

Robotic-assisted paraesophageal hernia repair—a case–control study

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Abstract

Aims The da Vinci® telemanipulation system offers a wide range of precise movements and 3D visualization with depth perception and magnification effect. Such a system could be useful for improving minimally invasive procedures—as in the case of large hiatal hernia with paraesophageal involvement (PEH) repair. Studies reporting on the robotic-assisted PEH repair are scarce, and a comparison to the standard operation techniques is lacking. Therefore, we decided to investigate the feasibility and safety of robotic-assisted surgery (RAS) compared to conventional laparoscopic (CLS) and open surgery (OS) for the first time.

Methods We investigated 42 patients for the perioperative outcome after PEH repair. Twelve patients were operated on with RAS, 17 with CLS, and 13 with OS. Operating time, intraoperative blood loss, intra- and postoperative complications, mortality, and duration of hospital stay were analyzed in each method.

Results On average, operating time in the RAS group was 38 min longer, and the intraoperative blood was loss 217 ml lower compared to OS. Both results were similar to the CLS group. The intraoperative complication rate was similar in all groups. The postoperative complication rate in the RAS group was significantly lower than the OS group, though again similar to the CLS group. The hospital stay was 5 days

shorter in the RAS group than the OS group and once again similar to the CLS group.

Conclusion The results show that RAS is feasible and safe. It appears to be an alternative to OS due to lower intraoperative blood loss and potentially fewer postoperative complications, as well as shorter hospital stay. Though, RAS is not superior to CLS.

Keywords Robotic surgery · Minimally invasive procedure · Paraesophageal hernia repair · da Vinci™ telemanipulation system

Introduction

In recent years conventional laparoscopic surgery (CLS) has been the favored method for paraesophageal hernia (PEH) repair. This is due to the supposed advantages of CLS over open surgery (OS), such as the decreased utilization of pain medication, faster return of gastrointestinal function, superior quality of life, shorter operating time, reduced blood loss, intensive care unit stay, hospital stay, and overall morbidity [1–3]. However, CLS has been shown to have some limitations and disadvantages, especially in advanced procedures, such as PEH repair. These drawbacks include a restricted visual field, limited motion of rigid instruments, 2D imaging, poor ergonomics, and a slow learning curve for the surgeon [4, 5]. These limitations could be eliminated by robotic-assisted surgery (RAS), which is one of the latest developments in minimally invasive surgery. The potential advantages of RAS over CLS are improved ergonomic conditions, 3D visualization, and the increased maneuverability of instruments, which could lead to general improvements within minimal invasive surgery. In the past, a variety of robotic-assisted surgical procedures in general surgery have been reported as feasible and safe, such as fundoplication, gastric bypass, colorectal resection, adrenalectomy,

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total and partial gastric resection, liver resection, and many others [6–10]. Studies reporting on the robotic-assisted PEH repair are scarce, and a comparison to the standard operation techniques is lacking so far. Performing a search in the Pubmed and Cochrane libraries with the search strategy including MeSH terms like “robotic [or] telemanipulat [and] paraesophageal hernia repair” and limit set for the publication language (English and German), we only found one pilot [11] and one case series [12]. Therefore, the aim of this present case–control study was to present our experience with the da Vinci® Surgical System in PEH surgery and to compare it to CLS and OS, which is done for the first time.

Material and methods

Patient collective

A total of 42 patients were investigated for the perioperative outcome after PEH (>5 cm) repair in our case–control study. All patients were operated on by our experienced senior minimally invasive surgeons from 2003 to 2007. In 12 patients, RAS was performed using the da Vinci® telemanipulation system (Intuitive Surgical, Mountain View, CA, USA); 17 patients underwent CLS and 13 patients OS. Perioperative patient risk was assessed using the American Society of Anaesthesiology (ASA) scoring system. The study design was a retrospective analysis of prospectively collected data.

Preoperative investigations

The preoperative evaluation included a chest x-ray for all patients, upper endoscopy for 41 patients (98 %), esophageal 24-h pH measurement for 25 patients (60 %), and barium contrast swallow for 33 patients (79 %). The presence of PEH was finally confirmed intraoperatively.

