

**Robot-assisted extraperitoneal laparoscopic radical prostatectomy: experience in
a high-volume laparoscopy reference centre**

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ABSTRACT

Objective: Robot-assisted laparoscopic radical prostatectomy (RALP) has increasingly become a treatment option for men with localized prostate cancer. To describe our current procedure, perioperative data, early oncological outcomes and functional results, and to assess the impact of the learning curve on these parameters.

Patients and Methods: 206 consecutive men underwent a RALP between July 2001 and November 2008 for localized prostate cancer. Among the overall cohort, the 175 men operated on by the same surgeon were distributed into 5 groups according to the chronological order of the procedures. Mean follow-up after RALP was 18.3 months. Patient demographics, surgical data and postoperative parameters were collected into a prospective database. Data were compared by chronological groups into single-surgeon cohort.

Results: Median operative time and blood loss were 140 minutes and 350 ml, respectively. The complication rate was 8.3%. Cancers were pT3-4 in 34.5%. Mean hospital stay and duration of bladder catheterization were 4.3 and 8.2 days, respectively. The rate of positive surgical margins (PSM) was 17.2% in pT2 cancers. Continence recovery was 98% at 12 months. Intraoperative time, blood loss and length of hospital stay were significantly improved after a short learning curve. The continence recovery, the rate and the length of PSM were also improved beyond the learning curve, but difference did not reach significance.

Conclusions: Robot-assisted laparoscopic radical prostatectomy is a safe and reproducible procedure and offers a short learning curve for experienced laparoscopic surgeons. Beyond the learning curve, continued experience may also provide further improvements in terms of operative, pathological and functional results.

INTRODUCTION

The first laparoscopic radical prostatectomy (LRP) was performed in 1992. In the following years, the development of minimally invasive surgery was driven in Europe in some centres able to report considerable experience and to standardize the technique [1, 2, 3]. Laparoscopic procedure is actually a validated treatment modality for localized prostate cancer. Lower blood loss and transfusion rate were demonstrated to be the main advantages of laparoscopic surgery. Improved cosmesis and shorter convalescence may also participate to increase patient acceptance of surgical procedures and its resultant side effects. These benefits occur without sacrificing the oncological standards established by the open approach [4]. Functional results on continence and potency appeared comparable than those obtained by open approach [5].

However, laparoscopic radical prostatectomy remains a technically demanding procedure and requires a learning curve estimated at 50-70 patients [6, 7]. The 2-dimensional vision with acquisition of different anatomical perspectives, the loss of some freedom of motion and hand-eye coordination contribute to the steep learning curve of laparoscopy. These difficulties and the emergence of robotic assistance that improves precision and accuracy of anatomical dissection lead American laparoscopic urologists to develop the technique of robot-assisted LRP (RALP) [8-11]. One of the purpose of the robotic assistance was to reduce the learning curve, even in laparoscopically naïve surgeons [10, 12]. In contrast the United States, the use of robots was likely to remain limited in Europe until the last years [13].

Based on high surgical volume and resultant increasing experience of extraperitoneal LRP, we performed the first RALP in 2001 and started to perform routinely RALP

since 2006 [13]. Herein we reported an analysis of our experience in the initial 206 robot-assisted extraperitoneal radical prostatectomy (RALP) performed in a high-volume laparoscopy reference centre. We described the current procedure, perioperative data, early oncological outcomes and functional results. We also studied the impact of the learning curve on these parameters.

PATIENTS AND METHODS

Patient selection.

Between July 2001 and November 2008, 206 men underwent da Vinci® RALP at our department. All procedures were performed by 2 surgeons at our institution (CCA, ADLT). The majority of procedures (175 RALP) were performed by the same surgeon (ADLT) who has used robotic assistance for each RP since 2006. Indications of surgery were localized prostate cancer and were identical to those in patients undergoing pure LRP. A history of previous abdominal surgery, transurethral prostate resection, hernia repair or hormone therapy were not contraindications. Mean follow-up after RALP in our cohort was 18.3 months.

