Robotic-assisted laparoscopic radical prostatectomy: report on the first 55 cases from the first year of experience at the Hospital Central Militar


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Received 17 September 2015; accepted 18 January 2016

KEYWORDS
Prostate cancer; Radical prostatectomy; Robotic surgery; Da Vinci® robot

Abstract
Aim: To present the first year experience of the robotic surgery project at the Hospital Central Militar that consisted of 55 consecutive cases of robotic-assisted laparoscopic radical prostatectomy.

Methods: With the incorporation of the robotic surgery system in November 2014 to November 2015, the same surgeon (JGCS) performed a total of 55 radical prostatectomies. In the present retrospective study, the following preoperative data were analyzed: ECOG, ASA risk, BMI, associated morbidities, previous radiotherapy, history of TURP, IPSS, erectile function, urinary continence index, PSA, prostatic volume, Gleason score, initial staging, and clinical stage. The intraoperative variables were: type of access, surgery duration, conversion rate, bleeding, blood transfusions, complications, type of anastomosis, and time with bladder catheter. The postoperative variables analyzed were: positive margins, biochemical recurrence, urinary continence, and erectile function.

Results: The mean age of the patients was 68 years and the mean PSA value was 7.80 ng/ml. In 50.9% of the cases, the Gleason score was 6 (3+3). Mean surgery duration was 270 min and mean estimated blood loss was 512 ml. Mean hospital stay and time with catheter was 5.9 and 8 days, respectively, and the positive margin rate was 18.1%. The rates for continence and potency at...
Introduction

Prostate cancer is the most frequently diagnosed malignant neoplasia in men and the second cause of cancer death in the United States. Surgery continues to be the most frequently used treatment for clinically localized prostate cancer and the only treatment that has demonstrated a survival advantage when compared with watchful waiting.1

There has been a recent notable expansion of treatment options for clinically localized prostate cancer. In the last 5 years, methods including laparoscopy, cryotherapy, and high-energy ultrasound, among others, have emerged as possible therapeutic alternatives to radical prostatectomy and radiotherapy. Robotic-assisted laparoscopic radical prostatectomy has been widely accepted by patients and physicians and is an increasingly common procedure in the United States and the rest of the world.2

The introduction of robotic surgery in urology is the most recent advance of the minimally invasive tools. Robotic-assisted laparoscopic prostatectomy has become the treatment of choice for localized prostate cancer and some of its advantages are reduced blood loss, shorter hospital stay, and faster convalescence. In addition, its functional and oncologic results are similar to those of the open approaches.3

The first robotic-assisted radical prostatectomy was performed in Frankfurt in May of 2000 by Binder, an expert surgeon in open approaches with no laparoscopic experience. The first robotic-assisted prostatectomy in the United States was performed by Vallencien in November 2000 at the Vattikuti Urology Institute (Detroit, Michigan) during a training program.4

Radical prostatectomy is chosen by the majority of men diagnosed with localized prostate cancer in Europe and the United States as the preferred treatment option. Both standard and robotic-assisted laparoscopy are used as alternatives to the open technique, given that they result in less blood loss and enable a quicker return to normal activities. Many surgeons prefer the robotic-assisted procedure because it has better ergonomics, but the technology continues to be expensive for health institutions.5 Only a few centers in Latin America offer

the follow-up at one, 3, 6, and 12 months were 41.8%, 78%, 88%, 100% and 29%, 41%, 68%, 66%, respectively.

Conclusions: The results of our initial experience with robotic radical prostatectomy are promising. We have been able to put robotic-assisted laparoscopic radical prostatectomy into practice at our hospital in a safe and reproducible manner with a minimum of adverse results.

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robotic surgery. It was acquired in November of 2014 in Mexico and has become the treatment of choice for clinically localized prostate cancer. The aim of this article was to present the initial experience with robotic-assisted laparoscopic radical prostatectomy with the Da Vinci® system at our hospital in 55 consecutive cases.

