

Oncological outcomes of robotic-assisted radical prostatectomy after more than 5 years

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Abstract

Introduction In the last 10 years, robotic-assisted radical prostatectomy (RARP) has become increasingly popular as witnessed by an increased number of publications. However, there is still little known about the long-term oncological outcomes of this technique. The aim of this study is to assess the oncologic outcomes of patients who underwent RARP at least 5 years ago, with an emphasis on biochemical recurrence-free survival (BCRFS).

Materials and methods In 2004, RARP was introduced at our institutions. Records of all patients having RARP were prospectively collected in a dedicated database as part of the NUVOLA-BAUS project. For the present study, we selected only patients who had a follow-up of at least 5 years. Endpoints were BCRFS rate and 5-year cancer-specific survival (CSS).

Results Overall, we identified 175 patients; 61.7 % of patients had Gleason 7–9 disease and 26.9 % had pT \geq 3 disease at final pathology. Eight patients (4.5 %) had biochemical recurrence at follow-up. Overall 5-year BCRFS rate was 95.4 %, while it was 97.6, 91 and 50 % in pT2, pT3 and pT4 diseases, respectively. Among the patients

who recurred, the mean time to recurrence was 22.1 ± 8.8 months. These patients received salvage external beam radiation treatment combined with hormonal therapy (anti-androgen + LHRH analogue) or hormonal therapy alone. 5-year CSS was 98.3 % (172/175): in 2 cases, the specimen showed pT4 cancer, while lymph node metastasis was noted in one case.

Conclusion The 5-year BCRFS and CSS after RARP are encouraging even in a population with significant high-risk disease

Keywords Prostate cancer · Robotic-assisted radical prostatectomy · Long-term oncological outcomes · Biochemical relapse-free survival

Introduction

Prostate cancer (PCa) is the fourth most frequent cancer in the UK population and the most common male cancer [1]. According to the UK cancer registries, 40841 new cases were diagnosed in 2009.

Radical prostatectomy (RP) is an effective treatment option for PCa and offers excellent long-term cancer control, especially in patients with localized disease [2]. Over the last 20 years, interest in minimally invasive surgery has increased, with the advent first of laparoscopic and then of robotic surgery. There is non-randomized data showing that both minimally invasive approaches (LRP and RARP) are as safe and effective as ORP [3–5].

The first significant series of RARP was reported in 2001 by Menon et al. [3] from Detroit. Thanks to the improved ergonomics and the enhanced 3D high-definition vision, RARP has progressively replaced LRP during the last 10 years, at least in the USA. The enthusiasm for this

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technique led to a significant increase in the number of publications in the contemporary literature. However, most of the data available are based on short-term functional outcomes, and only a few have reported the long-term oncologic outcomes of this technique.

The aim of this prospective study was to assess the 5-year oncologic outcomes of RARP at two high-volume centres (~350 cases/year) in the UK, with specific emphasis on biochemical recurrence-free survival (BCRFS) and cancer-specific survival (CSS).

Materials and methods

Robotic surgery was introduced at our centres between January 2004 and November 2005. Records of all patients who underwent RARP were prospectively collected in a dedicated database included in the NUVOLA–BAUS project (British Association of Urological Surgeons).

Clinical stage was determined according to the AJCCS guidelines [4], and patients were divided into risk groups according to D'Amico classification [5].

In the presence of intermediate- or high-risk disease (PSA > 10 ng/ml and/or Gleason score >7 and/or c > T3 disease), all patients underwent clinical staging with MRI/CT scan and bone scan.

After appropriate counselling about all therapeutic options, patients were offered RARP in the presence of a biopsy-proven organ-confined or locally advanced prostate cancer (cT1c–T3, cN0/M0).

Demographics, preoperative characteristics, postoperative parameters, pathological data and follow-up of all patients were collected prospectively.