Surgical procedure.

The surgical technique and the different steps of the surgery were the same as our LRP technique [14]. Two continuous polyglactin sutures were used to make a running vesicourethral anastomosis. Lymphadenectomy was performed prior to the completion of the vesicourethral anastomosis in case of Gleason score greater than 6 and/or PSA level greater than 10 ng/ml. Low-risk patients (primary Gleason grade of 3, clinical T1c stage, PSA level <10 ng/ml) underwent intrafascial nerve-sparing prostatectomy since March 2007. Intermediate-risk to high-risk patients underwent conventional nerve-sparing procedure. Urethral catheter was usually removed on postoperative day 7 with no cystogram.

Database and statistical analysis.

Data were collected prospectively into a database, including preoperative clinical and biological characteristics, patient demographics, surgical data and postoperative parameters. Surgical time was calculated from the time of initial incision for port placement to skin closure. Pathological Gleason score, surgical margin (SM) status, presence of extracapsular extension (ECE), seminal vesicle invasion (SVI) and pelvic lymph node positivity were recorded. All patients prospectively completed self-administered questionnaires concerning their quality-of-life (EORTC QLQ-C30) and their voiding and sexual (IIEF-5) disorders, preoperatively and 1, 3, 6, 12 and 24 months after RP. Potency was defined as the ability to achieve an erection sufficient for penetration with or without the use of phosphodiesterase-5 enzyme inhibitor (excluding cases with intracavernous injection of prostaglandin E). Urinary continence was assessed by questionnaires and defined as the absence of pads in a first analysis (strict urinary continence) and as the presence of 0-1 pad (“safety pad”) in a second analysis. Biochemical recurrence was defined as any detectable serum PSA (greater than 0.2 ng/ml). Perioperative complications were noted and reported according to the updated Clavien classification [15]. The single-surgeon cohort of 175 men was distributed into 5 groups of 30 patients according to chronological order of procedures. Data were compared for these 5 groups (except 55 for the last group). The qualitative data were tested using the chi-square or the Fisher’s test as appropriate. The quantitative data were analyzed by the Mann-Whitney test. A double-sided p value <0.05 was considered statistically significant. All data were analyzed using SPSS 13.0 software (Chicago, Illinois).

RESULTS

Overall cohort

The preoperative characteristics of the overall patient cohort are shown in Table 1 (206 men at baseline). The majority of cancers were clinical T1c cancers (85.4%) with a Gleason score 6 or less (65.5%) and with a median PSA of 6.6 ng/ml.

The operative parameters and the postoperative course are listed in Table 2. Median intraoperative time and blood loss were 140 minutes and 350 ml. The rate of complications was 8.3% with no Clavien IV or V complications. Complications were urinary infection, parietal or Retzius haematoma, acute urinary retention, postoperative bleeding with re-intervention (1 patient) and anastomotic leakage. Three patients developed urinary retention necessitating catheter replacement. Only 7 patients (3.4%) received transfusion units. Conversion to pure laparoscopic approach was reported in 1 patient.

Median hospital stay and duration of bladder catheterization were 4 and 8 days, respectively. When evaluating the timing of catheter removal, 95.1% of patients had their catheter removed when originally planned.

The pathological parameters on RP specimens are reported in Table 3. Final assessment revealed pT3-4 cancers in 34.5% of cases and a Gleason score 7 or more in 63.6% of cases (and a primary grade 4 or more in 33%). Five men (2.4%) had positive lymph nodes. The rate of positive surgical margins (PSM) was 27.7% in

overall analysis. When margin status was analyzed by stage, the pT2 and pT3-4 margin rates were 17.2% and 48.3% in the overall cohort, respectively.

Seventeen PSA recurrences (8.3%) appeared during a mean follow-up of 18.3 months. Thirteen patients (6.3%) received adjuvant radiation and/or androgen ablation treatment. No cancer-specific death was reported.

