The Impact of Narrow Band Imaging in the Detection and Resection of Bladder Tumor in Transitional Cell Carcinoma of the Bladder: A Prospective, Blinded, Sequential Intervention Randomized Controlled Trial

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OBJECTIVE To determine the impact of Narrow Band Imaging (NBI) in detection and resection of tumors during transurethral resection of bladder cancer.

MATERIALS AND METHODS This was a single center randomized prospective interventional study with a sequential intervention design. Patients with bladder tumors were randomized into 2 arms where they were resected under white light (WL) first followed by NBI in arm A, or NBI followed by WL in arm B. The number of patients in whom additional lesions were detected by the second light source, in both arms, was analyzed. The feasibility of initial resection of tumor under NBI was also studied.

RESULTS A total of 110 patients were randomized. Of 54 patients in arm A (WL first) additional lesions were identified at the second look in 20 patients (37%). In contrast, of 56 patients in arm B (NBI first), additional lesions were identified in 5(9%) patients. This difference of 28% was statistically significant (*P* value <.001). In arm B (NBI first), there were 7 breaches in protocol, and all these patients had high risk (more than or equal to 3 in number or 3 cm in size) tumors (*P* value <.002).

CONCLUSION Narrowband imaging is superior to WL in the detection of tumors, thus allowing a more complete resection. However, initial resection under NBI is difficult due to poor visibility, especially for high-risk tumors. UROLOGY 128: 55–61, 2019. © 2019 Published by Elsevier Inc.

Bladder cancer is the fourth most common cancer in men. Of the newly diagnosed tumors, 55%-60% are of low grade and stage with the majority of recurrences also being low grade.[1,2] The initial treatment of all bladder tumors involves a thorough transurethral resection of the tumor (TURBT). This is usually under white light (WL). Complete resection of all visible tumors is essential and the standard of care. However, WL may fail to detect small and flat lesions.[3]

Narrowband imaging (NBI), an optical image enhancement technique, uses wavelengths in the blue (415 nm) and green (540 nm) zone of the electromagnetic spectrum. These specific wavelengths are strongly absorbed by hemoglobin and vascular structures such as tumor and areas of carcinoma in situ, making them appear dark brown or green against a pink or white normal mucosal background, without the use of any dye.[4]

NBI has been used in gastroenterological endoscopic studies.[2,5] Its benefit in enhancing the detection of bladder tumors have also been reported. NBI has been shown to detect additional tumors in 9%-56% patients in comparison to WL cystoscopy.[3,6-11] By detecting extra tumors which would otherwise be missed by WL, NBI has been shown to decrease recurrence of tumors by 15% at 3 months and by 10% at 1 year.[12,13] Even in the setting of recurrent tumors, NBI improves detection of residual tumors as a "clean-up" light after WL resection.[14] However, it has been observed that visibility under NBI was limited with bleeding and inflammation, making it

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Submitted: November 26, 2018, accepted (with revisions): January 8, 2019

difficult to detect and resect lesions.[9] Therefore, further evidence is required to assess whether NBI is the optimal option for initial resection or whether its role is limited to detecting residual or tumors missed by WL cystoscopy.[15]

AIM AND OBJECTIVE

The primary objective of this study was to assess the number of patients in which NBI detected additional lesions during transurethral resection of bladder tumors. The secondary objective was to assess the role of NBI, as a primary light to resect tumors.

MATERIAL AND METHODS

This was a single-center prospective sequential interventional study with a randomized control trial design. After clearance from the Institutional Review Board (IRB no. 8392), it was registered under the clinical trial registry of India under the trial number CTRI/2015/03/005626. Consolidated Standards of Reporting Trials (CONSORT) guidelines were used to report all aspects of the trial.

All patients who underwent TURBT at our center from September 2013 to July 2015 were included in the study. New tumors and recurrent tumors (single or multiple tumors, largest tumor≤5 cm in size) were included. The diagnosis was made by cystoscopy findings or imaging. After being counseled about NBI and the procedure, informed consent was sought from the patients, after they were screened and found to meet the inclusion criteria. Those with tumors>5 cm, those who were unfit for anesthesia, and those who refused consent were excluded. Block randomization was carried out using blocks of 2 (40%), 4(40%), and 6 (20%) at the Department of Biostatistics of our institution. Sealed opaque envelopes were opened just before the surgery. The pathologist reporting the slides was blinded to the method of resection of samples.