Prostate specimens were serially sectioned and processed according to the Stanford protocol. The presence of tumour cells at the inked margin of resection was considered as a positive surgical margin (PSM). All biopsy and surgical specimens were analysed by two senior genitourinary pathologists.

From January 2004 to January 2009, the procedures were performed with the Da Vinci S system, whereas afterwards, Da Vinci Si dual consoles were acquired. These data, therefore, report on patients operated on using the standard system as it only includes patients who have completed at least 5 years of follow-up.

The technique of RARP was similar to that described from Detroit [3] using a transperitoneal approach. A nerve sparing procedure was carried out in the presence of a low-intermediate risk disease and preoperative preserved sexual function. A bilateral nerve sparing approach was chosen for a clinically bilateral organ-confined disease, whilst a unilateral nerve sparing approach was chosen in patients who had any palpable disease (\geq cT2a).

Lymph node dissection was carried out in the presence of a PSA > 10 ng/ml and/or Gleason score \geq 4 + 3 and/or c \geq T3 disease. The technique of lymph node dissection has evolved since we started our programme. We routinely performed extended dissection since January 2007. The template includes removal of nodes overlying the external iliac vessels, within the obturator fossa cranially and caudally to the obturator nerve, and the nodes medially and laterally to the internal iliac artery. Initially, node dissection (2004–2007) was limited to obturator and external iliac lymph nodes.

Follow-up was carried out in dedicated multidisciplinary clinics by urologists, medical and radiation oncologists and specialist nurses. PSA was tested at 6 weeks, then 3 months for the first year, 6 months for the second and annually thereafter.

Biochemical recurrence was defined as the detection of a serum PSA > 0.2 ng/ml in at least two consecutive measurements. In the presence of biochemical recurrence and/or symptoms likely due to metastases, patients underwent re-staging with MRI and bone scans.

Adjuvant and salvage treatments, when required, included external beam radiation treatment (EBRT) and/or hormonal therapy. When a castrate-resistant prostate cancer (CRPC) was noted at follow-up, patients were offered docetaxel as first-line chemotherapy and MDV3100 and/or abiraterone as a second-line treatment.

For this study, the follow-up was closed in April 2012, but continues prospectively as part of the database.

Primary endpoint of the study was biochemical recurrence-free survival rate (BCRFS). Secondary endpoints were 5-year cancer-specific survival (CSS), 5-year overall survival (OS), positive surgical margins rate (PSM) and safety.

Survival analysis for BCRFS and CSS was performed according to the Kaplan–Meier method.

Results

Since January 2004, over 2,500 patients underwent RARP at our two UK centres.

The preoperative characteristics of the 175 patients included in the study, who have completed at least 5 years of follow-up, are summarized in Table 1.

At the time of diagnosis, a serum PSA 4–10 ng/mL and PSA > 10 ng/ml was recorded in 64 % and 27.4 % of cases, respectively.

Prostate cancer was detected at biopsy (cT1c) in 140 patients (80.1 %), while disease was clinically palpable in 31 (17.6 %) cases. At the Guy's site, the rate of patients with palpable disease was higher (48 %).

Table 1 Characteristics of the 175 patients in the study

Variable	Value
Mean age (years)	60.1 ± 8
Mean i-PSA (ng/ml)	6.4 ± 1.6
PSA < 4 ng/ml	15 (8.6 %)
PSA 4–10 ng/ml	112 (64 %)
PSA > 10 ng/ml	48 (27.4 %)
Mean Gleason score at biopsy	6.3 ± 1.05
G.S. <7	108 (61.7 %)
G.S. 3 + 4	44 (25.1 %)
G.S. 4 + 3	15 (8.5 %)
G.S. >7	8 (4.7 %)
Clinical stage (n)	
T1b	4 (2.3 %)
T1c	140 (80.1 %)
T2a	12 (6.8 %)
T2b	11 (6.3 %)
T3	8 (4.5 %)
D'Amico risk group (n)	
Low	100 (57.2 %)
Intermediate	60 (34.3 %)
High	15 (8.5 %)
Prior abdominal surgery (n)	11 (6.3 %)
Mean SHIM score	18.1 ± 5.9
Mean IPSS score	8.7 ± 5.6
Mean CCI score	2.2 ± 0.7

