

# PERI- AND POST-OPERATIVE RESULTS OF INITIAL ROBOT-ASSISTED RADICAL PROSTATECTOMIES OF A SURGEON GRADUATING FROM A STRUCTURED FELLOWSHIP

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A – study design, B – data collection, C – statistical analysis, D – interpretation of data, E – manuscript preparation, F – literature review, G – sourcing of funding

## ABSTRACT

**Background:** No validated training curriculum for robotic surgery exists so far. International scientific societies like ERUS (EAU Robotic Urology Section) seek to validate a structured training program for robotic surgeons. In 2014, ERUS launched Pilot Study II, a 6-month structured training program to allow a surgeon without prior robotic training to perform a complete RARP (robot-assisted radical prostatectomy) independently and effectively.

**Aim of the study:** Here we report the detailed courses and training materials, specific surgical activities and perioperative efficacy and safety results of the first 52 RARP cases performed by a single surgeon after graduating from Pilot Study II. The aim is to compare these results with the literature and show if this sophisticated training helps patients undergoing this type of surgery achieve advantageous perioperative results.

**Material and methods:** The fellowship was conducted from January to June 2014 and consisted of lectures on technical and non-technical skills, as well as e-learning, bedside assistance (at least 20), intensive training consisting of laboratory training (i.e., virtual reality simulation, dry lab (plastic model), wet lab on animal cadavers and living anaesthetized pigs) and dual-console live surgery followed by five months of modular training, where the trainee performed different steps of the surgery at the host center. After passing the final evaluation (a full recorded video of RARP evaluated blindly by robotic experts), the trainee was deemed capable of performing efficiently and safely a full case of RARP. Here we retrospectively report the content of training and perioperative results of the surgeon's initial 52 RARPs performed from July 2014 to April 2015.

**Results:** After graduating from the fellowship, the surgeon performed 52 cases of RARP. The mean patient age was 65.2 years, initial PSA 12.9 ng/ml, prostate volume 43.7 ml in TRUS, BMI 27.5, and 61% of patients had a prior abdominal or pelvic surgery. Because of internal regulations, every patient had a pelvic lymphadenectomy performed, three of whom had positive lymph nodes. The average estimated blood loss was 225.7 ml, and no patient needed intraoperative blood transfusion. The average console time was 174.2 minutes. Final full-mount pathology identified 23 patients (44.2%) with a locally advanced prostate cancer (T3 or T4). Positive surgical margins were present in three cases. A further 29 patients (55.8%) had locally confined disease (T2). Positive surgical margins were observed in 2 cases. Catheters were removed on the 5<sup>th</sup> postoperative day followed by a cystogram, with no urine leakage observed in 96.2% of cases. The safety of the procedure was good with one major (Clavien 4) and 13 minor (Clavien 1 and 2, i.e., uncomplicated urinary infection, urinary retention) complications.

**Conclusions:** The study showed that graduating from an intensive and structured learning program in robotic surgery resulted in a faster learning curve, allowing the trainee to reach high safety parameters in performed surgeries. When compared with already published series, advantageous results could be observed. The study was limited by its retrospective design, the moderate number of patients and variables such as individual motivation, dexterity and attitude of the person in training. The advantages of such training should be further evaluated in controlled, multi-center trials.

**KEYWORDS:** radical prostatectomy, prostate cancer, learning curve, robot-assisted radical prostatectomy

## BACKGROUND

Robotic surgery was introduced 15 years ago, at a time when surgeons lacked validated training curricula to structurally teach the technical and non-technical skills required to perform such surgery in an efficient and safe manner. In 2013, ERUS (EAU Robotic Urology Section) proposed a 3 month-long training program known as Pilot Study I. The results showed that the program was too short, so a longer Pilot Study II was developed. The aim was to create a training modality to teach a novice the set of skills needed to perform robot-assisted radical prostatectomies successfully. The program consisted of e-Learning (e-BRUS), lectures, and 20 bedside assistances during robotic procedures followed by a one-week intensive course at a globally acknowledged training center in Belgium. The trainee was confronted with simulation tasks, operated on artificial and cadaver models, and subsequently on anaesthetized pigs. Upon completion of the training, the fellow returned to the host-facility where they performed steps of the surgery in order to achieve proficiency in every part of the surgery.

