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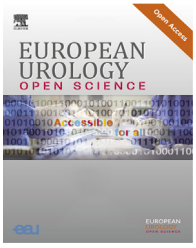

European Association of Urology

Prostate Cancer

Suitability of the MP1000 Platform for Robot-assisted Prostatectomy: A Prospective Randomised Controlled Trial

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Abstract

Background and objective: Robot-assisted radical prostatectomy (RARP) is widely used because of the many advantages of a robotic approach. The da Vinci Si robot is one of the most commonly used surgical robot systems, but it may be associated with higher costs owing to the use of consumable surgical supplies. Our aim was to conduct a preliminary investigation of the capability of the MP1000 system for RARP.

Methods: In this prospective, multicentre, single-blinded study, we randomly assigned 42 patients scheduled to undergo RARP between April and September 2021 to a da Vinci Si group (control) or an MP1000 group (intervention). Patients underwent RARP performed using the assigned robotic system and were followed up at 3-mo intervals. The primary outcome was the rate of conversion to open/laparoscopic surgery. Secondary outcomes were installation and operation times, intraoperative blood loss, postoperative surgical margin status, hospital stay, incontinence, complications, safety indicators, and surgeon ergonomics.

Key findings and limitations: All procedures were successfully completed without conversion to open/laparascopic surgery or major complications. Secondary outcomes, including oncological and ergonomic indicators, did not differ significantly between the groups over the study period. One patient in the control group experienced dysuria (Clavien-Dindo grade 3). No patients had incontinence at 3 mo. A limitation of the study is the small sample size.

Conclusions and clinical implications: RARP with the MP1000 system is feasible, safe, and effective in the management of localised prostate cancer.

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Patient summary: We assessed the effectiveness and safety of the new MP1000 robot system for robot-assisted removal of the prostate in comparison to the da Vinci Si robot. We found no difference in effectiveness or safety among 42 patients with prostate cancer who were assigned randomly to one of the two systems. We conclude that the MP1000 is a suitable robot for this surgery.

1. Introduction

Prostate cancer (PCa) is the second most common cancer diagnosed worldwide and the fifth leading cause of cancer-related death among men [1]. Radical prostatectomy (RP) is most commonly recommended for localised PCa. Over the past 40 yr, robot systems have been introduced and rapidly developed for a range of specialties, including urology [2]. Since the first robot-assisted RP (RARP) in 2000 [3] the procedure has gained in popularity for PCa treatment. Robotic systems provide an enhanced view via a sophisticated camera and intuitively reproduce delicate manipulations performed by surgeons using flexible arms [4]. RARP is popular worldwide owing to shorter hospital stays, a lower positive surgical margin (PSM) rate, and lower complication rates [5–8].

The da Vinci robot is the system most commonly used for various surgical procedures, including RARP. However, the costs for the system itself as well as consumables and maintenance are extraordinarily high [9,10]. Several robot systems are currently in development, with the hope that new robotic platforms may yield cost reductions.

The MP1000 is an independently developed, promising new robotic platform. In this study our aim was to verify whether the MP1000 system is suitable for RARP.

2. Patients and methods

2.1. Design

This prospective, multicentre, single-blinded, randomised controlled study was approved by the local regional medical and health ethics committee of the First Medical Centre of PLA General Hospital (S2021-595-01) and registered in the Chinese Clinical Trial Registry (ChiCTR2100045537). The trial was conducted at four centres in China and completed according to the protocol.

The MP1000 robotic system is developed and produced by Shenzhen Edge Medical Company.

2.2. Patients

Patients scheduled to undergo RARP were randomly assigned to the da Vinci Si robot (control) group or the MP1000 (intervention) group. The inclusion criteria were age 18-80 yr, body mass index of 18-30 kg/m^2, a biopsy diagnosis of PCa, the ability to tolerate RARP, and consent to undergo the required examinations and follow-up. The exclusion criteria were inability to tolerate surgery because of cardiovascular or other contraindications, a history of epilepsy or mental diseases, abdominal infection, peritonitis, diaphragmatic hernia, severe systemic infection, metastatic disease (prostate or otherwise), inability to comprehend the research procedure or refusal to sign informed consent, a history of surgery at the operative site, severe allergies, suspected/confirmed alcohol/drug addiction, and unsuitability for the study as deemed by the investigator.

