

Assessment of complication and functional outcome reporting in the minimally invasive prostatectomy literature from 2006 to the present

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To query the minimally invasive urological literature from 2006 to the middle of 2010, focusing on complications and functional outcome reporting in laparoscopic radical prostatectomy (LRP) and robot-assisted LRP (RALP), to see if there has been an improvement in the overall reporting of complications. We performed a Medline search using the Medical Subject Heading terms 'prostatectomy', 'laparoscopy', 'robotics', and 'minimally invasive'. We then applied the Martin criteria for complications reporting to the selected articles. We identified 51 studies for a total of 32 680 patients. When excluding functional outcomes the outpatient complications reporting was 20/51 (39.2%). In all, 35% and 43% of papers did not list any method for recording continence and potency, respectively. A complication grading system was only used in 30 studies (58.8%). Of the 16 papers using a grading scale in 2006–2007, only 31.3% used the Clavien system, compared with 69% from

What's known on the subject? and What does the study add?

Minimally invasive approaches to radical prostatectomy have been touted to lead to superior surgical and functional outcomes with less potential complications despite scant and often conflicting reports in the peer reviewed literature.

This review provides evidence that the minimally invasive prostatectomy literature still fails to meet the standards and critical benchmarks necessary for adequate complications reporting. Given our current reliance on observational studies. Increased efforts should be made to standardize all complications and functional outcomes reporting for minimally invasive prostate cancer surgery.

2008 to the first half of 2010. In all, 27% of papers used some form of risk-factor analysis for complications. Multivariate analysis was used in 43% of papers, 29% looked at body mass index, while one looked at prostate weight, and another age. There has been an overall improvement in complications reporting in the minimally invasive RP literature since 2005. However, most studies still do not fulfil many of the criteria necessary for standardised complication reporting. Functional outcome

reporting remains poor and unstandardised. Given our current reliance on observational studies, increased efforts should be made to standardise all complication outcomes reporting.

KEYWORDS

complications, prostatectomy, robotics, laparoscopy, outcomes

INTRODUCTION

Robot-assisted laparoscopic prostatectomy (RALP) has rapidly overtaken both open and laparoscopic approaches to the surgical management of prostate cancer in the USA. It is currently estimated that 60–70% of all prostatectomies in the USA are performed robotically [1] and they are often touted as improving patient recovery time, postoperative pain, infection rate, and overall being 'less invasive'. Despite this aggressive marketing campaign, there is

little data to support an overall benefit to the patient in terms of immediate and long-term surgical outcomes, with the probable exception of blood loss and initial hospital stay [2,3]. Recent data has also suggested that RALP may be associated with higher rates of urological complications, such as early postoperative genitourinary complications, incontinence and erectile dysfunction [3].

Martin *et al.* [4] in 2002 proposed standardised criteria for reporting

complications that has set the standard for delineating operative outcomes in the 21st century. Donat [5] performed a review of the urological oncology literature from 1995 to 2005 and found that the vast majority of studies within the peer-reviewed urological literature do not meet many of the suggested criteria. This variability in outcomes reporting is the probable explanation for the early RALP literature reporting complication rates as low as 2–4% [6], while more contemporary series report rates of 15–20% [7,8] despite surgical

Complication reporting criteria	Meeting criteria, n (%)	TABLE 1 <i>Fulfilment of the Martin et al. [4]] reporting criteria</i>
Method of accruing data defined	51 (100)	
Duration of follow-up indicated	15 (29.4)	
Outpatient information included*	42 (82.4)	
Definitions of complications provided	35 (68.6)	
Mortality rate and causes of death listed	31 (60.8)	
Morbidity rate and total complications indicated	46 (90.2)	
Procedure-specific complications included	43 (84.3)	
Severity grade used	30 (58.8)	*Most of these provided definitions for functional complications only.
Length of stay data	36 (70.6)	
Risk factors included in analysis	14 (27.5)	

experience and competition of the laparoscopic/robotic 'learning curve'. We sought to query the minimally invasive urological literature from 2006 to the middle of 2010 focusing on complications reporting in laparoscopic radical prostatectomy (LRP) and RALP, to see if there has been an improvement in the overall reporting of complications.

