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European Association of Urology

Platinum Priority – Collaborative Review – Prostate Cancer

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Downsides of Robot-assisted Laparoscopic Radical Prostatectomy: Limitations and Complications

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Article info

Article history:
Accepted December 10, 2009
Published online ahead of print on December 17, 2009

Keywords:
da Vinci
Complications
Continence
Erectile function
Laparoscopic
Prostate cancer
Radical prostatectomy
Robotic

Abstract

Context: Robot-assisted laparoscopic radical prostatectomy (RALP) using the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) is now in widespread use for the management of localised prostate cancer (PCa). Many reports of the safety and efficacy of this procedure have been published. However, there are few specific reports of the limitations and complications of RALP.

Objective: The primary purpose of this review is to ascertain the downsides of RALP by focusing on complications and limitations of this approach.

Evidence acquisition: A Medline search of the English-language literature was performed to identify all papers published since 2001 relating to RALP. Papers providing data on technical failures, complications, learning curve, or other downsides of RALP were considered. Of 412 papers identified, 68 were selected for review based on their relevance to the objective of this paper.

Evidence synthesis: RALP has the following principal downsides: (1) device failure occurs in 0.2–0.4% of cases; (2) assessment of functional outcome is unsatisfactory because of nonstandardised assessment techniques; (3) overall complication rates of RALP are low, although higher rates are noted when complications are reported using a standardised system; (4) long-term oncologic data and data on high-risk PCa are limited; (5) a steep learning curve exists, and although acceptable operative times can be achieved in <20 cases, positive surgical margin (PSM) rates may require experience with >80 cases before a plateau is achieved; (6) robotic assistance does not reduce the difficulty associated with obese patients and those with large prostates, middle lobes, or previous surgery, in whom outcomes are less satisfactory than in patients without such factors; (7) economic barriers prevent uniform dissemination of robotic technology.

Conclusions: Many of the downsides of RALP identified in this paper can be addressed with longer-term data and more widespread adoption of standardised reporting measures. The significant learning curve should not be understated, and the expense of this technology continues to restrict access for many patients.

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0302-2838/$ – see back matter © 2009 European Association of Urology. Published by Elsevier B.V. All rights reserved. doi:10.1016/j.eururo.2009.12.021

1. Introduction

Robot-assisted laparoscopic radical prostatectomy (RALP) using the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) enjoys a high profile, and there is considerable patient demand for this approach. RALP is now the dominant approach to radical prostatectomy (RP) in the United States and is increasing in popularity in other regions where health economic conditions permit. Patients are attracted by oft-unsubstantiated claims posted on commercial and health provider Web sites that RALP is minimally invasive and that outcomes are superior to other approaches [1,2]. Nevertheless, although randomised trials are lacking, there is reasonable evidence from reviews of case series and comparative studies to suggest that RALP is a well-tolerated, safe, and efficacious intervention for the management of localised prostate cancer (PCa) [3,4].

Although many reports of the feasibility, safety, and early functional and oncologic efficacy of RALP have been published, there are few specific reports of its limitations and complications. In this review, we evaluate the current status of RALP, with a particular focus on its limitations and complications.

2. Evidence acquisition

2.1. Literature search

A Medline search of English-language literature was performed in September 2009 using the following search terms: *robotic radical prostatectomy, robot-assisted radical prostatectomy*, and *da Vinci radical prostatectomy*. Original and review articles were included, and relevant editorials were considered. All papers providing data on technical failures, complications, learning curve, or other downsides of RALP were taken into consideration. Additional papers identified in the bibliography of selected papers were included, if relevant.

In total, 412 articles were identified. We reviewed them and selected those with the greatest relevance to this paper for inclusion. Sixty-eight papers were included in the final review.

3. Evidence synthesis

3.1. Da Vinci Surgical System device failure

A limitation specific to this procedure is device failure (see Table 1). However, such failures appear to be rare events, occurring in only 34 of 8240 cases (0.4%) in a multi-institutional study [5]. Of these, 24 events were identified preoperatively, leading to cancellation of the procedure. Of the 10 device failures that developed intraoperatively, eight cases were converted to open surgery, with two converted to a conventional laparoscopic approach. In a number of smaller studies, device failure has been reported in 0.2–2.6% of cases [6,7].

Two papers have reviewed adverse events related to mechanical failure of the da Vinci Surgical System that have been reported on the Manufacturer and User Facility Device Experience (MAUDE) database of the US Food and Drug Administration (FDA). Andonian et al estimated a device failure rate of 0.38% based on 168 da Vinci system malfunctions reported between 2000 and 2007 [8]. Of these, nine (4.8%) were associated with patient injury. Regarding failures of da Vinci instrumentation, Murphy et al identified 38 system failures and 78 adverse events reported on the MAUDE database between May 2006 and April 2007 [9]. Most of the adverse events relate to either broken instrument tips or failure of electrocautery elements of the da Vinci instruments. In one case, a robotic bipolar grasper was left on the patient's abdomen, and the console surgeon inadvertently activated the device. A 2-mm superficial burn was noted on the patient's abdominal wall. No further injury was noted. This is a specific complication relating to the remote position of the operating surgeon and highlights the need for clear communication between the console surgeon and operating surgeon in these cases.

Another issue with device failure is the consequence of an unrecoverable fault. If the bladder neck has not been divided, then abandoning the procedure remains an option. Otherwise, the surgeon must revert to conventional laparoscopy or convert to open surgery. Of the 38 such instances identified by Murphy et al in their review of the MAUDE database 2006–7, 32 procedures were converted to open surgery, which reflects the lack of experience with

Table 1 – Device failure and adverse events related to the da Vinci surgical system

Author	Study design	System failure rate	Adverse events	Comment
Lavery et al. [5]	Multi-institutional questionnaire	34/8240 cases (0.4%)	N/R	The majority of cases were cancelled, as device failure was noted before the procedure
Patel et al. [6]	Single-institution case series	1 of 500 cases (0.2%)	N/R	Case converted to standard LRP
Borden et al. [7]	Single-institution case series	9 of 350 cases (2.6%)	N/R	Two procedures converted to ORP; one converted to LRP
Andonian et al. [8]	Review of MAUDE database 2000–2007	0.38%	9 of 189 (4.8%) patient injury	One iliac vein injury resulting from insulation failure; one skin burn
Murphy et al. [9]	Review of MAUDE database May 2006–April 2007	38 reported in 1 yr (32 converted to ORP)	78	78 instrument failures (3 converted to open)

N/R = not reported; LRP = laparoscopic radical prostatectomy; ORP = open radical prostatectomy; MAUDE = Manufacturer and User Facility Device Experience (of the US Food and Drug Administration).

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