Table 4 shows the functional results after RALP. Nerve-sparing procedures were performed in 181 patients (87.9%) and bilateral in 152 patients. Intrafascial dissection was performed in 27.2% of men. Sexual intercourse (excluding cases with intracavernous injection of prostaglandin E) was maintained in 39.1% of men after 12 months. Continence recovery was 98% when “safety pad” was the selected criteria. Strict urinary continence (no pads) was reported in 74% of men 12 months after surgery.

Single-surgeon cohort (n=175) and learning curve

Table 5 compares the clinical, surgical and pathological data for the single-surgeon cohort which was distributed between 5 chronological groups of 30 patients (except 55 for the last group).

When comparing the groups, there was no statistically significant difference in patient age, clinical stage disease, BMI, PSA level, non organ-confined disease and lymph node dissection.

Blood loss, intraoperative time (Figure 1) and length of hospital stay were significantly improved between the 30 first RALP and the remaining procedure ($p=0.005$, 0.004 and 0.003). Complication and transfusion rates were also higher in the 30 first RALP (16.7%), but difference did not reach significance compared with other periods. Mean length of PSM was 10.5 mm in the first period (experience of 0-29 RALP) compared with 4.4 mm in the second period (experience of 30-59 RALP) with a $p=0.24$.

The rate of PSM did not decrease between the 2 first periods. However, the rate of PSM in pT2 cancers was 22.5% in the 60 first RALP (period 1 and 2) compared with 11.7% in the remaining RALP ($p=0.12$). The rate of PSM in pT3-T4 cancers was 48.7% in the 60 first RALP (period 1 and 2) compared with 28.6% in the last period ($p=0.14$).

Duration of bladder catheterization remained stable.

Concerning the urinary continence recovery 1 month after surgery, 46.2% of men who have undergone RALP during the 2 first periods (experience of 0-59 RALP) wore 0-1 pad, compared with 64.3% of men who have undergone procedure in the next periods (experience >60 RALP) ($p=0.19$).

DISCUSSION

Laparoscopic radical prostatectomy is becoming standard in many departments for treatment of localized prostate cancer. LRP has achieved equivalence to open surgery with regards to mid-term outcomes. Laparoscopic procedure combines the same oncological results than open retropubic radical prostatectomy with benefits in terms of blood loss, convalescence, postoperative pain and cosmesis [5]. Recently, robotic assistance has gained widespread acceptance, especially in the United States. The robot offers several technical advantages over pure laparoscopic RP such as the magnified 3D vision, the 6 degrees of freedom from the instruments tips and a comfortable console to reduce fatigue of the surgeon. Initial outcomes of earlier RALP series have shown the feasibility of the procedure [8, 9, 11, 13]. Some studies comparing pure LRP and RALP have also been published and showed interesting postoperative results for RALP [5, 16, 17]. Moreover, the use of robotic system reduces difficulty in performing complex laparoscopic techniques and seems to decrease strongly the learning curve compared with pure laparoscopic procedure. In the present study, we assessed the operative, pathological and functional outcomes of RALP in a highly experienced laparoscopic RP center. We also evaluated the learning curve of RALP comparing these results over time in single-surgeon patient cohort.

The extraperitoneal laparoscopic RP is routinely performed in our department since 2000 [2,14]. Extraperitoneal approach has been demonstrated to be a safe and

reproducible procedure, with a fast recovery after surgery [14]. The first RALRP was performed in our department in 2001 [13]. However, RALRP is routinely performed only since 2005 because the robot was not accessible for the urologists during this period (2001-2005). Only 16 RALRP have been performed in the two first years. Thus, the surgical team had a highly strong experience of extraperitoneal LRP when surgeons started performing routinely RALRP. We thought that this point was important. Indeed, the majority of the studies reported the experience of surgeons, particularly in the US, that made a transition from open to robotics, without learning laparoscopic techniques. Our experience of LRP before starting RALRP gives an additional value to our work compared with the published literature. The short operative time in our study may reflect this consideration.

