# Efficacy of Obturator Nerve Block During Transurethral Resection on Non-muscle invasive Intermediate and High Risk Lateral Wall Bladder Tumours: A Prospective Randomized Controlled Study

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**Key Words: Key Words**:bladder cancer; obturator nerve; progression; recurrence; transurethral resection

## ABSTRACT

**Purpose:** We aimed to investigate the effects of obturator nerve block (ONB) on obturator reflex, incomplete resection, perforation, progression and recurrence of tumor, presence of muscle tissue in the specimen, need for a second transurethral resection (TURBT) of bladder tumors, and postoperative complications in patients who underwent TURBT for intermediate-high risk lateral wall non-muscle invasive bladder cancers (NMIBC).

**Material and Methods**: Patients were assigned to one of two groups by drawing lots: ONB or none ONB. Early and late recurrence, tumor progression, obturator reflex beat, incomplete resection, perforation, presence of muscle layer in pathology, second TURBT application, operation time, postoperative hospital stay, and complications were compared between the two groups.

**Results:** The median follow-up time of the study was32 (23-41) months. Interquartile range (IQR) was 9. Tumor recurrence at the 3$^{rd}$ month cystoscopy controls was observed in 5 (9.8%) patients in the ONB group, while it was observed in 11 (20.8%) patients in the nONB group (p=0.01). Late tumor recurrence was observed in 10 patients (19.6%) in the ONB group, and in 20 patients (37.7%) in the nONB group ($p$=0.041). The RFS rate at 12$^{th}$ month was 84% in the ONB group, 69% in the nONB group, 79% in the ONB group at 36$^{th}$ month, and 58% in the nONB group at 36 months, the PFS rate was 94% in the ONB group, while it was 85% in the nONB group ($p$=0.041).

**Conclusions**: Our study showed that ONB decrease the early and late recurrence and increase recurrence free survival in patients with intermediate-high risk lateral wall bladder cancer.

## INTRODUCTION

Non-muscle invasive bladder cancers (NMIBC) are divided into three groups according to EORTC (European Organization for Research and Treatment of Cancer) as low, intermediate, and highrisk. In intermediate and high-risk NMIBC, early recurrence was reported as 15%, late recurrence was 25%, and progression was 9% with BCG therapy.[1] Transurethral resection (TURBT) of bladder tumors is the main approach in diagnosis and treatment.While performing TURBT of lateral wall located bladder tumors, electrical current and adjacent obturator nerve stimulation may occur during surgical resection, resulting in adductor contraction and leg jerk. This condition, called the obturator reflex, occurs in 55,3% to 100% of lateral bladder tumors.[2] In case of obturator reflex, serious complications may occur in TURBT, one of which is bladder perforation that may require laparotomy and open repair. Perforation is also associated with poor patient outcomes due to tumor invasion into the abdominal cavity and failure to administer early single-dose intravesical chemotherapy.[3] Various methods such as application of muscle relaxants under general anesthesia, less filling of the bladder, reduction of electric current, use of 90 degree classical loop, use of bipolar plasma kinetic energy and tumor resection with small pieces have been proposed to prevent failure and complications related to the obturator reflex.[4] However, these methods did not show the expected success and their effectiveness has not been proven.

There are studies in the literature showing that obturator nerve block (ONB) successfully reduces the obturator reflex, resulting in less incomplete resection and early tumor recurrence.[5,6] However, to our knowledge, there is no study investigating its effect on oncological outcomes with a mid-term follow-up period, especially in patients with intermediate-high risk NMIBC, where the risk of tumor recurrence and progression is higher.

In this study, we investigated the effects of ONB on obturator reflex, incomplete resection, perforation, progression with tumor recurrence, presence of muscle tissue in the specimen, need for a second TURBT, and postoperative complications in patients who underwent TURBT for intermediate-high risk lateral wall NMIBC.

