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Feasibility, safety and effectiveness of robot-assisted radical prostatectomy with a new robotic surgical system: a prospective, controlled, randomized clinical trial

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Abstract

Background Robot-assisted radical prostatectomy (RARP) gains increasing popularity in the surgical management of prostate cancer (PCa) but is challenged by its prohibitive expense. A domestic robotic system has been developed to address this issue, but data comparing the self-developed robot with the widely used robot is lacking. We performed a randomized clinical trial to compare KD-SR-01® and DaVinci® robots in terms of perioperative, short-term oncological and functional outcomes in RARP.

Materials and methods We prospectively enrolled patients with clinically localized PCa. Patients were randomized to undergo either KD-SR-01®-RARP (K-RARP) or DaVinci®-RARP (D-RARP) by the same surgical team. The baseline, perioperative, short-term oncologic and urinary functional data were collected and compared.

Results We enrolled 39 patients, including 20 patients undergoing K-RARP and 19 undergoing D-RARP. Demographic and tumor characteristics were comparable between groups. All surgeries were performed successfully with no conversion to open. The operative time was similar ($P=0.095$) and K-RARP offered less volume of intraoperative bleeding ($P<0.001$). Four patients in the K-RARP group and three in the D-RARP group developed postoperative complications ($P=0.732$). Patients undergoing K-RARP had less volume of drainage ($P=0.022$). Positive surgical margins were observed in three patients undergoing K-RARP and five undergoing D-RARP ($P=0.451$). During the follow up, one patient receiving K-RARP group and two receiving D-RARP group had measurable prostate specific antigen ($P=0.605$). Urine leakage, urinary control and pad usage were comparable between groups at six weeks post-surgery.

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Conclusions The two surgical robots yielded similar results in feasibility, safety and short-term oncologic and functional efficacy for RARP.

Trial registration The trial has been registered at www.chictr.org.cn with a registration number of ChiCTR2200057000 on 25th February 2022.

Keywords Prostate cancer, Robot-assisted radical prostatectomy, Randomized clinical trial, Perioperative outcome, Technological innovations

Introduction

Radical prostatectomy (RP) is recommended as the first-line management for intermediate to high-risk localized prostate cancer (PCa) [1]. With the development of minimally invasive and robotic technologies, robot-assisted radical prostatectomy (RARP) is expected to be an alternative surgical procedure. Comparative studies illustrated that RARP yields similar oncologic outcomes compared with open and laparoscopic RP [2–4]. Owing to its minimally invasive nature and delicate operation, RARP provides superior perioperative outcomes including shorter hospitalization, fewer transfusions and fewer complications and better short-term urinary control [2, 4, 5]. However, the most frequently used DaVinci® robot (Intuitive Surgical, Sunnyvale, CA, USA) for RARP was challenged by its unsatisfactory cost-equivalence, especially for patients in developing countries [6, 7]. With an increasing application of RARP in China, a self-developed robotic system is needed to address this issue. Recently, a domestic robotic platform called KD-SR-01® (SuZhou Kang Duo Robot Co., Ltd., Suzhou, China) has been developed. The feasibility and safety of KD-SR-01® for RARP has been preliminarily verified in a single-arm study [8]. A few comparative studies have thus far been performed to evaluate outcomes between KD-SR-01® and DaVinci® robots. Therefore, our clinical trial aimed to compare the perioperative and short-term postoperative oncologic and functional outcomes between two robotic systems in RARP.

Materials and methods

The trial has been registered at www.chictr.org.cn (ChiCTR2200057000) on 25th February 2022. The applicant's institution is the Suzhou KangDuo Robotics Co., Ltd. This study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and Declaration of Helsinki and was approved by the Ethics Review Committee of Peking Union Medical College Hospital (PUMCH) with a registration number of HS2021150. The CONSORT checklist and flow diagram are demonstrated in the Supplementary Tables 1 and Fig. 1, respectively. Informed consents were obtained from all patients.

Patients

Enrolled in this study were patients aged over 18 years who were newly diagnosed with clinically localized PCa with an indication for RARP in PUMCH from March 2022 to July 2022. Exclusion criteria included: 1) evidence of metastasis; 2): non-adenocarcinoma; 3) previous pelvic radiotherapy or major pelvic surgery; 4) severe systematic diseases.

Calculation of sample size

The required sample size was estimated with the following formula:

$$N_t = N_c = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \times \left[P_c(1-P_c) + P_t(1-P_t)\right]}{(|D| - \delta)^2}$$

Here, 1-P_C is the sum of mortality rate and re-operation rate during initial hospital stay of D-RARP. 1-P_T is the sum of mortality rate and re-operation rate of the K-RARP. We set 1-P_C =1-P_T =1.0%, which was determined based on previous data from a large-scale study containing 1847 RARP cases [9]. The difference D was set as 0. The noninferiority margin δ was set at 10%. The α level was set at 0.05. The β was set at 0.10. Patients were enrolled at a 1:1 ratio. The loss-to-follow-up rate was set at 5%. Considering all the above, the sample size was set at 20 patients per group finally.

Randomization and masking

Patients were randomly assigned in a 1:1 ratio to receive either KD-SR-01® robot-assisted RP (K-RARP) or DaVinci-S® robot-assisted RP (D-RARP). The randomization sequence was generated by an independent statistician utilizing an online random number generator (www.random.org) with a block length of 4. The results were sealed in opaque envelops and masked to both patients and investigators until the envelope was opened. Though the surgical procedure could not be masked due to different robot appearances, the pathological diagnosis, inpatient care, outpatient follow-up and statistical analysis were all masked.

