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Robotic-Assisted Pelvic Surgery: Early Outcomes in a Single Institution

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Rezumat

Chirurgie pelvină asistată robotic: rezultate inițiale ale unei singure unităti chirurgicale

Introducere: Acest articol raportează experiența autorilor cu primele 50 de intervenții chirurgicale consecutive în sfera pelvină asistate robotic, cu scopul de a determina fezabilitatea și siguranța adoptării chirurgiei pelvine robotice. Chirurgia robotică oferă mai multe beneficii pentru chirurgia minim invazivă, dar aplicabilitatea sa este împiedicată de costuri și de experiența regională limitată. Acest studiu a urmărit să evalueze fezabilitatea și siguranța chirurgiei pelvine robotice.

Material și metode: Aceasta este o analiză retrospectivă a experienței noastre inițiale cu chirurgia robotică pentru neoplazii colorectale, prostatice si ginecologice, între iunie si decembrie 2022. Rezultatele chirurgicale au fost evaluate din punct de vedere al datelor perioperatorii, cum ar fi durata operației, pierderea de sânge estimată și durata șederii în spital. Complicațiile intraoperatorii au fost înregistrate, iar complicațiile postoperatorii au fost evaluate la 30 de zile și la 60 de zile după intervenție. Fezabilitatea intervenției chirurgicale asistate robotic a fost evaluată prin măsurarea ratei de conversie la laparotomie. Siguranța intervenției chirurgicale a fost evaluată prin înregistrarea incidentei complicatiilor intraoperatorii și postoperatorii. Rezultate: Cincizeci de operații robotice au fost efectuate în 6 luni, reprezentate de 21 de intervenții pentru neoplazii digestive, 14 cazuri ginecologice și 15 cancere de prostată. Durata operației a variat între 90 și 420 de minute, cu două complicații minore și două complicații de gradul II conform clasificării Clavien-Dindo. Un

Received: 27.01.2023 Accepted: 26.02.2023 pacient a necesitat o spitalizare prelungită și colostomie terminală, pentru o fistulă de anastomoză apărută în ziua 6 postoperator. Nu au fost raportate mortalitate la treizeci de zile sau reinternări. *Concluzie:* Studiul a constatat că intervențiile chirurgicale pelvine asistate robotic sunt sigure și au o rată scăzută de conversie la chirurgie deschisă, ceea ce face chirurgia robotică o componentă benefică a laparoscopiei convenționale.

Cuvinte cheie: neoplazii pelvine, chirurgie robotică, cancer colorectal, cancer de prostată, cancer uterin

Abstract

Introduction: This article reports the authors' experience with their first 50 consecutive robotic pelvic procedures, aiming to determine the feasibility and safety of adopting robotic pelvic surgery. Robotic surgery offers several benefits for minimally invasive surgery, but its applicability is hindered by cost and limited regional experience. This study aimed to evaluate the feasibility and safety of robotic pelvic surgery.

Material and methods: This is a retrospective review of our initial experience with robotic surgery for colorectal, prostate, and gynaecologic neoplasia, between June and December 2022. The surgical outcomes were evaluated in terms of perioperative data, such as operative time, estimated blood loss, and length of hospital stay. Intraoperative complications were recorded, and postoperative complications were evaluated at 30 days and 60 days after surgery. The feasibility of the robotic assisted surgery was assessed by measuring the conversion rate to laparotomy. The safety of the surgery was evaluated by recording the incidence of intraoperative and postoperative complications. Results: Fifty robotic surgeries were performed over 6 months, including 21 interventions for digestive neoplasia, 14 gynaecologic cases, and 15 prostatic cancers. Operative time ranged from 90 to 420 minutes, with two minor complications and two grade II Clavien-Dindo complications. One patient required prolonged hospitalization and an end-colostomy, deriving from an anastomotic leakage requiring reintervention. No thirty-day mortality or readmissions were reported.

Conclusion: The study found that robotic-assisted pelvic surgery is safe and has a low rate of transfer to open surgery, making it a suitable addition to conventional laparoscopy.

Key words: pelvic neoplasia, robotic surgery, colorectal cancer, prostate cancer, uterine cancer

Introduction

Advantages of minimally invasive surgery (MIS), such as lower intraoperative blood loss, fewer hospital stay-related complications, and faster recovery with earlier social reintegration has led to its rapid growth and increase in surgeon confidence since the initial laparoscopic cholecystectomy (1).