## MATERIAL AND METHODS

### *Study population*

After the local ethics committee approval (E-20/495), it was planned to include patients who underwent TURBT operation as of January 2018 in Ankara Training and Research Hospital Urology Clinic and diagnosed with EORTCintermediate and high risk lateral wall primary NMIBC. Clinical Trials Registration number of the present study was NCT04885309. Our study was conducted in accordance with the principles of the Declaration of Helsinki, the planned study was explained to the patients in detail, and then written informed consent was obtained from each patient. Lateral bladder tumors were defined as tumors reported in the lateral wall of the bladder on preoperative cystoscopy, ultrasonography (USG), or computed tomography (CT). Incomplete resection was defined as the remaining visible tumor after the TUR-BT.Exclusion criteria in the study were defined as contraindications for spinal anesthesia, history of allergy to local anesthetic substances, coagulopathy, neuromuscular diseases affecting the central nervous system, and obturator nerve damage. Patients who were found to have muscle-invasive bladder tumor (MIBC) and low-risk NMIBC during the study, who refused to participate in the study, and who did not come for postoperative follow-up were excluded.

Patients were assigned to one of two groups by drawing lots: ONB (TURBT with spinal anesthesia and obturator block) or nONB (TURBT with spinal anesthesia). Our analysis in the

current study was per-protocol. There is a 90% change of correctly rejecting the null hypothesis of no difference between expected and observed proportions with 29 participants (Effect size 0.61 according to previous studies).[2,5]

After confirming the spinal anesthesia level while in the lithotomy position, ONB was applied unilaterally or bilaterally according to the tumor position to the patients in the ONB group. The high-frequency USG probe was placed proximal to the adductor longus muscle, and immediately after the obturator nerve was embedded in the pectineus, the adductor longus and adductor brevis muscles were observed, and the location of the nerve was confirmed by setting the stimulator current to 1.5-2 mA and its duration to 0.1 milliseconds. Under the USG image, a 50 mm insulated needle parallel to the long axis of the probe was guided through the skin to the anterior branch of the obturator nerve. When contraction was observed at 0.3-0.5 mA in the adductor muscle groups and the aspiration became negative, 1% lidocaine, maximum 10 mL, was injected to block the nerve. The operation was started 10 minutes after the injection. Obturator reflex was considered as adductor muscle contraction severe enough to affect the surgeon's resection. All TURBT operations were performed by the same surgeon.Demographic data and clinical features are included gender, age, ASA score, body mass index (BMI), tumor side, tumor number, tumor size. The 2006 EORTC scoring model was used for the recurrence and progression prediction score.

Indications for second TURBT were determined according to the EAU NMIBC guidelines. All second TURBTs were performed 2-6 weeks after the first operation.[7] A full dose of BCG treatment for 1 year in moderate-risk patients and for 1-3 years in high-risk patients was planned. Follow-up of all patients included in the study was planned as cystoscopy and cytology every 3 months for 2 years, then cystoscopy and cytology every 6 months for up to 5 years.Detection of the first recurrence at 3 months of cystoscopy was defined as early recurrence, and detection of the first recurrence at any cystoscopy after 3 months of

cystoscopy was defined as late recurrence. Progression was defined as detection of T2 tumor pathology or local-distance metastasis during follow-up.

Early and late recurrence, tumor progression, obturator reflex beat, incomplete resection, perforation, presence of muscle layer in pathology, second TURBT application, operation time, postoperative hospital stay, and complications were compared between the two groups. Recurrence-free survival (RFS) and progression-free survival (PFS) were evaluated. The main complications were identified as infection (postoperative fever > 38.2 °c) and the need for reoperation during hospitalization. Serious complications such as septic shock and acute abdomen were evaluated.

***Statistical Analysis***

Data analysis was performed with the software program PASW 23 (SPSS, IBM, Chicago, IL). Whether the continuous variables fit the normal distribution was evaluated with the Kolmogorov-Smirnov test and P-P plot. Data that fit to the normal distribution are shown as mean ± standard deviation, and data that do not fit are shown as median (minimum-maximum) and interquartile ranges (IQR). Categorical variables are shown as frequencies and percentage. Pearson's Chi-Square and Fischer's Exact test were used to compare categorical data between groups, and independent sample t-test was used together with Levene's test for equality of variances to compare continuous data. RFS and PFS were evaluated by Kaplan-Meier analysis. Calculation of RFS was based on the first detected recurrence or the last follow-up visit without recurrence. Calculation of PFS was based on the first detected progression or the last follow-up visit without progression. A value of $p<0.05$ was considered statistically significant.

