Research Article

Safety and efficacy of the MP1000 surgical system in robot-assisted radical cystectomy: A prospective study

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Abstract

Background: Robot-assisted radical cystectomy (RARC) has become widely adopted due to its numerous advantages, with the da Vinci robotic surgical system being the most commonly used across the globe. However, the high cost limits its broader application. Objective: This study aimed to evaluate the safety and efficacy of performing RARC using the more economical MP1000 surgical system. **Methods:** In this prospective, single-center, single-blind study, 21 patients scheduled for RARC between April and June 2024 were randomly assigned to undergo surgery with either the da Vinci Si system or the MP1000 system. The primary outcome was the rate of conversion to open or laparoscopic surgery. Secondary outcomes included robotic arm installation time, total surgery duration, intraoperative complications, intraoperative blood loss, post-operative positive margin rate, length of post-operative hospital stay, and short-term post-operative complications. Results: All surgeries were successfully completed without conversion to open or laparoscopic procedures, and no intraoperative complications related to robotic mechanical failure were observed. The robotic arm installation time was slightly longer with the MP1000 system compared to the da Vinci Si system (20.75 vs. 17.13 min, P<0.001). There were no statistically significant differences between the two groups in surgery duration, intraoperative blood loss, post-operative positive margin rate, post-operative hospital stay, or short-term post-operative complications. In addition, there was no significant difference in National Aeronautics and Space Administration Task Load Index scores, a measure of the operator workload. The primary limitation of this study was its small sample size. Conclusion: The study demonstrated that the MP1000 surgical system was a safe, feasible, and effective alternative for RARC, and achieved comparable outcomes to the da Vinci Si system.

Keywords: Robot-assisted radical cystectomy, Bladder cancer, MP1000 robot, Da Vinci robot, Robotic surgery

1. INTRODUCTION

Radical cystectomy, often performed alongside pelvic lymph node dissection, represents the cornerstone treatment for muscle-invasive bladder cancer and certain cases of high-risk non-muscle-invasive bladder cancer [1]. This complex procedure improves patient outcomes by achieving complete removal of cancerous tissues and reducing the risk of recurrence. Traditionally, radical cystectomy has been performed using open or laparoscopic methods, which, while effective, present significant challenges, including lengthy recovery times, higher post-operative complication rates, and considerable physical demands on the surgical team.

The introduction of robot-assisted radical cystectomy (RARC) by Menon in 2003 marked a transformative shift in urological surgery [2]. Leveraging the precision and advanced capabilities of robotic systems, RARC offers a minimally

invasive option that enhances operative accuracy and control. The benefits of RARC extend beyond technical improvements to include fewer post-operative complications, reduced blood

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loss, lower infection rates, and faster recovery times, allowing for quicker returns to normal activities [3,4]. In addition, the ergonomic design of robotic systems significantly lowers the physical strain on surgeons, which is of particular utility during complicated and protracted procedures [5,6].

The RARC has been increasingly adopted over the years, particularly in the United States, where, by 2017, it accounted for 32% of all radical cystectomies performed [7]. Similarly, in China, where the procedure was introduced more recently, over 2,000 RARCs had been performed by 2018, indicating the rapid uptake of this technique in the country [8]. Despite its advantages, the widespread adoption of RARC has been hampered by the high costs associated with the da Vinci surgical system, the predominant robotic platform in the field. The high cost of this system has prevented many healthcare facilities from procuring the system, particularly in resource-limited settings, thereby making the system inaccessible to a great many patients [9].

To address these challenges, several alternative robotic systems have been developed, offering more cost-effective solutions without compromising the technological capabilities required for intricate procedures. Notable among these are the Versius system from the United Kingdom [10] and the Senhance system from South Korea [11], both of which have shown promising results in various urological surgeries. In China, the introduction of the MP1000 robotic surgical system represents a significant advancement in making robotic surgery more accessible. This system has already shown favorable outcomes in other urological procedures, such as robot-assisted radical prostatectomy [12] and robot-assisted partial nephrectomy [13], suggesting that it could be a viable alternative to more established systems.

