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Adam S. Kibel
Washington University School of Medicine in St. Louis

et al.

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International Radical Cystectomy Consortium: A way forward


Department of Urology, Roswell Park Cancer Institute, Buffalo, NY, USA
Khurshid A. Guru
Correspondence Address
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Association annual meeting in 2008 regarding the oncological results of 162 cases. [4] In this article, we discuss our experience of establishing the global database - IRCC, findings from our would help better understand the outcomes of this new operative modality on a large cohort of patients. The first peer-reviewed abstract was presented at the American Urological Cystectomy Consortium (IRCC) was thus formed in 2006 with four participating institutions, with their results of RARC in a pooled database of 162 patients to begin with. This collective data limited number of patients spread out across the globe incited the idea of collectively reporting the robot-assisted radical cystectomy (RARC) patients. The International Robotic operative and oncological outcomes. [1], [2], [3] As this technique was initially performed at very few centers across the globe, the reported data suffered from a limited number of patients.

Robot-assisted radical cystectomy (RARC) is an emerging operative alternative to open surgery for the management of invasive bladder cancer. Studies from single institutions provide limited data due to the small number of patients. In order to better understand the related outcomes, a world-wide consortium was established in 2006 of patients undergoing RARC, called the International Robotic Cystectomy Consortium (IRCC). Thus far, the IRCC has reported its findings on various areas of operative interest and continues to expand its capacity to include other operative modalities and transform it into the International Radical Cystectomy Consortium. This article summarizes the findings of the IRCC and highlights the future direction of the consortium.

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INTRODUCTION

The recent development in minimally invasive techniques, especially robot-assisted surgery, has revolutionized the way healthcare is now delivered to a sub-set of patients. Its rapid adoption as an available alternative to open surgery has made it imperative to understand its feasibility and efficacy when compared with the "gold standard" technique, i.e. open surgery. Since the first description of robot-assisted radical cystectomy (RARC) as a treatment option for invasive bladder cancer in 2003, much work has been reported to describe its operative and oncological outcomes. [1] [2] [3] As this technique was initially performed at very few centers across the globe, the reported data suffered from a limited number of patients. The limited number of patients spread out across the globe incited the idea of collectively reporting the robot-assisted radical cystectomy (RARC) patients. The International Robotic Cystectomy Consortium (IRCC) was thus formed in 2006 with four participating institutions, with their results of RARC in a pooled database of 162 patients to begin with. This collective data would help better understand the outcomes of this new operative modality on a large cohort of patients. The first peer-reviewed abstract was presented at the American Urological Association annual meeting in 2008 regarding the oncological results of 162 cases. [4] In this article, we discuss our experience of establishing the global database - IRCC, findings from our publications, along with current status and future directions of this collaborative venture.
Summary of the peer-reviewed literature

After the first reports of RARC, robotic surgeons started to embrace it as an alternative to open cystectomy; however, concerns remained regarding outcomes, especially related to the oncologic results, before its incorporation into the main armamentarium. Unfortunately, the available data at that time reported single-institution experiences of surgeons who had spent an ample amount of time developing alternative methods of performing this procedure. [5] Thus, these results were not applicable across centers that were in the developmental phase. The IRCC was able to provide results from data of various centers during the evaluation and standardization of the technique.

Learning curve

With the use of a robotic approach toward the surgical management of prostate cancer, it was understood that the next advance would be RARC. In the initial development of this technique, the learning curve required to reach a level that safely allows RARC to be performed by a new robotic surgeon needed elaboration. In this study, Hayn et al. evaluated the learning curve of RARC using the IRCC database. [8] They analyzed results from 496 patients operated by 21 surgeons at 14 institutions across the world. The clinical and pathological features of these patients were determined after stratifying surgery into groups of <30, 31-50 and >50 cases. The operative time, estimated blood loss (EBL) and lymph node yield (LNY) were significantly different in the three groups. There was a decrease in the operative time, increase in the nodal yield and decrease in the EBL with an increase in the number of cases performed. Although the overall positive margin rate was 7% for the entire cohort, it did not significantly differ among the three groups. Using the fitted model, the IRCC was able to determine the number of cases required to achieve a pre-defined cut-off for each variable. This model demonstrated that 21 cases were needed to achieve an operative time of 390 min. It was also noted that 30 patients were needed to attain a LNY of 20. The EBL reported a flat line, while 30 patients were required to attain a 5% positive surgical margin rate. The study concluded that acceptable proficiency levels are attained by the 30th RARC case, with the aforementioned measures of quality.

