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Initial experience with the Carina™ platform in robotic-assisted hysterectomy for gynecological malignant disease

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Abstract

Objective This retrospective study was performed to evaluate the efficiency and safety of a new modular robotic system, the Carina™ Platform (Ronovo Surgical, Shanghai, China), in gynecological surgery.

Methods All patients underwent robotic hysterectomies (RH) using the Carina performed by a single gynecologist experienced in laparoscopic and robotic surgery from November to December 2023. Patients were evaluated for estimated blood loss (EBL), intraoperative and postoperative complications, length of hospital stay, conversion rate, as well as console and docking times.

Results Two separate populations were involved: 10 cervical cancer patients (group 1) and six endometrial cancer patients (group 2). There were no conversions to laparotomies or laparoscopies. The mean docking time was 5.75 ± 2.38 min. The mean console time and mean operative time were 154.60 ± 26.01 min and 211.90 ± 53.65 min in group 1, respectively. The mean console time and mean operative time were 98.67 ± 26.71 min and 153.33 ± 22.77 min in group 2, respectively. The median estimated blood loss for group 1 and group 2 were 30 ml (20, 50) and 20 ml (7.5, 20), respectively. No intraoperative or postoperative complications related to the device were recorded.

Conclusion Our experience allows us to state that the modular Carina Platform is safe and efficient in complex gynecologic surgery.

Clinical Trial Registration: researchregistry10353 https://www.researchregistry.com/browse-the-registry#home/registrationdetails/665c1a398a97c302739cce06/

Keywords Robotic-assisted surgery · Modular Carina™ platform · Gynecologic surgery

Hysterectomy is one of the most common surgical procedures performed on gynecological patients around the world [1, 2]. Approximately 33% of women over the age of 60 in the United States have undergone a hysterectomy [1]. Over the past decades, surgical techniques for hysterectomy have advanced from laparotomy to laparoscopic methods with smaller incisions and shorter hospital stays [2]. Unfortunately, for complex diseases, the laparoscopic approach can be associated with longer operative time, higher estimated blood loss (EBL), and higher conversion rates [3–5]. Crucially, this procedure should only be performed by experienced professionals.

Robot-assisted surgery has the potential to overcome the limitations of conventional laparoscopy by improving the surgeon's dexterity and, thanks to advanced 3D imaging, by reaching a higher precision, especially in narrow and deep areas of surgery [6]. Robotic surgery reduces the rate of laparotomies for complex hysterectomies, allowing more patients to benefit from a minimally invasive procedure. Furthermore, observational evidence suggests that robotic surgery's intuitive nature shortens the learning curve for surgeons compared to conventional laparoscopic surgery [7, 8].

Since the FDA approved the da Vinci surgical system for gynecological surgery in 2005, researchers have documented their experience with robotic surgery for endometrial and cervical cancers [9–14]. Boggess et al. reported the outcomes of 51 consecutive patients who underwent robotic radical hysterectomy with excellent outcomes

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[15]. These initial reports demonstrate the feasibility and potential benefits of robot-assisted technology in treating patients with early-stage cancer.

Several innovative robotic systems, including the Carina™ Platform (Ronovo Surgical), are either about to be launched or already in use. The Carina platform is designed to provide greater flexibility during minimally invasive surgery. It features an immersive surgeon console that controls four independent patient carts, unlike the monolithic structure of the da Vinci Surgical System. However, since the recent launch of the Carina platform, studies have been lacking in describing its performance in a clinical setting. This study describes our first clinical experience using Carina in gynecological surgeries.

Materials and methods

Data source and patient selection

This retrospective study analyzed gynecological surgeries performed using the Carina™ Platform at the First Affiliated Hospital of Zhengzhou University from November to December 2023. The ethics committee approved the utilization of the surgical robotic system in gynecological surgery (IRB No. L2023-Q299-001). The study is registered at https://www.researchregistry.com/browse-the-registry#home/registrationdetails/665c1a398a97c302739cce06/. Patients were selected based on no absolute contraindications for laparoscopic surgery, body mass index (BMI) range of 18.5–30 kg/m^2, and informed consent. A team with previous experience in robot-assisted laparoscopic surgery underwent training to ensure safe and effective robot utilization. All procedures were performed by the same experienced surgeon (more than 2000 cases performed).

