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Prevention and management of complications following robot-assisted radical cystectomy: Lessons learned after >250 consecutive cases

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Abstract

An increasing number of case series of robot-assisted radical cystectomy describe complication rates comparable to open series. Conflicting reports describe various pre-operative factors as predictors of post-operative complications. Furthermore, learning curves complicate these predictors and should also be taken into account. Despite these variables, there are a number of considerations, including patient selection, peri-operative care pathway, intra-operative technique and equipment choice that we have found to decrease post-operative complications and improve patient outcomes. In this topic paper, we briefly review the literature surrounding complication rates following robot-assisted radical cystectomy as well as describe our experience after >250 cases, outlining our suggestions for avoidance of surgical complications when building a practice that incorporates this technique.

Introduction

Radical cystectomy remains the gold standard for the surgical treatment of clinically localized, muscle-invasive urothelial carcinoma of the bladder and has also been employed for patients with aggressive non-muscle-invasive urothelial carcinoma, including recurrent carcinoma in situ (CIS) and selected high-grade T1 lesions. It is nevertheless a daunting operation associated with significant complication rates and a mortality rate of 2%.[1] With the advent of laparoscopic and robotic techniques in pelvic surgery, minimally invasive techniques for radical cystectomy began to develop. The first laparoscopic radical cystectomy was described by Parra *et al*[2] in 1992, but due to challenges associated with this technique, there were few other cases of laparoscopic cystectomy described in the ensuing decade. The development of robotic surgery helped refine this technically challenging approach, and the experience afforded by the widespread application of robot-assisted radical prostatectomy paved the way for the introduction of robot-assisted radical cystectomy (RARC).

Since the first reported series in 2003, there has been a significant increase in the use of the robotic technique for bladder cancer with an increasing focus on complications. Open radical cystectomy (ORC) is associated with overall complication rates approaching 70% (when utilizing strict reporting criteria).[3] Despite the large number of complications noted

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with this procedure, a wide range of figures has been reported. This disparity exists due to differences and duration in reporting methodology, thus representing a major limitation when comparing techniques and institutions. In this paper, we sought to briefly review the literature defining complication rates and establishing predictive factors contributing to complications, and discuss our experience and lessons learned with prevention and management of complications at the University of North Carolina at Chapel Hill after over 250 consecutive RARC cases.

Review of peri-operative and post-operative complications of robot-assisted laparoscopic radical cystectomy

Several single center series now exist, many reporting complication rates for RARC. These range from an overall complication rate of approximately 30–70% and major complication rate of 8–33% in various series.[4–8] The majority of most complications in these series are categorized as gastrointestinal, thromboembolic, infectious, and genitourinary. A cursory review of the literature reveals that complication rates vary widely due to difficulty in event capture, many of which occur at local, non-tertiary hospitals, remaining undiscovered. Furthermore, a number of prior studies do not adhere to standard reporting guidelines (such as the MSKCC grading or Clavien classification systems) although recent studies have begun to routinely include these categorizations. While understanding robotic complication rates is an important tool in quality improvement, another pertinent question is its comparison to the gold standard open technique.

Numerous studies have attempted to provide estimates of complication rates for RARC and also offer a comparison between this procedure and open cystectomy. However, the vast majority remains non-randomized and represents retrospective data series, with the inherent limitation of selection bias. Lower overall and major complication rates have been identified for RARC in several non-randomized case series,[9, 10] but a matched case comparison study, attempting to remove inherent selection bias, revealed no difference in complication rates between RARC and ORC patients.[11]

To further eliminate selection bias, two randomized trials comparing ORC and RARC have been published to date.[12, 13] Nix *et al* reported results of our prospective, randomized study, including 20 patients undergoing ORC and 21 in the RARC cohort. Although designed as a non-inferiority study comparing lymph node yield, several secondary endpoints, including complication rate, were evaluated. Patient characteristics were similar between both groups. Comparing those undergoing open and robotic procedures, there was no difference in complication rates (50% vs 33%, respectively; p=0.28). In a multivariate analysis controlling for age, body mass index, and pathologic stage there was a trend toward a lower complication rate in the robotic group, but it did not reach statistical significance (p=0.0503). In similar fashion, Parekh and colleagues published their results of randomization of 40 patients, with 20 patients undergoing robotic and 20 open. No differences were found in complication rates of Clavien grade 2 or higher. A multi-institutional, randomized study is currently underway, the results of which will clarify the differences between complications following either technique.