The subjects were randomized to either of these 2 arms (Fig. 1):

Arm A: In this arm, the bladder tumor was inspected and resected under WL first. The bladder was washed and evacuated of all tumor chips and blood clots. Hemostasis was achieved. This was immediately followed by reinspection of the bladder under NBI. If additional tumors or suspicious lesions were seen on NBI, they were resected under narrow band imaging and sent for histopathological examination separately.

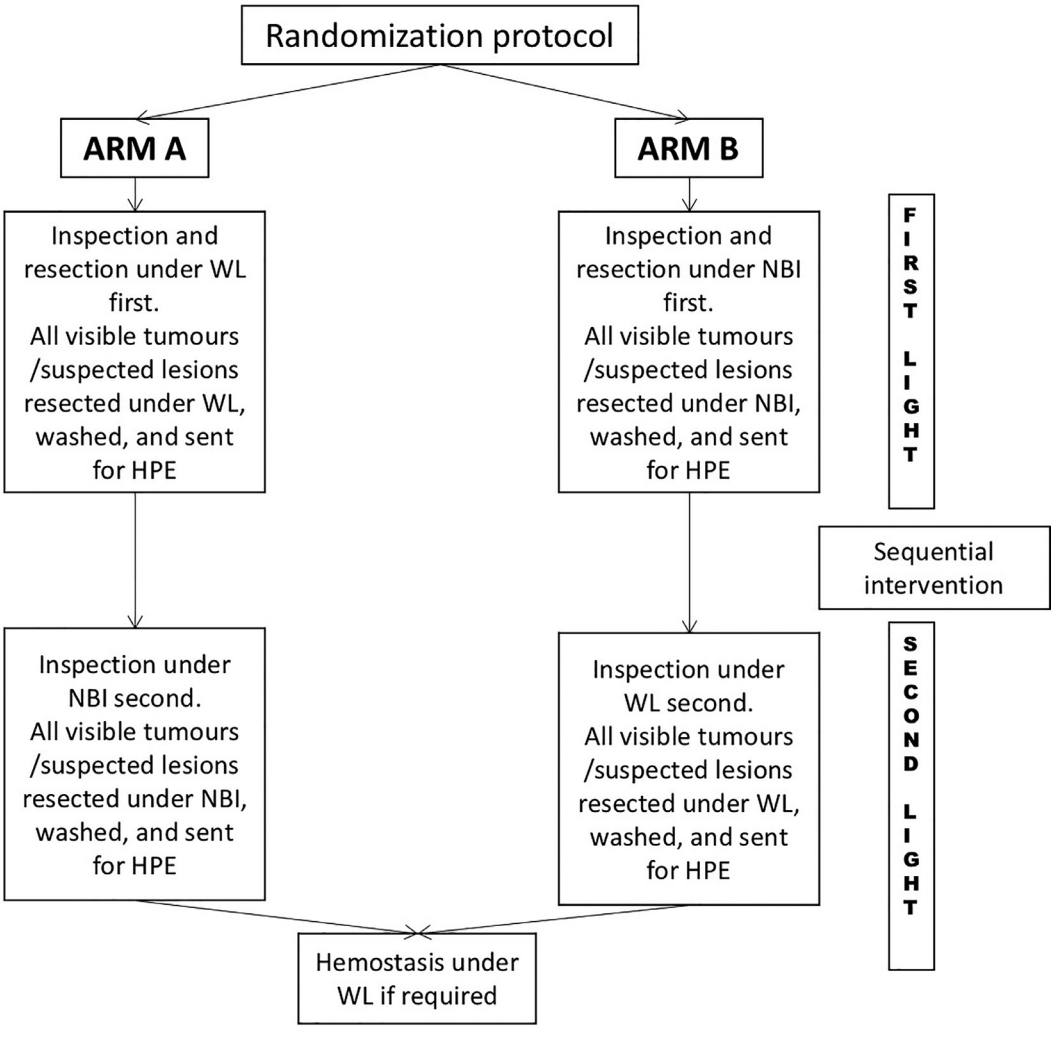

Figure 1. Randomization process.