Data collection

The collected data included age, BMI, history of abdominal operations, indications for surgery, docking time (from port placement to all carts being docked), console time (the duration spent by the lead surgeon controlling the robotic arm while seated at the console), total operative time (the interval from the start of the procedure to the suturing of the surgical incision), estimated blood loss (EBL) during operation, conversion rate, intraoperative and postoperative complications, postoperative pain scores (0 = no pain, 10 = agonizing pain), duration of the hospitalization, as well as physical and mental workload of the surgeon.

Carina platform

The Carina robotic system comprises three parts (Fig. 1A): an immersive surgeon console, four modular patient carts (one camera cart and three instrument carts), and an integration hub. This platform enables surgeons, sitting at an ergonomically adjustable console, to view the surgical field in stereoscopic 3D visualization and control the movements of the endoscope and instruments through manipulators. The integration hub, bridging between the surgeon console and patient carts, undertakes the functions of information transmission, peripheral connection, and system control during operation. Each patient cart is equipped with an individual robotic arm that can be fitted with either a wristed instrument with a full range of motion of seven degrees of freedom or a straight-stick instrument, providing surgeons with flexibility in choosing their tools. Each arm has a specific cart distance (Fig. 1B) and operational space (Fig. 1C) for optimal access to the surgical field.

Surgical technique

The modular design could allow surgeons to allocate patient carts around the patient and customize the docking on the basis of both abdominal anatomy and surgical procedure, but docking multiple robotic arms surrounding independently the patient instead of coming from a boom like the da Vinci surgical system also means a rise in variables. Therefore, the technical configurations, including patient positioning, port placement, and cart positioning for robotic hysterectomy (RH), were recommended based on the corresponding procedure cards developed by Ronovo Surgical using computer simulation. Prior to commencement of the clinical trial, these recommendations were verified and optimized in the cadavers by expert robotic surgeons. The procedure cards could aid in avoiding external collisions or restrictions of movement during surgery, while limiting the need for frequent moves of the patient carts.

While under general anesthesia, the patient is placed in a dorsal and steep Trendelenburg position using Allen stirrups. To avoid contact with the robot's arms, the left lower extremities are positioned in a slight degree of hyperextension. After achieving pneumoperitoneum (10–12 mm Hg), five trocars are inserted (Fig. 2A, B). A 10-mm camera trocar is placed 3–4 cm above the umbilicus. Two 8-mm robotic auxiliary trocars are placed bilaterally (approximately 8–10 cm away from the camera port to avoid collisions between the robotic arms). A 5-mm assistant trocar is located 3–5 cm above the mid-distance