Moreover, in the past two decades, there have been tremendous advances in robotassisted surgery. It offers a number of advantages, including greater orientation in the 3D image of the surgical site, superior manual accuracy and a more comfortable experience for the physician. These benefits are particularly evident when operating in constricted spaces, such as the pelvic cavity (2). However, despite the aforementioned theoretical advantages, in many hospitals applicability of robotic surgery remains limited mainly due to the increased cost associated with acquisition, supplies and maintenance.

In respect to rectal cancer, robotic approach offers a promising way to circumvent some of the challenges associated with laparoscopic

surgery. As for endometrial cancer, MIS is the recommended approach to treating this neoplasia (3). MIS has an important role to take on when it comes to managing cervical cancer, from initial treatment, to staging, fertilitypreserving measures, and secondary treatment (4). Concerning prostate cancer, robotic laparoscopic approach and result significantly less blood loss and transfusions, shorter hospital stays, indicating that these procedures are safe compared to open radical prostatectomy. However, the superiority of robotic-assisted radical prostatectomy with regards to post-operative complications, functional outcomes, or oncologic outcomes has not been demonstrated yet (5).

Recently, the north-eastern region of Romania has benefited from the introduction of its first robotic surgery programme in Iasi county, at the Regional Institute of Oncology, which is aimed at minimal invasive treatment of pelvic pathology, such as colorectal, prostate and uterine cancer.

Regionally, the experience with robotic surgery in the north-eastern part of Romania remains limited, in comparison with other regions of the country such as the capital, Bucharest (6,7) and the north-western part (8,9). In the present study, we report our experience with our first 50 consecutive robotic pelvic procedures. This study aims to determine the feasibility and safety of adopting robotic pelvic surgery.

Material and Methods

A retrospective review was performed of our prospective single institution robotic surgery database collected in the first 6 months of the programme, between the implementation of our robotic programme (June 2022) and December 2022. All participants in this study provided their signed informed consent. This investigation was carried out in accordance with the guidelines of the Declaration of Helsinki. We conducted a retrospective analysis of the hospital records of all participants, which included details about demographics, operative data, complications,

duration of hospital stay, and histopathological data.

Data were collected from a single institution specialised in oncology – the Regional Institute of Oncology in Iasi, Romania, thus robotic-assisted surgeries were mainly performed to patients with malignant tumours.

The cases were operated on using the Da Vinci-Xi Surgical System (Intuitive Surgical, Sunnyvalle, CA, USA), by four console surgeons (2 general surgeons, 1 urologist and 1 gynaecologist). The caseload for each varied accordingly with the type of neoplasia being treated.

The patients included in the study underwent one of the following robotic procedures: low (and very low) anterior resection of the rectum with total/partial mesorectal excision (TME), abdominoperineal excision (APE) of the rectum, sigmoid colectomy with complete mesocolic excision, radical prostatectomy, radical hysterectomy with bilateral adnexectomy and unilateral adnexectomy.

The exclusion criteria for robotic surgery were the following: tumour-related characteristics [such as tumours staged cT4 (according to the 8th edition of the AJCC TNM staging manual (13))], obstructing tumours, intestinal perforations, and tumours invading nearby organs) and patient-related aspects like severe cardiopulmonary illness or coagulation disorders that contraindicate laparoscopic surgery. Individuals with an American Society of Anesthesiologists (ASA) (11) score of III or higher were not enrolled in the study.

Definitions

Operation time was defined as duration between skin incision to closure. We documented any postoperative complications for up to two months, including hospital readmissions, using the Clavien-Dindo classification (12). We termed as 30-day mortality death occurring within 30 days of a surgical procedure or during the patient's hospital stay (including any readmissions due to complications). Any procedure which required a midline incision to be made in

order to access the surgical site was referred as conversion to open surgery.

Case Workup

All cases were positively diagnosed through biopsy, which was obtained through endoscopy in colorectal cancer patients, transrectal prostatic puncture in prostatic cancer patients, biopsy curettage for endometrial neoplasia and cervical conization for cervical cancer patients. In one instance, with ovarian cyst, biopsy was redundant.