MATERIALS AND METHODS

We performed a Medline search using the Medical Subject Heading (MeSH) terms 'prostatectomy', 'laparoscopy', 'robotics', and 'minimally invasive'. We limited our search to English language publications from 2006 to the middle of 2010 and those with ≥ 50 patients. Review articles, and articles from non-peer reviewed journals were also excluded as their data was noted to be markedly inferior to the peer-reviewed publications. We also excluded studies that specifically looked at functional outcomes after RP but did not report other surgical complications. We then applied the Martin *et al.* [4] criteria for complications reporting to the selected articles (Table 1). Briefly, Martin *et al.* devised 10 categories to critically evaluate the quality of the surgical literature as it relates to the reporting of complications. These criteria were initially evaluated in the general surgical literature, but are applicable to any surgical discipline.

RESULTS

Our initial query yielded 412 manuscripts. When limiting our criteria to the above mentioned fields, we identified 51 studies for a total of 32 680 patients (excluding the

open comparisons) with a mean (range) of 640 (50–5824) patients and a median (interquartile range) of 264 (119–646) patients. Of the 51 papers, 17 papers investigated pure LRP, 20 evaluated RALP, nine compared LRP vs retropubic RP (RRP), two compared RALP vs RRP, two looked at RALP vs LRP, and one compared RRP with either RALP or LRP.

Of the 51 studies, 19 were retrospective, one was retrospective population based, 28 were prospectively entered into databases, one was prospective and not randomized (RRP vs RALP) and two were prospective randomized comparisons (LRP vs RRP, and RALP extraperitoneal vs intraperitoneal).

Four of the 51 studies (7.8%) met *all* 10 Martin *et al.* [4] criteria. Seven (13.7%) met nine criteria, 18 (35.3%) met seven or eight, 12 (23.5%) met five or six, and 10 (19.6%) met three or four criteria. The only universally met criteria, was method of data accrual. Overall, 90.2% of papers reported morbidity rate and total complications, while only 28% controlled for any mitigating risk factors for complications (Table 1). This held true when we considered any paper that studied at least one potential risk factor. In all, 82% of papers considered outpatient information; however, the vast majority of these were for functional outcomes only. Most papers did not mention whether they assessed emergency room visits or unexpected outpatient visits. The complications reporting varied a great deal among papers with authors reporting complications they see most often or consider important. There was no uniform set of complications deemed necessary to publish for a particular operation. There did seem to be an improvement in category

fulfilment over time. For example, papers published before 2008 only met on average 6/10 categories, while those published subsequently fulfilled 7.7/10.

Most papers did not report the duration of follow-up for complications; those that did typically used complications ≤ 30 days. Most of the outpatient data was related to continence and potency statistics. Of the 42 papers to report on outpatient data, 13 did not report any average duration of follow-up, four used 6-month data, nine used 12-month data, and the remaining cited data ranging from 3 months to 3.7 years. When excluding functional outcomes the outpatient complications reporting fell to 20/51 (39.2%). Hospital re-admissions were reported by seven (13.7%) studies, while re-operations were indicated in 29 (56.9%), and conversions to open in 33 (64.7%).

Most studies (90%) reported morbidity rate, while only 60% reported death rates, which were exceedingly low. Most studies used procedure-specific complications, although most of them were related to functional outcomes. For functional outcomes, there was a range in methods for recording both continence and potency with 35% and 43% of papers not listing any method for recording continence and potency, respectively (Table 2). About one-third of studies used pad use/pad number to determine continence, while $>35\%$ did not list any method. For potency, the most commonly used questionnaire was the International Index of Erectile Function, but this was only used in 20% of papers, while $>40\%$ did not list any specific method for assessing potency.

A complication grading system was only used in 30 studies (58.8%), with the Clavien system and major vs minor reporting were used in 46.7% of the cases each, and two miscellaneous systems. Major complications were defined as death, rectal injury, intensive care unit stay of >24 h, re-operation for anastomotic leak or life-threatening haemorrhage. There was some disparity in definitions, e.g. some studies classified deep vein thrombosis (DVT) as a minor complication, while others grouped DVT and pulmonary embolism together as a major complication. There was a definite trend favouring the Clavien system in terms of publication dates. Of the

16 papers using a grading scale in 2006–2007, only 31.3% used the Clavien system, compared with 69% from 2008 to the first half of 2010. In all, 27.5% of papers used some form of risk-factor analysis for complications such as body mass index (BMI), prostate weight or age. Overall, 43% used multivariate analysis, 29% looked at BMI, while one looked at prostate weight, and another age. Eight of the 51 studies were specifically designed to look at complications of either LRP or RALP. These studies fared significantly better meeting, on average, 8.5/10 criteria.

