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Randomised Controlled Trial Comparing Laparoscopic and Robot-assisted Radical Prostatectomy

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Abstract

Background: The advantages of robot-assisted radical prostatectomy (RARP) over laparoscopic radical prostatectomy (LRP) have rarely been investigated in randomised controlled trials.
Objective: To compare RARP and LRP in terms of the functional, perioperative, and oncologic outcomes. The main end point of the study was changes in continence 3 mo after surgery.
Design, setting, and participants: From January 2010 to January 2011, 120 patients with organ-confined prostate cancer were enrolled and randomly assigned (using a randomisation plan) to one of two groups based on surgical approach: the RARP group and the LRP group.
Intervention: All RARP and LRP interventions were performed with the same technique by the same single surgeon.
Outcome measurements and statistical analysis: The demographic, perioperative, and pathologic results, such as the complications and prostate-specific antigen (PSA) measurements, were recorded and compared. Continence was evaluated at the time of catheter removal and 48 h later, and continence and potency were evaluated after 1, 3, 6, and 12 mo. The student *t* test, Mann-Whitney test, χ^2 test, Pearson χ^2 test, and multiple regression analysis were used for statistics.
Results and limitations: The two groups (RARP: $n = 60$; LRP: $n = 60$) were comparable in terms of demographic data. No differences were recorded in terms of perioperative and pathologic results, complication rate, or PSA measurements. The continence rate was higher in the RARP group at every time point: Continence after 3 mo was 80% in the RARP group and 61.6% in the LRP group ($p = 0.044$), and after 1 yr, the continence rate was 95.0% and 83.3%, respectively ($p = 0.042$). Among preoperative potent patients treated with nerve-sparing techniques, the rate of erection recovery was 80.0% and 54.2%, respectively ($p = 0.020$). The limitations included the small number of patients.
Conclusions: RARP provided better functional results in terms of the recovery of continence and potency. Further studies are needed to confirm our results.

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1. Introduction

Radical prostatectomy (RP) is a common treatment for patients with clinically localised prostate cancer (PCa) and a life expectancy >10 yr [1]. Surgery is traditionally performed by open retropubic RP, although laparoscopic RP (LRP) and especially robot-assisted RP (RARP) have become popular recently. Currently, the vast majority of RP procedures in the United States are performed robotically [2,3]. Although the advantages of laparoscopy over open surgery, at least in terms of minimal invasiveness, are well known, LRP and RARP have rarely been compared [4–6].

Some authors have suggested that the robotic system not only shortens the learning curve for LRP but also reduces short-term complications [4]. Recently, Tewari et al. published a systematic review comparing retropubic, laparoscopic, and robotic prostatectomy that seemed to confirm these data. The results of this review suggested that RARP decreases bleeding, shortens the length of hospital stay, and decreases the readmission and total perioperative complication rates compared with other approaches without impairing the oncologic outcomes [7].

Other authors have suggested that RARP improves continence (especially in the early postoperative period) and the recovery of potency with respect to LRP [4,5,8]. Despite these suggestions, a recent review failed to prove the superiority of any surgical approach in terms of functional and oncologic outcomes [9].

Only one prospective randomised study comparing LRP and RARP is available [10]. The vast majority of the available studies in the literature are retrospective studies that provide little evidence for the comparison.

Based on these findings, we aimed to contribute to this field by comparing LRP and RARP with a single-centre single-surgeon prospective randomised study. The primary end point of this study was to test the hypothesis that compared with LRP, RARP improves continence results 3 mo after surgery.

2. Patients and methods

The study lasted from January 2010 to January 2012 (enrolment phase: January 2010 to January 2011) and was conducted in accordance with the Good Clinical Practice Rules and the ethical principles of the Declaration of Helsinki as amended in Hong Kong. In addition, this study was approved by the local ethics committee of the San Luigi Gonzaga Hospital in Orbassano, Italy.

2.1. Eligibility criteria

Eligible patients were all males referred to our institution with PCa (T1–T2N0M0 clinically staged according to TNM 2009 [11], regardless of prostate size) and to whom RP was proposed. Patients were aged 40–75 yr.

2.2. Exclusion criteria

Exclusion criteria included previous radiation therapy, hormonal therapy, and/or transurethral resection of the prostate.

2.3. Randomisation

Immediately after signing a specific informed consent form, the patients were randomised by the staff members (M.L.C. and M.P.) into either the RARP or LRP groups using a computer-generated 1-to-1 simple randomisation list.

2.4. Justification of sample size

The sample size of our study was calculated to recognise significant differences (α level <0.05) of approximately 25% between the incidence proportions of tested outcome (continence at month 3 after the intervention, see section 2.10, "End points") with an adequate power ($1 - \beta = 80\%$). These conditions require a total of 52 + 52 = 104 observations. Considering an acceptable dropout or lost-to-follow-up rate of 15%, we enrolled 8 extra patients for each group (60 patients for each arm).

2.5. Interventions and principles of surgical techniques

All interventions were performed at San Luigi Gonzaga Hospital by a single surgeon (F.P.). Both the RARP and LRP procedures were performed using the same technique (the transperitoneal anterograde approach).

When indicated, unilateral or bilateral neurovascular bundle preservation (nerve-sparing [NS] procedure) and extended lymph node dissection (LND) were performed (see Table 1). The patients who underwent the NS procedure made up the so-called NS cohort.

2.6. Experience of the surgeon

Before the beginning of the study, the surgeon performed >600 laparoscopic prostatectomies (starting in 2000) and 100 robotic prostatectomies (starting in 2008).

2.7. Postoperative care

The surgical drain was removed in the absence of any suspicious signs of a urinary fistula or when the fluid drained fell to <100 ml/d. The patients were discharged on postoperative day 4 with a transurethral catheter that was later removed on an outpatient basis.

2.8. Principles of functional rehabilitation

Every patient was instructed to participate in pelvic floor rehabilitation, with the specific training beginning after catheter removal. All patients in the NS cohort were administered phosphodiesterase type 5 inhibitors (PDE5-Is) (tadalafil 20 mg twice per week) for the first month after surgery and afterwards as subjectively needed.

2.9. Data

The following data were collected and registered in a dedicated database by staff members and then analysed:

- Demographic data: Age, body mass index (BMI), prostate-specific antigen (PSA), prostate volume at the transrectal ultrasound, biopsy Gleason score (GS), and American Society of Anaesthesiologists (ASA) score.
- Intraoperative data: Skin-to-skin operative time, main steps time (see Table 1), estimated blood losses, complications, and transfusion rate.
- Postoperative data: Postoperative complications (classified according to the modified Clavien system [12] until 90 d after the surgery), hospital stay, and catheterisation time.