Table 1. Patient and tumour demographics

Parameters	Categories	ARM A (WL first) N = 54	ARM B (NBI first) N = 56	*P* value
Sex	Male	46 (85.2%)	51 (91.1%)	.339
	Female	8 (14.8%)	5 (8.9%)	
Age	≤50 years	9 (16.7%)	22 (39.3%)	.008
	>50 years	45 (83.3%)	34 (60.7%)	
Tobacco/Smoking	Yes	18 (33.3%)	22 (39.3%)	.516
Co-morbidities	No co-morbidities	23 (42.6%)	24(42.9%)	.380
	Lifestyle disease (diabetes, hypertension, ischemic heart disease)	23(42.6%)	22(39.3%	
	Others	8(14.8%)	7(12.5%)	
	Both	0(0.0%)	3(5.4%)	
Size	≤2 cm	34 (66.7%)	25 (45.5%)	.036
	2-3 cm	11 (21.6%)	13 (23.6%)	
	>3 cm- ≤5 cm	6 (11.8%)	17 (30.9%)	
Number	Single tumours	35 (64.8%)	35 (62.5%)	.739
	2 tumors	6 (11.1%)	9 (16.1%)	
	>2 tumors	13 (24.1%)	12 (21.4%)	
Recurrent tumors	Yes	14 (25.9%)	15(26.8%)	.919
T stage	pTa	18 (33.3%)	32 (57.1%)	.055
	pT1	27 (50.0%)	15 (26.8%)	
	pT2	6 (11.1%)	7 (12.5%)	
	No tumour	3 (5.5%)	2 (3.6%)	
Grade	Low grade	11 (21.6%)	19 (35.2%)	.268
	High grade	40 (78.4%)	35 (64.8%)	
Histopathology of lesions detected by second light source	No tumor	11(55.0%)	5(100%)	.060
	Tumor/CIS	9(45%)	0(0.0%)	
Clavien Dindo Classification of Complications	I	0	7(12.5%)	.191
	II	0	0	
	IIIA	1(1.8%)	2(3.6%)	
	IIIB	0	0	
	IVA	0	2(3.6%)	
	IVB	0	0	
	V	0	0	

Arm B: In this arm, the bladder tumor was inspected and resected under NBI first. The bladder was then washed and evacuated of all tumor chips and blood clots. Hemostasis was achieved. This was followed by reinspection of the bladder under WL. If additional tumors or suspicious lesions were seen under WL, these were resected under WL and sent for histopathological examination separately.

The 2 sets of histopathological specimens (narrowband and WL) in both arms were sent in identical containers with no labeling to indicate the method of resection but only indicating whether the "first" or the "second" light source had been used to resect it, thus blinding the pathologist. All resections were done by consultants trained in TURBT.

The study was designed to assess, and compare with WL, the attributes of NBI as a light source to not only detect but also to resect tumors, simultaneously.

The primary outcome studied was the number of patients in whom additional bladder lesions detected by the use of NBI as a second light source in arm A. The secondary outcome was to assess the role of NBI as a light for initial resection of a tumor or whether it is limited to being only an adjunct to WL resection.

Sample size calculation: The expected percentage of detection in the 79% is WL, while this is 95% for NBI. For an alpha error at 5% level and power at 80%, 54 subjects were required in each arm.[7]

Statistical method: The data were entered using EPIDATA and analyzed using STATA software. In Table 1, the clinically meaningful difference between the 2 arms, arm A and arm B was assessed using clinical acumen rather than statistical tests.[16-18]

The analysis was based on Intention to Treat principles. The total number of subjects randomized was kept as the denominator throughout the analysis. In the efficacy analysis, the comparison between mean (SD) was made using the Mann-Whitney *U* test. Otherwise, the counts were compared with the chi-square test.

RESULTS

The following Consolidated Standards of Reporting Trials diagram gives a picture of the recruitment process (Fig. 2).

One hundred and seventy-eight patients met the inclusion criteria. Five refused consent.

Fifty-six cases were excluded because of the surgeon's choice. They did not agree to resect under NBI. As only 1 set of NBI equipment was available in the theatre complex, simultaneous resections performed in other theaters were excluded from the

