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Platinum Priority – Prostate Cancer

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## Early Complication Rates in a Single-Surgeon Series of 2500 Robotic-Assisted Radical Prostatectomies: Report Applying a Standardized Grading System

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#### **Abstract**

**Background:** Perioperative complications following robotic-assisted radical prostatectomy (RARP) have been previously reported in recent series. Few studies, however, have used standardized systems to classify surgical complications, and that inconsistency has hampered accurate comparisons between different series or surgical approaches.

**Objective:** To assess trends in the incidence and to classify perioperative surgical complications following RARP in 2500 consecutive patients.

*Design, setting, and participants:* We analyzed 2500 patients who underwent RARP for treatment of clinically localized prostate cancer (PCa) from August 2002 to February 2009. Data were prospectively collected in a customized database and retrospectively analyzed.

Intervention: All patients underwent RARP performed by a single surgeon.

**Measurements:** The data were collected prospectively in a customized database. Complications were classified using the Clavien grading system. To evaluate trends regarding complications and radiologic anastomotic leaks, we compared eight groups of 300 patients each, categorized according the surgeon's experience (number of cases).

**Results and limitations:** Our median operative time was 90 min (interquartile range [IQR]: 75–100 min). The median estimated blood loss was 100 ml (IQR:100–150 ml). Our conversion rate was 0.08%, comprising two procedures converted to standard laparoscopy due to robot malfunction. One hundred and forty complications were observed in 127 patients (5.08%). The following percentages of patients presented graded complications: grade 1, 2.24%; grade 2, 1.8%; grade 3a, 0.08%; grade 3b, 0.48%; grade 4a, 0.40%. There were no cases of multiple organ dysfunction or death (grades 4b and 5). There were significant decreases in the overall complication rates (p = 0.0034) and in the number of anastomotic leaks (p < 0.001) as the surgeon's experience increased.

**Conclusions:** RARP is a safe option for treatment of clinically localized PCa, presenting low complication rates in experienced hands. Although the robotic system provides the surgeon with enhanced vision and dexterity, proficiency is only accomplished with consistent surgical volume; complication rates demonstrated a tendency to decrease as the surgeon's experience increased.

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#### 1. Introduction

Data from the Surveillance, Epidemiology and End Results registry indicate that the incidence of prostate cancer (PCa) in men under 50 has risen steadily over the past 10 yr, with an annual percent increase of 9.5% [1]. In addition, with the widespread diffusion of prostate-specific antigen (PSA) testing, PCa is frequently diagnosed in younger and healthier men with organ-confined disease. Consequently, patients desire to undergo definitive treatment with short recovery time and low complication rates while maintaining their baseline quality of life.

Since Reiner and Walsh [2] first introduced the anatomic nerve-sparing technique for radical retropubic prostatectomy (RRP), this procedure has become the gold standard and the most widespread treatment for clinically localized PCa, providing excellent cancer control in most patients with clinically localized disease [3]. However, although several modifications have been added to the original technique and most urologic surgeons are now familiar with the procedure, RRP still has an inherent morbidity.

In an effort to further decrease the morbidity of RRP, a laparoscopic minimally invasive surgical approach to treating PCa was first described by Schuessler and colleagues [4] in 1997. Although cancer cure with laparoscopic radical prostatectomy (LRP) was deemed comparable to open surgery, the technical demands of the surgery and the protracted learning curve has prevented the widespread adoption of LRP by most urologic surgeons. The da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) has been introduced to the field of urologic surgery and, with the advantages of three-dimensional vision, 7 degrees of freedom, and magnification, has raised new hopes of reducing both the morbidity and the learning curve of minimally invasive prostatectomy [5]. But as expected, the introduction of any innovative technology or surgical procedure is associated with an initial learning curve and with the potential of eliciting new risks and surgical complications [6].

Perioperative complications following robotic-assisted radical prostatectomy (RARP) have been previously reported in some recent series. Few studies, however, have used standardized systems to classify surgical complications, and that inconsistency has hampered accurate comparisons between different series or surgical

approaches. Based on these limitations, Clavien and colleagues proposed a grading system for surgical complications in 1992 and modified it in 2004 [7]. The Clavien grading system is a simple, objective, and reproducible approach for comprehensive surgical outcomes assessment and has been applied more frequently in recent publications reporting complications after RRP, LRP, and RARP.

In this study we analyzed early surgical complications in a single-surgeon series of 2500 consecutive RARPs. Complications were classified according to the modified Clavien grading system, and trends in the incidence of morbidities according to the surgeon's experience were analyzed.

#### 2. Materials and methods

We analyzed 2500 consecutive patients who underwent RARP for treatment of clinically localized PCa. All of the procedures were performed by a single surgeon (VRP) from August 2002 to February 2009. After institutional review board approval, data were prospectively collected in a customized database and retrospectively analyzed. Complications were classified in our database according to the modified Clavien grading system (Table 1) [7].

#### 2.1. Operative technique

All patients underwent a six-port transperitoneal technique, as described previously by the authors [8]. An anterior approach was adopted by dissecting the retzius space and ligating the dorsal venous complex (DVC). Recently, we have adopted a periurethral suspension stitch [9] after the ligation of the DVC. This step was followed by bladder neck dissection and athermal mobilization of the seminal vesicles. The nerve sparing was modified and performed athermally with an early retrograde release of the neurovascular bundle. Bilateral pelvic lymph node dissection (PLND) was performed in patients classified as intermediate or high risk, according to the D'Amico classification [10]. A modified posterior reconstruction of the rhabdosphincter [11] was then performed prior to vesicourethral anastomosis in the last 1500 patients of our series. The anastomosis was performed using a continuous running suture with two 3-0 monocryl sutures tied together. A 18-Fr Foley catheter was inserted. The specimen was then removed through the primary trocar incision, and a Jackson-Pratt (JP) drain was positioned in the pelvic gutter.

#### 2.2. Perioperative management

A single intravenous dose of a first-generation cephalosporin and 5000 U of low-molecular-weight heparin (5000 IU subcutaneously 2 h prior to

Table 1 - Classification of surgical complications: Clavien grading system [6]

Grade*	Description
1	Any deviation from the normal postoperative course with no specific treatment required.  Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
2	Requiring pharmacologic treatment with drugs other than such allowed for grade 1 complications.  Blood transfusions and total parenteral nutrition are also included.
3	Complications requiring surgical, endoscopic, or radiologic intervention (grade 3b if under general anesthesia and grade 3a if not).
4	Any life-threatening complication requiring intermediate or intensive care (grade 4a for single-organ dysfunction and grade 4b for multiple-organ dysfunction).
5	Death of a patient.

<sup>\*</sup> If the patient suffers from a complication at the time of discharge, the suffix "d" (for *disability*) is added to the respective grade of complication. This label indicates the need for follow-up to fully evaluate the complication.

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