All cases were thoroughly staged, using pelvic imaging through magnetic resonance imaging (rectal, uterine, and prostatic cancer) or computed tomography (distal sigmoid colon and ovarian cyst). Furthermore, staging was completed using thoracoabdominal computed tomography. Subsequently, the treatment plan was discussed and agreed upon in the multidisciplinary tumor board meeting.

Patients with extraperitoneal rectal tumors classified as cT3 or any cN1-2 underwent a five-week course of neoadjuvant chemoradiation therapy. Following completion of the therapy, surgery was scheduled between eight to twelve weeks later.

For uterine cancer, the indication for robotic assisted surgery was limited to stages as cT1-2, with negative lymph nodes, thus, patients were not considered for neoadjuvant treatment.

Preoperative Preparation

In colorectal cancer patients, when an anastomosis was planned, patients underwent bowel preparation comprising of low-fiber diet 2 days before surgery and 2 liters of cleansing solution (Fortrans) administered orally on the day prior to surgical intervention. Patients with planned abdominoperineal excision were prepared only with an enema. In addition, all patients received oral antibiotic preparation consisting of three doses of metronidazolum 500 mg and rifaximinum 200 mg on the day prior to intervention.

Gynaecologic patients were prepared

through vaginal washout and an enema in the evening prior to surgery.

Urologic patients required no special preparation apart from enema.

All patients were administered venous thrombosis prophylaxis 12 hours prior to the operation and antibiotic prophylaxis consisting of single dose cefuroximum 1.5 g and metronidazolum 1 g, 30 minutes before the induction of general anesthesia.

Surgical Procedure

After induction of general anaesthesia, the patient was positioned in one of three positions: supine position (in planned abdominoperineal excisions and adnexectomy), supine split-leg position (in low anterior resections, sigmoid colectomies and prostatectomies) and supine with legs resting on stirrups (in hysterectomies).

All patients had implanted central venous catheters and invasive arterial pressure monitoring in the radial artery. Subsequently, arms were safely tucked alongside the patients' body, and shoulder support was provided using shoulder cushions in order to prevent patient sliding during positioning. Nasogastric tubing and urinary catheterization were installed. Skin preparation with povidone-iodine and draping were followed by insufflation through one of two methods: Veress needle in Palmer's point in left upper quadrant or periumbilical port placement in Hasson's open-entry fashion.

Following initial port placement and patient positioning in Trendelenburg, the laparoscopic inspection of the abdominal cavity ruled out peritoneal dissemination. Docking of the Da Vinci Xi patient cart was performed through approach from patient's left side in colorectal patients and from leg side in urologic and gynaecologic patients.

The operative technique employed in this series was not uniform across surgeons and evolved as each surgeon gained experience. However, oncologic safety was paramount and technique relied on previous experience both in open and in laparoscopic surgery.

In abdominoperineal excisions, all patients

were positioned in prone position following stoma creation and port site closure. Perineal dissection was performed in extralevator plane and specimen extraction was performed at this level.

Specimen extraction was performed in different fashions, in accordance with the surgical intervention: 5 cm Pfannenstiel incision in low anterior resections and colectomies (which aided with mounting the anvil in the distal left colon), supraumbilical incision in prostatectomies, and transvaginal extraction in hysterectomies.

Results

Over a period of 6 months, there were 50 robotic operations performed in our unit. The caseload was different for the 4 console surgeons performing the operations. Thus, the caseload for the two general surgeons was of 18 cases for one and 5 cases for the other (two of the cases were gynaecologic pathology). The urologist performed 15 operations and the gynecologist performed 12 interventions.

Of the recorded cases, 21 (42%) presented with colorectal neoplasia, 15 (30%) with prostate cancer, and 14 (26%) with gynaecologic neoplasia.

Digestive interventions were performed for neoplasia situated in the pelvic area; thus, we had a total of 12 rectal cancers and 9 distal sigmoid cancers. In 5 cases with mid or low rectal cancer, neoadjuvant chemoradiation treatment was performed, followed by surgery at an average of 10 (9-12) weeks later.

The 14 gynaecologic operations were mainly performed for endometrial neoplasia (10 cases - *Table 1*). In 9 of these cases, pelvic lymphadenectomy was avoided and replaced with pelvic sentinel lymph node harvesting, in which mapping was performed using indocianine green (ICG) injected in the cervical area and the FireFly option of the robotic platform. In one case, we performed a right adnexectomy in a 69-year-old woman with suggestive imagistic aspect of a benign 6 cm benign right ovarian cyst.