Materials and methods

Since the arrival of the Da Vinci® surgical system at our hospital, 55 robotic-assisted radical prostatectomies have been performed within the timeframe of November 2014 and November 2015 by the same surgeon (JGCS). The approach was transperitoneal in all the cases and the information from the database was retrospectively evaluated.

The data obtained were categorized into preoperative, intraoperative, and postoperative parameters. The following preoperative clinical data were analyzed: ECOG performance status, risk according to the American Society of Anesthesiologists (ASA risk), body mass index, associated morbidities, previous abdominal surgeries, radiotherapy or brachytherapy, history of transurethral resection of the prostate, International Prostate Symptom Score (IPSS), erectile function (IIEF-5), urinary incontinence grade, total prostate-specific antigen, prostate volume, initial Gleason score, and initial staging and clinical stage. The intraoperative variables were: type of access, surgery duration (total and robot-patient coupling), conversion rate, blood loss, blood transfusion, complications, type of anastomosis, and bladder catheter time. Despite the short follow-up period, the postoperative variables analyzed included the oncologic results in relation to surgical margins, biochemical recurrence, and the functional results of urinary continence and erectile function.

Biochemical recurrence was defined as 2 consecutive prostate-specific antigen levels greater than 0.2 ng/mL. The postoperative follow-up included a clinical examination and prostate-specific antigen levels at 1, 3, 6, and 12 months. The oncologic results were evaluated through the presence of positive margins in the surgical specimen and biochemical recurrence in the follow-up. If there was recurrence in high-risk patients with positive margins or T3 disease, adjuvant therapy was administered based on the decision of a multidisciplinary committee in relation to each individual patient.

Conserved potency was defined as the ability of the patient to sexually penetrate his partner with or without the use of drugs and having an IIEF-5 score above 21. Urinary continence was defined as the patient’s not requiring the use of absorbent napkins or having stress urine leakage in the postoperative period. To this end, the International Consultation on Incontinence Questionnaire (ICIQ-SF) was employed, which is a self-administered questionnaire that identifies those persons with urinary incontinence and its impact on quality of life. Urinary incontinence diagnosis was considered with any score above 0. For purposes of the analysis, the evaluation was divided into 4 periods: continence at month 1, 3, 6, and 12 of the follow-up.

Results

The demographic data are summarized in Table 1. The mean age was 68 years (52-80) and the mean body mass index was 26.74 kg/m² (23.03-31.74). The most frequent clinical stage was T1c in 23 cases (41.8%). The rest were T2a in 14 cases (25.4%), T1a in 7 cases (12.7%), T2c in 5 cases (9.1%), T1b in 3 cases (5.5%), and T2b in 3 cases (5.5%). The mean preoperative prostate-specific antigen level was 7.8 ng/ml (1.56-16.8) and the most frequent preoperative Gleason score was 6 (3+3) in 28 cases (50.9%), followed by 7 (3+4) in 15 cases (27.3%), 7 (4+3) in 7 cases (12.7%), 8 (4+4) in 3 cases (5.5%), 8 (5+3) in one case (1.8%), and 9 (5+4) in one case (1.8%). The mean preoperative IPSS score was 13 points (0-30). Histopathologic diagnosis was made in 44 patients through transrectal biopsy (80%) and in 11 patients (20%) through transurethral resection of the prostate. The mean prostate volume obtained through transrectal ultrasound was 42 cc (17-86). Twenty-five patients (45.5%) had associated diseases, the most common of which was high blood pressure in 19 patients (34.5%), followed by type 2 diabetes mellitus in 7 patients (12.7%). The ASA risk was I in 42 patients (76.3%) and II in 13 patients (23.6%). Fifty-two patients were classified with an ECOG status of 0 (94.5%) and 3 patients with an ECOG status of 1 (5.5%). Nineteen patients (34.5%) had a past history of abdominal surgery, and one of those patients that had a past history of exploratory laparotomy due to perforated acute appendicitis presented with a detected intestinal injury upon introduction of the trocars. According to the National Comprehensive Cancer Network (NCCN) risk groups, 5 patients (9%) were classified as very low-risk, 20 patients

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(36.4%) as low-risk, 24 patients (43.6%) as intermediate-risk, and 6 patients (11%) as high-risk.