While comparisons between open and robotic cystectomy is a valid question, perhaps a more important inquiry involves the identification of preoperative factors that may predict postoperative RARC complications. Through stratification of multiple variables, several risk factors have been associated with RARC complications. However, these findings have not been replicated in other institutional series. For example, Butt et al[14] found advanced age to be a predictor of complications whereas two other studies, the latter of which was a multi-institutional study, revealed that increased age predicted fewer complications with the

robotic approach.[15, 16] Ultimately, better predictors of functional status and other more specific variables will be necessary to acquire reliable measures of risk stratification.

Another etiology for differing complication risk factors is the effect of surgeon experience and a steep learning curve. Whereas most studies have focused on the intra-operative and pathologic variables, a few have examined the impact of experience on complication rates. Pruthi *et al* evaluated the learning curve for their initial 50 patients.[18] Comparing complication rates between the first and second cohort of 25 patients, no differences were observed. Hayn *et al* performed a similar analysis on their first 164 consecutive patients.[19] Dividing patients into three groups (<50, 50–100, >100 cases), no significant differences were observed with both estimated blood loss as well as complication rates. Richards *et al* published their experience with the initial learning curve for robot-assisted radical cystectomy after 60 cases and found a significant decrease in complications from 70% in the first 20 cases to 30% in the second and third tertiles.[21] These studies offer conflicting data regarding the role of the learning curve for RARC, which most likely reflects the surgeons' prior experience with robotic surgery (and possibly the patient makeup of their practice) thereby making it difficult to draw definitive conclusions and provide recommendations of when a surgeon can expect to overcome these hurdles.

Preventive Strategies to Avoid Complications after RARC

As we outline above, the incidence of complications following radical cystectomy remains significant regardless of approach. Although one may believe that the robotic approach might decrease complications as suggested in non-randomized studies, this has yet to be shown definitively. As we detailed above, many studies have examined pre-operative and learning curve factors, and based on these data, an important surgeon-driven factor contributing to complications involves the adaptation of the robotic system for radical cystectomy. As an institution that has performed over 250 RARCs over the past six years and continues to routinely perform this procedure, we believe there are several preventive strategies which may help reduce complications.

First, appropriate patient selection cannot be overemphasized when early in one's experience. We would recommend beginning with a thin male patient with a non-bulky tumor. With a male patient, several parallels can be drawn from the maneuvers employed during robotic prostatectomy. This familiarity will maintain acceptable operative times early in the learning curve. Furthermore, patient size is often an important factor in difficulty level, with some of the most challenging robotic cases performed on the morbidly obese. Technical issues relate to appropriate retraction and left ureteral identification due to the large amount of retroperitoneal, mesenteric, and epiploic fat in obese patients. Lastly, avoidance of locally advanced and large T1/ T2 tumors is crucial. Bulky tumors can result in significant difficulty with anterior retraction of the bladder during the posterior dissection. This particular problem will place the surgeon at risk for rectal injury and inadvertent entry into the bladder due to the lack of a posterior working space. If this situation is encountered, use of a 0-degree or 30-degree upward-facing lens may be warranted, as this may provide improved visualization of the underside of the bladder. Nevertheless, we feel it is advisable to wait until one is past their learning curve before taking on these challenging cases to avoid complications.

While many complications during one's early operative experience may be avoided through patient selection, an emphasis should also be placed on preoperative and postoperative pathways. During the past six years, we have developed a "fast track" method to maximize outcomes and minimize morbidity. Preoperative bowel preparation has now been eliminated based on recent colorectal literature suggesting no significant benefit.[22] Based upon this evidence, we evaluated two sequential case series of 70 patients who underwent radical

cystectomy and urinary diversion with the first cohort undergoing preoperative mechanical bowel preparation (clear liquid diet, magnesium citrate solution, and an enema) and the second cohort given a regular diet before surgery without mechanical preparation (except for an enema prior to surgery to decrease rectal/colonic distension).[23] No differences in return of bowel function, length of stay, or overall complication rates were found between the two groups. More importantly, when specifically evaluating the rate of gastrointestinal complications, no differences were noted (p=0.494). Based on this evidence, we choose to omit a mechanical bowel preparation, with the exception of an enema which serves to debulk the rectum, thereby reducing the chance of rectal injury during posterior dissection.

