Comparative Analysis of Early Perioperative Outcomes Following Radical Cystectomy by Either the Robotic or Open Method

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ABSTRACT

Objective: We analyzed early perioperative outcomes following radical cystectomy by the robotic method compared with the conventional open method.

Methods: All relevant clinical information was entered in a Microsoft Access Database and queried. P<0.05 were considered statistically significant.

Results: The study cohort comprised 37 consecutive patients undergoing radical cystectomy; 24 (64.9%) cases were performed by the conventional open method and 13 (29.7%) by the robotic method. Body mass index, age, sex, blood transfusion rate, and median decrease in hemoglobin were comparable between the 2 groups. The robotic method resulted in significantly lower median estimated blood loss, shorter hospital stay, and longer operating time compared with the open group (P<0.05). Four (16.7%) perioperative complications occurred in the open group compared with 2 (15.4%) in the robotic group (P=1.0). The incidence of organ-confined (≤T2N0Mx) disease was 9 (37.5%) and 7 (53.8%) in the open and robotic groups, respectively (P=0.49).

Conclusions: Radical cystectomy by the robotic method produces early perioperative results comparable to those of the open method. Although intraoperative estimated blood loss and hospital stay were significantly lower in the robotic group, operative time was longer which likely reflects our early operative experience with radical cystectomy by the robotic method.

Key Words: Robot, Laparoscopy, Urological surgery, Cystectomy, Outcome.

INTRODUCTION

Bladder cancer (BC) is the fourth and fifth most commonly diagnosed malignancy in the United States and Europe, respectively. It is estimated that in the year 2005, 63,210 new cases of BC will be diagnosed in the United States alone. Approximately one fifth of these patients will undergo radical cystectomy (RC) and urinary diversion (UD). RC has become an established standard of care for patients with muscle invasive BC in the United States. Despite our better understanding of pelvic anatomy and improved surgical techniques, RC is still associated with significant perioperative complications, including significant intraoperative blood loss. Therefore, a need persists for technological advances that would minimize intraoperative blood loss and decrease perioperative complications in patients undergoing RC. The most notable of recent advances in surgical techniques is the increased application of minimally invasive laparoscopic surgery in the management of urological disorders. The established advantages of laparoscopic surgery include decreased pain, shorter hospital stay, and decreased intraoperative blood loss compared with these things in conventional open surgery. There is still room for improvement, however, as the current laparoscopic technology is limited due to the lack of 3-dimensional visualization and poor ergonomics.

Recently, the da Vinci Surgical Robotic System (DSRS) has been added to the armamentarium of minimally invasive surgery. The DSRS adds the much needed 3-dimensional vision, 6 degrees of freedom of movement, and improved ergonomics to laparoscopic techniques. The DSRS is being increasingly used to perform complex urological procedures including radical prostatectomy, radical cystectomy, and urinary diversions. Menon et al first reported the use of the DSRS to perform RC both in men and women with decreased blood loss and operative time less than 4 hours. Several other groups have also reported successful use of the DSRS in performing RC. However, most of the published studies are limited to a small cohort of patients without comparison with the conventional open method (OM). To establish the efficacy of robotic radical cystectomy, we compared the early perioperative outcomes of patients...
undergoing RC by either OM or the robotic method (RM).
This study includes a cohort of 37 consecutive patients undergoing RC by OM or RM over the same time period by a single surgeon, thereby minimizing the influence of selection bias and multiple surgeons on perioperative outcome.

