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Robotic radical prostatectomy in 93 cases: Outcomes of the first ERUS robotic urology curriculum trained surgeon in Turkey

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ABSTRACT

Objective: This study presents the surgical, oncological, and functional outcomes of the first 93 robotic radical prostatectomy (RARP) procedures performed in Erzurum, Turkey. These procedures were performed by a single surgeon who had completed the European Association of Urology Robotic Urology Section (ERUS) RARP curriculum in an ERUS-certified training center in Ankara.

Material and methods: The mean patient age was 63.62±7.04 years, and the mean preoperative serum prostate-specific antigen level was 8.34±4.96 ng/mL. Preoperatively, 82 and 4 patients had prostate biopsy Gleason scores of 3+3 and 4+3, respectively. Bilateral neurovascular bundle (NVB) sparing, unilateral NVB-sparing, and non-NVB-sparing surgery were performed in 21, 13, and 59 cases, respectively.

Results: The mean prostate weight was 85.34±47.57 g. Posterior rhabdosphincter reconstruction was performed in 60 (64.5%) cases. Mean console time, intraoperative blood loss, duration of hospital stay, and urethral catheter removal time were 170.49±36.50 min, 100.70±34.08 cc, 6.84±2.28 days, and 7.40±3.11 days, respectively. During the perioperative period (0–30 days), five minor (prolonged drain output, n=3; rectocele, n=1; gout arthritis, n=1) and six major (inguinal hernia, n=1; incisional hernia, n=2; anastomotic urinary leakage, n=2; myocardial infarction, n=1) complications were identified. No complication was detected during postoperative days 31–90. Postoperative pathological stages included pT2a, pT2b, and pT2c disease in 77 (82.8%), 9 (9.7%), and 7 (7.5%) patients, respectively. The positive surgical margin (SM) rate was 10.7% (n=10), including patients with pT2a (n=6) and pT2c (n=2) diseases. Eleven (11.8%) patients underwent pelvic lymph node (LN) dissection. The mean LN yield was 16.45±4.29. The mean length of follow-up was 11.17±8.01 months. Biochemical recurrence was observed in two patients, one of whom received maximal androgen blockage (MAB), and the other one received pelvic radiotherapy+MAB. All the patients with at least one-year follow-up (n=48, 51.6%) were fully continent (0 pads/day). Of the 40 (43%) patients with no preoperative erectile dysfunction (ED) and with at least three-month follow-up, 18 (45%) had no ED, with or without any additional medication including phosphodiesterase-5 (PDE5) inhibitors.

Conclusion: RARP is a safe minimally invasive procedure with acceptable morbidity, excellent operative, pathological and oncological outcomes, and satisfactory functional results. The ERUS RARP curriculum provides effective and sufficient training.

Keywords: ERUS; outcomes; robotic radical prostatectomy; training.

Introduction

In Turkey, prostate cancer is the second most common (12.7%) form of cancer among men.[1] It represents the most common form of cancer excluding non-cutaneous cancers, and is the third highest cause of cancer-related deaths in the USA.[2] Prostate cancer is now detected at earlier stages following the entry into routine use of prostate-specific antigen (PSA). This has led to more biopsies being taken, and thus more cases of prostate cancer being diagnosed. Increased diagnosis of organ-confined prostate cancer has increased the numbers of radical prostatectomy operations.[3] Radical prostatectomy is a recommended therapeutic technique in patients with localized prostate cancer with a life expectancy exceeding 10–15 years.[4] Radical prostatectomy can be performed by open, laparoscopic, or robotic techniques.

The first robot-assisted radical prostatectomy (RARP) was performed by Binder and Kramer[5] in Germany in 2000. With its various advantages, such as obtaining three-dimensional imaging, a high degree of freedom in instrument movements and preservation of the hand-eye-target axis, the robotic system today represents a powerful alternative to conventional techniques.[6] Because of such advantages, RARP has now become a widely used minimally invasive therapeutic technique in treatment of localized prostate cancer. The RARP technique leads to a shorter catheter application period and hospital stay, and less blood loss than open radical prostatectomy.[7] Because of its technical advantages and low complication rates, this robotic system has been used in approximately 80% of prostatectomy procedures in the USA in the last 10 years.[8]

The European Association of Urology Robotic Urology Section (ERUS) provides a structured training program for RARP.[9] A team of international specialists runs the ERUS-structured RARP training program. The training process lasts 12 weeks. It begins with theoretical online classes, and continues with simulation training and live case observation. It involves wet and dry laboratory training and mixed virtual reality. This is followed by a five-day intensive advanced robotic training program. This program contains a theoretical course, one-day live surgery, and intensive laboratory instruction. Modular training begins after the fifth week, and trainees begin to complete surgical stages with steps of increasing difficulty. After successfully carrying out all stages, the subjects then perform the entire procedure. A procedure completed after 24 weeks is recorded and transmitted to a committee of experts for blind evaluation. Successful candidates are awarded a certificate.[9]

This study presents the surgical, oncological, and functional outcomes of a transperitoneal RARP series performed by a single surgeon who had successfully completed the ERUS training program in Turkey.