Similar to this pre-operative strategy, our post-operative pathway for radical cystectomy is now standardized as well. We studied 362 consecutive patients undergoing open or robotic radical cystectomy and urinary diversion, with each undergoing a peri-operative care plan (also known as the “fast track” program).[24] This program includes extensive preoperative counseling with regard to expectations as well as an intra-operative surgical plan which includes deep venous thrombosis (DVT) prophylaxis with sequential compression devices and compression stockings, peri-operative antibiotics in accordance with the American Urological Association guidelines, continued for 24 hours post-procedure, and removal of the orogastric tube at the end of the procedure. Post-operatively, DVT prophylaxis is begun with early ambulation (on post-operative day 0), compression stockings, and subcutaneous enoxaparin begun on postoperative day 1. Additionally, patients are provided gastrointestinal ulcer prophylaxis with an H2 blocker as well as a pro-kinetic agent (metaclopramide 10mg daily × 48 hours), non-narcotic analgesics (e.g. ketorolac 30mg IV q6hr × 48 hours, converted to celecoxib 200mg po BID), and supplemental pain management with narcotics. With regard to diet, the fast track program begins with NPO status and chewing gum (ad lib) on post-operative day 1, 8 ounces of non-carbonated clear liquids every 8 hours on post-operative day 2, unrestricted non-carbonated clear liquids on post-operative day 3, and a regular diet on post-operative day 4. Diet advancement is performed regardless of bowel function, and is only held or decreased in the setting of vomiting or intractable nausea. Finally, patients are offered home health services to assist with ostomy care (or catheter flushing, in the case of an orthotopic diversion). With this pathway, we have found a lower rate of gastrointestinal complications and a favorable complication profile.

While pre-operative and post-operative care plans are central in standardization of care and avoidance of complications, several intra-operative techniques may also be employed to avoid post-operative complications. Ureteral dissection is an important part of RARC as ureteral strictures represent one of the most troubling late complications of urinary diversions. A majority of these strictures arise from ischemia of the distal ureter, which may result from poor surgical technique during ureteral mobilization. Care must be taken to avoid tension during dissection. After posterior dissection, the ureter is usually elevated by a robotic arm. Because there is a lack of tactile feedback, excessive tension may be inadvertently placed on the ureter. It is therefore critical to use visual cues to constantly assess this degree of tension. Just as one would ensure maintaining peri-ureteral tissue during an open cystectomy, this principle must be similarly applied during RARC.

Another modification which we implement to maximize ureteral vascular health is the limitation of proximal mobilization to just above the common iliac vessels. This enables mobilization of the ureter away from the working field during extended pelvic lymphadenectomy while maintaining perforating vessels to the ureter above the aortic bifurcation. Although it may be tempting to perform additional proximal dissection, this additional length is rarely needed to complete the urinary diversion, even if done through a small incision during extracorporeal reconstruction. When handling the ureter during this

reconstruction, it is important to make a larger incision for specimen extraction and creation of diversion. This will allow for the creation of the ureteroenteric anastomosis without additional ureteral tension exacerbated by a small incision. We believe that the benefits of a robotic approach will not be undone through extension of this incision. Ultimately, performance of an incorporeal urinary diversion may be the definitive solution to avoid tension-related insults to the ureteral blood supply, and we continue to evaluate this approach on an ongoing basis.

While ureteral complications are certainly troublesome, a rectal injury can be a disastrous complication which could result in a colostomy, rectal fistula, and even death if unrecognized. When performing the posterior dissection in male patients, particular attention should be paid to careful and thorough mobilization of the rectum to avoid injury during division of the vascular pedicles. Our preference for division of these pedicles is with use of a vascular stapler. The posterior dissection usually becomes more difficult as one progresses distally, and it should be kept in mind that the rectum lies in a more anterior location when approaching the prostatic apex. We recommend allotting adequate time to fully mobilize the distal aspect of the rectum away from the prostate in much the same fashion as one prepares for neurovascular bundle preservation during a robot-assisted radical prostatectomy. Once this is accomplished, the surgeon will be left with a narrow column of vascular tissue from the superior vesical artery to the prostatic apex. This will allow safe application of the vascular stapler above all rectal tissue. If the separation of the bladder/prostate and rectum is difficult, we would then recommend proceeding cautiously through isolation of individual pedicles as one progresses distally, using Hem-o-lok (weck) clips for vascular control.

If a rectal injury is encountered, primary repair can be performed robotically in the majority of cases. If the primary surgeon is uncomfortable, consultation from general surgery colleagues is recommended. However, most injuries can be repaired using the robotic technique by freshening the edges of the rectal opening after copiously irrigating the field. Anal dilation is not routinely performed. Duplicating open techniques, a meticulous 2-layer closure should be performed by approximating the mucosal layers followed by the outer seromuscular layer with 2-0 polyglactin (vicryl) suture. If possible, omentum can be carried down (which can be harvested during the urinary diversion) to tack over the repair to further aid in wound healing.