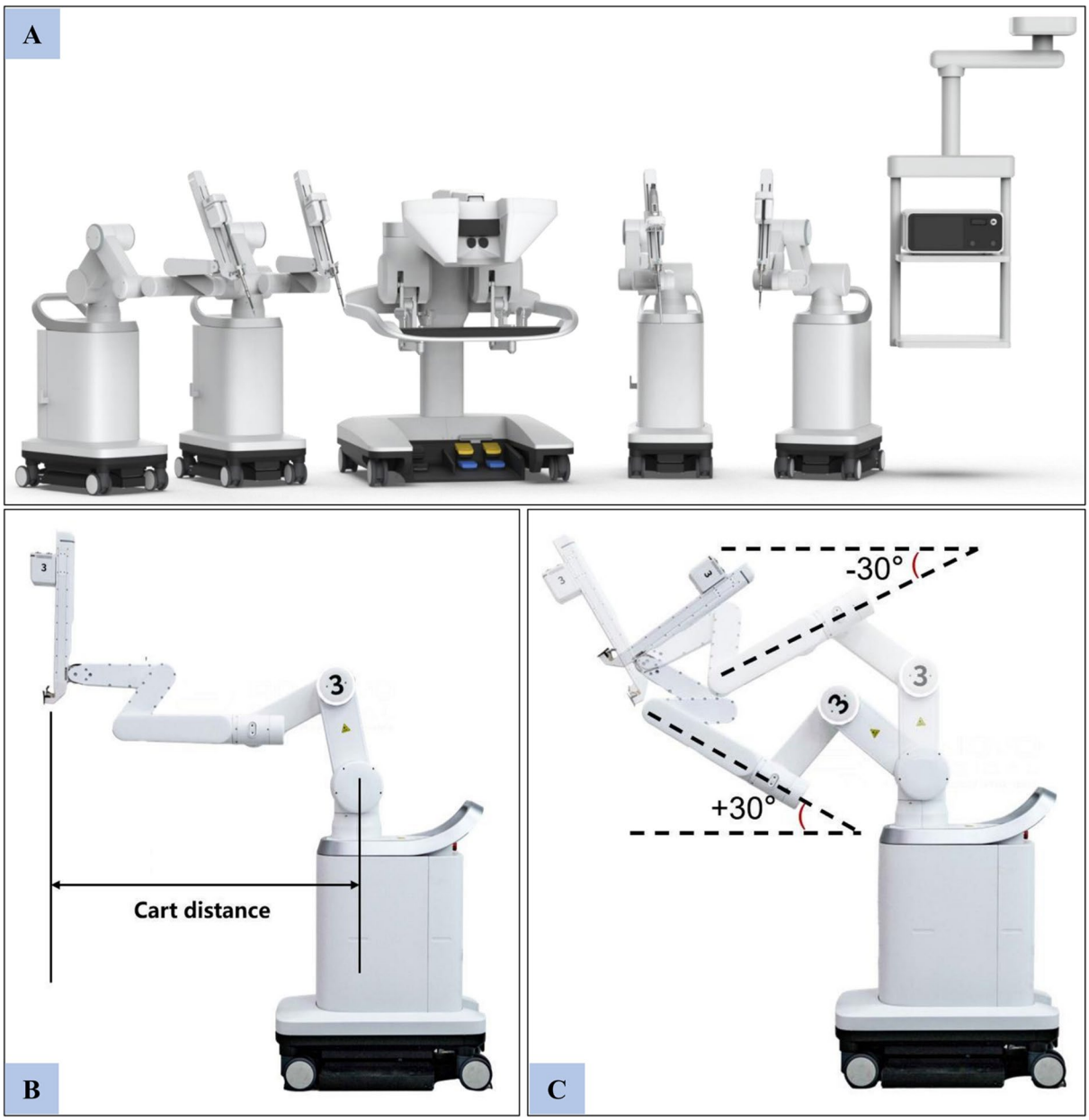

Fig. 1 The Carina™ Platform. **A** Four independent patient carts, a surgeon console, and an integration hub. **B** Example of cart distance. **C** Example of operation space setting: − 30° and + 30° position

between the camera port and the right robotic arm port, and another assistant trocar measuring 12 mm is inserted at the McBurney point. After trocar placement, the nurses assist the surgeon in performing docking procedures as follows: (1) automatically deploying each arm using buttons to determine the appropriate cart distance configuration for the procedure; (2) positioning the patient cart at the designated location indicated on the procedure card with the robotic arm directed toward the port site; (3) securing and locking the patient cart in place; (4) attaching trocars to each arm and adjusting them to the recommended operational space for the procedure; and (5) placing the endoscope and instruments. The camera cart is positioned laterally to the left leg, while the left robotic cart is placed laterally to the abdomen (below the waist), and the right robotic cart is placed laterally to the right leg (Fig. 2C). The surgeon sits ergonomically at the immersive console and can see the surgical site in 3D visualization, while the first assistant stands on the right side of the patient. The subsequent surgical steps are conducted in the context of standardized laparoscopic procedures.