## RESULTS

Of the 154 patients identified at baseline, 9 did not meet the inclusion criteria. Of the 145 patients who met the inclusion criteria, 18 were excluded from the study because they had a previous diagnosis of bladder cancer and 4 did not accept the operation. According to the computerized randomization list, 61 patients were assigned to the ONB group and 62 patients were assigned to the nONB group. While our study, which started with 123 patients, was continuing, 13 subjects were excluded from the study because they were in the low risk group for EORTC and 6 of them did not apply for follow-up. Our study was completed with a total of 104 patients (Figure 1). The demographic and clinical characteristics of the patients and the operation data are listed in Table 1 and 2.

Operative and oncological outcomes and complications are compared in Table 3. The presence of obturator reflex occurred in 5 (9.8%) of 51 patients in the ONB group and in 21 (39.6%) of 53 patients in the nONB group ($p$=.001). In TURBT, incomplete resection of the tumor was detected in 1 (2%) of 51 patients in the ONB group and in 8 (15.1%) of 53 patients in the nONB group ($p$=.031). Presence of detrusor muscle in the specimen was detected in 45 (88.2%) of 51 patients in the ONB group and 37 (69.8%) of 53 patients in the nONB group ($p$=.021).

While second TURBT was performed in 25 (49%) patients in the ONB group, it was performed in 30 (56.6%) patients in the nONB group. Second TURBT was performed in 3 (12.0%) of 25 patients in the ONB group and in 11 (36.7) of 30 patients in the nONB group because of the absence of detrusor muscle in the specimen without T1 tumor or incomplete

resection (*p*= .037).

In our study, bladder perforation was observed in 1 (2%) patient in the ONB group, while it was observed in 4 (7.5%) patients in the nONB group (*p*=.3). All patients with perforation were evaluated extraperitoneally, and none of the patients needed additional intervention after one week of bladder catheterization. Postoperative hematuria and fever were observed in 3 patients (5.9%) in the ONB group and in 8 patients (15.1%) in the nONB group (*p*=.10). Severe hematuria was not detected in any patient in both groups.

Tumor recurrence at the 3rd month cystoscopy controls was observed in 5 (9.8%) patients in the ONB group, while it was observed in 11 (20.8%) patients in the nONB group (p=.12). Late tumor recurrence was observed in 10 patients (19.6%) in the ONB group, and in 20 patients (37.7%) in the nONB group (*p*=.041). The number of patients with progression was 3 (5.9%) in the ONB group, while it was 7 (13.2%) in the nONB group (*p*=.32). The median follow-up time of the study was32 (23-41) months. The RFS rate at 12th month was 84% in the ONB group, 69% in the nONB group, 79% in the ONB group at 36th month, and 58% in the nONB group at 36 months, the PFS rate was 94% in the ONB group, while it was 85% in the nONB group (Figure 2 and 3). There was a statistically significant difference between the groups in RFS (*p*=.041) (28.5-34.4 95% CI) , but no significant difference was found in PFS (*p*=.20) (37.1-40 95% CI).

The median operation times and IQR of the patients were found as 45(15-120) minutes and 30; 45(15-120) minutes and 30 in the ONB and nONB groups, respectively (*p*=.80). The median postoperative hospitalization and IQR were found as 1 (1-4) days and 1;1 (1-6) days and 1 in the ONB and nONB groups, respectively (*p*=.02).

## DISCUSSION

In the current study, ONB group when compared to nONB group; early and late tumor recurrence, obturator reflex beat, incomplete tumor resection, postoperative complication rate and duration of hospitalization were significantly reduced; the presence of muscle tissue in pathology was found to be significantly increased.

Adductor muscle contraction due to obturator nerve stimulation during TURBT can cause bleeding, incomplete resection, hematoma, bladder perforation, and extravesical spread of the tumor.[8] In order to prevent the obturator reflex, succinylcholine was used immediately before tumor resection in a study conducted by Cesur et al, and the obturator reflex was successfully prevented in all 52 patients in succinylcholine applied group. In the ONB group, obturator reflex was prevented in 33 out of 39 (84.6%) patients. However, all patients had to undergo general anesthesia in succinylcholine applied group and no evaluation of the oncological results was performed in their study.[9]

The efficacy of ONB[10], which was 83.8% when performed blind, was 89.4-100% when performed with nerve stimulation technique.[11,12] More recently, USG-guided ONB techniques have been used, reporting a reduced incidence of vascular injury due to better nerve visualization as well as higher ONB success rates. In our study, all ONBs were performed with nerve stimulation technique under USG.