METHODS
All relevant clinical information on patients undergoing robotic urological procedures at our institution is maintained in a prospectively established Microsoft Access database. An Institutional Review Board (IRB) exempt status was obtained because all patient identifiers are deleted after pertinent clinical information is obtained. This study consists of 37 consecutive patients undergoing open and robotic RC since the approval of DSRS for human use in the year 2000. The procedures were carried out at 2 teaching institutions, a University hospital and Veterans Administration Medical Center, by a single surgeon. Because the DSRS was available only at the University hospital, the option to undergo RC by RM was offered to patients at the University site with the following exclusion criteria: morbid obesity (generally body mass index >35), prior pelvic radiation, or significant medical comorbidities including pulmonary obstructive airway disease. Variables analyzed included age, sex, body mass index (BMI), operative time, postoperative analgesic use, estimated blood loss (EBL), blood transfusion rate, hospital stay, final pathology results, and early perioperative complications before discharge from the hospital.

Surgical Technique (Robotic Radical Cystectomy)
The patients, while under general anesthesia, were placed in the lithotomy and steep head down position with a nasogastric tube and urethral catheter in place. The procedure was carried out intraperitoneally following insufflation of the abdomen with CO₂ up to 15 mm Hg pressure obtained using a Veress needle. Five ports were used including a 12-mm left paraumbilical camera port, two 8-mm robot working ports placed approximately 8 cm from the camera port on either side forming a 15° to 30° angle inferiorly and 2 additional 5-mm to 12-mm working ports (One Step Port, U.S. Surgical, Norwalk, CT) in the right lower quadrant of the abdomen. Operative steps in male patients, in order, included dissection of the vas deferens on both sides leading posterior to seminal vesicles, dissection of the prerectal space posterior to the prostate, bilateral ureteral mobilization from close to the lower pole of the ipsilateral kidney to the ureterovesical junction (UVJ) before clipping, division close to the UVJ and tagging using 12-inch long 2 “0” absorbable sutures, incision of endopelvic fascia on both sides, securing the lateral pedicles to the bladder using endovascular staplers, division of the medial umbilical ligaments to enter the retropubic space, division of deep dorsal venous complex, completely freeing up the specimen before trapping in an Endocatch II bag (U.S. Surgical, Norwalk, CT) and removal of the intact specimen through an approximately 5-cm midline periumbilical or suprapubic incision. A similar technique was used in women with appropriate modifications for female anatomy. The rent in the anterior vaginal wall was closed primarily with DSRS using 2 “0” Vicryl sutures supported by greater omental mobilization done extracorporeally at the end of the procedure. A bilateral limited pelvic lymph node dissection was carried out intracorporeally, which included obturator and external iliac groups of lymph node. This node dissection was performed either before or after the radical cystectomy. Urinary diversion was carried out extracorporeally through the same incision.

Statistical Analysis
The Wilcoxon rank sum test was used to compare distributions of continuous variables between the OM and the RM. Categorical variables were compared between the 2 surgical methods using Fisher’s exact test. \( P<0.05 \) was considered statistically significant.

RESULTS
During our study period, 37 patients underwent RC, 24 (64.9%) by OM and 13 (29.7%) by RM. All urinary diversions were performed extracorporeally in the RM group. Of these, 6 patients underwent ileal conduit, 5 underwent ileal neobladders, and 2 underwent Indiana pouch urinary diversions. In the open group, 16 patients underwent ileal conduits, 7 underwent ileal neobladders, and 1 underwent an Indiana pouch urinary diversion. Two patients in the OM group underwent simultaneous pelvic exenteration for a rectal malignancy. The BMI, age, sex, blood transfusion rate, and drop in hemoglobin were comparable between the 2 groups (Table 1). Median EBL and length of hospital stay for RM were significantly lower compared with that for OM \( (P=0.0002) \) and \( P=0.044, \) respectively. Operating time for RC and urinary diversion (UD) was significantly longer in the RM group \( (P=0.0002) \). There were 3 (12.5%) positive margins in the OM group and none in the RM group \( (P=0.54) \). Four
(16.7%) perioperative complications occurred in the OM group; and 2 (15.4%) occurred in the RM group, $P=1.0$ (Table 2). One perioperative death caused by central venous line sepsis occurred in the OM group. The incidence of organ-confined ($\leq T2N0Mx$) and nonorgan-confined disease ($\geq T3$) was 9 (37.5%) and 15 (62.5%) in the OM group compared with 7 (53.8%) and 6 (46.2%) in the RM group ($P=0.49$).