2.3. Randomisation and blinding

From April to September 2021, 42 patients were enrolled and allocated 1:1 to the two groups via web-based central randomisation software. Because the robot systems were different, patients were blinded to the treatment allocation using masks.

2.4. Procedure

Preoperative data including age, height, weight, history of adjuvant therapy, Gleason score, and serum prostate-specific antigen (PSA) were collected for the participants, along with other serum examinations, electrocardiography, and chest radiography performed to exclude surgical contraindications.

After randomisation, patients underwent RARP via the transperitoneal anterior approach using the robotic system to which they were randomised. Figure 1 shows steps in the RARP procedure using the MP1000 platform. All surgeries were performed by experienced surgeons.

Similar to the da Vinci Si, the MP1000 system comprises a surgeon control console, patient and vision carts, and reusable endoscopic instruments. Port placement is the same for both systems (Fig. 2). The patient cart has four integrated boom-mounted arms, allowing procedures in all four abdominal quadrants without patient repositioning. The endoscope can be placed on any of the four arms, giving greater flexibility for visualisation of the surgical site. The three-dimensional high-definition vision system provides a wider field of view at the same working distance, which is beneficial for surgical operations. Table 1 compares the two systems.

All prostate specimens were analysed by two experienced pathologists, and the postoperative Gleason score and tumour stage were reported. Postoperative follow-up visits were scheduled at 1 wk, 1 mo, and 3 mo. Follow-up assessments included serum PSA, imaging, postoperative complications, and urinary function.

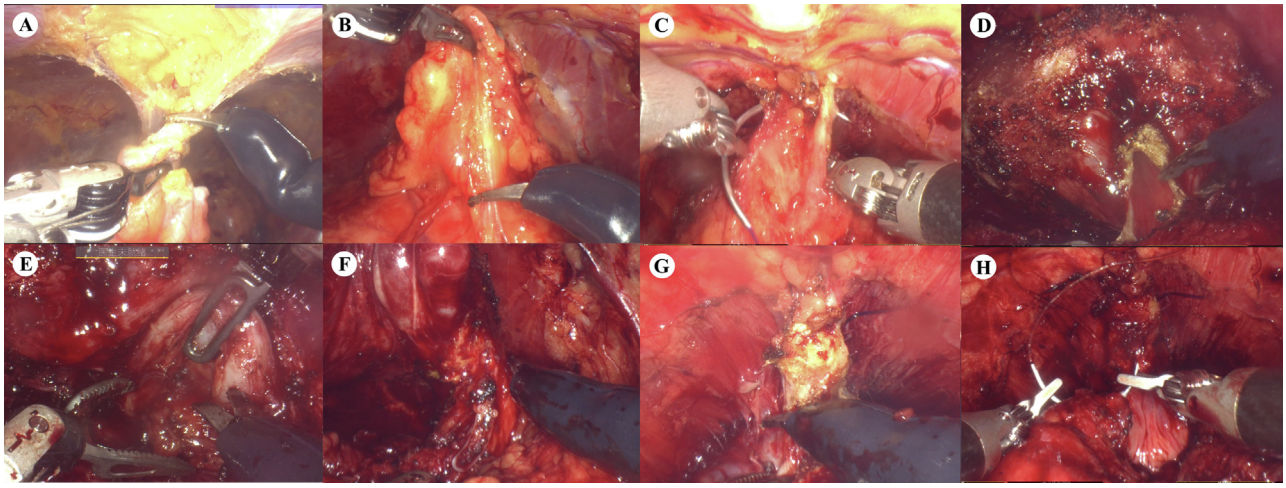

Fig. 1 – Robot-assisted radical prostatectomy with the MP1000 system. (A) Release of the bladder. (B) Removal of periprostatic adipose tissue. (C) Suture ligation of the dorsal venous complex. (D) Dissection of the bladder neck. (E) Identification of the seminal vesicles and vasa deferentia. (F) Disconnection of the prostatic pedicles. (G) Disconnection of the urethra. (H) Vesicourethral anastomosis.

