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International Radical Cystectomy Consortium: A way forward

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Abstract

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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Full Text

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 conventional open methods 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 evolution 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. [6] 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 surgeons 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 30 th 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. Contemporary 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 the IRCC. [10] This study reported a 6.8% (35 patients) margin positive rate on a total of 513 patients who underwent RARC. Patients older than 70 years with T3 or T4 stage and positive lymph nodes were more likely to have a positive margin. Sequential case number and institutional case volume was not associated with the positive margin rate. The IRCC concluded that the positive margin rate following RARC was comparable with open series, and case numbers that could be a surrogate for institutional volume and the learning curve did not influence it.

Previous robot-assisted radical prostatectomy experience

With the use of robotic techniques in minimally invasive surgery, robot-assisted radical prostatectomy became a common procedure as a well-established treatment option for prostate cancer. Soon this technique was able to provide oncological and functional outcomes comparative to the open technique, highlighting swift expertise at this procedure. [11] Therefore, it was interesting to determine whether the experience of RARP influenced the outcomes of the newly adopted RARC. Hayn and colleagues reviewed the IRCC database, with 496 patients, to determine the influence of RARP case volume on outcomes of RARC. [12] Twenty-one surgeons from 14 participating institutions were divided into four groups with previous experience of RARP, ranging from <50 cases to >150 cases. The mean duration of surgery was shortest in the 50-100 cases group (338 min), with a 20% decrease in time from those who had performed >50 cases to those who had performed >150 cases. The mean EBL was lowest in the most experienced group (188 mls). A 32% reduction in EBL was noted from increase in experience from >50 cases to 51-100 cases. Interestingly, previous RARP experience demonstrated an increase in margin status with increasing previous experience; however, this did not reach statistical significance. On a multivariable analysis, it was found that surgeons with 51-100 RARP experience were 60% less likely to have EBL of >300 mls and 75% less likely to have an operative time of >6 h. This group was also likely to remove more number of lymph node (LN) than those with <50 cases experience. The IRCC concluded that previous robotic experience affects outcomes, including operative time, EBL and LNY; however, it has no influence on the margin status.

Lymphadenectomy

Lymphadenectomy at the time of RC has been shown to improve oncological outcomes for patients with invasive bladder cancer. [9] In RARC, the number of LN removed was reported to be related to the surgical volume and surgeon's experience. [13] The study by Hellenthal et al. reviewed the IRCC database to determine the predictors of the quality of lymphadenectomy at the time of RARC. [14] The study reviewed data from 527 patients and categorized the cohort into various groups based on age, T stage, nodal status, previous surgical experience and surgeon and institutional volume. Overall, 83% patients had more than 10 LN removed. The study reported that the performance of lymphadenectomy was significantly associated with tumor stage (pT4), sequential case number, institution volume and surgeon volume. On a multi-variable analysis, it was found that higher-volume surgeons were 2.37-times more likely to perform lymphadenectomy. Each segmental increase in sequential case number also increased the likelihood of undergoing lymphadenectomy. The post-regression analysis predicted the possibility of lymphadenectomy to rise from 65% to 95% with one case volume to 100 case volumes. Similarly, the probability of lymphadenectomy increased from 70% to 90% with institutional sequential case number increase from the first 10 cases to 41 cases and beyond. The IRCC concluded that the rate of lymphadenectomy during RARC was comparable to the open series in the IRCC cohort. High-volume institutions and surgeons were more likely to perform lymphadenectomy.

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 the eLND group had >10 LN removed. Performance of an eLND was significantly associated with sequential case number, surgeon volume and institution volume. The IRCC reported that by the 51 st case, patients were 4.4-times more likely to undergo eLND. Surgeons with more than 50 cases were 9.5-times more likely to perform eLND. High-volume institutions (>100 cases) were 10-times more likely to perform eLND. On the multivariable model, institutional volume and sequential case number remained as significant predictors of eLND. The IRCC concluded that the results for eLND in the RARC group were comparable to the reported literature for the open technique. Institutional and surgeon volumes were the only predictors for performance of an eLND during RARC.

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.

Current status and future direction

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. However, access to the database is currently limited and is offered following an extensive process of Institutional Review Board (IRB) approval and 3 rd 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.

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