

Robot-assisted radical cystectomy – first Polish clinical outcomes

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Introduction Urothelial cell carcinoma is the most common neoplasm of the genito-urinary tract, which, in advanced stages, is treated with radical cystectomy with pelvic lymphadenectomy. It can be performed by an open or minimally invasive approach (laparoscopic and robot-assisted radical cystectomy). Large meta-analyses showed a significantly lower complication rate in the RARC (robot-assisted radical cystectomy) group compared to ORC (open radical cystectomy) in thirty and ninety days after surgery, with similar oncological and functional outcomes. The clinical outcomes of the first forty Polish RARC are explored in this article.

Material and methods The Polish Radical Robotic Cystectomy Program (PRRC) was started in 2016 at the Nicolaus Copernicus Hospital in Toruń. Forty consecutive patients, with indications for cystectomy were included into the study. During radical robot-assisted cystectomy, obturator, external, internal, common iliac and presacral lymph nodes were dissected. Oncological outcomes, early complication rate, and the clinical variables were analyzed.

Results The mean age in the study group was sixty-seven years, with the majority of patients being overweight and assessed as American Society of Anesthesiology Scale (ASA) – ASA III and ASA IV (2/3 of patients). RARC was performed, with the median time of surgery being 324 minutes (170 minutes being the shortest). Mean blood loss was 365 ml (lowest – 50 ml), and only 2 patients required intraoperative blood transfusion. Twenty patients had ileal conduit, and nineteen had other methods of urinary diversion. Only twenty-nine out of forty patients had minor complications (Clavien I and II), 11 had Clavien III and IV. Clavien V was not present. Only 3 patients required reoperation.

Conclusions RARC is a reproducible oncological procedure, which can be safely performed in centers with robotic expertise, with acceptable operative time, complications, and functional and oncologic outcomes.

Key Words: robot-assisted radical cystectomy

INTRODUCTION

Urothelial cell carcinoma (UCC) is one of the most common neoplasms of the genito-urinary tract. It accounts for 380,000 new cases each year worldwide, and more than 150,000 deaths per year. Radical cystectomy with pelvic lymphadenectomy, with neoadjuvant or adjuvant chemotherapy (in advanced cases) is the method of choice for muscle-invasive urothelial

carcinoma, and provides the best cancer-specific survival compared to other methods of treatment. Cystectomy provides a 5-year recurrence-free survival rate of 68% and overall survival rate around 66%, however, in the group of patients with node-positive disease, it accounts for 34–43% [1]. It is performed by an open (open radical cystectomy – ORC), or minimally invasive approach (laparoscopic radical cystectomy – LRC and robot-assisted radical cystectomy – RARC).

Radical open cystectomy can be related to a number of clinically significant perioperative complications and a prolonged recovery time [2, 3]. On the other hand the learning curve for the laparoscopic technique used in the radical cystectomy setting, is too long and demanding to become the standard approach. Since ORC is a procedure with high morbidity, associated with a number of possible complications, and LRC is difficult to learn, robot-assisted approach was proposed. Menon et al. reported the first series of RARC in 2003 and since that time it has gained its wide popularity [4, 5]. Minimally invasive approach for cystectomy reduces blood loss, analgesic consumption and postoperative complications, makes earlier recovery of bowel function and return to normal activity possible [6].

Since oncologic results for both methods (RARC and ORC) are comparable, robot-assisted approach gained lot of interest, due to its feasibility [7, 8]. Recently published meta-analyses showed an even significantly lower complication rate in the RARC group in thirty and ninety days after surgery ($p = 0.005$ and $p = 0.0002$ respectively) compared to LRC. In case of the minimally invasive approach, level of complications according to the Clavien-Dindo scale was significantly lower in the group with higher grades of complications [4, 5].

Operation time is usually longer in RARC and meta-analysis did show longer operation times in the RARC group compared to the ORC group ($p < 0.0001$), however it also showed lower blood loss in the robotic compared to the open approach group ($p < 0.00001$). The same applies to the length of hospital stay after surgery, which was significantly shorter in the minimally invasive group ($p < 0.0001$) [9].

Costs

Robotic approach is a demanding procedure, and it is associated with high costs, therefore cannot be applied widely in secondary or tertiary urological centers.

When comparing ORC and RARC, taking into consideration only direct costs of the procedure, it seems that RARC can represent a cost-efficient alternative to ORC only, if the robotic procedure can be performed with a short post-operative hospital stay (7 days) and operating room time (no more than 380 min). Those parameters can be met by the high-volume surgeons (at least 7 cases per year) and high volume hospitals (more than nineteen cases per year) [10].