Median operative time ranged between 90

Table 1. Clinicopathological data

	Total (n=50)
Median age, years (range)	64 (39-82)
Male gender, n (%)	27 (54%)
Neoplasia, n (%)	50 (100%)
Rectal cancer	12 (24%)
Sigmoid colon cancer	8 (16%)
Sigmoid villous adenoma	1 (2%)
Prostate cancer	15 (30%)
Endometrial cancer	8 (16%)
Cervical cancer	2 (4%)
Endometrial atypical hyperplasia	2 (4%)
High grade squamous intraepithelial lesion	1 (4%)
Right ovarian cyst	1 (2%)

minutes, for the right adnexectomy and 420 minutes for an abdominoperineal excision of the rectum in which the abdominal phase of the operation summed up a total of 300 minutes, with robotic time of 260 minutes, in which a major blood loss (800 ml) occurred through a lesion of the right obturator vein during the perineal dissection (*Table 2*).

In our experience, conversion to open surgery intervened in 3 instances: 2 cases

Table 2. Operative and evolution data

	Total $(n = 50)$
Surgical procedure, n (%)	50 (100%)
Low anterior resection	7 (14.0%)
Total mesorectal excision	6 (12.0%)
Partial mesorectal excision	1 (2.0%)
Abdominoperineal excision	5 (10.0%)
Sigmoid colectomy	9 (18.0%)
Radical prostatectomy	15 (30.0%)
Radical hysterectomy with bilateral adnexectomy	13 (26.0%)
Sentinel lymph node harvested	9 (18.0%)
Conversion, n (%)	3 (6.0%)
Median operative time, minutes (range)	240 (90-420)
Median blood loss, ml (range)	100 (20-800)
Median intensive care unit stay, days (range)	1 (0-5)
Median postoperative stay, days (range)	5 (2-53)
Complications, n (%)	6 (12.0%)
Clavien-Dindo I	2 (4.0%)
Clavien-Dindo II	2 (4.0%)
Clavien-Dindo III	2 (4.0%)
Clavien-Dindo IV	0 (0.0%)
Clavien-Dindo V	0 (0.0%)
Readmission, n (%)	0 (0.0%)
30-day mortality, n (%)	0 (0.0%)

presented with difficult anatomy which impaired surgical dissection (one digestive surgery case – abdominoperineal excision for low rectal cancer and one gynaecologic case – radical hysterectomy for endometrial cancer) and one case had a locally advanced distal sigmoid tumour that was not evident in preoperative imaging and that could not be dissected robotically.

The operated colorectal and prostatic cancers were mainly in stage II and III (15 cases), in contrast with gynaecological cancers, which were in early stages. In addition, 5 cases presented with preneoplastic lesions that indicated surgical resection (*Table 3*).

Oncologic radicality was optimal in 47 of the total of 50 cases. Thus, in 3 cases microscopic infiltration of the resection margin was present (R1).

There were 2 patients with minor complica-

Table 3. Pathological data

	Total $(n = 50)$
Colorectal cases, n (%)	21 (42.0%)
Sigmoid colon adenocarcinoma, n (%)	8 (16.0%)
Stage I *	1 (2.0%)
Stage II *	4 (8.0%)
Stage III *	3 (6.0%)
Rectal adenocarcinoma, n (%)	12 (24.0%)
Stage II *	4 (8.0%)
Stage III *	8 (16.0%)
Sigmoid villous adenoma, n (%)	1 (2.0%)
Urologic cases, n (%)	15 (30.0%)
Prostatic adenocarcinoma, n (%)	15 (30.0%)
Stage II *	5 (10.0%)
Stage III *	10 (20.0%)
Gynaecological cases, n (%)	14 (28.0%)
Endometrial adenocarcinoma, n (%)	8 (16.0%)
Stage I *	7 (14.0%)
Stage III *	1 (2.0%)
Cervical squamous carcinoma – Stage I *, n (%)	2 (4.0%)
High grade squamous intraepithelial lesion, n (%)	1 (2.0%)
Atypical endometrial hyperplasia, n (%)	2 (4.0%)
Right ovarian cyst, n (%)	1 (2.0%)
Completeness of resection	
R0	47 (94.0%)
R1	3 (6.0%)
R2	0 (0.0%)