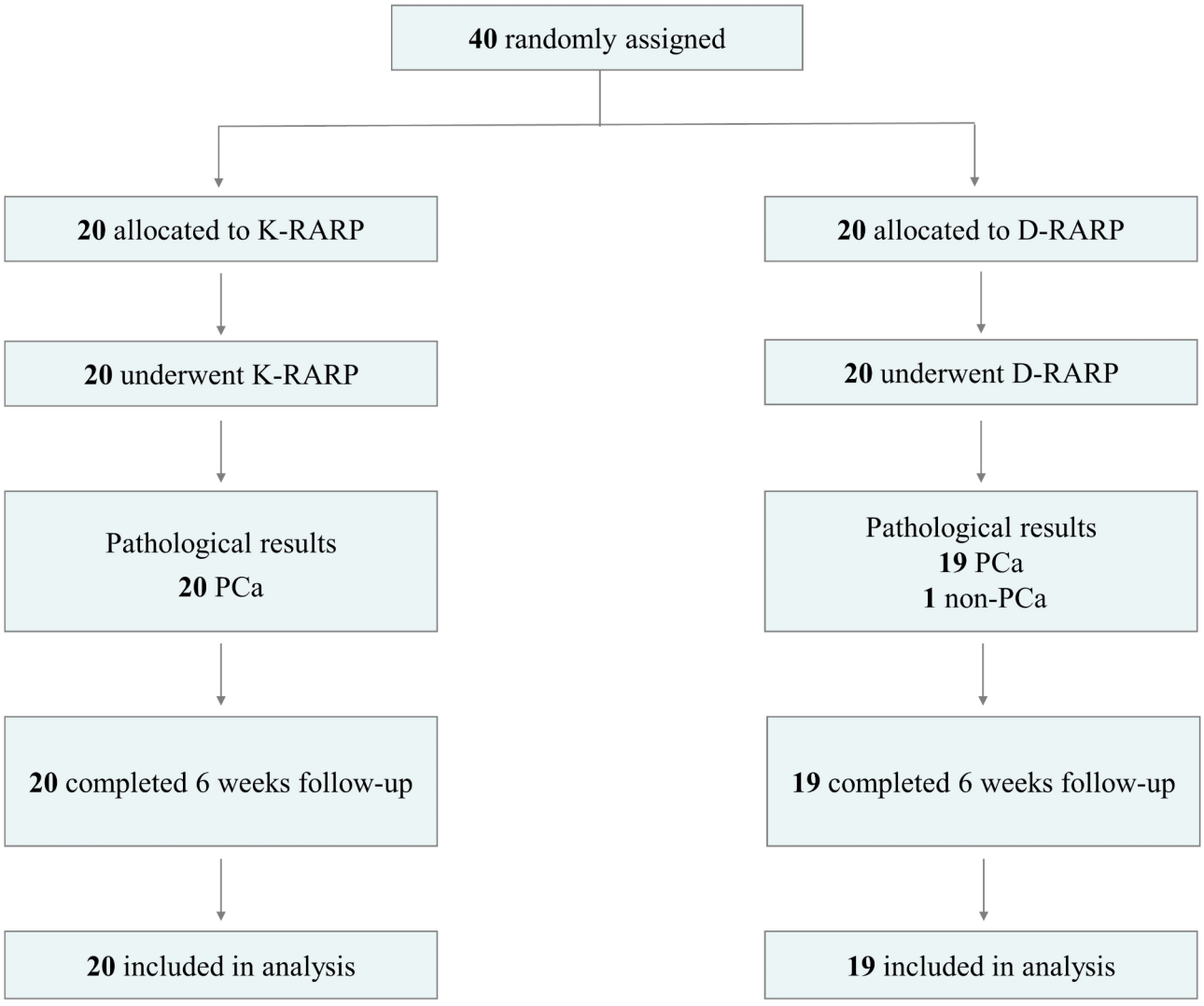

Fig. 1 CONSORT flow diagram. K-RARP = KD-SR-01® robot-assisted radical prostatectomy, D-RARP = DaVinci-S® robot-assisted radical prostatectomy. PCa = Prostate cancer

Preoperative management

All patients underwent abdominal and pelvic magnetic resonance imaging (MRI) to assess the clinical stating of the tumor. Baseline laboratory tests including complete blood count, liver and renal function test and total prostate specific antigen (T-PSA) were performed. Target and systematic biopsies were performed in all patients and a subsequent biopsy Gleason score was calculated.

The KD-SR-01® robotic platform

The KD-SR-01® robotic system has been approved by the National Medical Products Administration (NMPA) for innovative medical devices to enter the clinical trial in 2019 and for registration by NMPA in June 2022.

The KD-SR-01® robotic system is composed of a surgical console, a patient cart and a 3D imaging system (Fig. 2A and C). The surgical console is integrated with two master manipulators and a 3D high-definition monitor, combined with passive polarizing glasses, enabling surgeons to control the surgical arms and instruments precisely and synchronously without flexion of the neck [10]. The patient cart is designed as a three-arm system, which has seven degrees of freedom for movements and can filter out tremors of the hands. The imaging system adopts a modular interface, which can match various 3D laparoscopic display systems. In this study, Karl Storz IMAGE1 SD3-LinkTM laparoscopic systems were used with 30° 10-mm three-dimensional video laparoscopes.

