the Scottish TURBT Quality Performance Indicator (QPI) programme [14], we chose the indicator with the largest standard deviation (SI-IVC) to determine sample size. We performed the sample size calculation for a difference between two means using Stata18 command "power twomeans 0.751 0.651, sd(0.2) power(0.9)". With a mean achievement of 0.651 (standard deviation 0.2) for SI-IVC, recruitment of 172 sites (86 per arm) would give 90% power to detect a difference of 0.1 between the intervention and control groups at the 5% significance level.

2.8. Randomisation

Sites were randomised 1:1 in parallel arms and was minimised (using a sliding window modification of the maximum tolerated imbalance procedure [18]) for geographical region and the presence of a pre-existing TURBT audit. Sites randomised to control were blinded to the peer-comparison performance feedback and education tool; there was no allocation blinding.

2.9. Statistical methods

Full statistical methods are outlined in the published protocol and statistical analysis plan (Supplementary material).

2.9.1. Primary outcomes

The average, baseline-adjusted rates of achievement for the four coprimary outcomes per site were compared between the intervention and control sites using a mixed-effect linear regression. The regression model used fixed effects for the study arm (intervention), pre-existing audit, and baseline achievement. A random effect (intercept) was included for the region. Missing data were not imputed. A subgroup analysis was planned to describe the primary outcomes in low- and high-grade tumour groups for SI-IVC and detrusor muscle sampling.

2.9.2. Secondary outcomes

For (1) early recurrence rate, (2) Clavien-Dindo complications of grade $\geq$3, and (3) composite achievement of all coprimary outcomes, a mixed-effect logistic regression was used including random effects for surgeons nested within sites. Fixed effects were included for the intervention arm; tumour size, number, and grade; stage; and patient age and sex. After journal statistical review and recommendations, we imposed a time limit for patients to be included in the analysis for recurrence, which was a check cystoscopy within 12 mo of complete TURBT, and included a sensitivity analysis restricting to those patients with a check cystoscopy within 6 mo and a sensitivity analysis including multiple imputation for missing data. For multiple imputation of recurrence status, a logistic model with tumour size,

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number, stage, and grade in addition to gender, age, and treatment group was used to impute missing recurrence status.

2.9.3. Estimating the Hawthorne effect

The Hawthorne effect (impact of being observed) was a post hoc analysis undertaken to help in the understanding of observed effects in the primary and secondary outcomes. It was estimated by comparing the baseline performance with the in-study phase performance in the control group. For recurrence, this was estimated using a mixed-effect logistic regression as specified above with the addition of cohort (baseline vs in study) as a fixed effect.

2.9.4. Multiple hypothesis tests and significance level

Hypothesis tests were performed for the four coprimary outcomes, the key secondary outcome (early recurrence rate), and the composite outcome. Therefore, a Bonferroni correction was applied, and significance was accepted at $p = 0.0083$. Displayed confidence intervals (CIs) are not adjusted for multiple testing.

2.9.5. Consent and ethical approval

Site principal investigators gave written consent for enrolment. Local or national ethical and/or institutional approval or exemption was obtained at each participating site.

3. Results

3.1. Recruitment

Sites (220) were randomised between October 5, 2021 and March 15, 2023, and data were collected until July 31, 2023. There were 19 site exclusions (ten intervention and nine control; Fig. 1).

3.2. Study population characteristics and balance between arms

3.2.1. Sites

Sites were from mainland Europe (63 sites [31%]), UK (84 [42%]), Asia (25 [12%]), North America (19 [9.5%]), South America (two [1.0%]), Africa (seven [3.5%]), and Australia (one [1.0%]). Of the sites, 137 (68%) were academic hospitals. Site features were adequately balanced between arms (Table 1).

3.2.2. Cases

The primary analysis included 14 915 cases across both phases; 6705 cases were after randomisation. The median patient age was 72 (62, 77) yr; 1448/6699 (22%) patients were female.