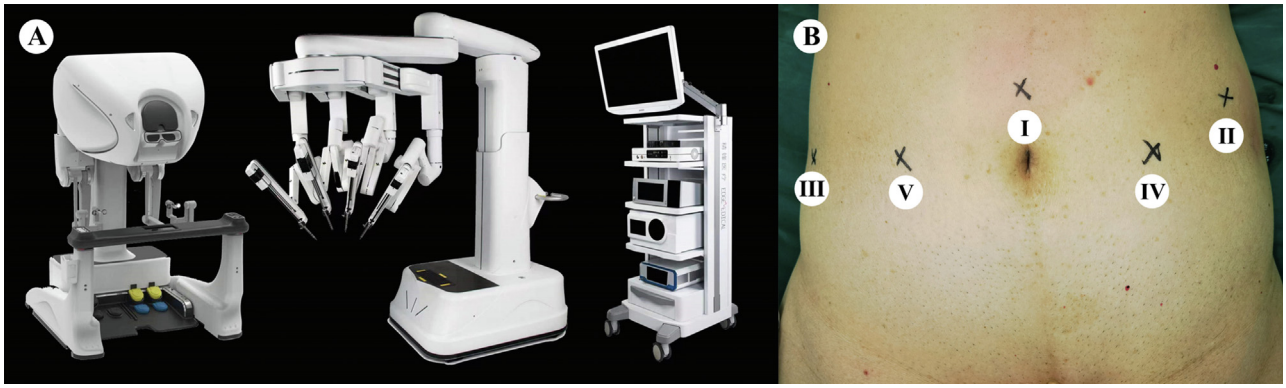

Fig. 2 – The MP1000 system and port placements. (A) MP1000 system components including the control console, patient cart, and ports. (B) Port placements: I, camera; II, assistant; and III-V, robotic instruments. Pneumoperitoneum was established by advancing a Veress needle from the umbilicus. A 1-cm skin incision was made for the camera approximately 2 cm above the umbilicus (point I). Under direct vision, two ports were placed approximately 8 cm from the umbilicus with the left trocar (point IV) for a bipolar Maryland grasper and the right trocar (point V) for a monopolar scissor. An additional port (point III) was placed approximately 8 cm from point V for ProGrasp forceps. All robotic instrument ports are placed at the horizontal umbilical line. The port for the assistant (point II) was placed approximately 6-8 cm from point IV and approximately 1-2 cm above the umbilicus for suction, retraction, and clip placement.

2.5. Outcomes

The primary outcome was the operative success rate, which was reported using descriptive statistics. Operative success was defined as surgery completed without conversion to a laparoscopic or open procedure.

The secondary outcomes were installation and operation times, intraoperative blood loss, PSM rate, postoperative hospital stay, serum PSA, and evaluation of ergonomics, urinary function, complications, and safety events. The installation time was the interval from draping to robot installation. The operation time was the interval from robot installation to closing. A PSM was defined as a portion of tumour found on the inked margin of the postoperative specimen [11]. Postoperative serum PSA levels were evaluated at the 1-mo and 3-mo follow-up visits, and cases with PSA $\geq$0.1 or $\leq$0.02 ng/ml were reported. Ergonomics were evaluated using the National Aeronautics and Space Administration Task Load Index (NASA-TLX) tool [12]. This assesses mental, physical, and temporal demands, performance, effort, and frustration for evaluation of the workload and satisfaction of surgeons [13]. Each item is scored on a scale from 1 to 21 points, with higher scores indicating higher demand. Complications were evaluated using the Clavien-Dindo classification [14] often recommended for urological procedures [15]. Urinary function was evaluated as the incidence of continence, defined as the use of either 0 or1 pad/d.

Safety events were defined as a linkage interruption between the control console and the patient cart, clamping issues whereby instruments could not be loosened, intraoperative robot error alarms, and instrument breakdown or damage.

2.6. Statistical analysis

Quantitative variables are described as the mean and standard deviation for variables with a normal distribution, or

Table 1 – Comparison of the MP1000 and da Vinci Si robotic systems

Specifications	MP1000	da Vinci Si
Components	Surgeon control console Patient cart Vision cart Reusable endoscopic instruments	Surgeon control console Patient cart Vision cart Reusable endoscopic instruments
Robotic movement mode	Master-slave	Master-slave
Response delay (master-to-slave)	≤80 ms	≤80 ms
Control console		
Robotic control	Finger grip type	Finger grip type
Pedal clutch	Present	Present
Camera control	Present	Present
Wrist motion	Present	Present
Hand clutch	Present	Present
Lateral arm-switching pedal	Present	Present
Scale motion	Present	Present
Patient cart		
Robotic arms	4 (1 camera and 3 working)	4 1 camera and 3 working)
Arm mount mode	Integrated boom-mounted	Separated mount
Endoscopic placement	On any of the 4 arms	Fixed on the middle arm
Three-dimensional vision system		
Field of view	80°	60°
Fluorescence imaging	Not present	Present