Surgical team and technique

The surgical team from our tertiary center has an experience of performing over 300 RARPs using the DaVinci-S® robot as well as over 50 standard urological surgeries using the newly developed KD-SR-01® robot

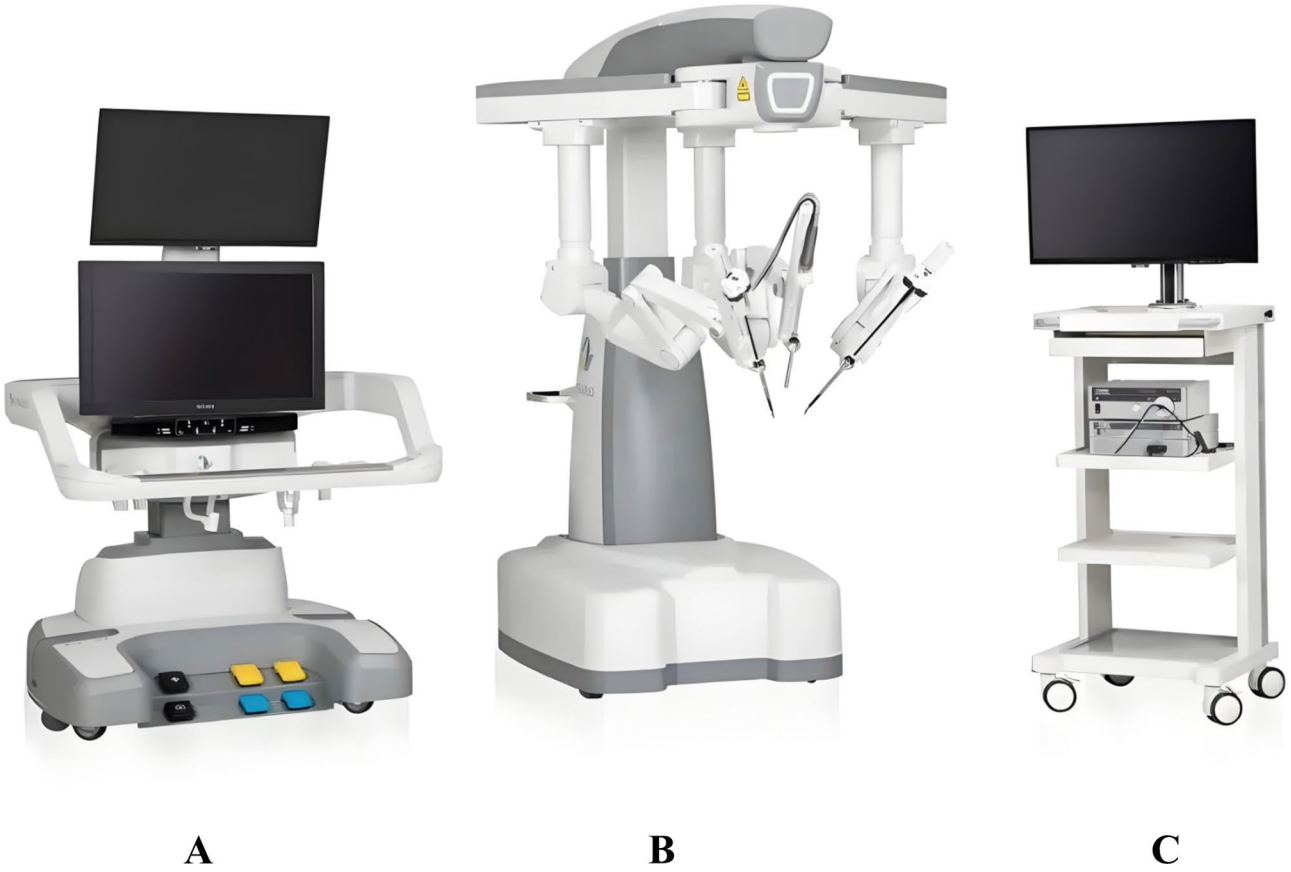

Fig. 2 The domestic KD-SR-01® robotic system is composed of a surgical console **(A)**, a patient cart **(B)** and a 3D high-definition vision system **(C)**

[11, 12]. Only one chief surgeon operated the surgical robot until completion of the trial. The chief surgeon has the experience of performing over 150 RARPs using the DaVinci-S® robot in recent 3 years as well as the experience of performing over 30 urological surgeries successfully (robot-assisted adrenalectomy and partial adrenalectomy, robot-assisted nephrectomy and partial nephrectomy, etc.) using the KD-SR-01® robot.

After anesthesia, the patient was placed in a Trendelenburg position. The pneumoperitoneum was then established, and a 12 mm TROCAR was inserted. In the K-RARP group, two 10 mm robotic cannulas were placed and docked at the umbilicus level of lateral edges of rectus abdominis muscle, monopolar scissors and bipolar forceps were then inserted. One 12 mm and one 5 mm assistant port were then placed at the umbilicus level of the left axillary front line and 2 cm below the rib margin of the left clavicle midline (Fig. 3A and C). In the D-RARP group, two 8 mm robotic cannulas were placed at both sides of the lateral edge of rectus abdominis muscle as well as one at the right axillary front line at the umbilicus level. Monopolar curved scissors, Maryland bipolar forceps and ProGrasp forceps were introduced respectively. One 12 mm assistant port was then established at the umbilicus level of the left axillary front line (Fig. 3B and D).