Radical prostatectomy was chosen for the procedure to train on, as prostate cancer is the most common malignancy in western countries in men [1-3]. The etiology of prostate cancer is still not fully clear, but risk factors include age and positive family history [4, 5]. Treatment modality depends on tumor stage and patient comorbidities. Radical prostatectomy is one of the main therapeutic options [6]. Radical prostatectomy can be performed in 3 different ways: open surgical, laparoscopic and robotic. The evidence is growing that the minimally invasive robotic approach is associated with fewer complications, less blood loss and advantageous functional results [7-9]. There is also a large body of evidence that surgical outcomes are strongly related to the surgeon's experience level [10-14].

## AIM OF THE STUDY

Aim of the study is to demonstrate the content of the model, intensive training-curriculum and whether this approach results in favorable surgery outcomes. We compare the results achieved by the trainee with historically published ones and determine whether and which safety points can be improved.

## MATERIALS AND METHODS

In the first part of this retrospective analysis we examined the specific content of the training for given surgeon. After completion of an intensive theoretical and practical training, a stepwise approach to performing surgeries was introduced. Robot-assisted radical prostatectomy was divided into 17 surgical steps and the trainee was asked to perform a given number of each step [15]. The crucial steps of the surgery were:

- Bladder detachment – 20 repeats
- Endopelvic fascia incision – 20 repeats

- Anterior and posterior bladder neck dissection – 15 repeats
- Seminal vesicles dissection – 15 repeats
- Posterior prostatic fascia dissection – 10 repeats
- Dissection of the prostate pedicle – 10 repeats
- Nerve-sparing procedure – 5 repeats
- Closing of the dorsal vascular complex – 10 repeats
- Apical dissection – 10 repeats
- Urethrovesical anastomosis – 15 repeats.

After sufficient modular training a full case of radical prostatectomy was performed and recorded. Video was taken of the main surgical steps and blindly reviewed by international experts. After passing this final evaluation, the second part of the study followed.

52 consecutive patients diagnosed with prostate cancer were operated on by the trainee. All data was evaluated retrospectively and written consent obtained from every patient. The study design was observational and patients underwent standard state-of-the-art treatment. The examined parameters included age, BMI, iPSA, Gleason score, prostate volume, previous abdominal surgery, operation time, blood loss, complications, and pathological results including TNM classification, surgical margin status and Gleason score.

In the final part of the study the achieved results were compared with those reported in historical learning curve studies as well as with results from experienced surgeons in order to see if the fellowship resulted in more rapid achievement of better results.

## RESULTS

In the first part of the study, the trainee participated and partially performed 67 RARPs. Altogether he performed 564 single steps of the surgery, from which the most important steps were performed above a set minimum:

- Bladder detachment – 35 repeats
- Endopelvic fascia incision – 25 repeats
- Anterior and posterior bladder neck dissection – 31 repeats
- Seminal vesicles dissection – 27 repeats
- Posterior prostatic fascia dissection – 16 repeats
- Dissection of the prostate pedicle – 14 repeats
- Nerve-sparing procedure – 13 repeats
- Closing of the dorsal vascular complex – 21 repeats
- Apical dissection – 16 repeats
- Urethrovesical anastomosis – 15 repeats.

The final examination consisted of a full surgery. The patient had a prostate cancer of intermediate risk, iPSA 6.3 ng/ml, T1c, Gleason score 7a, and prostate volume of 44 ml. The surgery took 250 minutes and the final pathology showed pT2c pN0 (0/17) R0, Gleason 7b. After international evaluation of the recorded video, the trainee was deemed capable of performing surgeries on their own.

Results of the main part – 52 surgeries performed by the trainee

In 10 months after graduating from the fellowship, the trainee was able to perform 52 robot-assisted radical prostatectomies. The demographic and initial urologic data of the patients is displayed in Table 1. On average, the surgery took 174.2 minutes and blood loss was 225.7 ml. No perioperative transfusions were required. Bilateral nerve sparing surgery was performed in 34.6%, unilateral in 44.2% and none in 21.2% of the patients. Grade 1 bladder neck preservation could be achieved in 51.9%, grade 2 in 46.2% and grade 3 in 1.9% of operated patients. There were no intraoperative complications [16].