Details of the surgical technique, tumour features, histology, follow-up, and operating surgeons are provided in Supplementary Tables 1 and 2.

3.3. Primary outcomes

The mean rate of documentation of all tumour features increased from 78.5% (baseline) to 86.7% (after intervention) and from 78.7% (baseline) to 81.0% (in study) in the control arm (adjusted mean difference 6.0%; 95% CI 1.8, 10.3; $p = 0.005$; Table 2 and Fig. 2).

The rate of documentation of resection completeness increased from 84.7% (baseline) to 90.9% (after intervention) and from 82.0% (baseline) to 84.3% (in study) in the control arm (adjusted mean difference 5.5%; 95% CI 1.5, 9.5; $p = 0.007$).

There was no statistically significant difference between the intervention and control groups in detrusor muscle sampling (increased from 77.1% [baseline] to 78.4% [after intervention] and decreased from 76.0% [baseline] to 73.6% [in study] in the control arm [adjusted mean difference 2.6% {–1.3, 6.4}; $p = 0.2$]).

There was no statistically significant difference between the intervention and control groups in SI-IVC administration rates (increased from 40.7% [baseline] to 44.9% [after intervention] and from 42.6% [baseline] to 46.5% [in study] in the control arm [adjusted mean difference 0.3% {–4.7, 5.3}; $p = 0.9$]).

3.4. Secondary outcomes

Of the patients receiving a check cystoscopy within 12 mo, 90% received it within 6 mo. Of 11 004 eligible patients, 1447 (13%) did not have a check within 12 mo or had missing data; this was similar between arms (Table 3) and reasons are given in Supplementary Figure 2. There was no statistically significant difference between the intervention and control groups in early recurrence (385/2090 [18.4%; intervention] vs 405/2199 [18.4%; control]; adjusted odds ratio [95% CI]: 1.02% [0.77, 1.36]; $p = 0.87$; Table 3 and Supplementary Fig. 2). The intervention appeared to improve the composite achievement of all applicable TURBT performance indicators, but without statistical significance (intervention arm increased from 24.9% to 32.2%; control arm increased from 24.5% to 27.6% [adjusted mean difference 4.3 {–0.3, 8.8}; $p = 0.07$]; Table 2). The rate of Clavien-Dindo grade $\geq$3 complications was similar between arms (intervention: 50/2945 [1.7%] vs control: 55/2902 [1.9%], odds ratio 0.75 [0.42, 1.35]; Supplementary Table 3).

3.5. Describing the Hawthorne effect

3.5.1. Primary outcomes

There were numerical improvements in all coprimary outcomes in the control arm between baseline and in study except for detrusor muscle sampling, which decreased (Table 2). The largest trend for improvement in the control arm was for SI-IVC, which increased from median (25th, 75th) 44.1% (21.5, 63.3) at baseline to 50.0% (26.1, 61.5), with an odds ratio of 3.7 (95% CI –0.5, 7.8).

3.5.2. Secondary outcomes

Early recurrence rate was lower in the control arm in-study than at baseline (24% [baseline] vs 18% [in-study]; patient and tumour factor-adjusted risk difference [95% CI] –5.4% [–7.7, –3.2]; Table 3). This effect was preserved after multiple imputation of missing data and when the analysis was restricted to first check cystoscopy performed within 6 mo (Supplementary Table 8). The characteristics of patients in