### Table 1.
Comparison of Characteristics of Patients Undergoing Radical Cystectomy by Open or Robotic Methods

| Characteristics                                      | Total (N = 37) | Open Method (N = 24) | Robotic Method (N = 13) | P  |
|------------------------------------------------------|----------------|----------------------|-------------------------|----|
| Age (years) median (range)                           |                |                      |                         |    |
|                                                      | 70 (27–88)     | 70.5 (27–86)         | 70 (38–88)              | 0.96|
| Sex (M:F)                                            | 28:9           | 18:6                 | 10:3                    | 1.00|
| Body mass index median (range)                       | 26.4 (16.1–53.6)| 26.5 (16.1–53.6)     | 25.05 (18.2–43.5)       | 0.67|
| Operative Time (minutes) median (range)              | 460.5 (240–828) | 395 (300–664)        | 697 (240–828)           | 0.0002|
| Estimated blood loss (mL) median (range)             | 750 (100–10200) | 1250 (300–10200)     | 500 (100–1000)          | 0.0002|
| Postoperative drop in Hgb (g/dL) median (range)      | 3.1 (0.4–8.1)  | 3.15 (0.5–6.8)       | 2.4 (0.4–8.1)           | 0.41|
| Blood transfusion rate (N)                           | 25 (67.6%)     | 18 (75%)             | 7 (53.8%)               | 0.27|
| Positive surgical margins (N)                         | 3 (8.1%)       | 5 (12.5%)            | 0 (0%)                  | 0.54|
| Stage (TNM staging, 1997 AJCC) (%)                   |                |                      |                         |    |
| Organ-confined ($\leq T2$)                           | 16 (43.2%)     | 9 (37.5%)            | 7 (53.8%)               | 0.49|
| Nonorgan-confined ($\geq T3$)                        | 21 (56.8%)     | 15 (62.5%)           | 6 (46.2%)               |      |
| Node positive disease at time of surgery (%)         | 6 (16.2%)      | 4 (16.8)             | 2 (15.4)                | 1.00|
| Final pathological diagnosis (%)                     |                |                      |                         |    |
| Transitional cell carcinoma                          | 33 (89.2%)     | 20 (83.2)            | 13 (100)                | 0.80|
| Rectal adenocarcinoma                                | 2 (5.4%)       | 2 (8.4)              |                         |      |
| Prostate adenocarcinoma                              | 1 (2.7%)       | 1 (4.2)              |                         |      |
| Leiomyosarcoma                                        | 1 (2.7%)       | 1 (4.2)              |                         |      |
| Hospital stay (days) median (range)                  | 10 (4–35)      | 10 (6–35)            | 8 (4–23)                | 0.044|
| Perioperative complication rate (N)                  | 6 (16.2)       | 4 (16.7)             | 2 (15.4)                | 1.00|

### Table 2.
Early Perioperative Morbidities Following Radical Cystectomy by Open or Robotic Methods

| Morbidity 4 (16.7%)                                   | Morbidity 2 (15.4%)                                   |
|-------------------------------------------------------|-------------------------------------------------------|
| 1. Wound dehiscence                                   | 1. Enterovesical fistula, small bowel obstruction     |
| 2. Myocardial infarction with new onset atrial fibrillation | 2. Abdominal abscess                                  |
| 3. Pneumonia                                          |                                                       |
| 4. Myocardial infarction with pulmonary embolus       |                                                       |
**DISCUSSION**

Because RC is usually performed in older patients with malignancy and associated nutritional deficiencies, RC is often associated with high postoperative complication rates.5 In spite of several modifications to the open surgical techniques, RC is still associated with increased intraoperative blood loss. Chang et al reported median blood loss of 600 mL in a series of over 300 patients undergoing RC.6 The increased use of minimally invasive surgical techniques to perform major urological operations, such as radical prostatectomy and nephrectomy, over the last decade has resulted in significantly decreased intraoperative blood loss compared with their respective open methods.15 Several published reports establish the feasibility of safely performing robotic radical cystectomy (Table 3). However, these cases have not been compared with open methods.