Thus, this study reported an important european series of extraperitoneal RALRP in a laparoscopically experienced centre.

Operative parameters

The mean operative time was in line with the last published values [18-20]. Mean blood loss was also in line with published values which ranged from 100 to 533 ml in the literature [10, 18, 19, 21, 22]. The median blood loss (350 ml) and median intraoperative time (140 minutes) were more representative of the procedures beyond the learning curve than the means which overestimated the majority of procedures because of the high values of the first RALP. Thus, mean operative and blood loss were 180 minutes and 851 ml in the first 30 RALP, compared with 146 minutes and 475 ml in the subsequent 30 RALP ($p=0.005$ and 0.004). No statistical differences were reported afterwards in the remaining cases. Only one conversion to pure laparoscopic approach was reported. The complication rate was also low (8.8%) with

no life-threatening complication and confirmed that RALP is a safe and reproducible procedure [20]. Mean length of hospital stay was 4 days and comparable with European series [18, 23]. North-American series reported shorter duration of hospitalization which was essentially explained by varying international hospital practice [10, 19, 22, 24].

Pathological parameters and oncological results

The overall rate of positive surgical margins (PSM) was 27.7%. The pT2 and pT3-4 margin rates were 17.2% and 48.3% in the overall cohort, respectively. These rates were consistent with the data of previous RALP series [10, 18-21, 23, 25]. We think that the surgical margin status of our series is accurate. During RALP, the lateral neurovascular bundle dissection and the apical transection are performed without electrocautery in order to reduce the cautery artifact. Interestingly, the overall rate of PSM was not higher in the sub-group of intrafascial dissection (12%). Thus, intrafascial dissection did not increase the risk of PSM in RALP for low-risk PCa. We could not report long-term oncological outcomes on PSA progression after RALP, but short-term data were encouraging. The Vattikuti Urology Institute reported an interesting 5-year actuarial biochemical recurrence-free survival of 84% which confirmed the promising outcomes noted in earlier series [19]. However, further large series reporting long-term outcome data are warranted.

Functional results

In our series, 98% of patients were wearing 0-1 pad per day and 74.1% of men had a complete urinary control (0 pads) at 1 year. Return of baseline urinary function was already excellent at 6 months (95.7%). At the 1-month clinical assessment, 23.4% of

men reported having complete urinary control. The definition of continence by pad number varies in the literature and comparisons are difficult. However, our results were strictly comparable to those reported in the largest published cohort [19]. At 1 year postoperatively, 39.1% patients reported successful sexual intercourse. The use of penile injections or vacuum erection device was excluded from this analysis. When an intrafascial dissection was performed (n=56), 30.3% of the patients were able to maintain spontaneously an erection suitable for sexual intercourse without medications. Seventeen patients (30.3%) needed to take phosphodiesterase-5 enzyme inhibitor and 22 patients (39.3%) used intracavernous injection of prostaglandin E. All of these selected patients with low-risk PCa were able to have sexual intercourse with or without medications after surgery. Mean preoperative IIEF score was 18 in the subgroup of intrafascial dissection. A limitation of our functional results is that patients required a minimum follow-up of 12 months for the evaluation of sexual and urinary function outcomes. Median follow-up of our series was 12.3 months. Thus, about 50% of data were available for this analysis.

Learning curve

The practice of pure laparoscopic RP requires a steep learning curve. Even experienced surgeons in laparoscopy require about 60 cases to obtain proficiency [6, 7]. Robotic assistance offers technical parameters which may reduce the learning curve: a magnified 3D visual field, a greater range of instrument motion (6 degrees of freedom), a minimization of tremor and an ergonomic console to improve surgeon's comfort. The learning curve for RALP has been studied by several centers. Surgical teams with extensive open surgical experience were able to accomplish comparable operative times after 12 or 18 cases [11, 12]. Same results were obtained by high-

volume laparoscopic centers [10, 18]. The criteria evaluated to define the learning curve were largely based on intraoperative times. In our series, we studied the learning curve in a single-surgeon cohort (ADLT) in which the patient selection has not changed significantly over time with regard to BMI, prostate weight and rate of non organ-confined disease, especially between the first and the last period. That provided a strong relevance for our statistical analyses.