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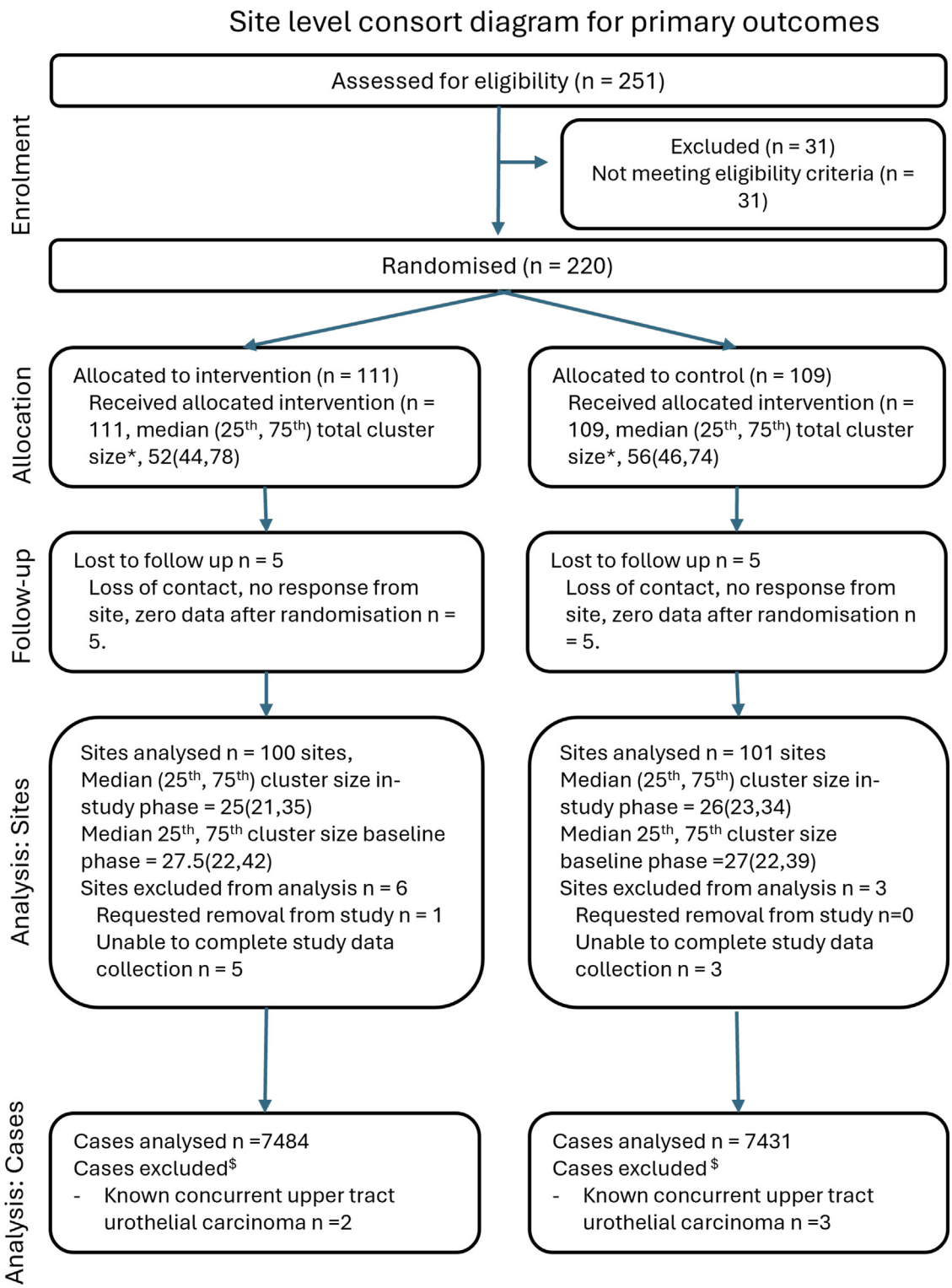

Fig. 1 – Site-level consort diagram.