The present study aimed to evaluate the safety and feasibility of the MP1000 system in performing RARC. By rigorously assessing the system's performance in this complex procedure, we sought to determine whether the MP1000 could provide a reliable, cost-effective alternative that expands patients' access to high-quality robotic surgery for more patient populations. The findings of this study could have profound implications not only for the treatment of bladder cancer but also, more broadly, for the field of robotic-assisted surgery.

2. DESIGN

This prospective, single-center, single-blind, randomized controlled study was conducted at the PLA General Hospital, Beijing, China, from April 2024 to June 2024, upon approval from the ethics committee. Written informed consent was obtained from all eligible patients willing to undergo RARC. Patients with a history of abdominal surgery, other malignancies, or contraindications to surgery due to

cardiovascular or other diseases were excluded. A total of 21 patients were enrolled and randomly assigned to either the MP1000 group or the da Vinci Si group in a 1:2 ratio. The randomization sequence was generated using SAS 9.4. All surgeries were performed by two experienced urologic surgeons who were proficient in RARC and familiar with the MP1000 system through prior animal experiments.

2.1. Procedure

Baseline data were collected pre-operatively, including gender, age, weight, height, body mass index (BMI), smoking history, alcohol use, chemical exposure, and history of diabetes, chemotherapy and radiation, as well as the American Society of Anesthesiologists (ASA) score and hemoglobin and creatinine levels (Table 1). The MP1000 robotic surgical system (Shenzhen Edge Medica, China), similar to the da Vinci Si system (Intuitive Surgical, USA, consists of a surgeon control console, patient carts, vision carts, and reusable endoscopic instruments (Figure 1). Following randomization, both groups underwent standardized RARC and pelvic lymph node dissection, with identical trocar placement and surgical steps performed for both the MP1000 and da Vinci Si systems (Figure 2). The standard pelvic lymph node dissection involved the removal of bilateral obturator fossa lymph nodes, internal iliac vascular lymph nodes, external iliac vascular lymph nodes, and common iliac lymph nodes.

Intraoperative data collected included robotic arm installation time, cystectomy time, pelvic lymph node dissection time, blood loss, intraoperative organ or vessel damage, and robot-related safety events (Table 2).

Post-operative data harvested included hemoglobin and creatinine levels, exhaust time, drainage tube retention time, and length of post-operative hospital stay. Post-operative specimens were reviewed by two experienced pathologists, reporting tumor stage, margin status, the number of lymph nodes removed, and the number of positive lymph nodes (Table 3).

2.2. Outcomes

The primary outcome of the study was the surgical success rate, which was defined as the completion of the surgery using the robotic system without conversion to an open or laparoscopic procedure, and with negative surgical margins confirmed by post-operative pathology.

Secondary outcomes included robotic installation time, cystectomy time, pelvic lymph node dissection time, blood loss, intraoperative organ or vessel injury, safety events, post-operative hemoglobin and creatinine levels, exhaust time, drainage tube retention time, post-operative hospital stay, short-term post-operative complications, and ergonomics. Safety events were defined according to previous