The Retzius space was dissected by cutting the anterior abdominal wall with an inverted U-shaped incision. Bladder mobilization, excision of pre-prostatic fat and incision of the endopelvic fascia were sequentially performed. The dorsal vein complex was divided and controlled. After identifying the prostatic vesical junction, the bladder neck was disconnected from the prostate. Vas deferens and seminal vesical were transected. The posterior wall of the prostate was separated along Denonvilliers fascia, and the lateral prostatic pedicles were clipped and incised. The intrafascial nerve-sparing surgical technique was offered in low to intermediate-risk patients, where the Denonvilliers fascia was preserved, and no coagulation was used close to the neurovascular bundle or on the surface of the prostate to avoid damage of the nerves. Once the dorsal vein complex and the urethra was incised at the level of the apex, the prostate was completely dissected. The vesicourethral anastomosis was then performed and a Foley catheter was inserted. Lymphadenectomy was performed in high-risk patients. The incision was sutured after drainage tube placement.

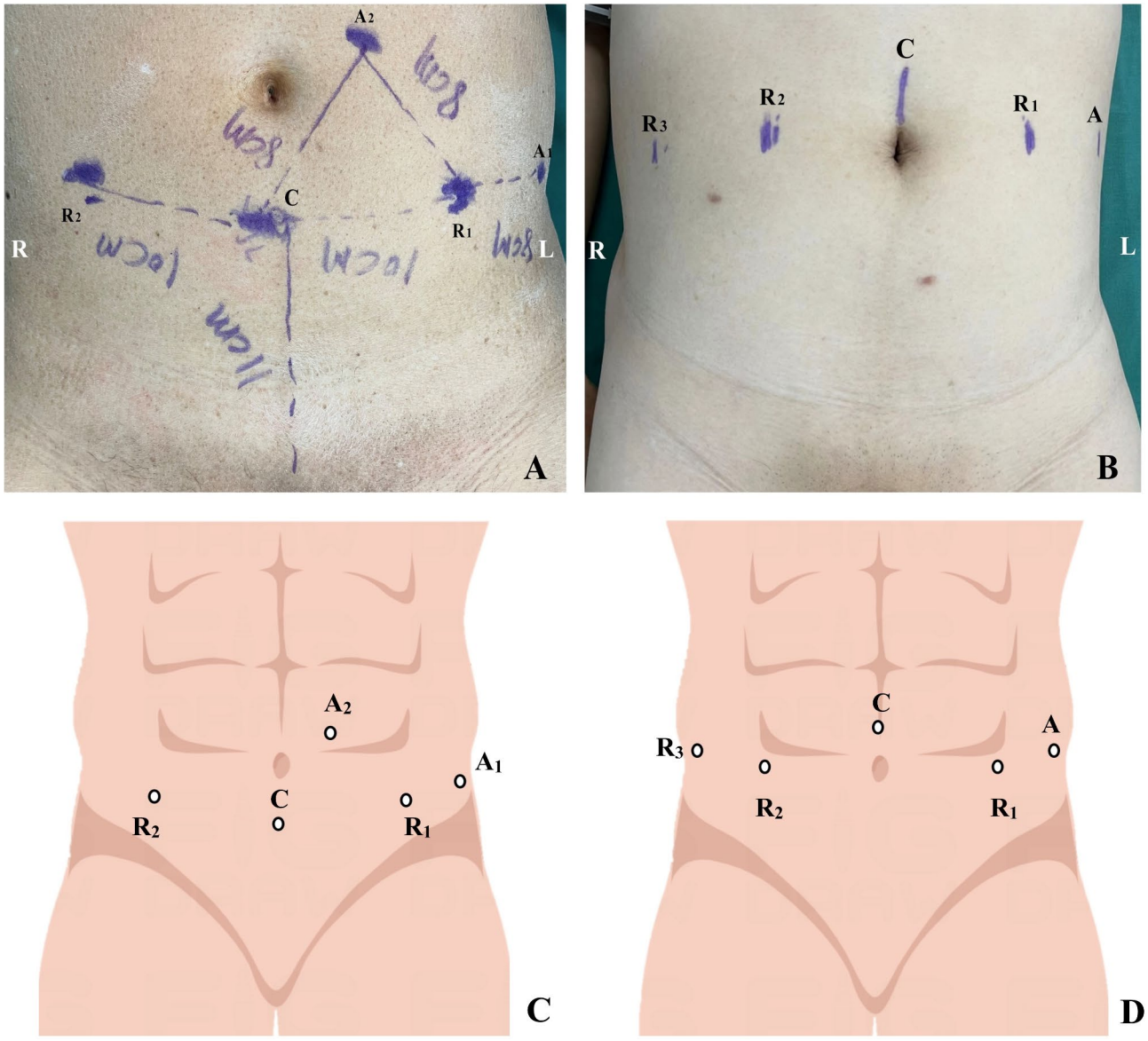

Fig. 3 Placements of ports in the K-RARP **(A)** & **(C)** and the D-RARP **(B)** & **(D)**. C refers to the camera port, R_{1-3} refer to robotic cannulas, A_{1-2} refer to assistant ports. K-RARP = KD-SR-01® robot-assisted radical prostatectomy, D-RARP = DaVinci-S® robot-assisted radical prostatectomy, L = left, R = right

Data collection and assessment

Data were collected from the electronic medical record system of PUMCH. Collected perioperative data were demographic variables including age, sex, body mass index (BMI), surgical history and American Society of Anesthesiologists (ASA) score [13]; baseline laboratory results; clinical staging, biopsy Gleason score [14] and informatiob of neoadjuvant therapy.