The same surgeon (JGCS) performed all the surgeries and the approach was transperitoneal. Rhabdosphincter reconstruction was carried out with the Rocco technique in all the patients and the neurovascular bundles were spared in 100% of the cases. Extended ilio-obturator lymphadenectomy was indicated and performed in 18 patients (32.7%). Robotic surgery duration was divided into total time and coupling time, with a mean of 270 min (150-420) and 7 min (3-20), respectively. There were no conversions to open surgery. Mean hospital stay and catheter time were 5.9 and 8 days, respectively.

In regard to estimated intraoperative blood loss, the mean was 512 ml, with a range of 150 to 1,300 ml. The transfusion rate was 11% (6/55), with 2 units transfused in 3 cases and one unit transfused in 3 cases. Preoperative and postoperative hemoglobin was determined and there was a mean drop in hemoglobin of 1.2 mg/dl after the procedure.

Ten patients (18.2%) presented with postoperative complications. There were 6 cases (11%) of anastomosis leakage, in which one patient (1.8%) developed a pelvic collection that required percutaneous drainage, one patient (1.8%) presented with a reaction to medication, one patient (1.8%) presented with a dysepsis and bilateral segmented pulmonary thromboembolism, and one patient (1.8%) developed an abscess at the insertion site of the supraumbilical trocar that was resolved through medical management. The complication was classified as Clavien I in 8 patients (14.5%) and as Clavien III in 2 patients (3.7%). Mean hospital stay was 5.9 days (3-20) and mean bladder catheter permanence was 8 days (6-17).

The definitive anatomopathologic study showed that all the cases were adenocarcinoma. According to TNM staging, the distribution was as follows: 24 patients pT2A (43.6%), 2 patients pT2B (3.6%), 9 patients pT2C (16.4%), 15 patients pT3A (27.3%), 4 patients pT3B (7.3%), and one patient pT4 (1.8%). There were positive surgical margins in the definitive surgical specimen in 10 cases (18.2%).

The follow-up protocol was at 1, 3, 6, and 12 months. Even though the follow-up period was short, a mean 4.2 months (1-12 months), we analyzed the initial results in relation to urinary continence, sexual function, and oncologic results. At the mean follow-up at 4.2 months, one patient (1.8%) had biochemical recurrence, was staged as pT2a, had positive surgical margins, and underwent rescue radiotherapy.

Of the total of the 55 evaluated patients, the continence rate at one month was 41.8% (23 patients). Of the 41 patients that were checked at 3 months, 78% (32 patients) had total continence. Of the 25 patients that had a check-up at 6 months, 88.9% (22 patients) had total continence. One hundred percent of the patients that had a check-up at one year (3 patients) had total continence.

According to the previously established criteria in the 55 evaluated patients in whom nerve bundles were spared and that had an IIEF-5 score equal to or greater than 21, the percentage of patients with erectile function at the first month was 29%. That percentage rose to 41% of those evaluated at 3 months, 68% of those evaluated at 6 months, and ended in 66.6% of those evaluated at one year.

Discussion

Laparoscopic radical prostatectomy is currently a widely accepted minimally invasive treatment option. Its technical viability and efficacy have been demonstrated in many case series from Europe and the United States. The application of robotic assistance for laparoscopic radical prostatectomy is a relatively recent addition to the urologist’s armamentarium. The Da Vinci® surgical system is the most widely used, providing 3-dimensional vision, a broader surgical field, and greater maneuverability and ergonomics. Image magnification enables more precise dissection and improved sparing of the neurovascular bundles.6

We reviewed the first 55 procedures performed at our hospital and compared the results with those of previously published international case series.