The 2 main methods – minimally invasive and open surgery, do not have many head to head trials comparing these two modalities. Since RARC is more widely used, it seems that it is slowly becoming an appropriate alternative to open radical cystecto-

my. Thus, in this study we explored the safety and efficacy of robot-assisted radical cystectomy.

In Poland there are currently 2 hospitals equipped with the Da Vinci Si system. Such small number is due to a conflicting policy of Intuitive Surgical Inc., deciding not to sell any robotic systems, and not to provide any support for the robotic surgery development in our country. Hopefully, this status will be changed upon reimbursement of the first robotic procedure (radical prostatectomy) by the Polish National Health Fund, which is expected in April/May 2018.

First system, working in Wrocław, is used to operate patients on general basis. System, which is used in Toruń, is intended to treat patients with invasive bladder cancer on the basis of Smart AUCI grant from the Polish National Centre for Research and Development.

On this basis, the Polish Radical Robotic Cystectomy Program (PRRC) was started in September 2016. The first hospital, which joined the program, was Nicolaus Copernicus Hospital in Toruń. The aim of the establishment of this program was to introduce a new method of minimally invasive treatment in the radical cystectomy patients, and to create a platform for conducting tutorials, including patients nationwide, and comparing results of the surgery in different robotic centers. First RARC in Poland was performed in September 2016 in Toruń.

MATERIAL AND METHODS

From September 2016 till May 2017, forty consecutive patients, with indications for cystectomy were included into the study. Inclusion criteria for cystectomy were, according to European Association of Urology (EAU) guidelines: urothelial cT2N0M0-cT4aN0M0 disease, or noninvasive papillary cancer, that cannot be controlled by a transurethral resection. All patients underwent preoperative examinations, which included routine laboratory tests, chest radiogram, abdominal ultrasonography and imaging – computer tomography or magnetic resonance. During the oncologic meeting, only 4 patients were subjected to neoadjuvant chemotherapy, due to renal impairment, bad general condition or advanced age. The same team, operator T.D., and the assistants W.M. and P. A performed all operations.

During the first few operations it took 1.5 hours to set up all of the robotic equipment, place the patient in the correct position, introduce robotic ports and to dock the robot. Later, after performing forty cases it took twenty-five to thirty minutes from anesthesia to dock the robot and start the resection of the bladder. The robot used in our department is the four-arm Da Vinci Si system. During radical cystectomy,

a camera port (13 mm) is introduced above the umbilicus, and two working robotic ports (8.5 mm) at the level of the umbilicus, about 8 cm away from the medial line. Laterally two laparoscopic ports for assistant on both sides are also placed (11 mm and 5 mm) for suction and Hem-o-lok clamp. Robotic instruments, which are used, are: monopolar scissors, fenestrated bipolar forceps for dissection, and two large needle drivers.

Principals of the radical robot-assisted cystectomy (including the prostate in a male and the reproductive system in a female) are similar to the laparoscopic technique and are described by Menon [5]. Apart from bladder and prostate removal, obturator, external, internal, common iliac and presacral lymph nodes were also dissected for pathological analysis, according to the procedures described by Campbell-Walsh Urology [11]. After bladder removal, extracorporeal urinary diversion was performed.

Age, gender, body mass index (BMI), co-morbidities, surgical history, laboratory test results, as well as the operating time (defined as duration of anesthesia), estimated blood loss, and transfusion rates were collected. Anesthesia risk was assessed and scored according to the ASA (American Association of Anesthesiology) Physical Status Classification System. Nutritional status of patients was assessed according to the NRS 2002 (Nutritional Risk Screening) scale [12].

Oncologic variables, and results were noted, and neoplastic disease was staged and classified, according to the TNM (Tumor Node Metastasis) classification system of the Union Internationale Contre le Cancer [13].

Oncological outcomes were analyzed, including positive surgical margin rates (PSM; including urethral/ureteric and soft tissue PSM) and lymph node involvement (LNI). The clinical outcomes were analyzed according to the following definitions: perioperative mortality, death within thirty days post surgery; early complications, occurring within ninety days post cystectomy and late complications, occurring more than ninety days after cystectomy, operative time (OT), estimated blood loss (EBL), transfusion rate (including perioperative and intraoperative transfusion), and postoperative length of hospital stay (LOS) [14]. Complications were classified according to the Clavien-Dindo classification [15].

RESULTS

Forty patients (thirty-one males and nine females) were included into the study with the median age of sixty-seven years. Median hemoglobin level was 13.57 mg/dL. Most of the patients (75%) were overweight, with the mean BMI more than twenty-five.