Material and methods

This study was approved by the institutional review board. It presents the results of 93 RARP procedures performed by a single surgeon (FB). The surgeon performing the operations completed an ERUS training program structured for RARP by two robotic surgeons (AFA and AEC) holding ERUS training certificates in an ERUS-approved academic robotic surgery training center in Ankara.[9] The RARP cases performed by the surgeon after completion of the training between April 2016 and August 2018 were retrospectively evaluated. The surgical technique applied was described previously by Canda et al.[10] using a transperitoneal posterior approach with Da Vinci four-armed robotic surgical system. Diagnosis of prostate cancer was based on transrectal ultrasound-guided Tru-cut prostate biopsy performed due to suspicious digital rectal examination findings and/or PSA elevation.

Clinical stages were recorded using the 2002 AJCC staging system. For all patients, age, body mass index (BMI), preoperative total PSA value, Gleason scores, ASA scores, clinical and surgical stages, prostate weight, duration of surgery, intraoperative estimated blood loss, time of removal of drain and transurethral catheter, and length of hospital stay were evaluated. Perioperative findings and procedures were obtained from examination of operation notes. The complication data were analyzed using the modified Clavien classification system.[11]

Preoperative risk was determined using the D'Amico classification.[12] Patients who were classified as moderate or high-risk based on the D'Amico system underwent extended pelvic LN dissection using the Partin's nomogram. All patients were invited to attend follow-ups at postoperative months one and three, and every three months thereafter. Patients' continence status, erectile functions, and PSA levels were assessed at these follow-ups. Biochemical recurrence was defined as PSA values twice exceeding 0.2 ng/mL.[13]

Urethral catheters were removed from patients with no anastomosis leakage at cystography performed on the first week postoperatively. In the case of leakage, catheters were removed based on cystography results after 14 and 21 days and one month. Postoperative continence was evaluated at early follow-up (first week) and at months 1, 3, 6, and 12. Patients using no pads or one security pad per day were regarded as continent.

Erectile function was evaluated at 6 and 12 months postoperatively. This was defined as the ability to achieve sufficient erection for vaginal penetration irrespective of use of phosphodiesterase type 5 (PDE5) inhibitors. Patients were followed-up for at least one year, and those with no preoperative erectile dysfunction (ED) were included in the erectile function evaluation. ED was defined as an International Index of Erectile Function (IIEF) score below 22. Patients were started on PDE5 inhibitors for penile rehabilitation in the early postoperative period following removal of the urethral catheter. Written informed consent was obtained from all patients prior to participation in the study.

Statistical analysis

Data analysis was performed with the IBM Statistical Package for the Social Science (IBM SPSS Statistics Corp.; Armonk, NY, USA) version 20 for Windows software. Categorical variables were expressed as number and percentage, and numerical variables as mean plus standard deviation.

Results

Preoperative patient characteristics are shown in Table 1. Ninety-three patients were included in the study. Patients' mean age was 63.62±7.04 (46–77) years, and mean BMI was 27.17±5.92 (20–36) kg/m^2. Mean duration of follow-up was 11.17±8.01 (3–27) months, and mean operative time was 170.49±36.50 (120–360) min.

Investigation of the surgical histories of the patients in our study revealed cases of coronary by-pass surgery (n=2), gastric perforation repair (n=1), appendectomy and colectomy together with melanoma in remission (n=1), transurethral prostate resection (TUR-P) (n=1), appendectomy and colectomy (n=8), unilateral inguinal hernia repair (n=12), and bilateral inguinal hernia repair (n=8).

The mean length of hospital stay was 6.84±2.28 (4–21) days. In our series, inguinal hernia repair with mesh was performed simultaneously with RARP in six patients. A 2-cm-sized vesical calculus was also determined in one patient, and this was removed during the RARP surgery.

Our patients' oncological results are summarized in Table 2. Positive surgical margin (SM) was reported in 10 (10.7%) patients, and biochemical recurrence occurred at follow-ups in two subjects. Of those, one received maximal androgen blockage (MAB), and one received pelvic radiotherapy and MAB. Positive SMs were reported at the apex in seven patients and as multifocal in three.