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Table 1 – Site-level characteristics

	Intervention (N = 100)	Control (N = 101)
Total number of urologists, median (quartiles)	8.0 (6.0, 10.5)	9.0 (6.0, 12.0)
Number of urologists performing TURBT, median (quartiles)	6.0 (5.0, 8.0)	6.0 (5.0, 9.0)
Number of trainee urologists, median (quartiles)	6.0 (4.0, 9.0)	6.0 (4.0, 10.0)
Estimated case volume per week (first tumour TURBT), median (quartiles)	3.0 (2.0, 5.0)	3.0 (2.0, 5.0)
Estimated case volume per week (recurrent tumour TURBT), median (quartiles)	3.0 (2.0, 5.0)	3.0 (2.0, 5.0)
Continent, n/N (%)		
Europe—UK	43/100 (43)	41/101 (41)
Europe—Non-UK	30/100 (30)	33/101 (33)
South America	2/100 (2.0)	0
North America	8/100 (8.0)	11/101 (11)
Australia and New Zealand	1/100 (1.0)	0
Asia including the Philippines	12/100 (12)	13/101 (13)
Africa	4/100 (4.0)	3/101 (3.0)
Type of institution, n/N (%)		
Nonacademic district or general hospital	25/100 (25)	28/101 (28)
Tertiary university hospital/academic hospital	66/100 (66)	71/101 (70)
Private hospital	5/100 (5.0)	2/101 (2.0)
Other	4/100 (4.0)	
Type of surgeon performing TURBT, n/N (%)		
(Mostly) one urological surgeon	4/100 (4.0)	5/101 (5.0)
(Mostly) only surgeons with a specialist interest in bladder cancer	15/100 (15)	18/101 (18)
Any urological surgeon	81/100 (81)	78/101 (77)
Dedicated TURBT lists exist, n/N (%)		
Yes	33/100 (33)	34/101 (34)
Pre-existence of a formalised routine TURBT audit, n/N (%)		
Yes	33/100 (33)	27/101 (27)

TURBT = transurethral resection of bladder tumour.

whom a first check cystoscopy within 12 mo was not available were similar between the intervention and control arms, and between the baseline and in-study phases (Supplementary Table 7). For the composite outcome at the site level (achievement of all of the four coprimary outcomes applicable), this was greater in study (27.6%) than at baseline (24.5%) in the control arm (mean difference [95% CI] 3.1% [−0.2, 6.5]; Table 2). The rate of Clavien-Dindo grade $\geq$3 complications appeared lower in study than at baseline in the control group (2.9% [baseline] vs 1.9% [in study], adjusted risk difference [95% CI]: −0.7% [−1.5, 0.1]; Supplementary Table 3).

3.6. *Tumour grade planned subgroup analysis*

For the primary outcomes, SI-IVC and detrusor muscle sampled were analysed in low- and high-grade tumour subgroups (Supplementary Table 4). Detrusor muscle sampling appeared greater in the intervention arm than in the control arm for low-grade tumours (adjusted mean difference 8.9% [3.4, 14.3]), but not for high-grade tumours (adjusted mean difference 0.2% [−5.2, 5.6]). There was no apparent difference between the intervention and control groups for SI-IVC in either low- or high-grade tumours (Supplementary Table 4).

3.7. *Intervention fidelity and contamination*

We did not record site- or surgeon-level interaction with the feedback and education resources, nor mandate any specific educational meetings beyond giving access to these. In the intervention arm, 96/100 (96%) sites confirmed compliance with dissemination of the intervention at their site. This included forwarding by e-mail (57%), presenting at departmental meetings (55%), and speaking to surgeons individually (45%; Supplementary Table 5).

In the postrandomisation evaluation, in the control arm, 13/101 (13%) sites reported some unprompted practice improvements (Supplementary Table 6).

Specific improvement actions undertaken in the intervention arm are shown in Supplementary Table 5.

The lead investigator at each site in the intervention arm also rated the perceived utility of the intervention components (Supplementary Table 5). The peer-comparison performance dashboard had the highest "very useful" rating (59/96 [61%] sites).