^{*} Prognostic stage group according to AJCC TNM cancer staging manual, $8^{\rm n}$ edition (13)

tions: one surgical site infection and one Pfannenstiel incision haematoma that did not require additional surgical treatment. Two patients presented with grade II Clavien-Dindo complications that were one deep vein thrombosis in one prostatic cancer patient with cardiovascular comorbidities (it required immobilisation and therapeutic anticoagulation and had a positive evolution over the course of one week) and one lymphatic drainage in quantities of up to 600 ml daily, onset on the fourth postoperative day, in a patient with pelvic irradiation (it required Somatostatin administration and resolved after 5 days, which permitted patient discharge). One patient with low anterior resection had an anastomotic leakage on the fifth postoperative day, which required prolonged hospitalisation and finally led to the creation of a diverting end-colostomy on the transverse colon. In one prostatectomy, an anastomotic leakage was discovered on the second day postoperative and required reintervention and redo-anastomosis.

There was no thirty-day mortality reported in any of the patients. Moreover, no readmission was registered.

Discussions

Laparoscopic surgery in the pelvic area may be difficult in certain cases, mainly due to impaired vision and difficult reachability with rigid laparoscopic instruments. Robotic surgery comes with certain advantages to surpass said difficulties and make the learning curve easier to go through. These advantages include three-dimensional magnified vision, a solid camera platform, and improved dexterity (14).

Laparoscopic surgery has become a popular approach to rectal cancer due to the advancement of laparoscopic technology. It offers many advantages compared to open surgery, like a shorter hospital stay, faster recovery, less post operative pain, and a quicker return to normal bowel activities (15,16). However, conventional laparoscopic rectal cancer surgery is technically demanding, especially for male and obese

patients with a narrow pelvis and low rectal cancer (17). Robotic surgery has the aforementioned advantages that can help it surpass some of the restrictions found in laparoscopic surgery.

During our initial case series, we observed a gradual decrease in the operative time both for sigmodiectomies and for rectal cancer surgery. In addition, surgeons performing these operations reported the ability of taking on more difficult cases, or patients with higher body mass index after several robotic interventions.

In abdominoperineal excisions, when talking about the duration of the operation, one must take into consideration the fact that all interventions were performed in prone position (18), that is more challenging from the anesthesiologist point of view, it extends operative time, but offers a better visualization of the perineal area. However, a good view and improved navigation offered by robotic surgery may be the basis of transabdominal levator transection, with good cited oncological outcomes that need further study before widely implemented (19,20).

Anastomotic leakage is one of the most crucial complications after a radical resection of rectal cancer. Acute diffuse peritonitis caused by anastomotic leakage is the most severe complication after rectal surgery and can result in the need for reoperation and even mortality (17). Studies cite the occurrence of anastomotic leakage between 3.0 and 12.1% in robotic rectal surgery and 2.6 and 6.8% in laparoscopic surgery (21,22). In our experience, we had only one incidence of anastomotic leakage that prolonged hospitalization to 53 days and needed a diverting stoma, due to apparition of a rectovaginal fistula.

In our experience, endometrial cancer was the main gynaecologic pathology approached by robotic surgery. Only 3 cases of cervical cancer were approached robotically; all of them were staged no higher than FIGO stage IA2 (13). Furthermore, in correlation to trend set by current studies, sentinel lymph node technique was used by ICG mapping (23).

Two large prospective randomised controlled

trials ("Laparoscopy Versus Laparotomy for Comprehensive Surgical Staging of Uterine Cancer: Gynecologic Oncology Group LAP2" (USA) (24) and "Laparoscopic Approach to Cancer of the Endometrium" (Australia, New Zealand, Hong Kong and Scotland) (25) compared laparoscopic surgery to open surgery. Laparoscopy offers greater recovery prospects, with shorter hospital stays, less blood loss and therefore no need for transfusion, fewer wound complications, reduced risk of thromboembolism in comparison to laparotomy, less need for intensive or high dependency care and a lower rate of 30-day mortality. Robotic-assisted MIS helps to reduce the physical strain on the surgeon by providing mechanical assistance with the robotic surgical instruments. This allows for longer and more intricate procedures compared to traditional laparoscopy. Furthermore, the learning curve related to robotic surgery is shorter (4).