DISCUSSION

Robotic RP is increasingly used as the preferred method of surgical treatment for localized prostate cancer. According to Intuitive Surgical (the manufacturer), 70% of all RPs performed in the USA in 2007 were performed robotically [1]. Aggressive marketing campaigns and advertising have been at the forefront of this shift [9], with centres promising superior outcomes compared with other surgical approaches including lower blood loss, decreased length of hospital stay, faster recovery, as well as equivalent if not improved oncological and functional outcomes [10,11].

However, most of the claims are based on retrospective observational cohorts, as recently reviewed by Ficarra *et al.* [12]. In this review of the RALP literature (post learning curve) before 2007, the incidence of complications ranged from 1.5% to 17.8%, showing considerable variability not likely to be related solely to surgical expertise or technique. Two recent, population-based studies by Hu *et al.* [3,13] have challenged the relative reported benefits of RALP for cancer control, urinary continence, and erectile function.

Since the sobering assessment of complications-reporting in the surgical literature by Martin *et al.* [4] in 2002, many efforts have been made to standardise the process including the most well-known Dindo-Clavien grading system [14]. Nevertheless, the Donat [5] review of complication rates in the urological oncology literature reported that only 2% met 9 or 10 of the Martin *et al.* [4] criteria and 21% met seven or eight criteria. Given the current controversies and aggressive

TABLE 2 Functional outcomes reporting

	Continence, <i>n</i> (%)	Potency, <i>n</i> (%)
No method/questionnaire listed	18 (35.3)	22 (43.1)
Pad use/number only	16 (31.4)	<i>n/a</i>
UCLA Prostate Cancer Index	7 (13.7)	5 (9.8)
International Consultation on Incontinence Questionnaire (ICIQ)	2 (3.9)	<i>n/a</i>
International Continence Society (ICS) Questionnaire	3 (5.9)	<i>n/a</i>
International prostate symptom score (IPSS)	2 (3.9)	<i>n/a</i>
Expanded Prostate Cancer Index Composite (EPIC)	1 (1.9)	1 (1.9)
Continence Quality of Life Questionnaire (CQLQ)	1 (1.9)	<i>n/a</i>
Telephone questionnaire	1 (1.9)	1 (1.9)
Sexual Health Inventory for Men (SHIM) Score	<i>Na</i>	3 (5.9)
International Index of Erectile Function (IIEF)	<i>n/a</i>	10 (19.6%)
Intercoarse +/- PDE5	<i>n/a</i>	9 (17.6%)

UCLA, The University of California Los Angeles; PDE5, phosphodiesterase type 5 inhibitor; *n/a*, non-applicable.

marketing strategies, we assessed the LRP and RALP literature in terms of complication reporting from 2006 to the first half of 2010.

There was an overall improvement in complication reporting for both LRP and RALP. Compared with the 13 studies Donat [5] reviewed, 20% of papers in the present cohort met nine or 10 of the 10 criteria listed by Martin *et al.* [4], with another 60% meeting at least five criteria. Nevertheless, 28.8% of studies still only met three or four criteria compared with 38% in the Donat review. It should be noted that eight of these 10 studies were from 2007 and earlier, and from journals with lower impact factors on average. There was a general trend of improvement in criteria fulfilment over time with an average of six criteria being met before 2008, and 7.4 criteria met from 2008 to the first half of 2010.

Some important limitations still remain. Most papers (70%) do not report the period used to capture complications. Nearly 40% did not list mortality rate or cause of death, which probably reflects the low mortality rates in these cohorts, but warrants reporting nonetheless. The use of a grading system remains low (58.8%), but has seen an improvement in the last 2 years, with only half of the studies using some system before 2008, and 73.7% using a system since then. There has been trend toward using the Clavien system, which we favour as well.

Only a fraction (27.5%) of papers performed any sort of analysis of risk factors for complications, with most of those being performed in studies specifically looking at complications. Of these, only six studies performed a multivariate analysis. Although a complication analysis study may aim to report a specific finding, it should always include a multivariate analysis looking at well-known risk factors pertinent to the operation, such as age, BMI, and prostate size, as well as a measure of the overall patients' functional status (Charlson Comorbidity Index or American Society of Anesthesiologists physical status classification system).