Minimum follow-up was 5 years

Legenda i-PSA PSA value at biopsy, *IPSS score* international prostate symptom score, *SHIM score* sexual health inventory for male score, *CCI score* Charlson comorbidity index score

Majority of patients (57.2 %) presented with low-risk disease according to the D'Amico risk group classification. Gleason score at biopsy was ≥ 7 in 67/175 (38.3 %) of cases, classifying these patients as intermediate- or high-risk group for disease progression.

History of prior abdominal surgery was recorded in 11 cases (6.3 %). Operative and postoperative outcomes are reported in Table 2. A nerve sparing (uni- or bilateral) procedure was carried out in 145 cases (82.8 %) and a lymphadenectomy was performed in 42.3 % (74/175) of patients.

There were 4 significant intra-operative complications. In 2 cases, there was a robotic arm malfunctioning. In the first case, the arm was repaired by the engineer and the procedure was completed robotically, but in the second, the operation was converted to an open approach. In the remaining cases, accidental perforations of the bladder and rectum were noticed and repaired. Table 2 lists

Table 2 Operative, postoperative, pathologic and oncological outcomes of the 175 patients in the study

Variable	Value
Mean operative time (min)	146.6 ± 51.3
Mean EBL (ml)	105 ± 68.7
Nerve sparing	145 (82.8 %)
Unilateral	42 (28.9 %)
Bilateral	103 (71.1 %)
Lymph node dissection	74 (42.3 %)
Mean number of lymph nodes retrieved	8.6 ± 5.4
Intra-operative complications	4 (2.4 %)
Robotic arm failure—no conversion	1 (0.6 %)
Robotic arm failure—conversion to open	1 (0.6 %)
Bladder/rectum perforation—repair	2 (1.2 %)
Blood transfusion	3 (1.8 %)
Mean hospital stay (days)	1.7 ± 2.1
Postoperative complications (during admission)	15 (8.5 %)
Clavien I	
Pneumonia—i.v. antibiotic therapy	3 (1.7 %)
Fever ($T > 38$ °C)—i.v. antibiotic therapy	2 (1.1 %)
Anastomotic leak—urethral catheter for 2 weeks	6 (3.4 %)
Clavien II	
Haemorrhage—blood transfusion	2 (1.1 %)
Haematuria—blood transfusion	1 (0.5 %)
Clavien IVb	
Sepsis—intensive care unit	1 (0.5 %)
Postoperative complications at follow-up	2 (1.1 %)
Anastomotic stricture	1 (0.5 %)
Urinary tract infection	1 (0.5 %)
Overall complications	21 (12 %)
PTNM	
pT2	128 (73.1)
pT3a	36 (20.5)
pT3b	9 (5.3)
pT4	2 (1.1)
pNx	100 (57.1)
pN0	74 (42.3)
pN+	1 (0.6)
Gleason score = 6	67 (38.3)
Gleason score = 3 + 4	74 (42.3)
Gleason score = 4 + 3	24 (13.7)
Gleason score = 8-9	10 (5.7)
Positive surgical margins	28 (16)
pT2	24 (13.7)
pT3	4 (2.3)
Metastasis at follow-up	4 (2.3)
Biochemical recurrence (PSA > 0.2 ng/ml)	8 (4.6)
pT2	3 (1.7)
pT3	4 (2.3)

Table 2 continued

Variable	Value
pT4	1 (0.6)
5-year BCRFS	167 (95.4)
5-year CSS	172 (98.3)
5-year OS	171 (97.7)

Mean follow-up was 85 ± 24.1 months

complication events classified according to the Clavien–Dindo classification system [6].