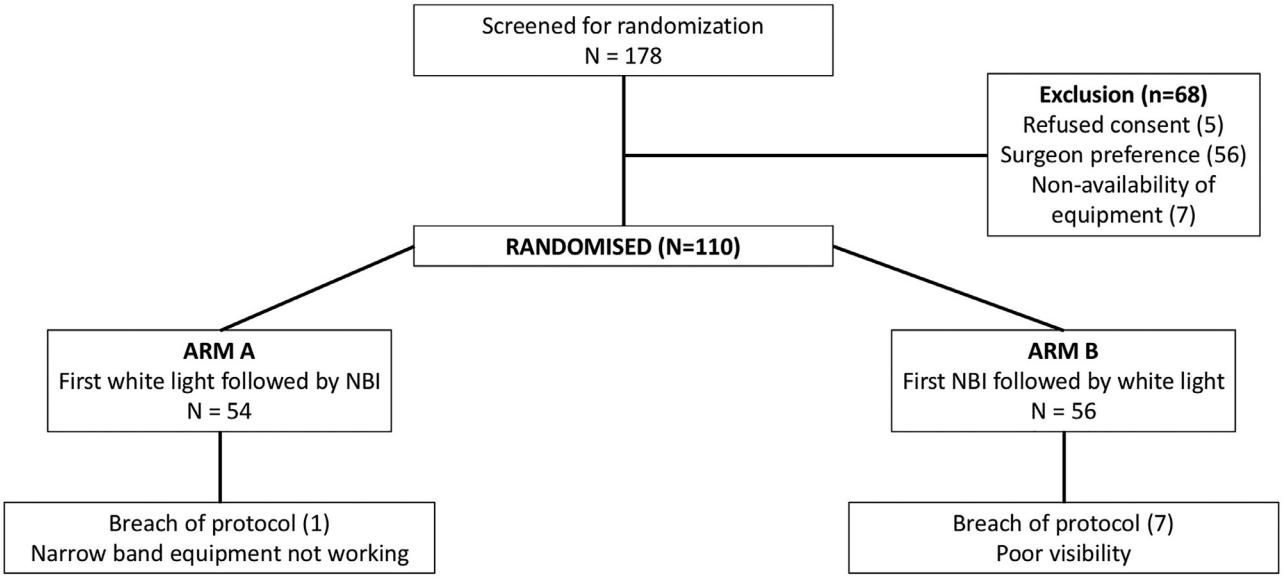

Figure 2. CONSORT diagram.

study. At the time of final analysis, a total of 110 patients were recruited, 54 in arm A (WL first) and 56 in arm B (NBI first).

One case had a protocol deviation in arm A (WL first) in which NBI could not be used due to technical failure. In arm B (NBI first), 7 had protocol deviations: Bleeding from the resected areas of the tumor, affecting visibility in 6 and an extra-peritoneal perforation in the initial part of the resection in one prompting the surgeon to break protocol and convert to WL for further resection.

The 2 arms were well matched with respect to baseline patient demographics (Table 1). Tumor distribution showed an unequal distribution of tumor size and T stage among the 2 arms, which was adjusted for by logistic regression analysis.

The primary outcome of the study was the number of recruits in whom additional lesions were identified in arm A (WL first) with NBI as a second light source, over arm B (NBI first) with WL as the second source. Resection was carried out in 54 in arm A (WL first) and 56 lesions in arm B (NBI first). Resection under the second light source identified additional lesions in 20 (37%) in arm A (WL first) and 5 (9%) in arm B (NBI first) (Table 2). The difference of 28% (95% confidence interval [CI]: 14%-44%) was statistically significant (*P* value <.001). The odds of detecting more tumors in arm A (WL first), before and after adjusting for the distribution of tumor size and T stage between the 2 arms were 6 (95% CI: 2.05-17.52) and 6.85 (95% CI: 2.07-22.58), respectively.

Table 2. Primary outcome: number of additional tumors detected by second light source

		Randomization				
		ARM A (WL first)		ARM B (NBI first)		
	Variable	n	%	n	%	*P* value
Number of tumors under 1st light:		35	64.81	35	62.50	.97
<=1		6	11.11	8	14.29	
2		5	9.26	5	8.93	
3		8	14.81	8	14.29	
>=4						
Number of tumors under 1st light: Mean ± SD		2.00 ± 1.90		2.02 ± 1.84		
Number of tumors under 2nd light:		16	80.00	4	80.00	<.001
1		4	20.00	1	20.00	
2-3		20	37.0	5	8.9	
Total						
Number of patients with confirmed additional tumors under 2nd light (true positives)		9		0		.06
Histopathology of true positives	Mild dysplasia	1		0		.06
	CIS	4		0		
	PUNLMP	1		0		
	pTa Low Grade	1		0		
	pT1 High Grade	1		0		

Of the 20 patients in whom additional lesions were found in arm A (WL first), histopathological malignancy (tumors or carcinoma in situ) was detected in 9 patients (Table 2). Among the additional lesions detected in 5 patients in arm B (NBI first), none had malignancy on histopathology (Table 1). The difference was 45% (45% vs 0%), and approached statistical significance (*P* value .06).