Our current study demonstrates a similar and significant decrease in EBL in the RM group compared with that in the OM group ($P=0.0002$) with a consequent decrease in blood transfusion rates. In this study, 18/24 (75%) patients in the OM group received blood transfusions compared with 7/13 (53.8%) in the RM group despite the fact that only 4 patients in the RM group had blood loss over 500 mL. Blood transfusion rates in this study are clearly much higher than rates of about 30% in other published studies. At our institution, blood transfusions are carried out without the benefit of well-established critical care pathways.6 In addition, because of the lack of prior experience in accurately estimating blood loss during robotic RC, patients received blood transfusions more readily, which accounts for the high blood transfusion rates in this series of patients. For purposes of calculation, postoperative hemoglobin was collected and recorded on postoperative

| Study                | No. of Cases (Male: Female) | Ports | PLND/ EPLND* | Operative Time* | Estimated Blood Loss | Surgical Margins | Urinary Diversion | UD Extracorporeal/ Intracorporeal | Conversion to Open |
|----------------------|-----------------------------|-------|--------------|-----------------|---------------------|-----------------|------------------|-----------------------------------|-------------------|
| Menon et al15        | 14 (14:0)                   | 5–6   | EPLND        | RC median = 140 min, UD-IC median = 120 min, UD-ONB median = 168 min | $<150$            | Negative W-pouch-19, Double chimney-2, T pouch-1 | IC-2               | Extracorporeal                     | None               |
| Beecken et al19      | 1 (1:0)                     | 5     | PLND         | RC + UD = 550 min | 200                | Negative          | UD-Hartman ileal neobladder | Extracorporeal                     | None               |
| Yohannes et al20     | 2 (2:0)                     | 5     | PLND         | 10 hours; 12 hours | 435; 1800          | Positive (1)     | IC reconstructed | Intracorporeal                     | None               |
| Menon et al16        | 3 (0:3)                     | 5–6   | EPLND        | RC = 150; 160; 170 min, UD = 130; 190; 170 min | 150; 250; 100      | Negative W-pouch-1, T pouch-3 | IC-1               | Extracorporeal                     | None               |
| Galich et al (present study) | 13 (10:3)      | 5     | PLND         | RC(P) + UD range = 240–828 min, RC(P) + UD median = 697 min | 100–1000           | Negative W-pouch-5, Indiana pouch-2 | IC-6               | Extracorporeal                     | None               |

*PLND = pelvic lymph node dissection; EPLND = extended pelvic lymph node dissection; IC = ileal conduit; ONB = orthotopic neobladder; RC(P) = radical cystectomy and cystoprostatectomy; UD = urinary diversion.
day one. Because several patients had received intraoperative or immediate postoperative blood transfusions, the lack of significance of postoperative hemoglobin change may not accurately reflect intraoperative blood loss.

The operative time for performing RC and urinary diversion was significantly longer in the RM group than in the OM group. Although several of the initial cases of RC by RM lasted for more than 4 hours, RC including pelvic lymph node dissection in the last 3 patients was completed consistently in less than 4 hours. The improving operative time corroborates the published conclusions in the literature\textsuperscript{15,16} that robotic surgery can be performed efficiently with operative time comparable to that of OM with increasing experience. In this study, we do not report the operative time for RC and urinary diversions separately because of lack of such data for the OM cases.