The use of MIS in the primary management of cervical cancer is a very disputed subject. This debate was started by the release of a large randomized control trial called the LACC (Laparoscopic Approach to Cervical Cancer) trial (26). Previously, MIS had been strongly established and was even the preferred surgery of choice for many due to its low morbidity rate and shorter hospital stay (27). We are eagerly awaiting the results of the international, multi-centre, open-label, RACC trial to see the impact that MIS has on cancer outcomes (28).

It is essential to the management of endometrial cancer that surgical staging with pelvic lymphadenectomy is carried out in order to determine prognosis and direct definitive treatment. Minimally invasive techniques used to perform pelvic lymphadenectomy are well-established, and have been proven to provide similar surgical and disease results as open methods, but with reduced intraoperative blood loss and shorter post-operative hospital stays (29).

Open radical prostatectomy is the usual procedure for treating clinically localized prostate cancer. However, it is linked to

significant blood loss, postoperative pain, and extended hospitalization. Laparoscopic radical prostatectomy was first reported in the early 1990s with the goal of lowering postoperative pain, postoperative morbidity and enabling quicker recovery (30). Therefore, LRP has become an alternate standard procedure for open prostatectomy. Unfortunately, some drawbacks of the laparoscopic approach led to a long-term learning curve for urologists which hindered its widespread application. Fortunately, the robotic-assisted radical prostatectomy was introduced in the 2000s and decreased the technical challenge of laparoscopic procedures, significantly decreasing the learning time (31). So far, there has been no difference in cancer treatment outcomes between robot-assisted and open radical prostatectomy (32). Research in the field found that the positive surgical margin was the same no matter which technique was used (33). However, given the lower blood loss and transfusion rate, as well as the shorter hospitalization duration (5), robotic prostatectomy is to be taken into account and has gained important popularity amongst surgeons. In addition, in terms of potency and early continence in those eligible for nerve-sparing radical prostatectomy, robotic assistance provides better functional outcomes as compared to laparoscopic prostatectomy (34).

In our experience, 15 radical prostatectomies were performed robotically, with 50-100 ml blood loss and a no reported conversion. Postoperative complications were Clavien-Dindo class II and III and were associated with cardiovascular comorbidities. This promotes the feasibility of robotic radical prostatectomy, with a learning curve that was easily crossed and operative timing that decreased from 300-360 minutes to 180-200 minutes after 15 operations.

Given the early stages in which the gynaecological tumours were operated, all cases suffered an R0 resection. In contrast, prostatic cancers were in more advanced stages, hence the two instances in positive resection margins were identified on the pathological specimen. It is important to

observe that all R1 resections (both prostatic and the one colorectal) were present in the first half of the operator's learning curve.

This article depicts the initial experience in robotic surgery in our unit which includes both digestive, as well as gynaecologic and urologic cases. Ninety-eight percent of patients presented with cancers, making the addressed pathology complex and noteworthy. The low conversion rate, as well as the acceptable complication rate are reasons to believe that robotic approach is feasible and safe for oncologic patients. In addition, the decrease in operative time was observed in surgeons, as caseload continued to build up, which makes us believe that tenacity must be proven, in addition to a favourable addressability in order to pass the learning curve.

To our knowledge, there are no other studies in the literature to cover such a wide range of robotic interventions — general surgery, urology, and gynaecology in one surgical unit and in this period of time (6 months). Thus, the novelty of this study relies in the versatility of information. Furthermore, the fact that it covers oncological pathology is a strong point, because of the complexity of cases, even in early staging. Further study needs to determine the oncological mid- and long-term outcomes of patients, to substantiate the safety of robotic approach to this pathology.

The main limitation of this study is that it depicts the initial phase of the surgeons' learning curve. As a consequence, it shows the feasibility and safety of robotic surgery in oncologic pathology. In addition, the fact that it includes colorectal, urologic, and gynaecologic pathology may be seen both as a strong point, and as a limitation of the study, with respect to reproducibility of data.

Conclusion

Our evaluation of the first 50 cases of pelvic robotic MIS demonstrated its safe adoption with a low rate of transfer to open surgery, making it suitable for a variety of procedures. Thus, we believe that robotic assistance is not

a replacement but an addition to conventional laparoscopy.

Conflicts of interest

The authors declare no conflicts of interest.

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