Table 1. Preoperative patient characteristics

	All patients (n=93)
Age (years)	63.62±7.04
BMI (kg/m^2)	27.17±5.92
Serum PSA (ng/mL)	8.34±4.96
Prostate volume (cc)	85.34±47.57
Biopsy Gleason score, n (%)	
3+3	82 (88.2)
3+4	7 (7.5)
4+3	4 (4.3)
Preoperative IIEF score	
No ED (22–25): n (%)	40 (43)
Mild ED (17–21): n (%)	18 (19.3)
Mild-to-moderate ED (12–16): n (%)	16 (17.2)
Moderate ED (8–11): n (%)	11 (11.8)
Severe ED (5–7): n (%)	8 (8.7)

PSA: prostate-specific antigen; BMI: body mass index; ED: erectile dysfunction; IIEF: International Index of Erectile

Eleven patients underwent pelvic LN dissection. Mean LN yield was 16.45±4.29. The LN metastasis was detected in any patient.

Nerve-sparing surgery was performed in 34 cases. Erectile function and urinary continence results are summarized in Table 3. In all our patients, complete urinary continence was achieved. Erectile function was preserved in 18 (45%) patients with full preoperative erectile functions at six-month postoperative follow-ups.

Various perioperative complications developed in 15 of 93 patients. No patients required intraoperative or postoperative blood transfusion. Myocardial infarction (MI) occurred in one patient

Table 2. Perioperative and postoperative patient characteristics

	All patients (n=93)
Mean operative (console) time (min)	170.49±36.50
Mean blood loss (cc)	100.70±34.08
NVD-protective technique, n (%)	
Not applied	59 (63.4)
Unilateral	13 (14)
Bilateral	21 (22.6)
Bladder neck reconstruction, n (%)	12 (31.6)
Posterior reconstruction suture, n (%)	60 (64.5)
Mean length of hospital stay (days)	6.84±2.28
Mean time to removal of urinary catheter (days)	7.40±3.11
Pathological Gleason scores, n (%)	
3+3	77 (82.8)
3+4	9 (9.7)
4+3	7 (7.5)
Positive surgical margin, n (%)	
Total	10 (10.7%)
pT2a	6 (6.5%)
pT2b	2 (2.1%)
pT2c	2 (2.1%)
Pathological T stage, n (%)	
pT2a	77 (82.8%)
pT2b	9 (9.7%)
pT2c	7 (7.5%)
Mean number of lymph nodes removed, n	16.45±4.29
Biochemical recurrence, n (%)	2 (2.1%)
Adjuvant ADT, n (%)	1 (1%)
Adjuvant ADT + radiotherapy, n (%)	1 (1%)

NVB: neurovascular bundle; ADT: androgen deprivation therapy

Table 3. Postoperative functional outcomes

	All patients (n=93)
Urinary continence, n (%)	93 (100.0)
Early continence (from catheter removal), n (%)	35 (37.6)
First month n (%)	67 (72.0)
Third month, n (%)	73 (78.5)
Sixth month, n (%)	83 (89.2)
12th month, n (%)	93 (100)
Potency (IIEF≥22), n (%) (preoperatively potent patients were included in the analysis)	40 (43.0)
6 months, n (%)	18 (45)
12 months, n (%)	25 (62.5)

IIEF: International Index of Erectile

Table 4. Perioperative and postoperative complications

	All patients (n=93)
Perioperative complications (0-30 days) (Clavien–Dindo classification), n (%)	15 (16.1)
Grade 1	5 (5.3)
Grade 2	0 (0.0)
Grade 3a	0 (0.0)
Grade 3b	9 (9.7)
Grade 4	1 (1.1)
Grade 5	0 (0.0)
Postoperative complications (30–90 days), n (%)	0 (0.0)

at the end of surgery. The patient was intubated, PTCA was performed, and the subject was transferred to the coronary intensive care unit. The patient was discharged without complications on day 7 postoperatively. In terms of Clavien complications, grade I complications (long-term drainage, rectocele, gout arthritis) occurred in five patients, grade 3b (appendicitis, inguinal hernia, incisional hernia, anastomosis leakage) in nine, and grade IV (MI) in one. Postoperative complications are summarized in Table 4.