On the first postoperative day, 3 patients (1.7 %) developed anaemia requiring transfusion, 1 from macroscopic haematuria and a pelvic haematoma in 2.

There were 2 cases of pyrexia ($T > 38$ °C) and 3 cases of pneumonia, treated with intravenous antibiotics. One patient developed sepsis and was admitted to ICU.

There were 6 anastomotic leaks. In these cases, a urethral catheter was left in situ for 2 weeks and a cystourethrogram was performed prior to catheter removal (15 days).

A pT ≥ 3 prostate cancer and a Gleason score ≥ 7 were recorded in 26.9 % (47/175) and 61.7 % (108/175) of cases, respectively, and positive surgical margins were found in 28 (16 %) cases. Among patients who received lymphadenectomy, the mean number of nodes retrieved was 8.6 ± 5.4 , and only in one case (0.6 %), a lymph node metastasis was noted (see Table 2).

Overall, 4 patients (2.3 %) died at follow-up: 3 of these patients have metastatic prostate cancer, while one developed a metastatic lung cancer. At a mean follow-up of 85 ± 24.1 months, 8 patients (4.5 %) had a biochemical PSA recurrence. The overall BCRFS rate was 95.4 % (171/175), while it was 97.6, 91 and 50 % among patients with pT2, pT3 and pT4 cancer, respectively. The actuarial 5-year CSS and OS were 98.3 and 97.7 %, respectively.

BCRFS rate for patients who had a Gleason score of 6, 7 and >7 was 98.5 % (66/67), 94.8 % (94/98) and 80 % (8/10), respectively.

Sixteen patients (9.1 %) received adjuvant radiation and/or hormonal treatment. Four patients (2.3 %) developed metastases from PCa at follow-up and received androgen ablation therapy: 3 of these patients have died, while the remaining has been treated with docetaxel.

Discussion

Robotic-assisted radical prostatectomy has progressively become the standard of care for localized prostate cancer, and in 2010, >80 % of radical prostatectomies in US were performed with the aid of the robot [7]. As a parallel

phenomenon, during the last 10 years, the number of publications on RARP has progressively increased, and today, there are over 1,000 papers.

The majority of the early studies were single-centre series focused on safety and functional outcomes of the technique. In the last 4 years, many authors focused the analysis on the comparison of such outcomes with the open and laparoscopic approach.

Recently, Ahmed et al. [8] conducted a thorough meta-analysis based on studies comparing RARP, LRP and open prostatectomy.

The authors proved that RARP offers benefits over the open approach in terms of reduced postoperative complications, hospital stay (1–5.5 vs 2–8 days), blood loss and transfusion rates. However, when RARP is compared to LRP, data are not consistent. In fact, Caceres et al. [9] reported a reduced incidence of sexual dysfunction in patients having RARP (22–85 %, median 61 %), but Ficarra et al. [10] could not find any difference in terms of erectile dysfunction and urinary incontinence rates ($P = 0.16$), being albeit both significantly lower than ORP.

Despite the increasing evidence of functional outcomes of RARP, until now, only a few series have reported the oncologic outcomes of this technique.

In fact, in 2007, Ficarra et al. [11] could include in a meta-analysis only 11 studies reporting preliminary oncologic data. In all these studies, the mean follow-up was 6 months and the percentages of patients with undetectable PSA (0.1–0.2 ng/mL) ranged between 82 and 100 %.

Few centres have reported the oncologic data of RARP with a longer follow-up. Menon et al. first described in 2007 the largest series of patients with a minimum follow-up of 12 months (12–36, median 36). The authors reported the outcomes of 1,142 patients and observed a 5-year BCRFS rate of 91.6 % [12]. The same group updated the oncologic outcomes on 2,766 patients. With a mean follow-up of 22 months (range 6–71 months), 95 patients (7.3 %) had a PSA recurrence. The 5-year actuarial BCRFS rate was 84 % [13]. On the contrary, Murphy et al. could not confirm such high rate of BCRFS. In fact, a BCRFS rate of 74 % was observed in a cohort of 400 patients [14]. In Murphy's series, the mean follow-up was 22 months (range 15–30).