In spite of the minimally invasive nature of RM, the difference in hospital stay in the RM group was only marginally better although statistically significant, median of 8 days (range, 4 to 23) compared with 10 days (range, 6 to 35) in the OM group ($P=0.044$). Following RC by RM, the specimen was removed through a small midline abdominal incision, and UD was performed extracorporeally in all patients. The patients’ hospital stay was directly related to the time required for return of the bowel function. Therefore, irrespective of the method of RC the return of bowel function was comparable between the 2 groups resulting in a minimal difference in hospital stays. Although we have previously reported on totally intracorporeal robot-assisted laparoscopic ileal conduit urinary diversions, we resisted our temptation to perform urinary diversions totally intracorporeally to limit operative time.\textsuperscript{14}

The primary goal of our study was to evaluate early perioperative outcomes. The sample size is relatively small and the follow-up data are currently not mature enough to evaluate oncological outcomes. All 3 cases of positive margins occurred with OM, 1 in a patient with locally advanced prostatic adenocarcinoma and the other 2 in patients with locally advanced pT3b and pT4a transitional cell carcinoma of the bladder. Although not statistically significant, almost two thirds of patients undergoing RC by OM had nonorgan-confined disease compared with about half in the RM group ($P=0.49$), which could possibly account for the increased positive margin rate in those undergoing OM. Alternatively, the DSRS provides excellent visualization by 10X magnification that facilitates meticulous dissection around the tumor, which could have contributed to decreased positive margin rates. Although, a large randomized cohort of patients comparing RC by OM or RM is necessary to resolve the issue, it nevertheless raises an interesting hypothesis that RC by RM may decrease positive surgical margins.

Overall perioperative complication rates were comparable between the 2 groups; 4(16.7%) and 2(15.4%) in OM and RM groups, respectively ($P=1.0$). One perioperative death in the OM group resulted from central venous line sepsis. Complication events are too few to identify a distinctive pattern for either method. Several studies evaluating outcomes of patients undergoing radical surgery for prostate and bladder cancer by open methods have demonstrated that the performing surgeon is an independent predictor of outcome.\textsuperscript{17,18} By comparing the perioperative outcomes using a contemporary cohort of patients undergoing RC by conventional OM and RM performed by a single surgeon using our prospectively established LRUSP institutional database, we minimized the influence of multiple surgeons performing the procedure at different institutions at different time periods on perioperative outcome. Therefore, our data suggest that the same surgeon familiar with the surgical techniques can perform RC by either RM or OM with similar efficacy.

In this study, we have not compared postoperative analgesic use between the 2 methods because several patients in the OM group received epidural analgesia compared with none in the RM group. Although we focused on early perioperative complications, longer follow-up is necessary to evaluate long-term complications. Although the demographics of both groups were comparable, morbidly obese patients were not offered RM as a treatment option, which may have biased the results of this study. Furthermore, the operative time discussed in this study includes the time taken for performing urinary diversions, which limits our ability to comment specifically on the operative time for performing RC alone. Nevertheless, our study establishes the feasibility of performing RC by RM with efficacy comparable to that of conventional OM.

A major impetus to explore the feasibility and efficacy of robotic RC is persistently high complication rates, such as increased intraoperative blood loss in patients undergoing RC by conventional OM, even at centers where a high volume of procedures are performed. Despite being a technically demanding operation, early reports of RC by RM, including the current study have demonstrated excellent perioperative outcomes including significantly decreased blood loss.\textsuperscript{15,16,19} Moreover, robotic pelvic surgery including radical prostatectomy is being increasingly performed, and it may only be a matter of time before RM is
more widely used to perform RC. Therefore, pioneering work such as this study can contribute towards establishing the safety, efficacy, and technical standards for performing RC by RM.

CONCLUSION

Radical cystectomy (RC) with urinary diversion (UD) is relatively commonly performed and arguably one of the most complex of urological operations. RM is technically demanding, but clearly this procedure can be done with early perioperative results comparable to results of conventional open methods. Currently, the operative time is longer with RM; however, it is associated with decreased EBL and hospital stay. Increasing experience may improve operating times for RM. Longer follow-up and a larger cohort of patients are required to establish oncological outcomes.

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