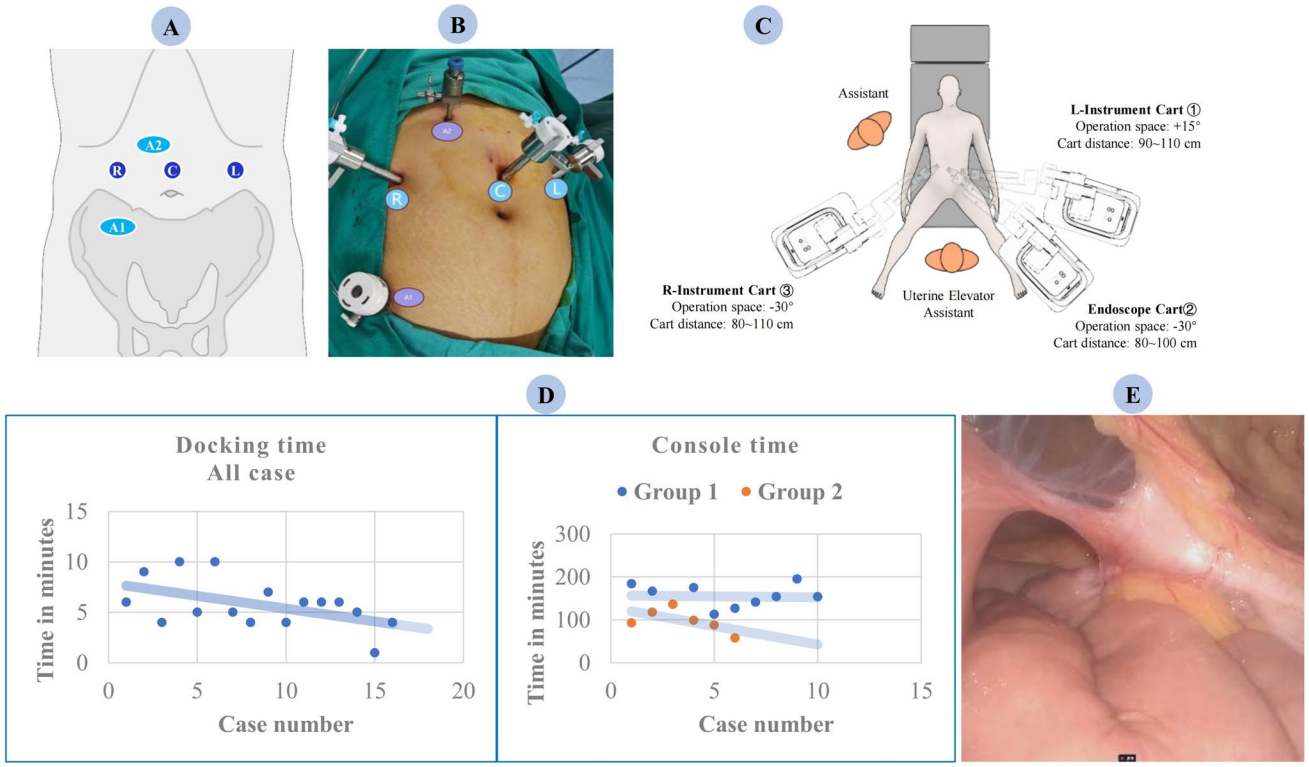

Fig. 2 Port placement, patient cart positioning for RH, and intraoperative information collected. **A** Recommended port layout for RH. **B** Example of port placement for RH. **C** Recommended patient cart positioning for RH. **D** Docking time and console time for hysterectomy performed with Carina. **E** Intraoperative images of the special case

In our surgery, we decided to use three patient carts. A 30° endoscope attached to the camera arm provides vision. Fenestrated bipolar forceps are used for grasping and coagulation with the left robotic arm, while monopolar curved scissors are attached to the right robotic arm for dissection and coagulation. The closure of the vaginal cuff is performed with a large needle driver, assisted by another person for suture placement. All wristed instruments are disposable.

Statistical analysis

All statistical analyses were performed using SPSS 26.0. The data are presented as mean, median, standard deviations (SD), and interquartile ranges (IOR), as appropriate.

Results

A total of 16 patients underwent RH with the Carina system, including six patients (37.5%) with early endometrial cancer and ten (62.5%) with early-stage cervical cancer. The baseline characteristics of the study population are described in Table 1, showing a mean age of 55.13 ± 10.2 years and a mean BMI of 25.08 ± 3.33 kg/m^2. Among them, ten patients (62.5%) had previous abdominal surgery experience, while eight patients (50%) had one or more medical comorbidities such as diabetes, hypertension, chronic obstructive pulmonary disease, or obesity.