The incidence of obturator reflex in ONB+ groups varies between 0% and 14%, and between 16% and 92% in ONB- groups in the literature.[5,6,13-15] In our study, the obturator reflex rate was 9.8% in the ONB group and 39.6% in the nONB group ($p$=.001). Most of the thesestudies in the literature were performed by anesthesiologists. For this reason, the primary end-point of these studies focused on whether there was an obturator reflex, and these studies were lacking

in terms of mid-long term oncological results. In our study, oncological results were followed up for an average of 32 months.

Residual tumor tissue due to incomplete resection during TURBT increases the tumor recurrence rate. In the study of Jancke et al., the recurrence rate was found to be significantly higher in cases in which residual tumor was found in the pathology in the NMIBC compared to cases in which no tumor was detected.[16] Erbay et al. reported incomplete resection rates as 36% and 12% in ONB- and ONB+ groups, respectively[6], similary Bolat et al. reported these rates as 22.9% and 2.9% in ONB- and ONB+ groups, respectively, and found a statistically significant difference.[5] In our study, the rate of incomplete resection was found to be 15.1% in the nONB group and 2% in the ONB group ($p$=.03), which was thought to contribute to the reduction in late recurrence rates and improvement in RFS.

The presence of the detrusor muscle in the TURBT specimen is crucial for accurate staging.[17] The absence of the detrusor muscle is an important risk factor for inadequate staging, which may result in inadequate management.[18] Studies have shown that detrusor muscle is absent in 15% to 66% of TURBT specimens taken without performing ONB.[19-21] In their retrospective study Erbay et al. reported the rate of absence of detrusor muscle in the TURBT specimen as 26.5% and 4.2% in the ONB- and ONB+ groups, respectively, and found a statistically significant difference.[6] In our study, it was found to be 30.2% in the nONB group and 11.8% in the ONB group ($p$=.03). Our study showed that ONB significantly increased the presence of the detrusor muscle in the specimen of patients with intermediate-high risk lateral wall NMIBC.

Some studies suggest that if muscle is present in the primary TURBT, a second TURBT may not be necessary for high risk NMIBC. It is shown that the potential benefits of second TURBT should be carefully weighed against the health care burden and side effects of the procedure.[22-24] In our study, second TURBT was performed in 25 of 51 patients in the ONB

group and in 30 of 53 patients in the nONB group. We evaluated patients who underwent second TURBT only because of the absence of detrusor muscle in the specimen, without presence of T1 tumor or incomplete resection. These were found to be 3 (12%) of 25 patients in the ONB group and 11 (36.7%) of 30 patients in the nONB group ($p$=.03), and it was found that the need for second TURBT due to the absence of detrusor muscle could be significantly reduced with ONB. In this way, the presence of detrusor muscle can be increased with ONB, and a significant reduction in health care burden and side effects due to unnecessary second TURBT can be achieved.

In a study evaluating the prediction of recurrence and progression in NMBIC patients, important prognostic factors were mentioned as number of tumors, tumor size, number of recurrences within 1 year, T-stage of tumor, presence of CIS, and tumor grade.[25] In our study, there was no difference in these prognostic factors between the groups. According to the EORTC risk classification, 17 (32.1%) of 53 patients in the nONB group were found to be at intermediate risk, 36 (67.9%) high risk; in the ONB group, 17 (33.3%) of 51 patients were found to be at intermediate risk, 34 (66.7%) at high risk, and no difference was found between the groups. There are many factors that affect recurrence and progression in NMIBC other than the obturator reflex. In our study, these factors were found to be similar in both groups. So,confounding factors that could affect the result were minimized and the possibility of bias was reduced.

In their retrospective studies, Tekgül et al. reported the recurrence rate in the first 12 months as 25% and 9% in the ONB- and ONB+ groups[2], respectively, similarly Erbay et al. reported the recurrence rate in the first 12 months as 24% and 6% in the ONB- and ONB+ groups, respectively.[6] In our study, the early recurrence rate was 9.8% in the ONB group and 20.8% in the nONB group ($p$=.12); late recurrence rate was 19.6% in the ONB group and 37.7% in the nONB group ($p$=.04). It was found that ONB significantly increased RFS ($p$=.04). We

thought that these results were due to the decrease in incomplete resection due to the occurrence of less obturator reflexes in patients with ONB, and the increase in the presence of detrusor muscle in the resection material.