Nourishment status was assessed, with nearly half of the patients without any nourishment problems (NRS = 0 points). Patient risk of anesthesia was established according to the ASA scale, with 2/3 of patients being assessed as ASA III or IV (Figure 1). Fifteen patients had either one or both sided hydronephrosis, with nephrostomy in order to protect the kidney.

Median time of surgery was 324 minutes, with 170 minutes as the shortest. Mean blood loss volume was 365 ml, with lowest amount of 50 ml. Only 2 patients required intraoperative blood transfusion (both 2 units of blood). Nine patients required blood transfusion up to forty-eight hours post operatively, with the mean of 0.55 units in the whole group. In total, ten patients required blood transfusion throughout the hospital stay.

Mean level of hemoglobin before surgery was 13.57 mg/dL, and after surgery – 11.3 mg/dL, with the mean perioperative hemoglobin loss of 2.27 mg/l. Median hospital stay from admittance till discharge from hospital was 8 days, with the shortest stay of 5 days.

Bladder removal was followed by urinary diversion, which in case of twenty patients was an ileal conduit, and in case of nineteen patients – a ureterocutaneostomy. Choice of urinary diversion was based on surgeons experience. In older patients with poor general status, the simpler diversion was chosen (ureterocutaneostomy). One patient had no urinary diversion because of total urinary tract removal due to panurothelial disease.

Left ureter was transferred to the right side, under the sigmoid colon, with the use of robotic instruments. Extracorporeal ileal conduit was performed by making a small incision in the place of the camera

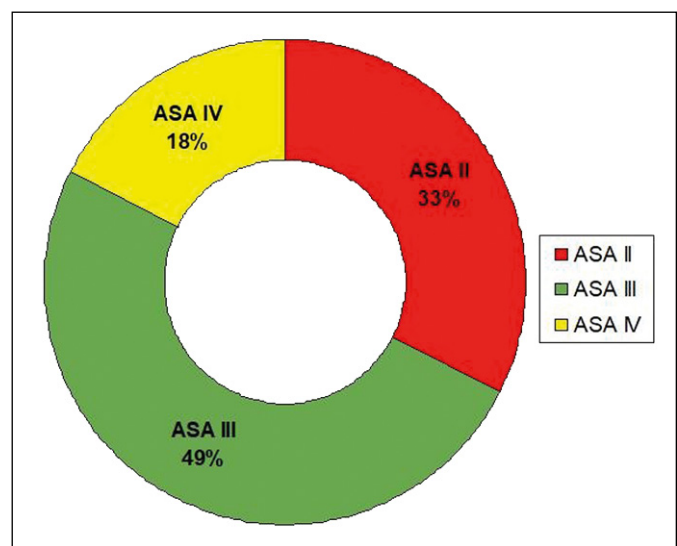


Figure 1. Risk of anesthesia according to the ASA scale.

port insertion (where the resected bladder was removed) and the small intestine was taken out.

Perioperative complications were analyzed, according to the Clavien-Dindo scale. Twenty-nine of the forty operated patients had only minor complications (Clavien I and II). Only eleven patients had Clavien III and IV. Clavien V was not present (Figure 2).

Vascular complications were the most common after surgery, with embolism of Left and right Internal Carotid Artery (LICA and RICA) and thrombosis of the femoral artery. Patency was restored in two patients by the intravascular approach, moreover one patient required an open embolectomy. One patient required a re-operation due to urine leakage from the ileal anastomosis, because of accidental ureteral stent removal on the second day after surgery.

One patient required a reoperation and ICU hospitalization, due to an ileus and rupture of ileo-ileal anastomosis. Clavien-Dindo complications (grades III and IV) are listed in Table 1.

Oncological outcomes

Patients included into the study were in different clinical stages of the disease (from cT1 to cT4a), according to the EAU guidelines. During the oncologic meeting, 4 patients were scheduled to neoadjuvant chemotherapy, and none of them were scored as pT0 disease after operation. Clinical and pathological extent of the disease is presented in Figure 3.

Mean number of lymph nodes removed was twelve, with highest number of thirty-one. In general common, external, internal iliac, obturator and presacral lymph nodes were removed. In twelve patients metastasis were found in resected lymph nodes. Positive surgical margins were found in 5 patients. All 5 patients were classified as pT4aN1-3M0 disease. Three patients had cancer, invading the urethra (with positive urethral margins) and 1 of them had sphincter infiltration. Two had positive ureteral margins.