Surgical margin status

A positive surgical margin following radical cystectomy (RC) offers a guarded prognosis along with T stage and lymph node metastasis and, majority of the time, is considered as a limitation in the surgical technique. [7] This remains one of the concerns when a new operative technique is adopted to treat invasive bladder cancer with curative intent. Current reports from open RC series reported a positive margin rate of 1-10%.[8],[9] Therefore, Hellenthal et al. determined the rate of positive surgical margins after RARC and factors influencing it using a large cohort of patients. [10] This study reported a 6.8% (35 patients) margin positive rate on a total of 513 patients. The IRCC concluded that previous robotic experience and surgeon volume may influence the rate of positive surgical margin.

Impact of surgeon and volume on robot-assisted extended lymphadenectomy

The fact that a quarter of the patients with invasive bladder cancer may have metastatic disease to the regional lymph nodes, the need to perform an extensive nodal clearance remains imperative. [15],[16] The use of RARC at attaining nodal clearance is well established; however, the factors that affect the extent of lymph node dissection (LND) remains to be determined, especially when a learning curve exists with the LNY. Marshall et al. reported the predictors for extended LND in 765 patients who underwent RARC using the IRCC database. [17] The study divided the entire cohort of patients into extended LND (eLND) and no or standard LND (sLND) groups. Overall, 58% patients underwent eLND. 40% had sLND and 2% had no LND. Eighty-eight percent of patients underwent eLND and incomplete LND was seen in 2 patients (0.35%). The IRCC concluded that with an increase in case number, risk of positive surgical margins increases.

Complications

Until recently, the adverse event reporting following any surgical procedure lacked a standardized reporting methodology. [18] With the increasing use of RARC as an alternative to open surgery, it was necessary to understand the morbidity related to this procedure using a standardized reporting methodology. Johar et al. queried the IRCC database to report the morbidity and mortality of RARC using the MSKCC complication reporting system on 939 patients. [19] The study reported an overall complication rate of 48%, with a 19% high-grade (grades 3-5) complication rate, mortality rate of 4.2% and readmission rate of 20% within 90 days of RARC. The three most common complications were gastrointestinal, infectious and genitourinary as per the organ systems, with 53 patients requiring reoperation within 30 days. On multivariable analysis, age (10-year group), body mass index, neoadjuvant chemotherapy, intraoperative blood transfusion and type of diversion were significantly associated with any grade complications. However, age, neoadjuvant chemotherapy and intraoperative blood transfusion were the only independent predictors of developing any and high-grade complications. Age (10-year group) and intraoperative blood transfusion were the only predictors of 90-day mortality on multivariable analysis. The IRCC concluded that RARC was associated with significant complications; however, most of them were low grade when reported using a standard reporting methodology. Age and receipt of blood transfusion were the only predictors for both 90-day morbidity and mortality.
Currently, the database runs as a secure, online system with over 75 variables that can be filed by the participating institutions in real time from the ease of their desktops in the clinics. Access to the database is currently limited and is offered following an extensive process of Institutional Review Board (IRB) approval and 3rd party networking agreement. In the year 2012, the IRCC was converted to the International Radical Cystectomy Consortium to help bring surgeons across the globe with open, laparoscopic and robotic techniques to share their experience. The common database of the three operative modalities and a larger cohort, with common variables, will be able to provide an improved comparative analysis. Currently, the IRCC is a consortium of partners from 15 countries at 33 participating institutions, with over 1400 patients. In the future, we anticipate providing all of the participating institutions/surgeons with access to the database, where they could compare their own techniques with other techniques and institutions across the globe.

**CONCLUSIONS**

Over the years, the IRCC has established itself at reporting various concerns related to the newer technology of RARC. The prime aim of this effort is to bring all the treatment modalities on a single platform and provide real-time standardized quality of care information for surgical (open, laparoscopic and robot-assisted) management of bladder cancer across the globe.

**References**