In the present study, the rate of progression was found to be 5.9% in the ONB group and 13.2% in the nONB group ($p$=.20). ONB was found to reduce the rate of progression, but no significant difference was found.

There are studies showing the efficacy of ONB in preventing resection complications in bladder tumors in the lateral wall.[16,26] During TURBT, bladder perforation, hematoma and severe bleeding may occur due to the obturator reflex. It has been reported that bladder perforation in TURBT significantly reduces disease-free survival and significantly increases tumor progression in case of development of recurrence.[27] Comparing bladder perforation in ONB- and ONB+ groups, Erbay et al. reported the rates of perforation as 4% and 0%[6], respectively, and Bolat et al. reported these rates as 5% and 0%[5] in ONB- and ONB+ groups, respectively. In our study, it was found as 7.5% in the nONB group and 2% in the ONB group ($p$=.10). All of the perforations were detected extraperitoneally and conservative treatment was applied. The perforation rate decreased in patients who underwent ONB, but no significant difference was detected similar to the literature.

Duration of hospitalization directly affects hospital-acquired infections and cost.[28] In our study, the postoperative duration of hospitalization was found as 1.3±0.6 days in the ONB group and 1.8±1.1 days in the nONB group ($p$=.02). Thus, it was thought that ONB could significantly reduce duration of hospitalization and reduce hospital-acquired infections and costs.

The main limitation of our study is the small sample size, as we only included patients with lateral wall intermediate and high-risk bladder tumors. Patients in the study are currently

being followed to investigate the mid-term efficacy of ONB on relapse rate, relapse time, and progression. To obtain more precise results, future studies should be conducted with larger batches over a longer period of time.

## CONCLUSION

Our study showed that spinal anesthesia combined with ONB prevents the obturator reflex, reduces incomplete resection, and increases the presence of detrusor muscle tissue in the resection material. For these reasons, it was determined that it reduces the recurrence rate and increases disease-free survival. It was also found that ONB shortens the postoperative duration of hospitalization.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.


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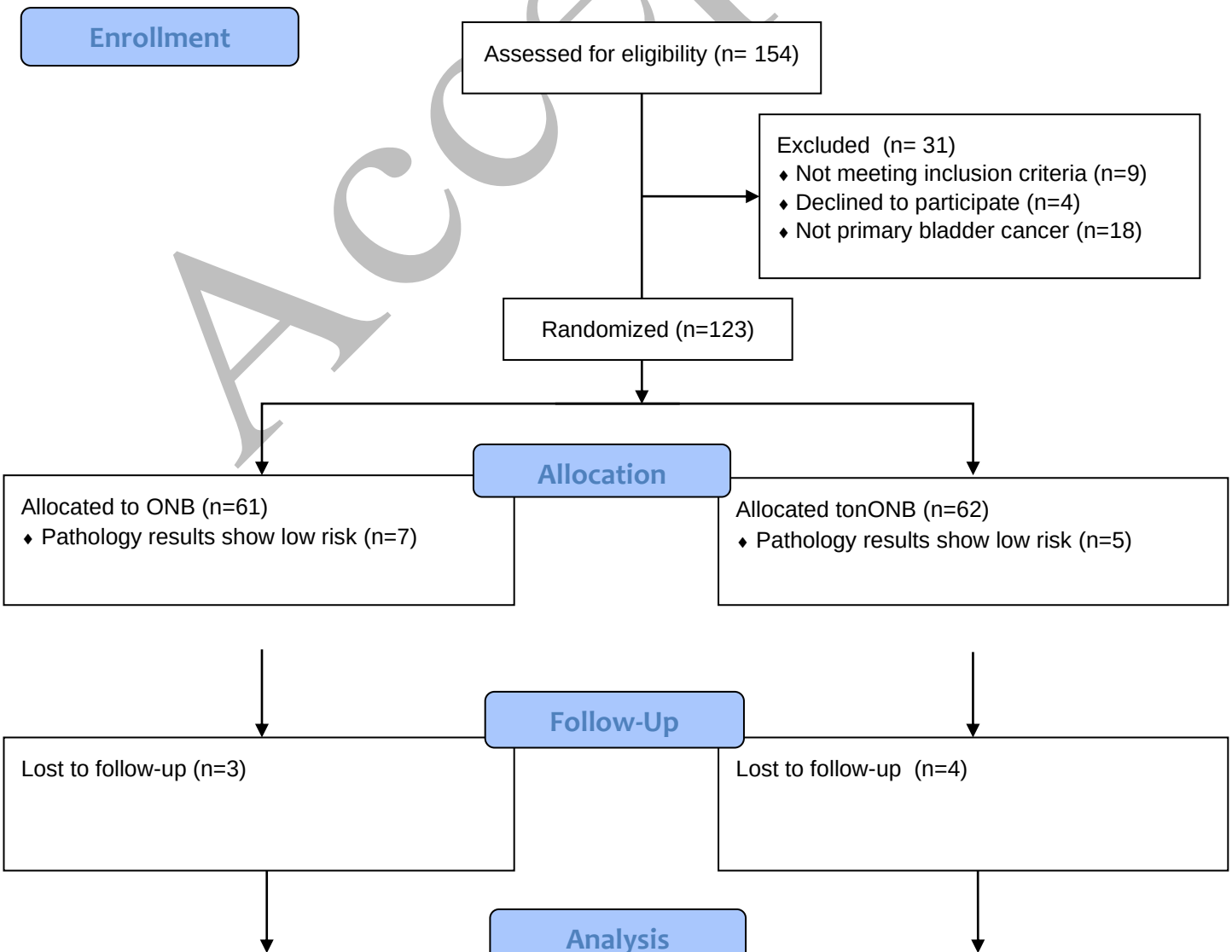
## Flow Diagram