Although the extirpative portion of RARC is undeniably the focus of the procedure, the prognostic and therapeutic benefits of an extended pelvic lymphadenectomy (PLND) at the time of radical cystectomy are also important and have been well established.[25] The ability to perform an adequate PLND during RARC has been a popular target for opponents of the robotic approach. However, this has been refuted by several authors,[12, 26, 27] and we contend that a meticulous dissection of any template can be performed robotically if the surgeon is committed to this goal. One of most challenging aspects of the PLND is performing an adequate and safe dissection of the lymphatic tissue in the bifurcation of the common iliac vessels. The difficulty of dissection can be greatly decreased by exposing the space of Marseille through medial mobilization of the external iliac vessels and all associated lymphatic tissue. This will expose the medial aspect of the psoas muscle and the most proximal aspect of the obturator nerve while releasing all lateral attachments of this nodal packet. It will further allow the surgeon to return to the medial side of the vessels and easily withdraw the entire lymph node packet from the bifurcation of the vessels. Overall, this will not only help decrease the risk of a vascular injury to the hypogastric vessels and alleviate the anxiety associated with dissection in this challenging area but also allow excellent access for the hypogastric vein dissection.

The development of a symptomatic lymphocele is a rare event, <1% in our experience. This is mainly due to the transperitoneal nature of the surgery, but an attempt is made to seal all distal lymphatics with locking clips. Another possible complication during lymphadenectomy includes obturator nerve injury, also a rare event (<1%) in our experience due to careful identification of the structure prior to proceeding with node dissection. However, if the nerve is transected, end-to-end repair with interrupted 6-0 nylon or braided polyester (Ethibond) sutures can be performed to achieve a tension-free anastomosis, usually with consultation from neurosurgery or plastic surgery.

Radical cystectomy and pelvic lymphadenectomy can also be associated with significant blood loss. Reports of robotic cystectomies have consistently shown decreased blood loss, which is likely related to the use of pneumoperitoneum. Despite this, surgeons need the ability to address acute hemorrhage from a vascular injury during RARC. Although rare (<5%), the most common site of bleeding is from avulsion of a small branch of the common iliac vein during extended lymph node dissection, in our experience. If a stump remains on the iliac vein, this can be controlled by grasping the stump with a Prograsp while the assistant places a small, locking clip. If no stump is present, the pneumoperitoneum can be increased to 20mmHg while bleeding is controlled with pressure applied by the 4th robotic arm or bedside assistant. This allows time to exchange the working robot arms to needle drivers, enabling suture repair of the injury. Bleeding from pre-sacral vessels is generally less brisk, but can be troubling and impair visualization. These vessels can be controlled with bipolar electrocautery or suture ligation, which may require placement of the suture through the periosteum of the sacrum. If a larger injury in encountered which cannot be controlled by the above techniques, then one can consider attempting to obtain proximal and distal control of the involved vessel. This can achieved with the use of laparoscopic vascular and/or bulldog clamps. If open conversion is required, the bedside assistant should hold pressure on the injury as the robot is undocked and the incision is made.

In addition to operative technique, the proper equipment is also critical to avoid complications. There are several instruments/ports which will simplify the procedure. First, use of a 12mm and 15mm port for the bedside assistant is essential. The 15mm port can be placed in the lateral position, and this larger port will allow easier extraction of lymph node packets as well as placement of a 15mm extraction bag for the final specimen. The 12mm assistant port is placed in the medial position, cephalad and just medial to the left robotic arm (for a left-sided bedside assistant). This allows placement of an endovascular stapler directly across the pedicles of the bladder. If this port is placed lateral to the ipsilateral working arm, the approach to the bladder pedicle can be difficult as the stapler cannot articulate enough to overcome the acuity of the angle. We use a bariatric/long stapler which will easily reach the pelvis despite the fairly cephalad port location. As previously mentioned, Hem-0-loc (weck) clips are commonly used for portions of the cystectomy. We strongly recommend the use of the 15mm (gold) clips to allow control of larger tissue pedicles.

With the use of the above-mentioned advice for patient selection, perioperative care pathways, intra-operative technique and instrument selection, we believe that many complications can be avoided. Vascular, obturator nerve, and rectal injury rates have decreased to less than 1–5% in our series. Furthermore, reoperation rates are equally low; due in part to the implementation of the techniques we describe above.

Conclusions

An increasing number of case series of robot-assisted radical cystectomy describe complication rates comparable to open series. Conflicting reports describe various pre-

operative factors as predictors of post-operative complications. Furthermore, learning curves complicate these predictors and should also be taken into account. Despite these variables, there are a number of considerations, including patient selection, peri-operative care pathway, intra-operative technique and equipment choice that we have found to decrease post-operative complications and improve patient outcomes.

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