

available at www.sciencedirect.com
journal homepage: www.europeanurology.com



European Association of Urology



Platinum Priority – Editorial and Reply from Authors

Referring to the article published on pp. 930–937 of this issue

Low Quality of Evidence for Robot-Assisted Laparoscopic Prostatectomy: What About the Evidence for Open?

Vipul R. Patel*

University of Central Florida School of Medicine, Global Robotics Institute, Florida Hospital Celebration Health, Celebration, FL, USA

In the United States, robot-assisted radical prostatectomy (RARP) is now the most common surgical procedure for the treatment of localized prostate cancer, accounting for >75% of all radical prostatectomies (RPs) currently performed [1]. This transition has occurred quite rapidly, in less than a decade since the introduction of the robotic technology. The speed of this change was initially attributed to “marketing of the robot”; however, the test of time has shown significant advantages of this technology in the hands of experienced surgeons. This dramatic paradigm shift has been driven by the need for a less invasive surgical approach to RP and by the preference of surgeons and patients alike.

Kang et al [2], in their article published in the current issue of *European Urology*, attempt to explore the paradigm shift and to discern the reasons for the change from open to robotic surgery as well as the validity of such a change. The article focuses on evaluating the methodology and presentation of published literature regarding the results of RARP. The conclusion of the analysis is quite obvious: improvements in the standards and the quality of reporting of clinical research are necessary. The authors imply that because the published robotic literature is imperfect, the clinical outcomes must also be suboptimal and that there is no reason for this paradigm shift. This conclusion is far fetched and without merit.

What is woefully lacking from Kang et al's study [2] is an evaluation of the level of evidence of the major open RP (ORP) studies, which this article implies are the reference standard. It is difficult to give credence to an article that chastises the lack of reporting quality in one field but fails to evaluate and validate the supposed reference standard. Over recent decades, the quality of scientific publications has improved as we have established criteria for evidence-based medicine [3]. What is published today is likely of a

higher standard than previous research because the benchmarks of quality also have been set higher. Most of the larger ORP series, if analyzed, would also be found to be lacking validated questionnaires, randomization, and institutional review board or ethics committee approval. Therefore, to challenge the validity of a dramatic change in clinical practice patterns based solely on how the procedure is reported is somewhat meaningless.

The authors have cited a few key articles to support their assumption that, based on the quality of the literature currently presented, the transition to robotics should not have occurred. These articles, however, also have some clear limitations. The publication by Ficarra et al [4], in 2009, evaluated the results of only comparative series for open, laparoscopic, and robotic prostatectomy. A small number of studies met their criteria, with the majority of the larger experienced series being excluded because they were not comparative analyses. These authors concluded that, based on comparative series, patients undergoing laparoscopic RP (LRP) or RARP had less blood loss and blood transfusion; however, the available data were not sufficient to prove the superiority of any surgical approach in terms of functional and oncologic outcomes. Additionally, in their analysis, the surgeons' experience was found to be an important factor influencing patient outcomes. They clearly acknowledge that the literature for all three approaches was “not excellent” and that “due to the limitations of the currently available literature, further prospective, comparative studies are needed.” These authors have shown that the literature in all three approaches is limited to studies of low methodologic quality.

Based on prior studies such as that by Ficarra et al [4], it is clear that the only way to actually show any conclusion would be to focus solely on one technique (eg, robotic), not

DOI of original article: 10.1016/j.eururo.2010.01.034

* 410 Celebration Place, Suite 200, Celebration, FL 34747, USA. Tel. +1 407 303 46 73; Fax: +1 407 303 46 32.

E-mail address: Vipul.patel.md@flhosp.org.

0302-2838/\$ – see back matter © 2010 European Association of Urology. Published by Elsevier B.V. All rights reserved. doi:10.1016/j.eururo.2010.02.017

assess or establish a reference standard (evaluation of open literature), and come to the conclusion that the methodology of reporting in the literature for robotic is flawed. The assumption would be that the robotic literature is flawed but that the other is not; however, this conclusion cannot be substantiated without proper analysis.

The authors also quote the article recently published by Hu et al [5], in 2009, and warn about the outcomes of RARP. This study was population based and used Medicare database coding to evaluate the outcomes of ORP versus minimally invasive RP (MIRP). The authors concluded that MIRP had higher rates of impotence and incontinence. This article was significantly flawed because it combined two very different procedures in the MIRP category (LRP and RARP) and, more important, had no outcomes to measure. There was no evaluation of a patient's preoperative status, of whether the patient had a nerve-sparing procedure, or of what happened to the patient during or after surgery. No data were collected. The article was purely based on coding of incontinence or erectile dysfunction, and the definitions of these outcomes were not standardized. In addition, only data prior to 2007 were analyzed; thus, many outcomes were included from series carried out during the initial learning curve for RARP. Although the statistical analysis performed in this study was impressive, the clinical validity and practicality of this article were meaningless because it focused on coding rather than on actual outcomes. The code circled for billing has little to do with how patients actually perform; this is why specific, validated questionnaires for RP outcomes have been developed.