**Figure 1** Flow chart



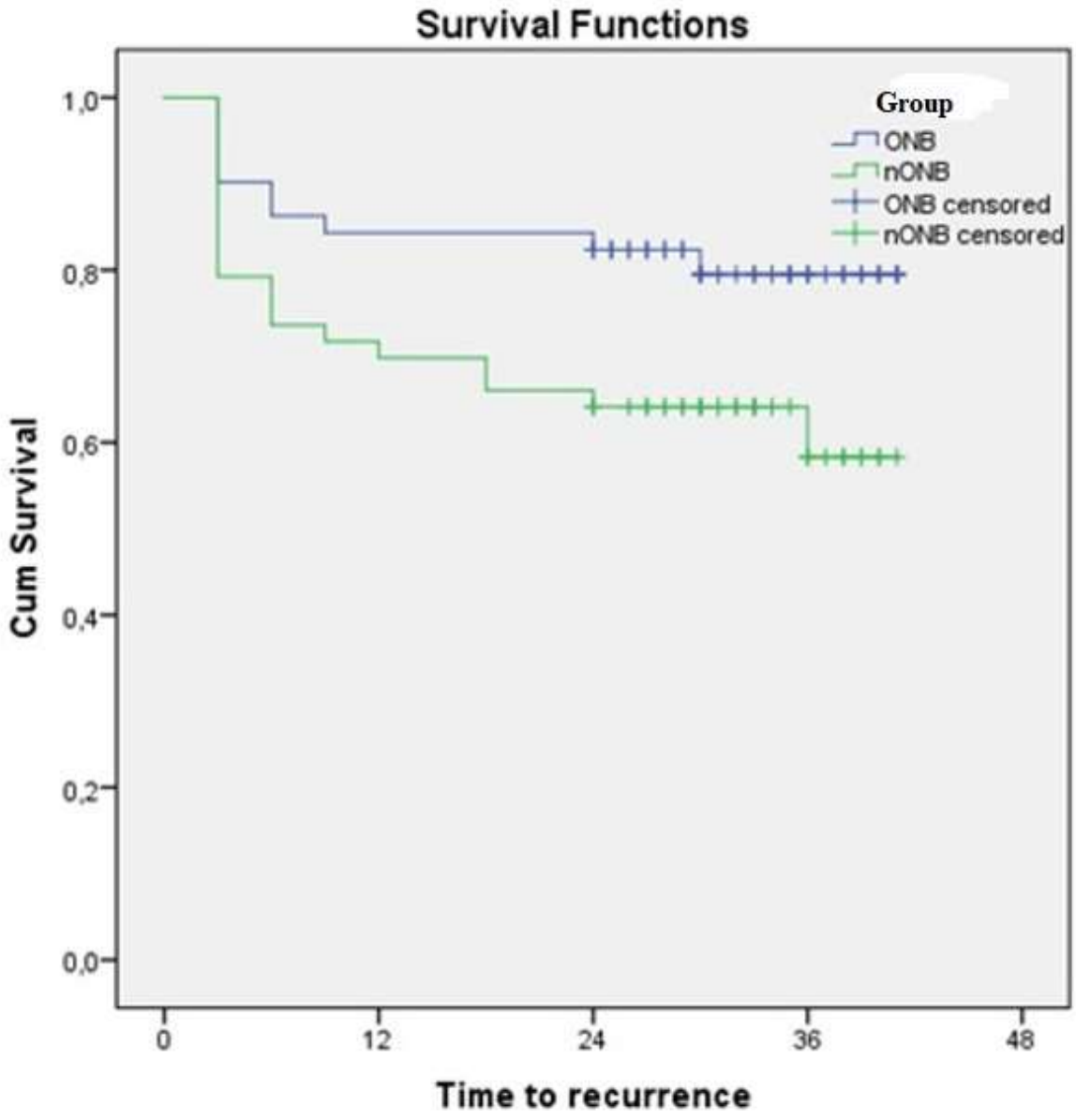



**Figure 2** Comparison of RFS rates of the Groups

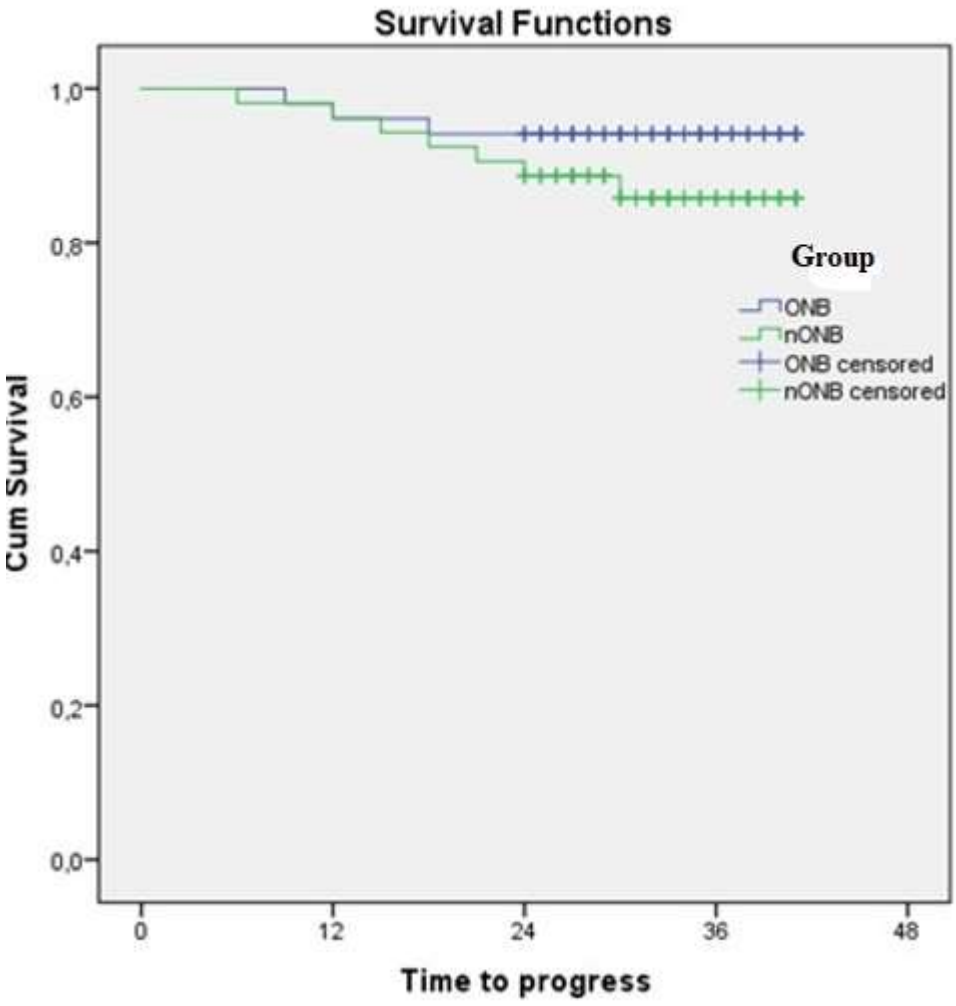



**Figure 3**Comparison of PFS rates of the Groups

**Table 1** Demographic and surgical data results

| | ONB group (n=51) | nONBgroup (n=53) | p value |
|---|---|---|---|
| Age (year) | 64.6±11.7 | 64.3±16.2 | 0.90 |
| BMI (kg/m²) | 27.3±2.1 | 27.0±2.2 | 0.57 |
| Tumor size (cm) | 2.9±1.56 | 2.9±1.50 | 0.76 |
| EORTC Recurrence Score | 8.2±4 | 7.8±4.1 | 0.59 |
| EORTC Progression Score | 9.3±4.6 | 8.8±4.6 | 0.59 |
| Follow up Time (month) | 32.3±5.3 | 32.1±5.2 | 0.99 |
| Operation Time (min)<br>Mean ± SD and median (min-max) | 52.5±24.8<br>45(15-120) | 51.7±24.5<br>45(15-120) | 0.87 |
| Hospitalisation Time (day)<br>Mean ± SD and median (min-max) | 1.3±0.6<br>1(1-4) | 1.8±1.1<br>1 (1-6) | **0.02*** |

(*) Statistically significant difference, EORTC: European Organization for Research and Treatment of Cancer

**Table 2** Demographic and clinical data of the groups

| | ONB group (n=51) | nONBgroup (n=53) | p value |