In arm A (WL first) NBI detected extra tumors in 20 patients after completing the resection with WL. There was 1 breach of protocol in arm A (WL first) due to NBI equipment failure after WL resection was over. There was no breach of protocol due to poor visibility. However, in the arm B (NBI first) there was a breach of protocol in 7 patients due to poor visibility during the initial resection of the tumor under NBI (*P* value .032).

The adverse events that occurred in both the ARMS are noted in Table 1. Of the 7 patients who had Clavien-Dindo Grade 1 complications in arm B, 3 were a breach of protocol. There was no statistically significant difference in patients requiring surgical re-exploration in either ARMS. The 2 Clavien-Dindo Grade 4 adverse events occurring in arm B were due to the patients' premorbid cardiac conditions and not caused by the surgical procedure.

DISCUSSION

In prior studies, NBI has been found to detect extra tumors in 9%-56% extra patients, when compared to WL.[3,6-11] In our study, NBI detected additional lesions in 28% (95% CI:14%-44%) more patients. On histopathological analysis, malignancy was detected in 9 (45%) more patients in arm A (WL first). Both these results were clinically significant.

The secondary objective of the study was to examine if NBI is superior to WL as a light source for initial resection of bladder tumors or, as an adjunct, to detect residual or "missed" tumors after WL resection. It has been shown by some groups that the identification of tumors under NBI had no "learning curve."[19] All the surgeons in our study were well versed with transurethral resection techniques under WL. One group found no significant difference between complication rates or operating times between NBI and WL,[20] while others observed that NBI had limited visibility in case of bleeding and inflammation.[9] A retrospective study from Japan found similar technical limitations in the use of NBI.[21] This may be because the wavelengths of NBI are actively absorbed by free hemoglobin caused by bleeding.[9] In our study as well, we observed that in arm A (WL first) there was no breach of protocol due to poor visibility. However, in the arm B (NBI first) there was a breach of protocol in 7 patients due to poor visibility during the initial resection of the tumor under NBI (*P* value .031). Two of the 3 patients who underwent relook cystoscopy and coagulation of bleeders following the TURBT belonged to arm B (NBI first).

In a prospective randomized control trial with 981 patients,[22] Naito attributed the benefit of NBI only in lowering the rate of recurrence low-risk tumors (<30 mm), due to a more complete resection of the tumors by NBI. In our study, all the patients who had a breach of protocol in arm B (NBI first) had multiple (≥3) and/or larger tumors (≥3 cm) in size, compared to 18 of the 39 who did not have protocol breach (*P* value <0.002).Therefore, in our experience as well, the resection of larger (≥3 cm) or multiple (≥3) tumors was found to be difficult initially under NBI. However, in arm A (WL first), once the initial resection and hemostasis were achieved with WL, NBI scored over WL in identifying "missed" or "residual" tumors, thus making the resection more complete.

False positives, where lesions "suspicious" of being malignant under NBI were benign on histopathology, lead to unnecessary resection of mucosa. Two meta-analyses, with 1040 and 1022 patients, respectively, comparing NBI to WL, reported NBI having a higher false positive rate than WL.[11,23] Contrary to these reports, we found false positives in 55% of patients in arm A (WL first). In contrast, 100% of the "suspicious" lesions identified by WL in arm B (NBI first) were benign on histopathologic examination. It is possible that after WL is used initially to resect a tumor and achieve hemostasis, NBI can delineate residual or missed lesions with more accuracy.

In concurrence with the established superiority of NBI in detecting extra tumors, our study also was found NBI to detect additional lesions in 28% more patients. However, the place of resection under NBI in the algorithm of transurethral resection is yet to be clearly defined.[15] The strength of this study is its design, which enables us to not only assess if NBI has any advantage over WL in detecting additional bladder tumors but also to ascertain whether NBI is ideal for primary resection or to detect residual or "missed" tumors immediately after resection with WL. A similar type of randomized sequence light source for gastroscopy was used in a gastroenterological study.[5] A randomization sequence with 2 arms with WL inspection followed by NBI inspection and vice versa has been used earlier but only used cold-cup biopsies to establish a diagnosis.[24] Our study, on the other hand, tests the difference in the feasibility of resection under WL and NBI. Due to the inherent design of the study, it allows us to highlight the role of NBI as an adjunct light source for detection of residual or missed lesions after primary resection with WL, primarily when used for initial resection of multiple (≥3) and large (≥3 cm) tumors.