Collected intraoperative data were docking time, console time, operative time (OT), estimated blood loss (EBL) and intraoperative complications. The docking time was defined as the interval from the movement of the robotic cart to docking of the last canula to the corresponding arm. The console time was defined as the time from robot docking to undocking.

Collected postoperative and follow-up data (until six weeks post-surgery) were admission to intensive care unit (ICU), complications, time to first flatus and defecation, time to removal of drainage tube, use of analgesics and antibiotics, length of stay (LOS), laboratory results, 30-day readmission, adjuvant therapy, catheterization time and short-term urinary function. We also collected pathology findings including tumor size, histology, lymph node dissection, margin status, pathological Gleason score and staging.

Complications were graded using the Clavien-Dindo classification system, and grade III-IV complications

were defined as major complications [15]. In our study, the measurable PSA at was defined as two consecutive PSA ≥ 0.2 ng/mL at four and six weeks after surgery. The PSA failure was defined as two consecutive PSA nadir ≥ 2 ng/mL. The urinary function was evaluated based on items listed in the UCLA Prostate Cancer Index [16] at six weeks after surgery.

Statistical analyses

Continuous variables were described as median [interquartile range (IQR), p25–p75] or median (range) or mean ± standard deviation (SD) according to whether the distribution of the data followed the normal distribution. Categorical variables were described as absolute value and percentages. Continuous variables were compared by Mann-Whitney U test. Analyses were performed using SPSS 25.0 for windows (SPSS institute, Chicago, IL, USA) and P value < 0.05 was considered statistically significant.

Results

Patient characteristics

Operations were performed in 40 patients. One patient with a pathological result of the sclerosing adenosis based on benign prostatic hyperplasia was excluded. The remaining patients all completed the short-term follow-up. Altogether, 39 patients, including 20 (51.3%) patients undergoing K-RARP and 19 (48.7%) undergoing D-RARP were ultimately enrolled, whose baseline characteristics were summarized in Table 1. The median age of all patients was 65.0 years (range, 56.0–76.0 years). Baseline demographic characteristics including age, BMI, ASA score and history of abdominal surgery did not differ between groups. None of enrolled patients has undergone previous prostate surgery except prostate needle biopsies. Five (25.0%) patients in the K-RARP group and two (10.5%) in the D-RARP group received neoadjuvant hormone therapy (P=0.405). The information of neoadjuvant hormone therapy is detailed in the Supplementary Table 2. The baseline T-PSA level was non-significantly higher in the D-RARP group than that in the K-RARP group (11.00 [interquartile range (IQR), 7.92–18.70] ng/ml vs. 8.17 [IQR, 4.81–12.08], P=0.166). Also, the biopsy Gleason score (P=0.574) and clinical tumor staging (P=0.841) were comparable between two groups.

Perioperative outcomes

All RARPs were performed successfully with no conversion to open (Table 2). K-RARP required non-significantly longer OT than D-RARP (200.0 [IQR 165.0-223.8] min vs. 160.0 [IQR 130.0-225.0] min, P=0.095). The docking time was similar between two groups (5.0 [IQR 3.4–5.8] min vs. 5.0 [IQR 3.8-6.0] min, P=0.264), but the console time was prolonged, though statistically non-significant, in the K-RARP group (146.2 [IQR 116.61–161.6] min vs. 110.0 [IQR 84.4-169.2] min, P=0.089). Patients undergoing K-RARP had less intraoperative bleeding than patients undergoing D-RARP (229 ± 100 ml vs. 269 ± 161 ml, P<0.001). One (5.3%) patient in the D-RARP group had an EBL of 500 ml due to complicated operative procedures and received two units of red blood cell transfusion. One (5.3%) planned transfer to ICU occurred in the D-RARP group.

Altogether, four (20.0%) patients in the K-RARP group and three (15.8%) in the D-RARP group developed postoperative complications (P=0.732). One in each group

Table 1 Baseline characteristics of patients undergoing robot-assisted radical prostatectomy

	KD-SR-01® (*n* = 20)	DaVinci® (*n* = 19)	*P* value
Median age, year (range)	65 (59–76)	65 (56–74)	0.813
Median BMI, Kg/m^2 (IQR)	24.1 (23.1–26.0)	23.6 (21.8–25.2)	0.411
Median ASA score (range)	2 (1–3)	2 (1–3)	0.572
Abdominal surgery history, *n* (%)	6 (30.0%)	7 (36.8%)	0.651
Prostate surgery history, *n* (%)	0 (0.0%)	0 (0.0%)	-
Neoadjuvant hormone therapy, *n* (%)	5 (25.0%)	2 (10.5%)	0.405
T-PSA (ng/ml)	8.17 (4.81–12.08)	11.00 (7.92–18.70)	0.166
Biopsy Gleason score, *n* (%)			
6	6 (30.0%)	3 (15.8%)	0.574
7	8 (40.0%)	9 (47.4%)	
8–9	6 (30.0%)	7 (36.8%)	
Clinical staging, *n* (%)			
T1a	0 (0.0%)	1 (5.3%)	0.841
T2a	4 (20.0%)	5 (26.3%)	
T2b	5 (25.0%)	4 (21.1%)	
T2c	10 (50.0%)	8 (42.1%)	
T3a	1 (5.0%)	1 (5.3%)	

BMI = body mass index; IQR = interquartile range; ASA = American Society of Anesthesiologists; T-T-PSA = total prostate specific antigen

Table 2 Perioperative and pathological outcomes of patients undergoing robot-assisted radical prostatectomy