Table 2 also addresses the relatively poor functional outcomes reporting. A large percentage of studies did not use a questionnaire or report their method for assessing continence or potency. Without some means of standardisation for functional outcomes reporting, it becomes very difficult to compare results from different centres, experiences, or techniques. Our rationale for including functional outcome reporting in the assessment of complication reporting is due to the inconsistencies in the literature regarding when a delay or lack of return of potency or continence should be deemed a complication, rather than the normal postoperative course. We therefore felt it necessary to describe how the reporting of these outcomes shows considerable heterogeneity, making inter-study

comparisons quite difficult. Further efforts by the urological community should consider providing guidelines and standards for the expected postoperative return of function.

Kang *et al.* [15] recently performed a systematic review of publications on RALP and concluded that the vast majority of publications are limited to observational studies of low methodological quality. They challenged the notion of inherent superiority of RALP over conventional RRP or LRP given the lack of randomized trials. They did acknowledge the difficulties in establishing such trials in the surgical setting such as 'blinding' patient and surgeons, controlling for experience, and the unwillingness for patients to be 'blinded' to invasive procedures. All these factors make it critical for our observational studies to be methodologically rigorous and as standardised as possible.

We think that any papers in the urological literature reporting surgical outcomes and complications should be obligated to fulfil most of the Martin *et al.* [4] criteria, and should use validated questionnaires for any functional outcome details. The current marketing strategies aimed at equating technological advances with improved outcomes, underscores the need for the urological community to demand the most rigorous standards possible for assessing these techniques with the tried and true 'gold standards'. The current methodological shortfalls particularly for robotic RPs are troubling. Further, any study or review attempting to compare one method (open, laparoscopic, or robotic) should only limit themselves to papers with meticulous reporting standards.

Future considerations should include establishing a set of at least the five most common complications for each major urological procedure. Each study would list their outcomes for each of them, creating a baseline for accurate comparative analysis across institutions. Reporting a rate of 0% for a specific complication is important because otherwise it is unknown whether it did not occur, or simply was not reported. There should also be some considerations for a requirement to use validated questionnaires both pre- and postoperatively. It is up to the urological community to embrace the significance of

this rigid reporting system and criteria. Report using variable, unstandardised and unvalidated means of outcome reporting, especially with inadequate complication data, should not be accepted for publication as the data can be misconstrued.

In this era of the World Wide Web, the results can be misinterpreted by patients and the mainstream media outlets providing a sense of security or raise unjustified expectation of unrealistic or exaggerated outcomes as has been the case for robotic RP recently. This can only lead to patient dissatisfaction when these undue expectations are not met [16]. Limitations of this review include the possibility of using only PubMed MeSH results, and limiting it to English language journals.

CONCLUSION

There has been an overall improvement in complications reporting in the minimally invasive RP literature since 2005. However, most studies still do not fulfil many of the criteria necessary for standardised complication reporting. Functional outcome reporting remains poor and unstandardised. Given our current reliance on observational studies, increased efforts should be made to standardise all complication outcomes reporting. Any report on surgical series with scant or inadequate complication data with unvalidated outcome analyses should be assessed with extreme caution.

CONFLICT OF INTEREST

None declared.

REFERENCES

- 1 Badani KK, Kaul S, Menon M. Evolution of robotic radical prostatectomy: assessment after 2766 procedures. *Cancer* 2007; **110**: 1951–8
- 2 Smith JA Jr, Herrell SD. Robotic-assisted laparoscopic prostatectomy: do minimally invasive approaches offer significant advantages? *J Clin Oncol* 2005; **23**: 8170–5
- 3 Hu JC, Gu X, Lipsitz SR *et al.* Comparative effectiveness of minimally invasive vs open radical prostatectomy. *JAMA* 2009; **302**: 1557–64
- 4 Martin RC 2nd, Brennan MF, Jacques DP. Quality of complications reporting in the surgical literature. *Ann Surg* 2002; **235**: 803–13
- 5 Donat SM. Standards for surgical complication reporting in urologic oncology: time for a change. *Urology* 2007; **69**: 221–5
- 6 Menon M, Shrivastava A, Kaul S *et al.* Vattikuti Institute prostatectomy: contemporary technique and analysis of results. *Eur Urol* 2007; **51**: 648–58
- 7 Rabbani F, Yunis LH, Pinochet R *et al.* Comprehensive standardized report of complications of retropubic and laparoscopic radical prostatectomy. *Eur Urol* 2010; **57**: 371–86
- 8 Novara G, Ficarra V, D'Elia C, Secco S, Cavalleri S, Artibani W. Prospective evaluation with standardised criteria for postoperative complications after robotic-assisted laparoscopic radical prostatectomy. *Eur Urol* 2010; **57**: 363–70
- 9 Ghavamian R. The urologic oncologist, robotic, and open radical prostatectomy: the need to look through the hype and propaganda and serve our patients. *Urol Oncol* 2009; **27**: 233–5
- 10 Ahlering TE, Woo D, Eichel L, Lee DI, Edwards R, Skarecky DW. Robot-assisted versus open radical prostatectomy: a comparison of one surgeon's outcomes. *Urology* 2004; **63**: 19–22
- 11 Rassweiler J, Seemann O, Schulze M, Teber D, Hatzinger M, Frede T. Laparoscopic versus open radical prostatectomy: a comparative study at a single institution. *J Urol* 2003; **169**: 1689–93
- 12 Ficarra V, Cavalleri S, Novara G, Aragona M, Artibani W. Evidence from robot-assisted laparoscopic radical prostatectomy: a systematic review. *Eur Urol* 2007; **51**: 45–56
- 13 Hu JC, Hevelone ND, Ferreira MD *et al.* Patterns of care for radical prostatectomy in the United States from 2003 to 2005. *J Urol* 2008; **180**: 1969–74
- 14 Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004; **240**: 205–13
- 15 Kang DC, Hardee MJ, Fesperman SF, Stoffs TL, Dahm P. Low quality of