CONCLUSION

NBI is superior to WL in the detection of additional tumors. NBI is not ideal for initial resection of larger and multiple tumors due to poor visibility. However, NBI may play a role in detecting residual/missed tumors after initial resection with WL. It may be safe to propose the adage "white to resect, blue to detect" for future use.

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EDITORIAL COMMENT

A visibly complete transurethral resection (TUR) of non–muscle-invasive bladder tumors is essential to achieve local control and optimize response to intravesical therapy. To remove bladder tumors, they must first be seen. And once detected, how does one verify all tumors have been completely resected? Cystoscopy and TUR are usually performed using white light imaging (WLI). WLI may not reveal every papillary tumor or mucosa involved with carcinoma in situ, leading to incomplete resection and treatment failures. As an adjunct to WLI, cystoscopy enhancement technologies have now entered clinical practice. One of these is narrow band imaging (NBI) cystoscopy. NBI filters white light into 2 narrow bands that enhances contrast between normal mucosa and mucosal vascular tumors (Ref#15 article).

In this well-designed, prospective, randomized study, and with the 2 goals of TUR in mind (tumor detection and feasibility of complete resection), the authors evaluated how WLI and NBI complement each other as a "surgical tool and technique." The 2 light modes were sequenced by inspection/TUR (WLI first, then NBI TUR vs NBI first, then WLI TUR). After WLI inspection/TUR, NBI detected additional lesions (half malignant) in 37% patients. After initial NBI/TUR, WLI saw more lesions (none malignant) in 9% of patients. Thus, NBI detected additional tumors in 28% more patients as a secondary adjunct to WLI/TUR vs the alternative sequence, albeit with more false positives.

Urologists participating in the study found NBI was not ideal to resect large (>3 cm) or multiple (>3) tumors because bleeding reduced visualization. The authors concluded that NBI was better suited to detect residual or "missed" disease as an adjunct to WLI rather than first inspection and TUR using NBI. NBI reduces light illumination about 20%, and since the filtered light is absorbed by hemoglobin, fields of vision can be compromised if there is bleeding.

Authors correctly conclude that NBI is superior to WLI in detection of tumors, and intuitively should facilitate more complete resections. However, "seeing" tumors by any method does not mean they are verifiably removed! The quality of the TUR (and the urologists') is unknown and unquantified variables confounding all studies of non–muscle-invasive bladder tumors. Further, some surgeons opted out of the study and others broke protocol with one arm of the study, which also illustrates how urologists (experience and practice patterns) might impact cancer outcomes. Nevertheless, the study is convincing that NBI detects more tumors than WLI alone and facilitates more visibly complete TURs, using either WLI- or NBI. Not addressed by this study is whether NBI plus WLI-TUR impacts recurrence and/or progression-free survival. That is yet to be determined.

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https://doi.org/10.1016/j.urology.2019.01.040
UROLOGY 128: 60, 2019.

AUTHOR REPLY

The authors are grateful for the review.

The insightful point raised about "seeing" tumors by any method not necessarily meaning they are verifiably removed, describes, simply yet succinctly, the conundrum faced by urologists in the use of narrowband imaging (NBI) for transurethral resection of bladder tumors.

This study was designed to assess NBI not only as a surgical tool but also as a technique of resection. The primary outcome of our study was to assess NBI as a surgical tool, where NBI yet again proved itself effective in detecting tumors which were missed by white light.

The secondary outcome, however, was derived due to the design of the study. It revealed that although NBI was better than white light in detecting tumors, it had its handicaps as a technique for surgical resection, especially in larger or multiple (high-risk) tumors. This finding echoes the finding of the largest NBI-related randomized controlled trial[1] where NBI showed a decrease in the recurrence of low-risk non–muscle-invasive bladder cancer only. It is likely that the surgeons in this trial also found it challenging to resect high-risk tumors completely under NBI, thus leading to higher rates of recurrences in these patients.

This study helps us to identify the right niche for NBI in the algorithm of bladder cancer therapy. We may, therefore, recommend that, in high-risk bladder tumors, NBI be used to detect residual tumors after initial resection under white light.

We agree that this study would be more comprehensive with additional information about the recurrence rates. We are in the process of collating it.

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https://doi.org/10.1016/j.urology.2019.01.041
UROLOGY 128: 61, 2019.