Although the methodology of the RARP literature reviewed by Kang et al [2] may have been imperfect, this limitation is clearly present in all of the literature published for ORP, LRP, and RARP. It is implied in the article that the published literature on ORP is the gold standard by which RARP is being judged. It is likely that if we examined the ORP literature, there would also be a deficit in evidence and the quality of reporting because most of the ORP studies published are also case series and nonrandomized studies. The authors have discovered an obvious methodologic flaw that is prevalent throughout the literature, regardless of the approach to RP. It would be nice to say that we should backtrack now and perform the randomized controlled trials we would all love to see; however, this is unlikely to happen because patients are unwilling to submit to randomization at this point.

Even the systematic review published by Kang et al [2] is subject to some clear methodologic limitations. In this article, the authors sought to analyze all original research publications on RARP from 1966 to December 2008; however, the comparative study carried out by Smith et al [6] in 2007, for example, was not included in the analysis. Smith et al [6] published the largest series comparing positive surgical margin (PSM) rates between ORP and RARP. They reported lower overall incidence of PSMs after RARP compared to ORP (15% vs 35%; $p < 0.001$). Furthermore, although Kang et al [2] updated their

systematic review in November 2009, the RARP series published in 2009 were not included in the analysis. Therefore, some mature RARP series and comparative studies recently published in the literature were not evaluated [7–9].

In conclusion, the era of robotic surgery for the treatment of prostate cancer has come and is here to stay. The benefit to patient care in the hands of experienced surgeons is known. Although the methodology by which some of the studies have been performed and published may not have been “perfect,” the fact remains clear that, in experienced hands, patients undergoing RARP perform very well, with shorter hospital stay, less blood loss, and faster recovery of potency and continence [9,10]. Oncologic outcomes have proven to be equivalent, with a trend toward lower positive margin rates in the RARP group [4,6,8]. At least in the United States, it is unlikely that we will see a reversal of the trend toward RARP because the clinical benefits are seen on a daily basis by both patients and surgeons performing the procedure. At this point, it is evident that the only limitation of the technique is its use by surgeons without adequate training or surgical experience. The debate may continue for many more years, but the overall numbers and the dramatic paradigm shift speak volumes about what works better for the patient.

Conflicts of interest: The author has nothing to disclose.

References

- [1] Orvieto MA, Patel VR. Evolution of robot-assisted radical prostatectomy. *Scand J Surg* 2009;98:76–8.
- [2] 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; 57:930–7.
- [3] Brooke BS, Nathan H, Pawlik TM. Trends in the quality of highly cited surgical research over the past 20 years. *Ann Surg* 2009;249:162–7.
- [4] Ficarra V, Novara G, Artibani W, et al. Retropubic, laparoscopic, and robot-assisted radical prostatectomy: a systematic review and cumulative analysis of comparative studies. *Eur Urol* 2009;55:1037–63.
- [5] Hu JC, Gu X, Lipsitz SR, et al. Comparative effectiveness of minimally invasive vs open radical prostatectomy. *JAMA* 2009;302:1557–64.
- [6] Smith Jr JA, Chan RC, Chang SS, et al. A comparison of the incidence and location of positive surgical margins in robotic assisted laparoscopic radical prostatectomy and open retropubic radical prostatectomy. *J Urol* 2007;178:2385–9.
- [7] Rocco B, Matei DV, Melegari S, et al. Robotic vs open prostatectomy in a laparoscopically naive centre: a matched pair analysis. *BJU Int* 2009;103:448–53.
- [8] White MA, De Haan AP, Stephens DD, Maatman TK, Maatman TJ. Comparative analysis of surgical margins between radical retropubic prostatectomy and RALP: are patients sacrificed during initiation of robotics program? *Urology* 2009;73:567–71.
- [9] Patel VR, Palmer KJ, Coughlin G, Samavedi S. Robot-assisted laparoscopic radical prostatectomy: perioperative outcomes of 1500 cases. *J Endourol* 2008;22:2299–305.
- [10] Badani KK, Kaul S, Menon M. Evolution of robotic radical prostatectomy: assessment after 2766 procedures. *Cancer* 2007;110:1951–8.