evidence for robot-assisted laparoscopic prostatectomy: results of a systematic review of the published literature. *Eur Urol* 2010; **57**: 931–5

- 16 **Schroek FR, Krupski TL, Sun L et al.** Satisfaction and regret after open retropubic or robot-assisted laparoscopic radical prostatectomy. *Eur Urol* 2008; **54**: 785–93

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Abbreviations: RALP, robot-assisted laparoscopic prostatectomy; (L)(R)RP, (laparoscopic) (retropubic) radical prostatectomy; MeSH, Medical Subject Heading; DVT, deep vein thrombosis.

EDITORIAL COMMENT

ASSESSMENT OF COMPLICATION AND FUNCTIONAL OUTCOME REPORTING IN THE MINIMALLY INVASIVE PROSTATECTOMY LITERATURE FROM 2006 TO THE PRESENT

Complications after radical prostatectomy (RP), open, laparoscopic or robot-assisted, have been reported by many authors. The frequency and nature of those complications

(in the absence of appropriately powered randomised studies) are frequently seen as a surrogate endpoint of success in what are predominantly observational studies. However, there is a lack of uniformity in such reporting. Nevertheless, in recent years the surgical community has made several concerted efforts to standardise the presentation of such complications, the best known of which is the Clavien-Dindo classification. In its time, it represented a novel approach to the classification of complications of surgery based on a therapy orientated four-level severity grading that was subsequently refined to improve its utility [1]. Subsequently, Martin *et al.* [2] have proposed a series of 10 standardised criteria, which should ideally be incorporated into such reports and range from risk stratification analysis to procedure-specific complications. More recently, Sherri Donat [3] has defined a series of procedure-specific complications for urology (such as visceral injury, urinary leak etc.) in a further attempt to standardise reporting patterns. A literature review by the author for the period 1995–2005 identified only one article, which adhered to the proposed reporting standards. In the present article by Hakimi *et al.* [4], the authors review the published literature in relation to functional outcomes and complication reporting for laparoscopic RP and robot-assisted laparoscopic RP for the period 2006–2010. Fewer than 8% met all of the 10 Martin-Donat criteria, whilst 20% reported nine or 10 of the criteria. Whilst the authors acknowledged the

improvement in the quality and nature of complication reporting (and the trend in improved criteria fulfilment) they also make a plea for future reports to comply with the Martin-Donat criteria, which in-turn should allow a more robust and accurate comparison of surgical techniques in the future.

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REFERENCES

- 1 **Dindo D, Demartines N, Clavien PA.** Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004; **240**: 205–13
- 2 **Martin RC 2nd, Brennan MF, Jaques DP.** Quality of complication reporting in the surgical literature. *Ann Surg* 2002; **235**: 803–13
- 3 **Donat SM.** Standards for surgical complication reporting in urologic oncology: time for a change. *Urology* 2007; **69**: 221–5
- 4 **Hakimi AA, Faleck DM, Sobey S et al.** Assessment of complication and functional outcome reporting in the minimally invasive prostatectomy literature from 2006 to the present. *BJU Int* 2011 [Epub ahead of print]