Recently, Menon et al. published the oncological results of 1,384 patients who underwent RARP between 2001 and 2005, with a median follow-up of 5 years [interquartile range (IQR) 37.2–69.7 months]. The actuarial BCRFS estimates at 3, 5 and 7 years were 90.6, 86.6 and 81.0 %, respectively [15].

This study was based on an impressive number of patients and represents the largest series with the longest follow-up. However, the reported 5-year BCRFS rate is limited by a significant number of patients included in the

study who did not reach a follow-up of at least 5 years. Therefore, it is not possible to extrapolate the real 5-year BCRFS rate.

Conversely, in our study, according to the applied inclusion criteria, we assessed the oncologic outcomes of the only patients who had RARP at least 5 years ago.

Recently, Suardi et al. analysed a cohort of 182 patients who received RARP 5 years ago at a single European institution. The overall 3-, 5- and 7-year BCRFS rates were 94, 86 and 81 %, respectively [16]. This is similar to our 5-year BCRFS rate of 95.4 % which may be partly accounted for by our aggressive approach to wider excision in men with palpable disease and enthusiastic selection for adjuvant prostate bed radiotherapy for those likely to recur locally. Although the studies of Menon and Suardi are based on two different populations with a different length of follow-up, we could identify similar outcomes in a UK population. These data thus support the long-term oncologic effectiveness of RARP.

However, the UK population shows different clinical characteristics compared to both the European and US population. Regarding tumour stage, we identified a larger proportion of patients with pT \geq 3 disease at final pathology. These data are different from those reported from the USA (25.5 %), but similar to our European colleagues (38 %). These findings could be explained by the lack of an extensive UK testing programme for PCa with PSA .

Of note, we reported an overall PSM rate of 16 % that is similar to the one reported in the European series from Suardi et al. (15.7 %). This series included a proportion of patients with intermediate-high risk prostate cancer similar to the present series. However, we recorded a higher rate of positive margins among patients with a pT2 disease, despite encouraging 5-year BCRFS rate.

As regards the comparison between RARP on ORP, only a few studies are available. Krambeck et al. [17] did not observe significant difference in terms of BCRFS rates at a median follow-up of 15 months among patients who had RARP or ORP (92.4 vs 92.2 %, respectively). In 2009, Drouin et al. compared the oncological outcomes of 83 patients who underwent RARP with 85 and 71 patients who received LRP and ORP, respectively. The mean follow-up of the study cohort was 49.7 months (18–103), and the 5-year BCRFS rate was 89.6, 88.1 and 87.8 % among patients treated with RARP, LRP and ORP, respectively [18]. Similar results were reported by Barocas and Magheli [19, 20].

Our study has a few limitations. First, it is limited to a relatively small number of cases, compared with the larger series from USA. Second, we report data from two high-volume centres which may not reflect UK-wide results. This could be argued as a possible bias that influenced the oncologic outcomes of this technique. However, the

patients included in the study were part of the initial learning curve of the whole surgical team and it is unlikely to be affected by surgical or selection bias. Despite these limitations, no patient was lost to follow-up, which adds strength to the longitudinal data.

To our knowledge, this is the first study reporting the long-term outcomes of RARP in a representative UK population.

Conclusions

The long-term oncological outcomes of RARP in patients who had surgery at least 5 years ago are encouraging. RARP provides effective long-term BCRFS rates, which are comparable to those reported for LRP or ORP.

Although the present study is not focused on a large series, it supports the oncologic effectiveness of RARP even in a population with a significant proportion of patients with high-risk disease.

Conflict of interest The authors declare that there is no conflict of interest.

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