4. Discussion

This is the first audit and feedback RCT in TURBT surgery. The principal findings of this study include that receiving feedback and education increased rates of documentation of important TURBT procedural findings and outcomes that are strongly recommended in international guidelines (since these are crucial to subsequent cancer treatment decision-making). This intervention neither increased the rates of detrusor muscle sampling and SI-IVC, nor decreased the recurrence rate after TURBT surgery. Improvements in practice were seen in the control arm, particularly for SI-IVC, which could explain the lack of difference attributable to the intervention.

There was an apparent clinically significant Hawthorne effect for the early recurrence rate—patient and tumour factor–adjusted recurrence rates improved in the control arm during the study compared with baseline (a 6% absolute and 24% relative reduction). The Hawthorne effect (or

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Table 2 – Site-level outcomes [a]

Outcome	Study phase	Intervention (*N* = 100) Mean (SD); *N*; median; [25th, 75th] (Min, Max)	Control (*N* = 101) Mean (SD); *N*; median; [25th, 75th] (Min, Max)	Adjusted mean difference Difference (95% CI); ICC; *p*– value	Hawthorne effect estimate Difference (95% CI)
Tumour documentation complete	Baseline	78.5 (22.6); *N* = 100	78.7 (20.8); *N* = 101		
		85.0; [65.4, 96.5]	85.7; [68.2, 95.7]		
		(0.0, 100.0)	(7.4, 100.0)		
Tumour documentation complete	In study	86.7 (16.2); *N* = 100	81.0 (21.8); *N* = 101	6.0 (1.8, 10.3); 0.256; 0.005	2.3 (−1.5, 6.1)
		92.2; [76.1, 100.0]	87.5; [74.6, 96.2]		
		(4.3, 100.0)	(4.2, 100.0)		
SI-IVC received	Baseline	40.7 (30.1); *N* = 96	42.6 (27.6); *N* = 94		
		42.0; [14.0, 64.6]	44.1; [21.5, 63.3]		
		(0.0, 100.0)	(0.0, 100.0)		
SI-IVC received	In study	44.9 (29.3); *N* = 97	46.5 (26.4); *N* = 95	0.3 (−4.7, 5.3); 0.336; 0.9	3.7 (−0.5, 7.8)
		47.6; [20.0, 65.7]	50.0; [26.1, 61.5]		
		(0.0, 100.0)	(0.0, 100.0)		
Resection completeness documented	Baseline	84.7 (20.1); *N* = 97	82.0 (21.1); *N* = 99		
		92.0; [83.3, 96.9]	89.4; [72.7, 97.3]		
		(0.0, 100.0)	(0.0, 100.0)		
Resection completeness documented	In study	90.9 (13.3); *N* = 98	84.3 (19.3); *N* = 97	5.5 (1.5, 9.5); 0.224; 0.007	1.9 (−1.9, 5.6)
		95.7; [88.2, 100.0]	91.3; [75.8, 100.0]		
		(38.9, 100.0)	(2.9, 100.0)		
Detrusor muscle in specimen	Baseline	77.1 (18.4); *N* = 98	76.0 (16.4); *N* = 97		
		81.4; [70.0, 90.0]	78.8; [65.0, 87.5]		
		(0.0, 100.0)	(26.9, 100.0)		
Detrusor muscle in specimen	In study	78.4 (18.2); *N* = 99	73.6 (16.4); *N* = 98	2.6 (−1.3, 6.4); 0.130; 0.2	−1.8 (−5.0, 1.4)
		82.4; [68.3, 92.6]	72.1; [62.5, 88.0]		
		(5.0, 100.0)	(13.6, 100.0)		
Composite success	Baseline	24.9 (23.7); *N* = 100	24.5 (20.3); *N* = 101		
		21.4; [4.3, 37.3]	20.0; [7.5, 40.0]		
		(0.0, 93.8)	(0.0, 95.5)		
Composite success	In study	32.2 (25.6); *N* = 100	27.6 (20.5); *N* = 101	4.3 (−0.3, 8.8); 0.276; 0.07	3.1 (−0.2, 6.5)
		30.0; [11.1, 45.2]	24.2; [11.3, 41.7]		
		(0.0, 100.0)	(0.0, 76.0)		

ICC = intraclass correlation coefficient; Max = maximum; Min = minimum; SD = standard deviation; SI-IVC = single-instillation intravesical chemotherapy.