Table 1. Demographic characteristics of the study patients

Parameter	MP1000 group (<i>n</i> =7)	Da Vinci Si group (n=14)	p
Sex			0.056
Men, <i>n</i> (%)	5 (71.43)	11 (78.57)	
Women, <i>n</i> (%)	2 (28.57)	3 (21.43)	
Age (year), mean (SD)	65.43±8.98	63.00±5.83	0.532
Height (cm), mean (SD)	168.86 ± 6.82	172.07 ± 6.02	0.313
Weight (kg), mean (SD)	72.43±8.87	75.00±9.10	0.546
BMI (kg/m²), mean (SD)	25.31±1.32	25.29±2.46	0.983
Smoking history			0.056
Yes, <i>n</i> (%)	2 (28.57)	11 (78.57)	
No, n (%)	5 (71.43)	3 (21.43)	
Alcohol history			>0.999
Yes, <i>n</i> (%)	3 (42.86)	7 (50.00)	
No, n (%)	4 (57.14)	7 (50.00)	
Chemical exposure history			>0.999
No, n (%)	7 (100.00)	14 (100.00)	
Diabetes history			>0.999
Yes, <i>n</i> (%)	2 (28.57)	5 (35.71)	
No, n (%)	5 (71.43)	9 (64.29)	
Chemotherapy history			0.337
Yes, <i>n</i> (%)	6 (85.71)	8 (57.14)	
No, n (%)	1 (14.29)	6 (42.86)	
Radiation history			>0.999
No, n (%)	7 (100.00)	14 (100.00)	
ASA score			0.100
II, n (%)	5 (71.43)	14 (100.00)	
III, n (%)	2 (28.57)	0 (0.00)	
Biochemical indicators			
Preoperative hemoglobin (g/L), median (IQR)	123.00 (115.00–139.50)	132.50 (123.75–145.50)	0.331
Preoperative creatinine (µmol/L), median (IQR)	100.00 (83.75–105.20)	95.25 (77.88–119.10)	0.743

ASA: American society of anesthesiologists; BMI: Body mass index. SD: Standard deviation.

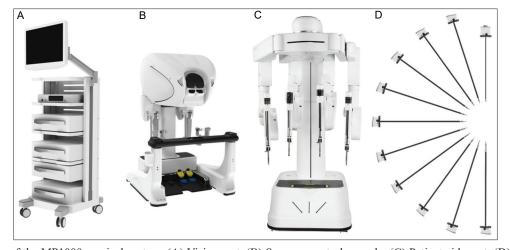


Figure 1. Components of the MP1000 surgical system. (A) Vision cart. (B) Surgeon control console. (C) Patient-side cart. (D) Reusable endoscopic instruments.

studies [12,13], and included instances such as interruptions in the connection between the console and robotic arms with failure to reconnect, failure to loosen instruments when

clamping tissues, robot error alarms, and instrument failure or damage. Follow-up assessments were conducted 1 month after surgery, with complications classified using the Clavien-

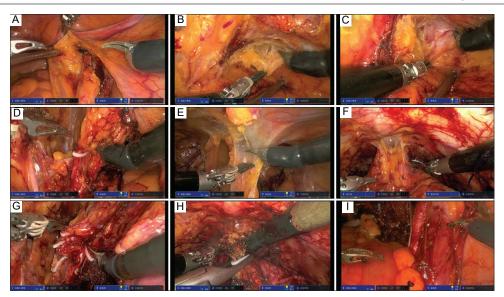


Figure 2. Robot-assisted radical cystectomy procedures with the MP1000 system. (A) Ureteral dissection. (B) Incision of the Denonvilliers' fascia. (C) Dissection to the prostatic apex. (D) Transection of lateral bladder pedicle vessels. (E) Mobilization of the bladder into the retropubic space. (F) Suturing and ligation of the dorsal venous complex. (G) Transection of prostatic lateral pedicles. (H) Dissection and transection of the apical urethra. (I) Pelvic lymphadenectomy.

Table 2. Operative variables

Parameter	MP1000 group (<i>n</i> =7)	Da Vinci Si group (n=14)	p			
Operative success, n (%)	7 (100.00)	13 (100.00)	0.247			
Difference in operative success rate, n (%)	0 (0.00)	0 (0.00)				
Installation time (min), median (IQR)	20.75 (20.10–21.23)	17.13 (16.81–17.44)	< 0.001			
Cystectomy time (min), mean (SD)	104±20.28	84.79 ± 19.06	0.094			
Pelvic lymph node dissection time (min), mean (SD)	39.57±10.71	41.29±14.64	0.765			
Blood loss (mL), median (IQR)	300.00 (275.00-300.00)	100.00 (100.00-200.00)	0.068			
Intraoperative organ or vessel damage, n (%)	1 (14.29)	0 (0.00)	0.983			
Safety events, <i>n</i> (%)						
Interruption of connection between console and robot arms and reconnection failure	0 (0.00)	0 (0.00)				
Instruments could not be loosened when clamping tissues	0 (0.00)	0 (0.00)				
Error alarm of robot	0 (0.00)	0 (0.00)				
Instrument failure or damage	0 (0.00)	0 (0.00)				

IQR: Interquartile range; SD: Standard deviation.