Discussion

The first robotic system permitted for the surgical procedures was the Da Vinci robotic surgical system prototype that was approved by the Food and Drug Administration in 2000.[14] Robotic systems have since rapidly improved because of their numerous advantages, and their use has spread worldwide. Currently, very few surgeons are exposed to robotic surgery during their training. This has led to questions of licensing and authorization for surgeons in the context of robotic surgery.[15] There are no regulatory arrangements for the provision of authorization/licensing documents in Turkey. However, studies have recommended that familiarity with the devices and equipment used, length of robotic surgical activity, total operative time, estimated blood loss, numbers of complications and return to open surgery, appropriate patient selection, and compliance with general safety rules should be considered while evaluating the competence of a surgeon.[16]

The 93-case RARP series in this study consists of operations performed by a single surgeon (FB) who had completed the first part of the training within this program abroad at ORSI Academy in Melle, Belgium, and the remaining part in Ankara, Turkey. We think that before using robotic surgical systems, undergoing training in experienced and preferably internationally certified centers, and spending training periods under supervision make a positive contribution to the surgeon's training process. Following the training, the proctors (AFA and AEC) personally attended the initial RARP operations performed by the surgeon at his own center in Erzurum, and observed and supervised the entire procedures. We think that this additional effort resulted in a safe and effective surgical process for both the patients and the surgeon.

Due its lower incisional morbidity, intraoperative blood loss, transfusion rates, and shorter healing times, minimally invasive techniques are preferred as an alternative to open surgical techniques.[13] Several studies examining the outcomes of open radical prostatectomy and RARP have supported the use of RARP.[6]

Basiri et al.[17] reported that operative times were generally longer with RARP compared with those in open radical prostatectomy. In a multicenter RARP study from Turkey, Tasci et al.[18] reported a mean length of surgery of 181.9 min in their study of 1499 patients undergoing RARP. The mean operative time in our study was 170.49±36.50 (120–360) min that is compatible with the previous literature.

Significantly less blood loss is observed in robotic surgery than in open radical prostatectomy. Both the tamponade effect of intra-abdominal pressure and using robotic instruments effectively to prevent bleeding under magnified vision contribute to decreased blood loss.[19] Hashimoto et al.[20] reported results for 200 patients undergoing RARP, and observed a mean blood loss of 225 mL. Canda et al.[10] reported an estimated blood loss of 215 cc in their study of initial 70 patient series. The mean blood loss in our study was 100.7±34.08 (50–250) cc, and no transfusion was required in any case. The mean estimated blood loss in our study was similar to that in other series in the previous literature.

It should be kept in mind that the primary aim in prostate cancer is cancer control. Studies have frequently discussed biochemical recurrence and positive SMs in terms of cancer control. Tasci et al.[18] determined a positive SM in 14.1% of a 1499-patient RARP series. Badani et al.[21] reported a positive SM in 12 out of 200 patients, and biochemical recurrence in eight. In our series, a positive SM was present in 10 (10.7%) patients. Pathological grade was pT2a in six patients, pT2b in two patients, and pT2c in two patients. The mean follow-up time in our series was 11.17±8.01 (3–27) months, and biochemical recurrence was observed in two patients at follow-up. Previous publications have reported that positive SM was frequently identified in the apical portion of the prostate.[22] SM positivity was also in the apex in all of our patients.

Urinary incontinence and ED are two important functional parameters requiring evaluation following radical prostatectomy. Frota et al.[23] reported continence at 95% in their meta-analysis evaluating 416 patients undergoing RARP. Zorn et al.[24] reported a continence rate of 90% at the end of one year in their 300-case series. In our study, patients using one or more pads per day were regarded as incontinent. Our continence rates were compatible with the previous literature as 72% at one month and 78.5% at three months.

Erectile function following radical prostatectomy is known to be associated with NVB preservation.[25] Studies comparing retropubic radical prostatectomy with RARP have shown that patients undergoing RARP achieved earlier rapid erectile functions.[26] In a study of 100 patients, Mikhail et al.[27] reported a postoperative return rate of sexual function as 58% at three months and 80% at the end of one year. When the 40 patients in our study with IIEF >22 were evaluated, 45% (n=18) had IIEF scores >22 and sufficient erectile function for sexual intercourse at the end of the postoperative third month.

In their randomized prospective study, Yaxley et al.[28] determined no superiority between retropubic radical prostatectomy and RARP in terms of urine retention or sexual function, and reported similar functional outcomes at the end of 12 weeks. They also emphasized the need for patients to prefer a highly experienced surgeon over the operative technique. However, a criticism aimed at that study stated that the two surgeons taking part were not equally experienced, and that the tendency in that study was directly contrary to the current trend toward minimally invasive robotic surgery.[29]

In conclusion, with its acceptable morbidity rates, excellent operative, pathological and oncological outcomes, and satisfactory functional results, RARP is a safe and minimally invasive technique. The ERUS-structured RARP curriculum provides a well-established, adequate, and effective training.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Erzurum Training and Research Hospital (07.01.2019/37732058-514.10).

Informed Consent: Written informed consent was obtained from all patients who participated in this study.

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