Operative outcomes were analyzed for all cases identified. The mean docking time was 5.75 ± 2.38 min. The study population was divided into two groups based on cancer type: 10 cervical cancer patients (62.5%) were submitted to radical hysterectomy (group 1), and six endometrial cancer patients (37.5%) underwent hysterectomy with bilateral pelvic and/or para-aortic lymphadenectomy (group 2). The mean docking time, mean console time, and mean operative time in group 1 were 5.4 ± 1.9 min, 154.60 ± 26.01 min, and 211.90 ± 53.65 min, respectively (Table 2). While in group 2, the mean docking time, console time, and operative time were 6.33 ± 3.14 min, 98.67 ± 26.71 min, and 153.33 ± 22.77 min, respectively. A trend in docking time and console time reduction was observed (Fig. 2D). The overall median EBL for cervical cancer patients and endometrial cancer patients was 30 ml (20, 50) and 20 ml (8.75, 20), respectively. No intraoperative complications, such as lacerations or injuries of abdominal organs, were recorded.

Procedures were successfully performed by Carina without conversion. Of 16 procedures, one patient with cervical cancer received a different port placement during the

Table 1 Baseline study population characteristics

Parameter	Mean ± SD or *N* (%)	Range (percentage)
Age (years)	55.13 ± 10.20	(37–69)
Body mass index (kg/m^2)	25.08 ± 3.33	(18.49–29.71)
Number of pregnancies	2.81 ± 1.42	(0–5)
Number of deliveries	1.75 ± 0.93	(0–3)
Previous abdominal surgery	10	62.5%
Diagnosis		
Endometrial cancer	6	37.5%
FIGO stage		
IA1	1	16.7%
IA2	4	66.7%
IIIC1	1	16.7%
Types of pathology		
Endometrioid carcinoma	6	100%
Pathological stage		
Stage I	3	50%
Stage II	1	16.7%
Stage III	1	16.7%
Unclear	1	16.7%
Cervical cancer	10	62.5%
FIGO stage		
IB1	2	
IB2	5	
IIICp	3	
Types of pathology		
Squamous histology	7	70%
Adenocarcinoma histology	3	30%
Pathological stage		
Stage2	7	70%
Stage3	2	20%
Unclear	1	10%
Medical comorbidities*	8	50%

*It means people with hypertension, diabetes mellitus, or heart disease

Table 2 Operative findings

	Group 1	Group 2
No. of patients	*N* = 10	*N* = 6
Docking time (min), mean ± SD	5.4 ± 1.9	6.33 ± 3.14
Console time (min), mean ± SD	154.60 ± 26.01	98.67 ± 26.71
Operative time (min), mean ± SD	211.90 ± 53.65	153.33 ± 22.77
EBL (mL), median (IQR)	30 (20, 50)	20 (7.5, 20)
Intraoperative complications, *N* (%)	0	0
Conversion, *N* (%)	0	0
Postoperative stay (day), mean ± SD/median (IQR)	7.30 ± 2.58	5 (4, 5)

procedure due to severe abdominal adhesions resulting from prior abdominal surgery (Fig. 2E).

Mean pain scores at the time of postoperative one day for group 1 and group 2 were 4.33 and 7.30, respectively. At the first follow-up visit 30 days post-surgery, the median pain scores for group 1 and group 2 were 0. See Table 3 for specific details.

Postoperative complications occurred in one cervical cancer patient who experienced a Clavien-Dindo grade IVA complication. A pulmonary embolism appeared on the third postoperative day, and the patient was transferred to the Respiratory Intensive Care Unit for further treatment. This is not directly related to the robotic system.

Similar to the methods described by Grochola et al. [16], surgeons' physical and mental stress during surgical procedures is assessed using two validated visual analogue scales: a Local Experienced Discomfort (LED) and a Subjective Mental Effort Questionnaire (SME). LED scores are on a 0–10 scale for each part of the upper body, with 0 indicating no discomfort and 10 indicating extreme discomfort. SME scales range from 0 to 150, with 0 being no effort at all and more than 110 being an exceptional amount of effort. The results are presented in Table 4. Physical discomfort LED scores were below 4 for each upper body component, while the SME questionnaire showed a median physical effort of 25 points.

