

# Models of Assessment of Comparative Outcomes of Robot-Assisted Surgery: Best Evidence Regarding the Superiority or Inferiority of Robot-Assisted Radical Prostatectomy



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## KEYWORDS

- Radical prostatectomy • Prostate cancer • Robot-assisted radical prostatectomy
- Comparative effectiveness • Models of assessment

## KEY POINTS

- The best evidence comparing the effectiveness of robot-assisted radical prostatectomy (RARP) with open radical prostatectomy (ORP) for patients with clinically localized prostate cancer (PCa) is based on observational retrospective studies.
- The adoption of standardized endpoints is mandatory when evaluating the comparative effectiveness of different surgical approaches for the treatment of PCa.
- The currently available retrospective studies evaluating oncologic and nononcologic outcomes of RARP are limited by selection bias, short follow-up, and the inclusion of patients for the most part treated in high-volume tertiary referral centers.
- Well-designed prospective investigations are needed to comprehensively assess the benefits of RARP compared with other treatment modalities in patients with clinically localized PCa.

## INTRODUCTION

PCa is the most common noncutaneous malignancy in the United States and Europe. For the year 2014, 233,000 men are estimated diagnosed with PCa in the United States alone.<sup>1</sup> Radical prostatectomy (RP) represents one of the standard-of-care treatment approaches for patients with clinically localized PCa.<sup>2</sup> Since its description in a landmark study by Walsh and Donker in 1982,<sup>3</sup> ORP has been the most commonly performed approach for

the surgical treatment of patients with clinically localized PCa. This surgical technique is associated with excellent cancer control rates, where only 14% of patients treated with ORP experience cancer-specific mortality at long-term follow-up.<sup>4</sup> Long-term side effects, however, such as erectile dysfunction and urinary incontinence, might substantially affect patient health-related quality of life.<sup>5–8</sup> This holds particularly true in young and physically active individuals.

Disclosure Statement: Dr Q-D. Trinh reported having received an honorarium from Intuitive Surgical.

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Urol Clin N Am 41 (2014) 597–606

<http://dx.doi.org/10.1016/j.ucl.2014.07.014>

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Over the past 15 years, the introduction of minimally invasive technologies has revolutionized the treatment of clinically localized PCa.<sup>9,10</sup> In particular, the adoption of RARP immediately gathered much enthusiasm in the field. First described in a case report by Abbou and colleagues,<sup>11</sup> Menon's standardization<sup>12–16</sup> of RARP has resulted in the dissemination of robotics in the United States, where a majority of RPs are now done robotically.<sup>10,17</sup>

Robot-assisted surgery offers many hypothetical benefits, such as stereoscopic vision, enhanced visual magnification, and more degrees of freedom for surgical instruments. As such, many investigators hypothesized that this surgical approach would lead to lower rates of short- and long-term side effects, including urinary incontinence and erectile dysfunction, relative to the conventional ORP.<sup>18–22</sup> Additionally, these technical advantages may also result in better oncologic outcomes compared with ORP. For example, several investigators postulated that the adoption of minimally invasive approaches would result in lower rates of positive surgical margins and additional cancer therapies after surgery.<sup>23–26</sup> Conversely, the dissemination of RARP took place in the absence of high-level evidence supporting its efficacy or safety. There are now enough data to suggest that market competition between hospitals and patient demands in response to aggressive marketing strategies were the main drivers of its adoption.<sup>9</sup> The rapid adoption of robotic surgery has had an impact on the costs of PCa care, because RARP is generally more expensive than ORP.<sup>27–33</sup> For example, investigators have estimated that the widespread adoption of minimally invasive surgery is associated with excess expenditures of approximately \$2.5 billion per year in the United States alone.<sup>31,33</sup> Given the concerns and the demand for greater value, these considerations highlight the need for a comprehensive evaluation of the safety and efficacy of minimally invasive approaches. Understanding and quantifying the benefits of RARP would allow policymakers to better estimate the true value of this technique to health care systems, providers, and patients. On the basis of these considerations, this study aims to systematically evaluate the models adopted in investigations assessing the comparative effectiveness of RARP versus ORP.

## OUTCOMES DEFINITION

There is tremendous variation in the reporting of postoperative complications, functional outcomes, and oncologic results in urologic oncology, regardless of the surgical approach.<sup>5,34–36</sup> Consequently,

the implementation of commonly accepted definitions for postoperative endpoints is necessary to compare the results of RARP with ORP. Currently, the lack of such standardized endpoints undermines the validity of studies comparing RARP with ORP. In this context, several efforts have been recently made to standardize the definition of postoperative endpoints.

## Short-Term Outcomes

The manner in which perioperative outcomes or complications are reported is a significant confounder when trying to assess differences in complication rates between RARP and ORP.<sup>37</sup> Such confusion has led to efforts to standardize the reporting of complications after surgery. Specifically, Martin and colleagues<sup>38</sup> developed 10 criteria for the evaluation of studies reporting postoperative complications (**Table 1**). These include methods of data accrual, definition of complications, outpatient information, severity grading, procedure-specific complications, length of stay, mortality rates and cause of death, duration of follow-up, and data on preoperative risk factors.<sup>38</sup> These criteria were subsequently modified and adapted for urologic surgery by Donat.<sup>39</sup> Although many notable studies<sup>40–42</sup> have adopted the Martin-Donat criteria for standardized reporting of complications, these criteria are not routinely applied in most settings. For example, a recently published systematic review comparing the perioperative outcomes of RARP and ORP identified only 1 publication that fulfilled all of the 10 Martin criteria.<sup>19,43</sup> Regardless, retrospective comparative assessments critically need to fulfill these criteria to be considered valid and relevant.<sup>19,44</sup>

The cornerstone of the Martin-Donat criteria is using a standardized grading system for complications.<sup>38</sup> The most commonly used grading system is based on the work by Clavien and colleagues.<sup>45</sup> In their pioneering investigation, the investigators systemically categorized postoperative complications into 4 grades according to their severity. In 2004, this grading system was updated by Dindo and colleagues,<sup>46</sup> who modified these criteria to improve their accuracy and applicability to the surgical community.

The current grading system uses the following definitions:

- Grade 0: absence of any complications
- Grade 1: presence of any deviation from the normal postoperative course
- Grade 2: management that includes not more than intravenous blood transfusion
- Grade 3: complications that require surgical, endoscopic, or radiologic intervention

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