	KD-SR-01® (*n* = 20)	DaVinci® (*n* = 19)	*P* value
Intraoperative outcomes			
Conversion to open	0 (0.0%)	0 (0.0%)	-
Median operative time, min (IQR)	200.0 (165.0-223.8)	160.0 (130.0-225.0)	0.095
Median docking time, min (IQR)	5.0 (3.4–5.8)	5.0 (3.8-6.0)	0.264
Median console time, min (IQR)	142.6 (116.6-161.6)	110.0 (84.4-169.2)	0.089
Mean EBL, ml (SD)	229 (100)	269 (161)	< 0.001
Transfusion, *n* (%)	0 (0.0%)	1 (5.3%)	0.487
ICU transfer, *n* (%)	0 (0.0%)	1 (5.3%)	0.487
Postoperative outcomes			
Death during hospital stay, *n* (%)	0 (0.0%)	0 (0.0%)	-
Re-operation, *n* (%)	0 (0.0%)	0 (0.0%)	-
Complications, *n* (%)	4 (20.0%)	3 (15.8%)	0.732
Claviene-Dindo grade I, *n* (%)	3 (15.0%)	2 (10.5%)	0.676
Claviene-Dindo grade II, *n* (%)	1 (5.0%)	1 (5.3%)	0.970
Analgesic use for pain relief, *n* (%)	2 (10.0%)	1 (5.3%)	0.579
Absorption fever, *n* (%)	9 (45.0%)	10 (52.6%)	0.634
Median decrease in hemoglobin, g/L (IQR)	17.5 (7.5–30.1)	23.0 (14.0-28.5)	0.667
Median time to first flatus, day (Range)	2 (1–3)	2 (1–4)	0.588
Median time to first defecation, day (Range)	3 (2–4)	3 (2–6)	0.113
Median time of drainage, day (Range)	5 (3–12)	4 (3–25)	0.647
Median drainage volume, ml (IQR)	147.5 (117.5-293.8)	295.0 (190.0-590.0)	0.022
Median LOS, day (IQR)	7.5 (7.0–9.0)	7.0 (6.0–9.0)	0.142
Pathological outcomes			
Median diameter of tumor, cm (IQR)	1.8 (1.5–2.6)	2.3 (1.5–3.6)	0.311
Pelvic lymphadenectomy, *n* (%)	2 (10.0%)	5 (26.3%)	0.235
Positive surgical margin, *n* (%)	3 (15.0%)	5 (26.3%)	0.451
pT2	2 (10.0%)	2 (10.5%)	
pT3	1 (5.0%)	3 (15.7%)	
Pathological Gleason score for patients without neoadjuvant hormone therapy, *n* (%)			
6	3 (20.0%)	3 (17.6%)	0.530
7	7 (46.7.0%)	11 (64.7%)	
8–9	5 (33.3)	3 (17.6%)	
Pathological Gleason score for patients receiving neoadjuvant hormone therapy, *n* (%)			
6	0 (0.0%)	0 (0.0%)	-
7	0 (0.0%)	0 (0.0%)	
8–9	5 (100.0%)	2 (100.0%)	
Pathological staging, *n* (%)			
T1a	0 (0.0%)	1 (5.3%)	0.389
T2a	2 (10.0%)	1 (5.3%)	
T2b	4 (20.0%)	2 (10.5%)	
T2c	11 (55.0%)	10 (52.6%)	
T3a	3 (15.0%)	2 (10.5%)	
T3b	0 (0.0%)	3 (15.8%)	

IQR = interquartile range; EBL = estimated blood loss; SD = standard deviation; ICU = intensive care unit; LOS = length of stay

developed grade II complication (P=0.970), including a urinary tract infection requiring therapeutic antibiotics in the K-RARP group and a lymphocele in the D-RARP group. Patients in both groups had comparable analgesic use (P=0.579), development of absorption fever (P=0.643) and decrease in hemoglobin (P=0.667), postoperatively. No Grade III/IV postoperative complication occurred in both groups.

During hospitalization, the median time to first flatus (2 [range, 1–3] days vs. 2 [range, 1–4] days, P=0.588) and first defecation (3 [range, 2–4] days vs. 3 [range, 2–6] days, P=0.113) were similar between two groups. The drainage tube was maintained for a median of 5 (range, 3–12) days post-surgery in patients receiving K-RARP and a median of 4 (range, 3–25) days in patients receiving D-RARP (P=0.647). Patients undergoing K-RARP

had significantly lower drainage volume than patients undergoing D-RARP (147.5 [IQR 117.5-293.8] ml vs. 295.0 [IQR 190.0-590.0] ml, $P=0.022$). LOS was similar between two groups (7.5 [IQR, 7.0–9.0] days vs. 7.0 [IQR, 6.0–9.0], $P=0.142$). There is no re-operation or death during the hospital stay. No patient was readmitted within 30 days after the discharge.

Pathological outcomes

The median tumor diameter was 1.8 (IQR, 1.5–2.6) cm in the K-RARP group and 2.3 (IQR, 1.5–3.6) cm in the D-RARP group ($P=0.311$). Two (10.0%) patients undergoing K-RARP and five (26.3%) patients undergoing D-RARP received lymph node dissections ($P=0.235$). None of the yielded lymph nodes is positive. Positive surgical margins (PSM), as recorded in the pathological reports, were observed in three (15.0%) patients undergoing K-RARP and five (26.3%) patients undergoing D-RARP ($P=0.451$). The pathological Gleason score ($P=0.530$) and tumor staging ($P=0.389$) were comparable between groups.