The final pathology results were: pT2a-c in 55.8%, pT3a in 36.5%, pT3b in 3.8% and pT4 in 3.8% of the patients. Lymph node dissection was performed on every case and 5.8% of the patients were already N+. The mean number of removed lymph nodes was 14.94. The guidelines recommend removing at least 10 lymph nodes as a quality measure of surgical performance [6].

A positive surgical margin (R1) was detected in 6.9% of organ-confined disease and in 13% of locally advanced disease. There were no R2 (macroscopically incomplete resection) cases.

Table 1. Results

Parameter	Value	
Age (years, mean)	65.2	
BMI (mean)	27.5	
TRUS (ml)	43.7	
Prior abdominal/pelvic surgery (%)	61	
Mean iPSA-Value (ng/ml)	12.9	
Average console time (min)	174.2	
Estimated blood loss (ml)	225.7	
Mean catheterization time (days)	5.5	
T2	55.8%	
T3	40.4%	
T4	3.8%	
N+	5.8%	
Positive surgical margin (%)	T2	6.9%
	T3/T4	13.0%

Postoperative histological grading of prostate cancer was as follows: Gleason 6 in 30.8%, Gleason 7 in 63.5% and Gleason >7 in 5.7% of cases.

Postoperatively, a cystogram was performed to check for urinary leaking in urethra-vesico anastomosis. This was inconspicuous in 100% of cases and the catheter was removed on day 5 after the surgery.

During the postoperative course we diagnosed 15 complications. 14 (93.3%) of all complications were minor, mostly urinary infections and retention. There was one major complication—a postoperative bleeding revised laparoscopically by the trainee themselves.

## DISCUSSION

Compared to other participants in Pilot Study II, the trainee underwent more intense training, performing 67 partial surgeries and 564 single steps of the procedure. The mean for the cohort was 28.4 and 231, respectively [15]. It may have been due to the multi-center design of the training and individual differences in motivation, drive and professional situation.

In order to compare the results of this study, we identified a number of publications addressing learning curves in robotic prostatectomy. Abboudi et al [11] published a review covering 17 series reporting initial results and learning curves. That study was limited by the lack of methodological description of specific robotic training, probably due to a lack of curricula offered in that time. Some authors such as Wolanski et al [17] describe their training, in this particular example, a 3 day course, much less than what was done in Pilot Study II. These differences in study design may contribute to the observed differences in achieved results. When it comes to the number of performed surgeries, other publications are more or less comparable, with 20 to 50 patients each [16-22]. In regard to age and body mass index the results presented here were comparable to those in the literature. In our study the percentage of patients with previous abdominal surgeries (with increased risk of surgical complications) was much higher (61%) than that found in the literature (Mattei et al [23] 28.4%, Horovitz et al [24] 21.2%).

Preoperative oncological parameters such as iPSA, T-Stage, and Gleason score were comparable with the literature.

Average console time is considered one of the most important factors in evaluating the learning curve. The surgery times published by other authors were 145–260 [11], 195.3–371.3 [25], and 190 [17] minutes. These numbers are comparable but higher than the 174.2 minutes observed in our study. Yet another important factor is intraoperative blood loss; here also comparable values were observed: 152–310 [11], 285–725 [25], 200 ml [17] and 225.7 ml in the current study.

Complications rates were also similar with 17–27% [11] and 12.9–19% [17].

When comparing positive surgical margins rates, one can see much higher rates published historically: 5–42% [11], 12.3% [17] and 34.2% [26]. In a meta-analysis covering experienced surgeons, Novara et al [27] demonstrated an R1 Rate of 6.5–32% and a weighted mean of 15%. All historical data are higher than the 9.6% observed in the current study. We hypothesize that favorable surgical and oncological results achieved in this study were due to well-organized, structured performance of surgeries in the high volume host facility.

## CONCLUSIONS

Pilot Study II was a sophisticated, well-designed and structured intensive training program which allowed a novice surgeon to gain sound surgical skills in a rea-

sonable time. Comparison of our results with historical data revealed that the Pilot Study II training curriculum was more intense, presumably the reason for the marginally more advantageous results. This applies mostly to the lower positive surgical margins rate as well as shorter surgeries and less blood loss. The con-

clusions drawn from this study should be interpreted cautiously due to this report's limitations of retrospective design, literature comparison, the moderate number of cases and the single surgeon involved, since results may vary significantly based on individual characteristics.

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