Discussion

Recently, robotic surgery, which is FDA-approved, has become essential in modern gynecology, with advancements including wristed instruments, tremor filtering, 3D stereoscopic vision, and ergonomic operating positions driving more surgeons to embrace this approach [17]. The da Vinci Surgical System has been dominant, but its high cost and space requirements have limited its use to hospitals that could not afford or accommodate it [18]. Additionally, the mounting of all four arms on a single boom that confined the operative field to a target anatomy of finite range led to the development of modular robotic systems, such as Senhance (Asensus Surgical, USA) [19], Versius (CMR Surgical, UK) [20], and Hugo RAS (Medtronic, USA) [21]. These modular carts offer flexibility in placement while occupying less equipment footprint.

Table 5 compares the Carina, Versius, and da Vinci robotic system, highlighting their features and main differences. The Versius robotic system features an open console design that allows surgeons to operate in a sitting or a standing position while controlling the system through joystick handles, reducing strain on the neck and back muscles. Furthermore, the open console facilitates the communication between the surgeon and the surgical team. However,

Table 3 Postoperative pain assessment

Case	Indications	Pain Day 1	Pain Day 4	Pain Day 30
1	Group1	6	6	0
2	Group1	2	2	0
3	Group1	8	4	0
4	Group1	2	2	0
5	Group1	4	4	0
6	Group1	2	0	0
7	Group1	6	2	0
8	Group1	4	2	0
9	Group1	6	4	0
10	Group1	6	4	0
11	Group2	6	6	0
12	Group2	4	2	2
13	Group2	4	4	6
14	Group2	4	6	0
15	Group2	8	4	0
16	Group2	0	0	0
Mean ± SD/median (IQR)				
Group1		4.60 ± 2.12	3.00 ± 1.70 (P = 0.039)	0
Group2		4.33 ± 2.66	3.67 ± 2.34 (P = 0.327)	0 (0, 2)

Table 4 The level of surgeon's stress

Variables	Score, mean ± SD/ median (IQR)
LED Score	
A	2.94 ± 0.93
B	2.69 ± 0.6
C	3.5 ± 0.63
D	2.75 ± 0.45
E	2.38 ± 0.5
F	2.38 ± 0.5
G	2.69 ± 0.6
H	2.56 ± 0.89
I	3.06 ± 0.77
J	2.69 ± 0.79
K	3.56 ± 0.51
L	2.69 ± 0.48
M	2.38 ± 0.5
N	2.31 ± 0.48
SME Score	25 (10, 40)

this can lead to more distractions for the surgeon due to the frequency of movements in the operating room. Furthermore, wearing 3D glasses can be challenging for surgeons accustomed to the immersive experience of the da Vinci surgical system, especially for those prone to vertigo, which increases surgery difficulty. The Carina robotic surgical system incorporates immersive imaging technology and ergonomics analogous to the da Vinci surgical system, providing surgeons with a clearer and stereoscopic three-dimensional visual experience. Surgeons already skilled in operating the da Vinci will likely find Carina is easier to adapt to. In this study, surgeons promptly completed LED and SME scales after surgery to evaluate surgeon's physical discomfort and mental stress during the operation. The results demonstrated that the surgeon was satisfied with the physical and mental stress associated with Carina. The Carina's use of single-use wristed instruments eliminates sterilization costs. Alternatively, Carina system allows for incorporation of reusable straight-stick instrument, which are less costly than robotic wristed instruments.

Carina offers the advantage of flexible positioning and a small footprint like other modular surgical systems, particularly if fewer robotic arms were required. Meanwhile it also did not require any remodeling or use of larger operating rooms, which was a significant benefit. However, a new surgical device entering the clinic must be supported by good performance, including system stability and minimized robotic arm collisions to avoid subsequent laparoscopic or open surgery. In this study, the Carina system was employed to complete 16 cases of hysterectomy without any incidents, malfunctions, or system reboots. Furthermore, there was no conversion about laparoscopic or open surgery. With three consecutive surgeries performed daily on two surgical days, the Carina system demonstrated continuous functionality for over 14 h without malfunctions. The results indicate that the Carina system is well-engineered and reliable for minimally invasive gynecological surgery. One patient experienced a postoperative pulmonary embolism, classified as a grade IVA complication according to the Clavien system. The

Table 5 Similarities and differences between Carina, da Vinci, and Versius robotic surgical platforms