DISCUSSION

The classical treatment method of urothelial MIBC (Muscle Invasive Bladder Cancer) is an open radical cystectomy in both men and women. According to the 2016 EAU guidelines, this type of treatment should be proposed to all patients, since cure rate is the highest when comparing to other methods used alone (radiotherapy, chemotherapy) [1]. It provides the longest cancer-specific survival, and is considered to be the standard method of treatment. Ten-year recurrence free survival rates range between 50-59% and overall survival rate is around 45% [4]. Recently, neoadjuvant chemotherapy was proposed

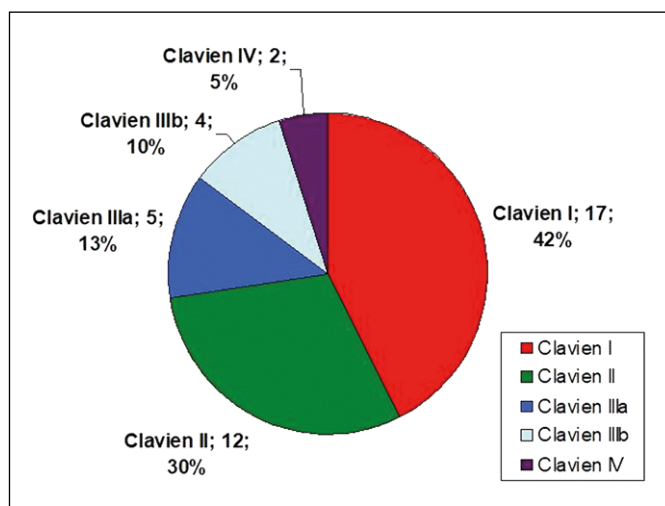


Figure 2. Perioperative complications according to the Clavien-Dindo scale.

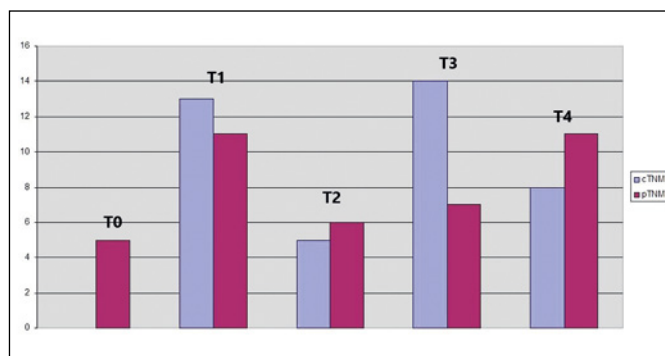


Figure 3. Clinical and pathological stage of neoplastic disease.

Table 1. Clavien-Dindo complications (grades III and IV)

Complication	Number of patients
Hemorrhage	1
Cardiac	1
Gastrointestinal	2
Urinary	2
Infective	1
Embolism	3
Other	1

to improve the five-year survival rate by 5–8%, when applied to patients with advanced disease [16]. Since the end of the 20th century, the minimally invasive approach gained its large popularity. It is considered to be less invasive, with less blood loss and lower number of perioperative complications. It provides good cancer control, with similar oncological outcomes, evaluated as level of local recur-

rence, positive surgical margins, lymph node yield, and recurrence-free survival [17]. Oncological safety, defined as the level of PSM, and number of lymph nodes removed, was questioned in a few older series [18, 19]. Herr et al proposed, that when 10–14 lymph nodes are removed, and PSM level is less than 10%, oncologic results of minimally invasive cystectomy reach the level of ORC [20]. In available studies, the oncological variables (local recurrences, number of lymph nodes extracted, positive surgical margins and cancer free survival), and functional outcomes are similar in case of both open and robot-assisted cystectomy [21].

In our series, the mean number of lymph nodes removed was twelve, which seems to be sufficient for oncologic staging. PSM was positive in 5 out of 40 (12.5%) patients, which is slightly higher than the accepted cumulative PSM ratio, but this may be possible in the operated group of patient, where high volume of disease (pT4) prevails.

When taking into consideration the low risk disease (pT2 and less), none of patients have PSM, which proves, that PSM level depends mainly on pathological advancement of the disease.

Operating time

RARC is a demanding procedure, but our data suggests, that localized muscle invasive bladder cancer can be successfully treated by this approach. The learning curve is not as long as in case of the laparoscopic procedure, and after forty to fifty cases it is possible to achieve operating times, intraoperative blood loss, and length of hospital stays comparable, or even better, than in the largest published ORC studies [22]. If the operator is experienced, time of surgery can be even shorter than in the open type of procedure. Time of surgery for the first patient, enrolled into the study, was 340 minutes and is far longer than the time of the shortest procedure (170 minutes-cystectomy with ileal conduit), but being shorter than times generally seen during open procedure [23].