[a] Four coprimary outcomes and the composite outcome "achievement of all applicable coprimary outcomes". Outcomes are the mean difference obtained from a mixed-effect linear regression. *N* numbers vary and are thus displayed because sites are excluded from individual outcomes if there were fewer than ten eligible or assessable (data available) cases for the given outcome and excluded from the SI-IVC outcome if it is not possible to give SI-IVC at that site; see Methods section and protocol for further details. The Hawthorne effect estimate is not hypothesis tested, and confidence intervals are not adjusted for multiple testing.

research participation bias in this context) may explain why the intervention showed a lack of effect in some outcomes. This is of clinical importance and comparable with that seen with chemotherapeutic trials evaluating the administration of SI-IVC [6]. We acknowledge that the estimation of the Hawthorne effect size was a post hoc analysis and caution that further investigation is needed to draw firm conclusions.

Other studies show that well-designed, theory-informed feedback and education can improve surgical performance in the right circumstances. A similar cluster RCT in orthopaedic surgery demonstrated an increase in the absolute probability of outcome achievement of 4.34% due to the intervention [23]. The context dependence of such interventions is highlighted in a study of emergency laparotomy, where no statistically significant difference of audit and feedback versus control was seen in a well-designed cluster RCT [24]. NMIBC is a disease for which the quality of TURBT operative and perioperative practice and clinical outcome are known to be variable (confirmed in this study), so it is a good context for such an intervention. Small absolute improvements may translate to large relative improvements in common disorders such as NMIBC across populations.

Strengths of the study include its size, scale, pragmatism, randomised design with the use of a control group, and behavioural theory–informed design of the intervention.

There were limitations. Our intervention was a pragmatic tool for self-reflection against evidence-based targets and anonymous peer comparison without accountability. In a similar real-world example, the Scottish QPI programme [14,16], reporting (at site level) was government mandated, published publicly without anonymisation, with consequences for not achieving targets (one to one discussion