Dindo system [14]. Ergonomics were evaluated using the National Aeronautics and Space Administration Task Load Index (NASA-TLX) [15] (Table 4).

3. STATISTICAL ANALYSIS

Quantitative variables following normal distribution were reported as means with standard deviation, while non-normally distributed variables were presented as median and interquartile range. Statistical analysis involved t-tests or Wilcoxon tests after normality testing. Categorical variables were expressed as frequencies and proportions and analyzed using either a chi-square test or Fisher's exact test. All statistical analyses were carried out using SPSS 26, with statistical significance defined as a P < 0.05.

4. RESULTS

4.1. Participants

All participants underwent RARC and completed the post-operative follow-up without any dropouts. One patient in the MP1000 group also underwent a unilateral nephroureterectomy in addition to RARC. The demographic characteristics of the two groups were generally comparable, as shown in Table 1.

4.2. Operative variables

Table 2 presents the key variables related to the surgical procedures. All patients successfully underwent RARC

Table 3. Perioperative variables

Parameter	MP1000 group (<i>n</i> =7)	Da Vinci Si group (n=14)	p
Biochemical indicators			
Post-operative hemoglobin (g/L), median (IQR)	111.00 (103.00–116.50)	123.00 (109.50–128.50)	0.165
Post-operative creatinine (µmol/L), median (IQR)	85.80 (85.00–111.40)	97.25 (86.60–118.03)	0.502
Exhaust timeV (day), median (IQR)	2.00 (1.00–2.00)	2.00 (2.00–3.00)	0.109
Drainage tube retention time (day), mean (SD)	8.71±3.20	8.71±3.02	>0.999
Post-operative hospital stay (day), median (IQR)	8.00 (8.00-12.00)	9.00 (7.00–9.75)	0.880
Post-operative complications, n (%)			>0.999
Clavien-Dindo grade 2	0 (0.00)	1 (7.14)	
Clavien-Dindo grade 3	1 (14.29)	2 (14.29)	
Positive surgical margin, n (%)	0	0	
Tumour stage, <i>n</i> (%)			0.054
ypT0	0 (0.00)	3 (21.43)	
Tis	0 (0.00)	1 (7.14)	
T1	0 (0.00)	2 (14.29)	
T2	6 (85.71)	2 (14.29)	
T3	1 (14.29)	4 (28.57)	
T4	0 (0.00)	2 (14.29)	
Lymph nodes removed (n), median (IQR)	14 (10–24)	21 (13–22)	0.913
Positive lymph nodes (n), median (IQR)	0 (0)	0 (0)	0.743

IQR: Interquartile range; SD: Standard deviation.

Table 4. Evaluation of ergonomics by National Aeronautics and Space Administration Task Load Index

2			
Item (median [Interquartile range])	MP1000 group (<i>n</i> =7)	Da Vinci Si group (n=14)	p
Mental demand	8 (5.5–11.5)	9.5 (8.25–11)	0.535
Physical demand	9 (6.5–10)	9 (6–10.75)	0.743
Temporal demand	10 (6.5–12.5)	7.5 (6.25–11.25)	0.400
Performance	10 (6.5–11)	8 (6–10.75)	0.856
Effort	9 (7.5–11.5)	10 (7.25–11)	0.799
Frustration	9 (8.5–10)	9.5 (6–11)	0.856

without any conversions to open or laparoscopic surgery. The median robotic arm installation time was significantly longer in the MP1000 group than in the da Vinci Si groups (20.75 vs. 17.13 min; P < 0.001). The median blood loss (300 vs. 100 mL; P = 0.068), cystectomy time (104.00 \pm 20.28 vs. 84.79 \pm 19.06 min; P = 0.094), and pelvic lymph node dissection time (39.57 \pm 10.71 vs. 41.29 \pm 14.64 min; P = 0.765) were similar between the groups. Notably, no intraoperative organ or vascular injuries occurred in the da Vinci Si group. In contrast, one patient in the MP1000 group experienced iliac vascular injury due to extensive adhesions resulting from tumor invasion into the bladder serosa, leading to vascular damage during tissue separation. Importantly, no safety incidents were reported in either group.