Follow-up of oncologic outcomes and urinary functional

All patients were followed up until six weeks after surgery (Table 3). Two groups shared comparable T-PSA value at two weeks (0.045 [IQR, 0.006–0.057] ng/ml vs. 0.043 [IQR, 0.016–0.135] ng/ml, $P=0.385$) and six weeks (0.009 [IQR, 0.003–0.027] ng/ml vs. 0.010 [IQR, 0.003–0.048] ng/ml, $P=0.557$) post-surgery. Six patients in each group received adjuvant androgen deprivation therapy ($P=0.915$). One patient (5.0%) in the K-RARP group and two patients (10.5%) in the D-RARP group had measurable PSA at six weeks postoperatively ($P=0.605$). No patient had PSA failure in both groups.

The median duration of urinary catheter placement was 15 (IQR, 14–17) days and 15 (IQR, 14–20) days for patients undergoing K-RARP and D-RARP, respectively ($P=0.513$). At six weeks post-surgery, four (20.0%) patients undergoing K-RARP and five (26.3%) undergoing D-RARP were leakage free, while the rest patients experienced varying degrees of urine leakage ($P=0.743$). Seven (35.0%) patients undergoing K-RARP and eight (42.1%) undergoing D-RARP had total urinary control, while dribbling occurred in the remaining patients ($P=0.844$). Usage of pads showed few differences between two groups ($P=0.704$).

Discussion

In the era of robotic technology, robot-assisted surgery gains increasing popularity in the management of PCa. The safety, feasibility and efficacy of DaVinci® robot, which is the most frequently used surgical robot worldwide, in prostatic surgery have been confirmed by previous studies [3, 17]. However, prohibitive expenses limit its wide adoption in China. Therefore, a self-designed KD-SR-01® robotic system is developed to address this

Table 3 Oncologic and urinary functional follow-up data in patients undergoing robot-assisted radical prostatectomy

	KD-SR-01® (*n* = 20)	DaVinci® (*n* = 19)	*P* value
Oncologic data			
Median T-PSA at two weeks post-surgery, ng/ml (IQR)	0.045 (0.006–0.057)	0.043 (0.016–0.135)	0.385
Median T-PSA at six weeks post-surgery, ng/ml (IQR)	0.009 (0.003–0.027)	0.010 (0.003–0.048)	0.557
Measurable PSA (PSA ≥ 0.2 ng/mL), *n* (%)	1 (5.0%)	2 (10.5%)	0.605
PSA failure (PSA nadir ≥ 2 ng/mL), *n* (%)	0 (0.0%)	0 (0.0%)	-
Androgen deprivation therapy, *n* (%)	6 (30.0%)	6 (31.6%)	0.915
Urinary function			
Median duration of urinary catheter placement, day (IQR)	15 (14–17)	15 (14–20)	0.513
Urine leakage*			
Every day, *n* (%)	3 (15.0%)	1 (5.3%)	0.743
About once a week, *n* (%)	7 (35.0%)	6 (31.6%)	
Less than once a week, *n* (%)	6 (30.0%)	7 (36.8%)	
Not at all, *n* (%)	4 (20.0%)	5 (26.3%)	
Urinary control*			
No control, *n* (%)	2 (10.0%)	1 (5.3%)	0.844
Frequent dribbling, *n* (%)	2 (10.0%)	3 (15.8%)	
Occasional dribbling, *n* (%)	9 (45.0%)	7 (36.8%)	
Total control, *n* (%)	7 (35.0%)	8 (42.1%)	
Pads used per day*			
≥3, *n* (%)	7 (35.0%)	6 (31.6%)	0.704
1–2, *n* (%)	7 (35.0%)	9 (47.4%)	
0, *n* (%)	6 (30.0%)	4 (21.0%)	

T-PSA = total prostate specific antigen; IQR = interquartile range

*Evaluated according to the first three items of the urinary function domain in UCLA Prostate Cancer Index

issue, whose feasibility and safety has been preliminarily verified by a single-arm study [8]. However, its comparison with DaVinci® robot has not yet been extensively validated. In this randomized study, K-RARP was proved to be non-inferior to D-RARP in perioperative, oncologic and functional outcomes and even offered less EBL and lower postoperative drainage volume.

Utilizing the KD-SR-01® robotic system, all RARP were performed smoothly without conversion to open and intraoperative transfusion. Despite considerable gaps in operating experiences and differences in the number of robotic arms between two robotic systems, the console time was not prolonged significantly in the K-RARP group, and was also comparable with that reported by previous meta-analyses [18, 19], suggesting it manageable in transitioning from other robotic systems to KD-SR-01® system for surgeons. In our study, K-RARP was found to correlate with less intraoperative bleeding. The EBL could not be directly compared across two groups, as the D-RARP group had more, even non-significant, stage T3 patients and lymphadenectomy was more frequently performed. Also, the result was biased by an outlier in the D-RARP group. We demonstrate that at a minimum, KD-SR-01® robot is reliable in controlling intraoperative bleeding. Together, these findings confirm the feasibility of KD-SR-01® robot in performing RARP.

The minimally invasive nature and delicate operation of robotic system enables improved safety and rapid recovery in RARP. In the present study, the overall complication rate was 20.0% in the K-RARP group, similar to the 15.8% observed in the D-RARP group, with no major complication occurred in both groups. Two retrospective studies with large sample size reported an overall complication rate of 20.6% and 22.2% in RARP, respectively [20, 21], consistent with our result. Also, K-RARP was non-inferior to D-RARP regarding the recovery of flatus and defecation, as well as the length of drainage. Unexpectedly, the total drainage volume was significantly reduced in the K-RARP group, which we speculate to be related to less bleeding and lymphadenectomy intraoperatively. The hospitalization length was 7.5 days for patients undergoing K-RARP, longer than those reported by institutions in USA [17, 22], but is close to those reported by other Chinese medical centers [23, 24]. This may be explained by variations in criteria for admission and discharge, as well as medical insurance policies between countries. These results, taken together, underline the safety of KD-SR-01® robotic system for RARP.