the median and interquartile range for variables with a non-normal distribution. The t test or Wilcoxon's test was applied to compare groups after testing for a normal distribution. Categorical variables are described as the frequency and proportion, and a χ^2 or Fisher's exact test was used for comparisons. The Wilson method was used to calculate the 95% confidence interval (CI) for the operative success rate. All data were analysed using SAS v9.4. Statistical significance was set at $p < 0.05$ unless stated otherwise.

2.7. Ethics approval

All study participants provided written informed consent for participation in and publication of this study. The study was conducted in accordance with the Declaration of Helsinki.

3. Results

3.1. Participants

The trial ended when the last participant completed the final follow-up visit at 3 mo after surgery. Supplementary Figure 1 reports the number of patients not completing the trial (with reasons). Patient characteristics are listed in Table 2. Age, height, weight, and body mass index were comparable between the groups. The mean preoperative PSA level was 7.61 ± 7.82 ng/ml in the MP1000 group and 9.17 ± 7.98 ng/ml in the control group ($p = 0.531$). No difference in the distribution of Gleason scores was observed ($p = 1.000$).

Table 2 – Demographic characteristics of the study patients

Parameter	MP1000 group	Control group	*p* value
Patients, *n* (missing)	21 (0)	21 (0)	
Mean age, yr (SD)	65.67 (6.92)	66.29 (7.37)	0.781
Mean height, cm (SD)	166.52 (7.76)	167.05 (4.68)	0.792
Mean weight, kg (SD)	66.51 (8.07)	70.27 (8.79)	0.157
Mean body mass index, kg/m^2 (SD)	23.94 (1.91)	25.09 (2.00)	0.064
Mean preoperative PSA, ng/ml (SD)	7.61 (7.82)	9.17 (7.98)	0.531
Biopsy Gleason score, *n* (%)			1.000
3 + 3 or 3 + 4	7 (47.18)	9 (45.00)	
4 + 3 or 4 + 4	9 (52.94)	9 (45.00)	
4 + 5 or 5 + 4 or 5 + 5	1 (5.88)	2 (10.00)	
Unevaluable [a]	4	1	

PSA = prostate-specific antigen; SD = standard deviation.
Gleason scores for patients with previous hormone therapy were unevaluable.

3.2. Operative variables

Table 3 presents results for the operative variables. All 42 surgeries were completed successfully without conversion. Two patients in the MP1000 group and four in the control group required pelvic lymph node dissection. All 21 participants in each group were included in all the analyses, which were based on the original assigned arm. The 95% CI for the operative success rate was 84.54-100% in both groups. The difference in the operative success rate was 0% (95% CI −15.46% to 15.46%).

The groups did not differ regarding median installation time (20 vs 21 min; $p = 0.389$) or median blood loss (50 vs 100 ml; $p = 0.707$). Operation time was comparable (174.76 ± 55.28 vs 155.67 ± 35.37 min; $p = 0.190$; Supplementary Fig. 2). No intraoperative organ or vascular damage occurred in either group. No adverse safety events were recorded.

3.3. Intraoperative and perioperative variables

Table 4 lists complication rates and follow-up data. No complications occurred in the immediate postoperative period. One urinary tract infection (Clavien-Dindo grade 2) occurred in the MP1000 group and one case of dysuria (Clavien-Dindo grade 3) in the control group. Patients from both groups developed fever or flatulence (Clavien-Dindo grade 1). Five patients (23.81%) in the MP1000 group and four (19.05%) in the control group reported incontinence at 1 mo ($p = 1.000$). No patients reported incontinence at 3 mo. The median postoperative hospital stay was 7 d in the MP1000 group and 8 d in the control group ($p = 0.014$). The postoperative pathologic tumour stage was similar between the groups ($p = 1.000$). Three patients (14.29%) in the MP1000 group and seven (33.33%) in the control group ($p = 0.277$) had PSMs. One patient in the control group missed serum PSA measurement at 1 mo. PSA ≥0.1 ng/ml was observed for two patients (9.52%) in the MP1000 group and two (9.52%) in the control group at 1 mo, and three patients (15%) in the MP1000 group and two (9.52%) in the control group at 3 mo. PSA ≤0.02 ng/ml was observed for 12 patients in the MP1000 group (57.14%) and 17