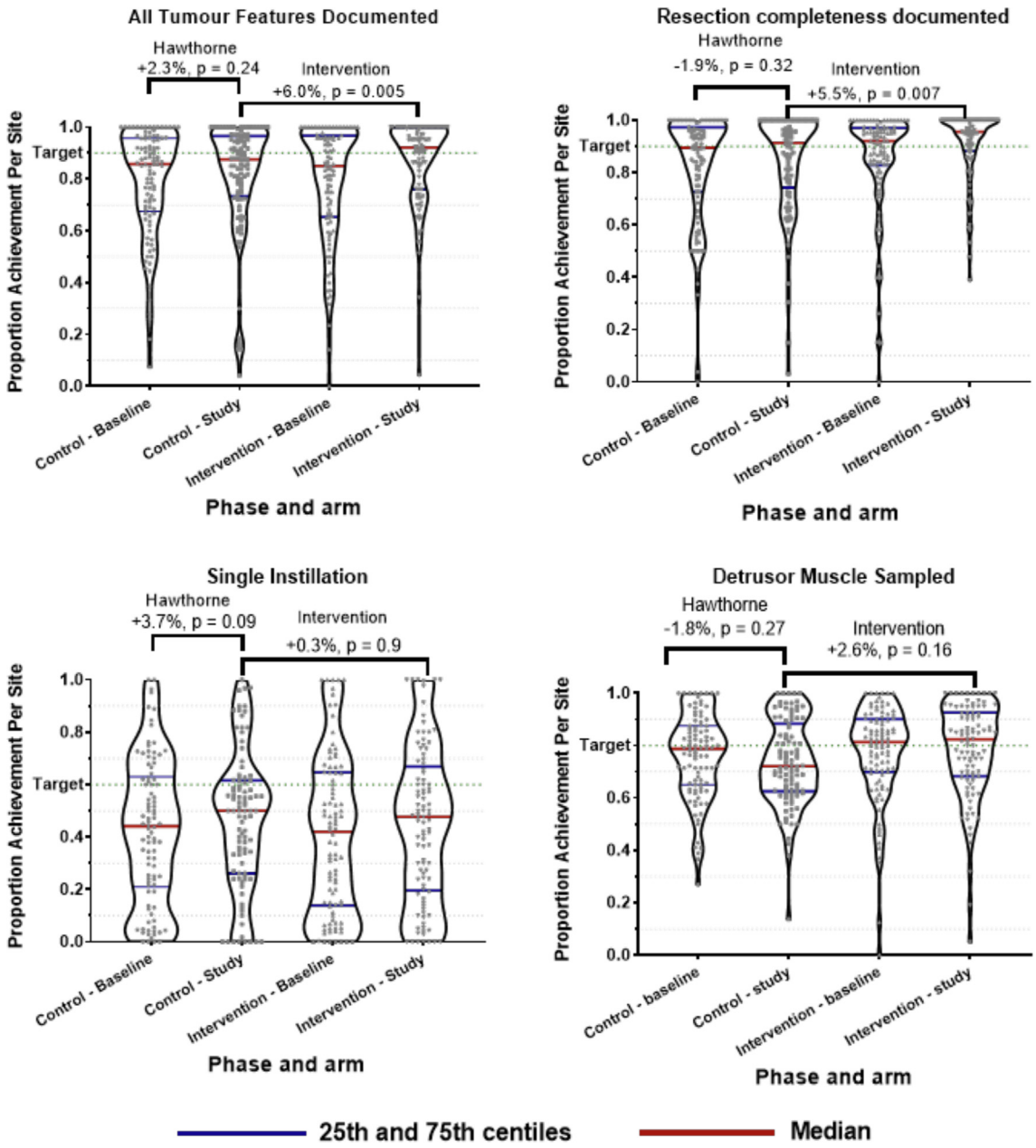

Fig. 2 – Distribution density (violin) plots of coprimary outcome achievement rates (%) per site in the control and intervention arms at baseline and in study. Median, and 25th and 75th centiles are highlighted. The *p* values are from a mixed-effect linear regression.

Table 3 – Recurrence outcome analysed at the case level using a mixed-effect logistical regression for check cystoscopy performed within 12 mo of complete TURBT

		Intervention (*N* = 5510), *n*/*N* (%)	Control (*N* = 5494), *n*/*N* (%)	Odds ratio (95% CI); *p* value	Hawthorne effect adjusted odds ratio (95% CI)
Recurrence—baseline	No	2089/2641 (79)	1989/2627 (76)		
	Yes	552/2641 (21)	638/2627 (24)		
	Missing	492/3133 (16)	455/3082 (15)		
Recurrence—in study	No	1705/2090 (82)	1794/2199 (82)	1.0 (0.8, 1.4); 0.9	0.7 (0.6, 0.8)
	Yes	385/2090 (18)	405/2199 (18)	1.1 (0.8, 1.4); 0.7 (multiple imputation)	
	Missing	287/2377 (12)	213/2412 (9)		

CI = confidence interval; TURBT = transurethral resection of bladder tumour.

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with leaders and mandatory enacting of improvements). These techniques may further enhance performance and cancer outcomes.

Owing to the pragmatic nature of this study, the first check cystoscopy evaluating recurrence was performed at varying time points after TURBT. However, we restricted the analysis to those patients with check cystoscopies performed within 12 mo, within which time the first check is most likely to be representative of primary surgery quality. Of note, 90% of check cystoscopies were performed within 6 mo. Further, in our sensitivity analyses, we confirmed that the differences seen in recurrence between the intervention and control arms and between the baseline and in-study phases were consistent if we used multiple imputation for missing data or restricted analyses to those patients having cystoscopy within 6 mo.