Surgery duration in our case series was longer than duration reported in the literature of a majority of case series with a much higher number of cases. As is to be expected, surgery duration decreases in relation to a higher number of cases in a series. In their series of 50 cases in 2005, Patel et al. reported a mean surgery duration of 202 min.6 The mean total surgery duration (the sum of the trocar, coupling, and console times) in our series was 270 min.

In the majority of case series, catheter removal takes place at the end of one week, but some authors prolong that time between 14 and 16 days.7 In our study, the mean days with bladder catheter was 8 days. Hospital stay varies from 1 to 3 days in different series and in ours the mean was 5.9 days.

In regard to estimated intraoperative blood loss, in their series of 200 cases published in 2003, Menon et al. reported a mean blood loss of 153 ml. In our study, the mean blood loss was 512 ml, with a range from 150 to 1,300 ml. Our transfusion rate was 11%, with a total of 6 patients undergoing transfusion. Both of these parameters were higher than those described in the international literature.

The perioperative complications most frequently described in the literature are hernias and infections at the entrance ports and pelvic and cutaneous hematomas. Different authors have reported ureteral injury, but it is an uncommon event. Rectal injury during radical prostatectomy is unquestionably the most dangerous injury that has traditionally concerned the urologist. Paralytic ileus is relatively constant in all the case series and is often related to hematomas, urinary fistulas, etc. Bladder neck stricture and anastomosis dehiscence have also been described. As with any surgery, this procedure is not exempt from complications such as thrombosis, pulmonary edema, atelectasis, and infarction, among others.8

The severity of complications was determined according to the criteria proposed by Clavien. Grade I complications are considered deviations from normal recovery that could require pharmacologic intervention. Grade II complications are considered minor ones that could require medical intervention, such as blood transfusion, hyperalimentation, lying on one side only, or the placement of a urethral catheter, nasogastric tube, etc.). Grade III complications are those requiring surgical or endoscopic management or radiologic treatment, but with no residual deficits. There
are 2 subclassifications based on the necessity of general anesthesia, that is to say, Ila does not require it, whereas IIb does. Grade IV complications are those that are potentially lethal and require management in an intensive care unit. Death due to complications are classified as grade V. In their series of 2,766 cases, Badani et al. reported a complication rate of 12.2% (Clavien I, 8%; Clavien II, 3.7%; Clavien III, 13%; Clavien IV, 0.01%; Clavien V, < 0.01%). In contrast, Patel et al., in their series of 1,500 RRs, reported a complication rate of 5.08% (Clavien I, 2.24%; Clavien II, 1.8%; Clavien III, 0.08%; Clavien IIb, 0.48%; and Clavien IVa, 0.40%) with only one case requiring conversion due to a malfunctioning robot. In our series, the complication rate was 18.2% and the most frequent complication was anastomosis leakage in 11% of the cases. Complications were classified as Clavien I in 14.5% of the cases and as Clavien III in 3.7%. Our findings differed from those observed in larger case series with a lower complication rate.

A positive surgical margin after radical prostatectomy due to clinically localized prostate cancer is an independent predictor of disease recurrence. A positive margin is defined as the presence of tumor in the stained margin of the surgically resected prostate. Surgical margin status depends on a variety of factors that include tumor biology, patient characteristics, pathologic evaluation method, and the surgical technique. Disease characteristics, such as a high Gleason score, an increased prostate-specific antigen level, seminal vesical infiltration, tumor stage, and extracapsular extension have been correlated with increased positive surgical margin incidence. The published positive surgical margin rates vary widely and are disease-dependent, with higher rates in patients with more advanced disease stages. Nevertheless, these rates are also surgeon-dependent and therefore modifiable. In a multi-institutional study involving 8,095 patients, the general positive surgical margin rate was 15.7%, and their most frequent locations after robotic-assisted radical prostatectomy were the apex of the prostate (36%), followed by the posterolateral edge (29%). A multinational, multicenter study that included 22,393 patients showed lower crude positive margin rates for robotic prostatectomy of 3.8%. Data stratification by pathologic stage was between 4.7 and 27% in pT2 cancers and between 26 and 67% in pT3 disease. In our series we reported 10 cases (18.1%) with positive surgical margins, which was similar to the results we found in large case series.