Robotic surgical platforms	da Vinci	Versius	Carina™ Platform
Manufacturer	Intuitive Surgical	CMR Surgical	Ronovo Surgical
Mode of robotic movement	Master–slave	Master–slave	Master–slave
Ergonomic console	Seated, Closed	Seated/standing, Open	Seated, Closed
3D viewing	Immersive viewfinder	Passive 3D glasses	Immersive viewfinder
Surgeon control	Finger grip, foot pedals	Joystick hand controls	Finger grip, foot pedals
Patient cart	Single	Multiple	Multiple
Number of robotic arms	1 (camera) + 3 (working)	1 (camera) + 3 (working)	1 (camera) + 3 (working)
Optics	8 mm, 3D, HD	10 mm, 3D, HD	10 mm, 3D, HD
Instrument, diameter	Wristed, 8 mm	Wristed, 5 mm	Wristed, 8 mm; Straight-stick, 5 mm
Instruments' Reusability	Reusables, 10 times	Reusables, 13 times	Disposables (8 mm); Reusables (5 mm), 20 times
Haptic feedback	Yes	Yes	No
Simulator available	Yes	Yes	Yes
Approvals	FDA	FDA	Pending in China
Cost of device	USD 1.5–2 million	Undisclosed	Undisclosed

patient's condition improved after receiving anticoagulant therapy, oxygen therapy, and other supportive treatments. The patient was elderly and had a history of cerebral infarction. The emergence of postoperative complications was determined to be unrelated to the use of the new robotic surgical system.

The port placement of robot-assisted surgery must meet certain requirements to accommodate arm movement space. The da Vinci Xi system has a "straight" placement [22], while the Hugo RAS system offers a "straight" or "bridge" placement [23]. The Versius surgical robotic system has a similar placement to laparoscopic surgery [24], requiring assistants to be trained in advance to correct port placement [25, 26]. In the study, the endoscopic port was positioned 3–4 cm above the umbilicus, facilitating a more precise dissection of paraaortic lymph nodes. Due to the non-uniform nature of the patient's pneumoperitoneum, the right-hand and left-hand ports were not precisely situated at the camera port level, as observed intraoperatively. Nevertheless, the right-hand and left-hand instruments can function smoothly without any collisions between the internal and external robotic arms during the procedure. The trocar layout is similar to that used in the da Vinci robotic surgical system, allowing for a shorter training period and more efficient skill development. Despite the limited number of cases in the study, there was a noticeable trend toward a reduction in docking and console time.

In robot-assisted gynecological surgery, flexibility and adaptability are particularly crucial due to the diverse range of complex clinical scenarios that may arise. In this study, a case of cervical cancer had previously undergone laparoscopic radical surgery for colon cancer, resulting in a visible vertical scar measuring approximately 7 cm above the umbilicus. The preoperative assessment anticipated the presence of adhesions around the umbilicus. The laparoscope was inserted through a 12-mm assistant port (A1) at the McBurney point to observe the abdominal cavity, avoiding potential bowel damage. Intestinal adhesions were observed above the umbilicus, extending from left to right, requiring an adjustment in the initial port location. The camera port was placed under the umbilical edge in adhesion-free areas, with the R and L ports positioned slightly below on either side. A 5-mm assistant port (A2) was inserted 5 cm above the pubic bone. The surgical procedure was completed successfully. Our previous cadaver laboratories have shown that adding an extra arm can also help meet the patient's requirements. This outcome illustrates the advantage of the modular independent design, allowing for various port placements and improved flexibility in cart positioning.

Conclusion

The study represents an initial report on a limited-sized patient cohort without long-term follow-up data regarding oncologic outcomes. Further large-scale, multicenter clinical studies are required in the future to comprehensively assess the safety and efficacy of Carina in gynecological surgery. To conclude, Carina has demonstrated positive outcomes in gynecological clinical trials. This technology offers a potential new option for gynecological surgery and has the potential for further exploration in future research.

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Data availability The dataset supporting the conclusions of this article is included within the article.

Declarations

Disclosures Yafen Liu, Zhao Zhao, Penglin Xu, Yue Li, Weizhong Chang, and Mei Ji have no conflicts of interest or financial ties to disclose.

Ethical approval This study was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University (IRB No. L2023-Q299-001).

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