|---|---|---|---|
| Gender (n,%) | | | 0.93 |
| Male | 43 (84.3) | 45 (84.9) | |
| Female | 8 (15.7) | 8 (15.1) | |
| ASA(n,%) | | | 0.72 |
| 1 | 4 (7.8) | 4 (7.5) | |
| 2 | 23 (45.1) | 28 (52.8) | |
| 3 | 24 (47.1) | 21 (20.2) | |
| Tumor site(n,%) | | | 0.40 |
| Right | 32 (62.7) | 29 (54.7) | |
| Left | 19 (37.3) | 24 (45.3) | |
| Tumor number(n,%) | | | 0.53 |
| Solitary | 25 (49) | 30 (56.6) | |
| Multiple | 26 (51) | 23 (43.4) | |
| Tumor stage(n,%) | | | 0.99 |
| Ta | 27 (52.9) | 28 (52.8) | |
| T1 | 24 (47.1) | 25 (47.2) | |

| | | | |
|---|---|---|---|
| Tumor grade(n,%) | | | 0.88 |
| Low | 19 (37.3) | 19 (35.8) | |
| High | 32 (62.7) | 34 (64.2) | |
| CIS (concomitant)(n,%) | | | 0.801 |
| Present | 5 (9.8) | 6 (11.3) | |
| Not present | 46 (90.2) | 47 (88.7) | |
| EORTC riskclassification(n,%) | | | 0.891 |
| İntermediate | 17 (33.3) | 17 (32.1) | |
| High | 34 (66.7) | 36 (67.9) | |

Data are shown as n (%).