Two of the most important long-term side effects of radical prostatectomy are urinary incontinence and erectile dysfunction. They have a relevant negative impact on quality of life-related satisfaction and health and they are also an important source of morbidity after radical prostatectomy. Plausible predictors for the return to continence from different surgical perspectives include patient demographic data, such as age, body mass index, previous lower urinary tract symptoms and diabetes mellitus, as well as anatomic considerations, such as the presence of the middle lobe, previous transurethral resection or resection, enlarged prostate, and technical aspects of the surgery that include the experience of the surgeon, the degree of nerve-sparing, and changes in the surgical technique. In recent years, there has been increased use of laparoscopic radical prostatectomy with the Da Vinci® surgical system and continence rates have been reported of 30-89% at 3 months, 50-95% at 6 months, and 62-97% at 12 months. Another recent case series of radical prostatectomy showed a urinary continence recovery rate at 12 months that ranged from 60-93%, depending on the different methods used to evaluate this parameter. In our series, the continence rate at one month was 41.8% (23 patients); of the patients that arrived for monitoring at 3 months (41 patients), 78% (32 patients) presented with total continence; of the patients that arrived for monitoring at 6 months (25 patients), 88% (22 patients) presented with total continence; and all the patients that arrived for monitoring at 12 months (3 patients) presented with total continence. Studies evaluating possible predictors showed that patient age is an important factor in urinary continence recovery, together with body mass index, comorbidity rate, urinary tract symptoms, and prostate volume.

Nerve-sparing robotic-assisted radical prostatectomy was associated with erectile dysfunction incidence at 12-24 months ranging from 10-46% and from 6-37%, respectively. The different erectile dysfunction rates are attributable to various factors: (1) different erectile dysfunction definitions and measures have been used from study to study, (2) surgery characteristics and patient selection vary between studies, and (3) postoperative rehabilitation varies greatly from one center to another. Potency recovery rates at 3, 6, 12, and 24 months were 44, 50, 62, and 69%, respectively, through the application of a validated questionnaire, and 57, 63, 82, and 93%, respectively, through a medical interview. In our series, sexual potency was determined through the application of a validated questionnaire and the sexual potency rate for patients at one month was 29%. The percentage rose to 41% at 3 months, and to 68% at 6 months. This trend was maintained at 12 months with conserved sexual potency in 66.6% of the patients. The introduction of type 5-phosphodiesterase inhibitors has revolutionized erectile dysfunction treatment. Their use after radical prostatectomy has been shown to be efficacious. Age, body mass index, and smoking are recognized as risk factors. Some authors have recently stated that the use of type 5-phosphodiesterase inhibitors can have a negative impact on biochemical recurrence.

Conclusions

Our initial experience with robotic-assisted radical prostatectomy is promising. We have been able to safely and reproducibly put into practice the technique of robotic-assisted laparoscopic radical prostatectomy at our hospital with a minimum of adverse events. The oncologic and functional results obtained are adequate, added to the benefits of minimally invasive surgery for the patient.

Even though ours was not a comparative study, the results in certain aspects were similar to those published in the international literature. Because this was an initial study, a longer follow-up period is necessary to better evaluate the oncologic and functional results. Adequate patient selection, individual improvement with greater experience on the part of the surgeon or surgeons, and a longer follow-up period will allow the evolution of the technique and its results to be evaluated.
Ethical responsibilities

Protection of persons and animals. The authors declare the procedures followed conformed to the ethical standards of the responsible committee on human experimentation and were in accordance with the World Medical Association and the Declaration of Helsinki.

Data confidentiality. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Financial disclosure

No financial support was received in relation to this article.

Conflict of interest

The authors declare that there is no conflict of interest.

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