4.3. Intraoperative and post-operative variables

Table 3 presents the perioperative and follow-up data. No statistically significant differences were observed between the two groups in post-operative hemoglobin levels (111.00 vs. 123.00 g/L; P = 0.165) or creatinine levels (85.80 vs.

97.25 μ mol/L; P=0.502). Indicators of post-operative recovery, such as exhaust time (2.00 vs. 2.00 day; P=0.109), drainage tube retention time (8.71 \pm 3.20 vs. 8.71 \pm 3.02 day; P>0.999), and length of post-operative hospital stay (8.00 vs. 9.00 day; P=0.880), also show no significant differences between the groups.

No reoperations were required during the hospitalization period for patients in either group. One-month post-operative follow-up revealed that one patient in the MP1000 group and three patients in the da Vinci Si group developed intestinal obstruction. In the da Vinci Si group, one patient's clinical symptoms improved spontaneously (Clavien-Dindo grade 2), while the remaining patients showed improvement after the insertion of an intestinal drainage tube (Clavien-Dindo grade 3).

Post-operative pathological stages were similar between the two groups (P = 0.054), with no positive surgical margins reported. The median number of detected lymph nodes was also comparable (14 vs. 21; P = 0.913).

4.4. Satisfaction of surgeons

Table 4 shows the results of the NASA-TLX scoring. There were no statistically significant differences between the MP1000 group and the da Vinci Si group in items of mental demand (8 vs. 9.5; P = 0.535), physical demand (9 vs. 9; P = 0.743), temporal demand (10 vs. 7.5; P = 0.400), performance (10 vs. 8; P = 0.856), effort (9 vs. 10; P = 0.799), and frustration (9 vs. 9.5; P = 0.856).

5. DISCUSSION

In recent years, surgical robots, particularly the da Vinci system, have been extensively utilized for radical cystectomy, especially in the treatment of muscle-invasive bladder cancer [16]. The da Vinci system and similar robotic platforms offer a multitude of advantages associated with minimally invasive laparoscopic surgery, such as reduced blood loss, small incisions, and quick recovery times [17]. At the same time, these robotic systems allow surgeons to perform more precise operations, achieving outcomes comparable to those of traditional open surgery [18,19]. This combination of precision and minimal invasiveness affords significant benefits, including reduced post-operative complications and enhanced patient recovery [20]. Given these advantages, it is no surprise that robotic surgery has become a favored approach for many complex surgical procedures, including radical cystectomy.

However, despite the apparent clinical benefits and mounting acceptance of surgical robots in the medical field, the widespread adoption of these technologies confronts several significant challenges. One of the primary barriers is the high cost of acquiring and maintaining these advanced systems. For instance, the da Vinci system comes with a hefty price tag, rendering it unaffordable to many hospitals, especially those in resource-limited areas or regions. In addition, the maintenance requirements for these systems are significant, further increasing the overall cost burden [9]. These financial constraints have slowed down the adoption of robotic surgical systems, limiting the access of patients who could have benefited from them.