**Table 3** Surgical data, complications and oncological results

| | ONB group (n=51) | | nONBgroup (n=53) | | p value |
|---|---|---|---|---|---|
| | Present | Not present | Present | Not present | |
| Obturator reflex | 5 (9.8) | 46 (90.2) | 21 (39.6) | 32 (60.4) | **0.001*** |
| İncomplete resection | 1 (2) | 50 (98) | 8 (15.1) | 45 (84.9) | **0.031*** |
| Bladder perforation | 1 (2) | 50 (98) | 4 (7.5) | 49 (92.5) | 0.363 |
| Complication | 3 (5.9) | 48 (94.1) | 8 (15.1) | 45 (84.9) | 0.127 |
| Detrusormuscle in specimen | 45 (88.2) | 6 (11.8) | 37 (69.8) | 16 (30.2) | **0.021*** |
| Second TURBT | 25 (49) | 26 (51) | 30 (56.6) | 23 (43.4) | 0.439 |
| Second TURBT due toabsenceof detrusormuscle | 3/25 (12) | 22/25 (88) | 11/30 (36.7) | 19/30 (63.3) | **0.037*** |
| Early recurrence | 5 (9.8) | 46 (90.2) | 11 (20.8) | 42 (79.2) | 0.122 |
| Late recurrence | 10 (19.6) | 41 (80.4) | 20 (37.7) | 33 (62.3) | **0.041*** |
| Tumor progression | 3 (5.9) | 48 (94.1) | 7 (13.2) | 46 (86.8) | 0.32 |

(*) Statistically significant difference.TUR-BT:Transurethral resection of bladder tumor