Whilst having a control group is a strength, by virtue of collecting data from these centres, their behaviour and performance appeared to improve, which impacted the observed intervention effect sizes. Outside of a study, it is possible that the impact of audit, education, and feedback could therefore be even greater. It is a strength of the study that we measure and account for the Hawthorne effect, since deficiencies in this regard have been noted in previous surgical research [25,26]. Relatedly, it could be the case that expert centres were more likely to participate in the study despite our attempts to recruit widely. Expert centres may not have as much room for improvement and contribute to ceiling effects. However, there was an observable reduction in recurrence rate during the study versus at baseline. This suggests that ceiling effects may be related to the choice of quality indicators rather than a lack of any room for improvement [16]. There should be no ceiling effect in the documentation outcome since this is plausible in all cases. Detrusor muscle sampling has remained between 74% and 80% after 9 yr of the Scottish QPI programme, suggesting that this is the ceiling and may indeed not go higher since it is not always appropriate or safe [15,16]. After years of implementation, the Scottish QPI programme reached a single instillation rate of 54%, suggesting that the SI-IVC outcome was not subject to ceiling. Indeed, there were observable improvements in SI-IVC instillation in both arms during the study, indicating the Hawthorne effect as a possible reason for a lack of difference between the arms.

The wider clinical implications of this research are that multicentre audit, feedback, and education should be recommended within health services providing TURBT surgery, since we have shown that it has the power to improve components of evidence-based practice and that audit alone may reduce recurrence rates. This study has implications relevant to other contexts in medicine, as it demonstrates the potential pathway to impact that audit, feedback, and education can have and gives a method of achieving this on a widely disseminated scale.

Future studies should aim to confirm and explain what drives the Hawthorne effect on recurrence in this setting, and explore the impact of not anonymising institutional outcomes on a global level and the role of individual leaders championing improvements in outcomes with direct provider engagement.

5. Conclusions

Multicentre audit, peer-comparative feedback, and education can improve some components of evidence-based practice in TURBT surgery. Taking part in an organised audit of one's own practice may reduce recurrence rates regardless of whether specific feedback or education is provided. National audits are likely to improve bladder cancer surgery quality, and we propose that these should be implemented.

Author contributions: Kevin Gallagher had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition of data: Gallagher, Bhatt, Clement, Zimmermann, Khadhouri, Kulkarni, Gaba, Anbarasan, Asif, Light, Ng, Chan, Nathan, Cooper, Aucott, Sakthivel, Akand, Piazza, Marcq, O'Brien, Nielsen, Del Giudice, Simpson, Orecchia, Teixeira, Dawam, Geisenhoff, Hill, Fukuokaya, Hidalgo, El-Hajj, Elgamal, Fanshawe, Wang, Lee, Manecksha, McCann, Rivas, Arda, Elhadi, Rossi, Teoh, Mariappan, Kasivisvanathan.
Analysis and interpretation of data: MacLennan, Gallagher, Kasivisvanathan, Cooper, Aucott, O'Brien, Nielsen, Mariappan.
Drafting of the manuscript: MacLennan, Gallagher, Kasivisvanathan, Cooper, Aucott, Mariappan.
Critical revision of the manuscript for important intellectual content: MacLennan, Gallagher, Kasivisvanathan, Cooper, Aucott, O'Brien, Nielsen, Mariappan.
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Supervision: MacLennan, Gallagher, Kasivisvanathan, Aucott, O'Brien, Nielsen, Mariappan.
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Data sharing statement: The data sets generated and analysed during this study are not publicly available due to an agreement to maintain anonymity of the included sites as set out in the study agreement, but are available from the corresponding author on reasonable request subject to data transfer agreement. All statistical code will be made available upon request.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.eururo.2025.09.4174.

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