To address this issue, we conducted a comparative study between the domestically developed MP1000 robotic surgical system in China and the da Vinci Si system for RARC. Both systems successfully completed surgeries without conversion to laparoscopic or open procedures, and post-operative pathological resection margins were negative, demonstrating the viability of the MP1000 surgical system for performing RARC. The pre-operative baseline data of patients in the MP1000 and da Vinci Si groups, including age, gender, BMI, ASA score, hemoglobin, and creatinine levels, were well-matched, ensuring comparability between

the groups. Post-operative outcomes, such as exhaust time, drainage tube retention time, length of post-operative hospital stay, and post-operative short-term complication rates, were comparable between the two groups, suggesting that post-operative recovery with the MP1000 system is similar to that with the da Vinci Si system. This indicates the feasibility of the MP1000 system. Moreover, post-operative pathological results showed negative resection margins in both groups, with no significant difference in the number of detected lymph nodes, demonstrating that both systems are equally effective in tumor resection. However, a longer follow-up is warranted for further verification.

Both groups underwent RARC and pelvic lymph node dissection, with one patient in the MP1000 group also receiving a unilateral nephroureterectomy, demonstrating that the MP1000 surgical system was able to handle complex surgeries. Both robotic systems operated uneventfully without any safety incidents or organ or vessel injuries resulting from machine failure. Although one patient suffered from an iliac vessel injury during the operation in the MP1000 group, the injury was ascribed to the advanced stage of the tumor and invasion of the bladder serosa, which caused severe adhesion with adjacent tissues. The injury was not related to the robotic surgical system per se. The iliac vessel was damaged during tissue separation, but the surgeon successfully used the MP1000 system to repair the vessel. The patient experienced no post-operative complications, highlighting the MP1000 system's capability to handle emergencies and perform intricate surgical procedures. There were no significant differences between the two groups in terms of cystectomy time, pelvic lymph node dissection time, and blood loss. The arm installation time for the MP1000 system lasted slightly longer than that for the da Vinci Si system due to differences in the installation process. Despite the similarity in operational logic, this required the assistants to learn and familiarize themselves with the procedure. However, this minor delay exerted a negligible impact on the safety and feasibility of the surgery. Overall, the study suggests that the MP1000 system is a safe and effective option for RARC. The domestically developed MP1000 system was less costly and its use poses less cost on patients compared to the da Vinci Si system. This cost advantage could make robotic surgical systems more accessible to a broader patient population, thereby enhancing the effectiveness of the healthcare system.

The MP1000 system has several key features. First, its operating console provides a three-dimensional vision without the need for glasses, ensuring high resolution and accurate color reproduction for precise operations. Second, the system's operational logic and component layout closely resemble those of the da Vinci Si system, facilitating a seamless transition for surgeons familiar with the da Vinci

Si system and minimizing additional training costs. Third, the MP1000 system leverages 5G networks, enabling surgeons to perform robot-assisted surgeries remotely [21], which could expand access to high-quality medical care for patients in remote areas. However, the system does have some drawbacks. For instance, the installation time for the MP1000 system's robotic arm is marginally longer than that of the da Vinci Si system, which might be attributed to the assistants' need to familiarize themselves with the installation process. In addition, the robotic arm's movement is restricted at certain extreme angles during RARC, necessitating collaboration between surgeons and engineers for further optimization.

One limitation of the study is its small sample size. It recruited only 21 patients from a single center. While our findings suggested that the MP1000 system could successfully perform RARC and pelvic lymph node dissection, further research with larger sample sizes and longer follow-up periods is necessary to validate these results. In addition, there is a lack of research on the applicability of the MP1000 system for total intraluminal urinary diversion. However, its demonstrated precision in completing operations shows promise, encouraging us to pursue related studies in the future.

6. CONCLUSION

The MP1000 robotic surgical system appeared to be a safe and effective option for performing RARC, offering several advantages that could make it a more accessible alternative to the da Vinci Si system. The preliminary results of our study are encouraging, but further research is needed to validate these findings and fully establish its role in the field of robotic surgery.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

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Writing – original draft: Qing Ai, Xupeng Zhao, Yi Feng

Writing – review & editing: Hongzhao Li, Xu Zhang

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted at the PLA General Hospital from April 2024 to June 2024, following approval from the ethics committee of the institution (Approval ID: 20223011623). Written informed consent was obtained from all eligible patients who agreed to undergo the procedures.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA

Data used in this work are available from the corresponding author upon reasonable request.

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