The short-term oncologic efficacy of RARP was also compared between the two robotic systems. Our results did not demonstrate a significant difference in the rate of PSM between s groups (15.0% for K-RARP and 26.5% for D-RARP). In prostate cancer, the surgical margin status is a surrogate for surgical quality and is also an important prognostic factor. The PSM relates to biochemical relapse and often results in an early initiation of adjuvant therapy [25]. A meta-analysis calculated a pooled PSM rate of 24.6% (ranging from 15.8 to 36.0%) in RARP based on 15 studies reporting this outcome [26]. The PSM rate could be biased by tumor staging and pathologists' experience and subjective criteria [27]. Therefore, direct comparison of PSM rates across studies or groups can be misleading, as a slightly elevated PSM rate of D-RARP here might mainly be related to a higher proportion of pT3 patients. According to PSA levels at four and six weeks postoperatively, measurable PSA was tested in one patient undergoing K-RARP and two patients undergoing D-RARP, but PSA failure did not occur in any patient. The early occurrence of measurable PSA was found to have a negative effect on the prognosis of PCa, and ought to be noted clinically [28]. In recent years, researchers found that the prognosis of patients with elevated PSA levels after radical therapy is strongly heterogenous, and a various of risk-stratification criteria have been established, but their prognostic value remain debatable [29], Therefore, these analyses based on PSA levels can only partially reflect the short-term oncologic efficacy of K-RARP, the mid-term or long-term results are lacking, and a longer follow-up is still required.

There was little difference in terms of urinary function at six weeks post-surgery between two groups, indicating that K-RARP was non-inferior to D-RARP in the early recovery of urinary function. Though the RARP enabled a rapid functional recovery within the first three months after surgery [17], a one-year follow-up study reported a continuous pad use or urine leakage in about 20% of patients [30]. Therefore, the performance of K-RARP in retaining urinary continence remains to be assessed through a longer follow-up. Regrettably, data on sextual function was absent due to advanced age and conservative attitudes towards sexual issues in our patients, which should be investigated in future studies, if possible.

To our knowledge, few studies compared the self-developed KD-SR-01® robot and the widely used DaVinci® robot in RARP. The prospective nature, together with matched demographic and tumor characteristics between groups, has improved the reliability of our results. The KD-SR-01® surgical robot is completely self-developed with intellectual property rights. It was estimated that the price was 25–30% of that of the DaVinci® robot, largely reducing the economic burden for Chinese patients with PCa which ranked sixth in the ranking of tumor incidence in China [31]. Despite this, the current study has several limitations. The single center setting, small sample size and a single medical center design limit generalizations and interpretations of our findings. Also, we are unable to evaluate the mid-term or long-term oncologic and functional efficacy of K-RARP

due to the very short follow-up duration. Therefore, whether K-RAPR offers non-inferior overall prognosis compared to D-RARP remains ambiguous. Additionally, we only evaluated the urinary function during the follow up, while sextual function and hormone function which have been paid expanded attention nowadays, were not assessed here [32]. Further analyses addressing these issues are warranted.

Conclusions

The results of this randomized clinical trial showed that the KD-SR-01® robot is non-inferior to the DaVinci® robot in feasibility, safety and short-term efficacy for RARP, and may be an inexpensive alternative clinically. With the continuous application of K-RARP in China, a multicenter comparative study with a larger sample size and a longer follow-up is warranted to confirm our findings and for further investigation.

Abbreviations

RP	Radical prostatectomy
RARP	Robot-assisted radical prostatectomy
PCa	Prostate cancer
RCT	Randomized clinical trial
K-RARP	KD-SR-01® robot-assisted radical prostatectomy, D-RARP = DaVinci-S® robot-assisted radical prostatectomy
NMPA	National medical products administration
ASA	American society of anesthesiologists
MRI	Magnetic resonance imaging
BMI	Body mass index
T-PSA	Total prostate specific antigen
EBL	Estimated blood loss
ICU	Intensive care unit
LOS	Length of stay
PSM	Positive surgical margin
IQR	Interquartile range
SD	Standard deviation

Supplementary Information

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Supplementary Material 1

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None.

Author contributions

XWF and JZG were guarantors of this research and initiated this study. XWF, DJ and CL contributed to the design of the study. XWF, DJ, LGH, XY, ZJM, WHZ and JZG were members of the surgical team. JRY contributed to the patient follow-up, data collection, data analyses and drafted the manuscript. DJ and XWF revised the manuscript. All authors contributed to result interpretation and final approval of the manuscript.

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Data availability

Data are available from the corresponding author on reasonable request.

Declarations

Competing interests

Liang Cui is the co-founder and stock owner of Suzhou KangDuo Robot Co., Ltd. He was not involved in the data collection, data analysis, or data interpretation. All other authors have nothing to declare.

Ethical approval and consent to participate

This study was approved by the Ethics Review Committee of Peking Union Medical College Hospital with a registration number of HS2021150.: Informed consent was obtained from all participants.

Consent to publication

Informed consent containing relevant information was obtained from all participants.

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