Table 3 – Operative variables

Parameter	MP1000 group	Control group	*p* value
Operative success, % (95% CI) [a]	100 (84.54-100)	100 (84.54-100)	
Difference in operative success rate, % (95% CI) [b]	0 (−15.46 to 15.46)		
Median installation time, min (IQR)	20 (18-21)	21 (18-22)	0.389
Mean operation time, min (SD)	174.76 (55.28)	155.67 (35.37)	0.190
Median blood loss, ml (IQR)	50 (50-150)	100 (50-100)	0.707
Intraoperative organ or vascular damage, *n* (%)	0	0	
Safety events (*n*)			
Interruption of connection between console and robot arms and reconnection failure	0	0	
Instruments could not be loosened when clamping tissues	0	0	
Error alarm of robot	0	0	
Instrument failure or damage	0	0	

CI = confidence interval; IQR = interquartile range; SD = standard deviation.
[a] Operative success was defined as surgery completed without conversion to a laparoscopic or open procedure.
[b] Difference in operative success rate = operative success rate in the MP1000 group − operative success rate in the control group. The noninferior intermediate value is 10%.

Table 4 – Intraoperative and perioperative variables

Parameter	MP1000 group	Control group	*p* value
Postoperative complications, *n* (%)			0.471
Overall	4 (19.05)	2 (9.52)	
Clavien-Dindo grade 1	3 (14.29)	1 (4.76)	
Clavien-Dindo grade 2	1 (4.76)	0	
Clavien-Dindo grade 3	0	1 (4.76)	
Incontinence, *n* (%)			
1 mo after surgery	5 (23.81)	4 (19.05)	1.000
3 mo after surgery	0	0	-
Median hospital stay, d (interquartile range)	7 (6-8)	8 (7-9.25)	0.014
Positive surgical margin, *n* (%)	3 (14.29)	7 (33.33)	0.277
Tumour stage, *n* (%)			1.000
T1	2 (9.52)	3 (14.29)	
T2	16 (76.19)	16 (76.19)	
T3	2 (9.52)	2 (9.52)	
T4	1 (4.76)	0	
Prostate-specific antigen level, *n* (%)			
At 1 mo after surgery			
≥0.1 ng/ml	2 (9.52)	3 (14.29)	0.954
0.02-0.1 ng/ml	7 (33.34)	6 (28.57)	0.739
≤0.02 ng/ml	12 (57.14)	12 (57.14)	0.853
At 3 mo after surgery			
≥0.1 ng/ml	2 (9.52)	2 (9.52)	1.000
0.02-0.1 ng/ml	2 (9.52)	0 (0)	0.488
≤0.02 ng/ml	17 (80.96)	19 (90.48)	0.659
Recurrence at 3-mo follow-up (*n*)	0	0	

(80.95%) in the control group at 1 mo, and 12 patients (60%) in the MP1000 group and 19 (90.48%) in the control group at 3 mo. At 3-mo follow-up, no evidence of recurrence was evident in either group.

3.4. *Surgeon satisfaction*

Supplementary Table 1 lists median NASA-TLX scores for the MP1000 versus control group for mental demand (6 vs 9), physical demand (6 vs 8), temporal demand (8 vs 8), performance (11 vs 10), effort (7 vs 9), and frustration (5 vs 6). The differences were not significant.

4. Discussion

The development of novel robotic systems with telepresence and accurate repeatable performance has helped surgeons in performing RP steps that are technically demanding [14] such as clamping, resection, ligation, suturing, and anastomosis. The recognised advantages of robot-assisted surgery include perioperative monitoring of parameters, operating performance, and the learning curve. However, costs for purchasing and maintaining the robotic systems are extraordinarily high. We selected RARP to compare the performance of the MP1000 and da Vinci Si systems. Regarding the primary outcome, all surgeries in both groups were successfully completed without conversion to laparoscopic or open surgery, confirming the feasibility of RARP with the MP1000 system.