It is a common impression, that preparation for a robotic surgery is a long and demanding procedure. At the beginning of the Polish Radical Robotic Cystectomy Program, initiation of the surgery from start of anesthesia to start of surgery, took 1.5 hour (to set up all robotic equipment, place patient in correct position, introduce robotic ports and to dock a robot). After forty cases, it takes twenty-five to thirty minutes from anesthesia to the beginning of the proper surgery, which is only ten to fifteen minutes longer than in case of a laparoscopic procedure. It seems that the length of preparation can be shortened to

a reasonable time after performing few operations. It may also be concluded that such improvement can be achieved only when experienced laparoscopic team performs the robotic surgery. At the time of initiation of the PRARC program, our laparoscopic team was well experienced in laparoscopic cystectomy, so the learning time was much shorter than is usually foreseen. After performing forty cases it can be concluded, that the robot-assisted radical cystectomy is the standard method of treatment of invasive urothelial disease in our department. When comparing LRC and RARC it was noticed by other authors, that the learning curve for the robotic approach is shorter, and all post-operative results are comparable to LRC. In a comparative analysis between LRC and RARC, Abraham concluded, that both procedures may be performed safely with good oncological results [24].

Blood loss

Transfusions during surgery were very rare in the operated group (only two patients out of forty required a transfusion), and in seventy-two hour period, only 9 required a transfusion, with a median number of 2.3 blood units per patient. It seems that a good visualization of the operating field, anatomic structures and a better comfort of surgery (than in other types of approaches) improves hemostasis. The same trend was observed in a large meta-analysis done by Bochner, where the estimated blood loss and transfusion rate recorded from sixteen studies were significantly lower in RARC than in ORC ($p = 0.001$ and 0.002 respectively) [25].

Hospital stay

Low blood loss, low analgesic use and fast bowel recovery, together with implementation of ERAS (Early Recovery After Surgery) program, allows safe home discharge in 5–7 days after minimally invasive surgery (recent, not published own data). Bowel recovery time can be reduced by the use of early mobilization and early oralisation, gastrointestinal stimulation with metoclopramide and chewing gum. In this study, median time to home discharge was 8 days, and it was shorter in the subgroup of patients with simple ureterocutaneostomy by one day. Other authors in large series have also noticed shorter hospital stays after the minimally invasive operations [23].

Intraoperative and postoperative complications

Perioperative complication rate is a marker of surgical safety. Recently, urology adopted Clavien-Dindo scale to report post-surgical complications. In our

group of operated patients it was predominantly grade I and II. Only eleven out of forty patients had complications grade III and IV. None of the patients died after surgery. Conversion from RARC to open or laparoscopic approach was not common. This occurred only in one case, where the disease load was very high, which caused the robotic approach to be too risky. In the case of this patient, conversion to the laparoscopic approach was performed.

In the subgroup of patients who were operated, with simple ureterocutaneostomy, serious complications were rare, and only in one patient were grade III, where the rest of them were scored as Clavien I group.

In the subgroup of patients with ileal conduit, complication (grade III and IV) happened in more than half. Since it is known, that the highest number of life threatening complications is linked to urine leakage, with later intestinal complications due to urine contact with bowel anastomosis, in selected cases of very high load of the disease or poor general status, ureterocutaneostomy has also to be taken into consideration, when deciding on the type of urine diversion [26]. It is also important, that most of the patients included into the study were in poor general condition. More than 2/3 were assessed as ASA III and ASA IV, therefore complication rate in such patients is much higher.

Main limitations of this study are a low number of patients included, and an observational type of research, without a control group. Bigger study group could lead to different and interesting conclusions.

This study is intended to focus on patients with high load of the disease, advanced age, and high number of comorbidities. Younger patients with high risk disease, or subjected to vast urological surgery were also included, which lead to a selection bias.

CONCLUSIONS

Robot-assisted radical cystectomy; especially in patients with high load of the disease, is a safe and reproducible oncological procedure, with number of complications similar to the ones found in the literature. It provides good oncological results, and fast recovery, when compared with results of the open technique from the literature. Number of perioperative complications, low blood loss and fast home discharge seen in the operated group, and feasibility of the operating technique can lead to the conclusion that this technique can become the method of choice in patients with advanced urothelial disease. In experienced hands, after forty to fifty cases, it seems, that the robot-assisted procedure is easy to perform, and difficult cases can be managed in a safe way.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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