The mean operative time was 216 minutes in the first 10 patient, 174 minutes in the 10 following patients and 150 minutes in the 10 following men. Thus, we observed a abrupt decline after the 10 first patients and afterwards, a more gradual improvement thereafter [18, 19]. Blood loss and length of hospital stay were significantly improved between the 30 first RALP and the remaining procedure. Thus, experience was rapidly achieved for these parameters with a gradual decrease and the improvement was then constant over time. Comparable results have been reported by Zorn and coworkers, but no difference was noted concerning hospital stay and blood loss in Montsouris' and Vattikuti Institute's series [18, 19, 26]. Mean blood loss decreased from 852 to 321 ml between the first and the last RALP, mean operative time from 180 to 133 minutes and hospital stay from 6 to 3 days. Estimated blood loss decreased when comparing our earlier and later series. This outcome of estimated blood loss decrease with experience was only reported in a study [26], but not in the other series [18, 19]. Our study also demonstrated improvements in the rate and in the length of PSM. The rate of PSM in pT2 cancers was 22.5% in the 60 first RALP compared with 11.8% in the last series, but with no significant difference. This impact of experience of margin status has been reported in several studies [18, 19, 26].

The 60 first operated patients had a longer time to continence recovery. At 1 month, 46.2% of these men were continent compared with 64.3% of men who have

undergone procedure in the next periods. The statistical difference did not reach significance but these results may be indicative of the impact of surgical experience on functional results [19].

Worse parameters were noticed in men who have undergone RALP in the period 4 (experience of 90-119 procedures). The increase of blood loss, rate of PSM, length of PSM and duration of bladder catheterization might be explained by an overconfidence of the surgeon. However, differences were not significant and may be also explained by the increase of pT3 cancers which required a more technically demanding procedure. The men in group 4 had worse pathological characteristics than the other groups and the rate of PSM in pT2 cancers remained stable (11.1%) during this period.

To discuss the limitations of our study, we'd like also to emphasize that data were collected prospectively but reviewed in a retrospective manner which introduced a selection bias.

To resume, an experience of 30 procedures appeared as a correct learning curve for RALP, in terms of intraoperative time, blood loss, complication and transfusion rates, hospital stay and length of PSM. Operative time was the most quickly mastered parameter with reasonable durations (<3 hours) after 10 procedures. Concerning the rate of PSM, a surgical experience of about 60 patients seemed necessary to achieve a stable rate of about 11.5% in pT2 cancers. Globally, the experience can improve pathological and operative outcomes well after the initial curve [19, 26]. Although the differences were not significant, urinary recovery seemed to be also improved with experience. Interestingly, each operative, pathological or functional data requires a different learning curve which should be assessed separately for each of these

parameters. The operative time should not be the single variable evaluated to define the learning curve and the surgeon's expertise.

CONCLUSION

Our outcomes confirm the favorable results obtained by the robotic assistance in laparoscopic radical prostatectomy. Robot-assisted LRP is a safe and reproducible procedure and offers a short learning curve for experienced laparoscopic surgeons. Beyond the learning curve, continued experience may also provide further improvements in terms of operative (blood loss, hospital stay), pathological (margins status) and functional (continence recovery) results.

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LEGENDS

Table 1. Preoperative characteristics in overall cohort (n=206).

Table 2. Perioperative parameters in overall cohort (n=206).

Table 3. Pathological data on radical prostatectomy specimens in overall cohort (n=206).

Table 4. Functional results (urinary and erectile function, quality-of-life) in overall cohort (n=206).

Table 5. Learning curve: comparisons over time in the single-surgeon cohort (n=175).

Figure 1. Evolution of operative time over time in the single-surgeon cohort: analysis by 10-patient groups.