The two systems were comparable regarding urinary function outcomes and complications immediately after surgery and at 1 and 3 mo postoperatively. Hospital stay was significantly shorter for the MP1000 group than for the da Vinci Si group, which may be because of many contributing factors. No adverse safety events occurred in either group, and there was no damage to important vascular structures, nerves, or organs due to machine errors or connection interruptions. This confirms the safety of the MP1000 system. Both preoperatively and postoperatively, Gleason score, tumour stage, and risk stratification were consistent between the groups, indicating that the baseline factors matched. The PSM rate in the MP1000 group was 14.29%, concordant with previous findings [15]. PSM rates and postoperative serum PSA did not differ between the groups, and no recurrence was detected on 3-mo imaging examinations. Therefore, early oncological outcomes were comparable. The RP goal of eliminating tumour growth while preserving the pelvic organs is achieved via resection of the prostate and seminal vesicles, followed by vesicourethral anastomosis. The surgical technique requires delicate manipulations, including clamping, resection, ligation, suturing, and anastomosis, which are technically demanding [16]. Therefore, the MP1000 system might also be suitable for wider applications in other urological procedures, and future study is warranted.

Several valuable features of the MP1000 system were identified. First, the components and controls are similar to those of the da Vinci Si platform. Surgeons with experience in using the da Vinci Si encountered no difficulties in switching systems, and the similar operating mode and ani-

mal trials make it easy to master the new platform. Second, the MP1000 arms are suspended on a beam above the positions occupied by the patient and the surgical assistants, so interference is rare. Third, the MP1000 control console provides the surgeon with glasses-free three-dimensional vision, and the high resolution and accurate colour reflection render it highly suitable for precision surgeries. These features were reflected in the ergonomics results, despite the surgeons' lack of experience with the platform. A single-port robotic system is currently being developed by the MP1000 manufacturer. The control console has been designed to work for both systems, so the purchase cost would be reasonable.

Some disadvantages of the MP1000 system were identified. First, surgeons needed to acclimatise to the movement of the arms and the clamping force of the graspers, so additional training is required. The mean operation time was longer in the MP1000 group than in the da Vinci Si group, although the difference was not statistically significant. Second, the MP1000 platform includes a safety feature whereby it can detect when the surgeon leaves the control console and stop the robotic arms. This feature was inadvertently activated several times, although surgeons were still manoeuvring the robot. This highlights the need for software updates.

The development of more surgical robot systems will increase industry competition and should result in lower prices and better technology. For hospitals on the Chinese mainland, installation of each da Vinci Si robotic system costs US$3 million, with a further cost of US$6000 for each patient undergoing robot-assisted surgery. This cost could be expected to decrease by approximately 50% with popularisation of the MP1000 system. Several surgical robotic systems have been developed and are currently used for RARP [14,17,18] but comparative studies are rare. Alip et al [19] matched 66 patients one-to-one to undergo RARP with the Revo-i and da Vinci robotic systems. Our study also demonstrated promising results for the new platforms. An application for approval of MP1000 use in humans approval has been submitted to the Chinese National Medical Products Administration (CQZ2200086) and an international application is being prepared. Patients may benefit from these new systems as they become more affordable. In addition, with more platforms installed in hospitals, especially hospitals in developing countries, surgeons will have greater exposure to advanced technology.

The main study limitation is the small sample size of only 42 patients. Although our data show a success rate of 100% for the MP1000 group without serious complications, future research with a larger sample is required. Second, only RARP procedures were performed using the MP1000 system, and other procedures should be verified in the future. Our 3-mo follow-up period is also insufficient to assess long-term outcomes such as continence, which is reported to improve gradually over time and stabilise at 1 yr after RP [20].

Further studies are needed to verify that the performance of the MP1000 platform matches that of other robots for various surgical indications.

5. Conclusions

RARP using the MP1000 system is feasible, safe, and effective in the management of localised PCa.

Author contributions: Xu Zhang had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Xu Zhang, Huang, Xuepei Zhang.
Acquisition of data: Niu, Ao, Gao, Zhou, He, Tao, Guo.
Analysis and interpretation of data: Niu, Ao, Gao, He.
Drafting of the manuscript: Niu, Ao, Gao.
Critical revision of the manuscript for important intellectual content: Zhou, Ma, Li, Xuepei Zhang.
Statistical analysis: Zhou, He, Tao, Guo.
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Administrative, technical, or material support: Wang, Xuepei Zhang, Huang.
Supervision: Wang, Ai, Li.
Other: None.

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Data sharing statement: The deidentified database, study protocol, statistical analysis plan, and informed consent form will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2024.02.017.

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