Surgical technique

For all surgical groups, the operation was performed under general anesthesia. A combined reverse Trendelenburg and French position was chosen for the laparoscopic approach. For the RAS group, the da Vinci® Surgical System was used as previously described for robotic-assisted fundoplication [13]. In all surgical groups, attention was paid to a complete reduction of the hernia sac and a circular dissection of the esophagogastric junction. Posterior crurorrhaphy was routinely performed using 3–6 non-absorbable 2-0 multifilament sutures (Ethibond* Excel, Ethicon, INC., Somerville, New Jersey, USA) depending on the size of the PEH. For calibration, a 56-Fr esophageal tube was used. A short floppy Nissen fundoplication obtained 21 patients (six patients in the RAS group, nine in the CLS group, and six

in the OS group; $p=0.052$ when RAS was compared to OS and $p=0.785$ when RAS was compared to CLS). In 15 patients, a circular 8×8 cm polypropylene mesh (Surgi-pro™, Covidien, Germany) with a 1.8-cm excentric hole was applied to the diaphragm around the esophagus as described recently [14] (five patients in the RAS group, seven in the CLS group, and three in the OS group; $p=0.785$ when RAS was compared to OS and $p=0.785$ when RAS was compared to CLS). Four patients in the OS group received posterior crurorrhaphy without fundoplication and without mesh reinforcement.

Surgical outcome

Data were analyzed including operating time, intraoperative blood loss, intra- and postoperative complications, duration of hospital stay after the operation, and mortality. Operating time was recorded from the incision to skin closure for the CLS and OS group. The operating time for the RAS group included the docking time of the da Vinci® telemanipulation system. The set-up time and demounting time of the robot were excluded. Intraoperative blood loss and complications were documented at the end of operation. Postoperative complications, length of hospital stay, and mortality were registered at the end of the hospital stay. For an adequate comparability of complications and to show the clinical relevance of specific complications, we used the Clavien classification [15].

Statistical analysis

All calculations were conducted using SAS® Release 9.1 (SAS Institute, Inc., Cary, NC, USA). The quantitative parameters of age, BMI, operating time, intraoperative blood loss, and hospital stay are presented as mean ± standard deviation and range. The distributions of operating time and intraoperative blood loss in the three groups have been graphically presented as box-and-whisker plots. The distributions of the quantitative parameters were analyzed using the Shapiro–Wilk test. The non-parametric Kruskal–Wallis test was used as an overall test to compare the quantitative parameters between the three groups. A further analysis of quantitative parameters between two groups was performed using the Mann–Whitney U test. The categorical parameters of sex, ASA classification, and intraoperative and postoperative complication rates were analyzed using Fisher's exact test. A two-sided p value ≤ 0.05 was considered statistically significant.

Results

As shown in Table 1, patients were well matched with regard to gender, age, body mass index, and operative risk according to the ASA score.

Table 1 Patient characteristics, demographic data and operative risk

	RAS group (<i>n</i> =12)	CLS group (<i>n</i> =17)	OS group (<i>n</i> =13)	<i>p</i> value
Sex (female/male)	9/3	5/12	7/6	0.049 (3 groups) 0.253 (RAS vs. CLS) 0.411 (RAS vs. OS)
Average age (years) ^a	68.1±7.9 (56–81)	60.2±11.8 (41–81)	64.9±15.4 (47–90)	0.249 (3 groups) 0.084 (RAS vs. CLS) 0.703 (RAS vs. OS)
BMI (kg/m ²) ^a	25.7±2.6 (20.8–29.4)	26.6±4.4 (18.8–38.9)	26.2±3.8 (21.0–31.2)	0.894 (3 groups) 0.611 (RAS vs. CLS) 0.892 (RAS vs. OS)
ASA classification				
ASA I	–	–	–	0.219 (3 groups)
ASA II	7	13	6	0.422 (RAS vs. CLS)
ASA III	5	4	5	0.591 (RAS vs. OS)
ASA IV	–	–	2	

BMI body mass index, ASA American Society of Anaesthesiologists

^a Values are mean plus/minus standard deviation and range

Intraoperative data

The operating time of RAS was 172±31, range 115–220 min. The operating times of CLS and OS were 168±42, range 130–290 min, and 134±52, range 65–241 min, respectively ($p=0.052$ when RAS was compared to OS, $p=0.785$ when RAS was compared to CLS, and $p=0.057$ when all three groups were compared; Fig. 1). The intraoperative blood loss was 33±85, range 0–300 ml, for RAS. The blood losses for CLS and OS were 24±42, range 0–150 ml, and

250±191, range 50–600 ml, respectively ($p=0.002$, $p=0.742$, and $p<0.0001$; Fig. 2). The intraoperative complication rate was similar in all groups (Table 2). Apart from one pneumothorax in each group, no other intraoperative complications occurred. All three patients with intraoperative pneumothorax could be treated conservatively and no drainage was necessary. All intraoperative complications were Grade I complications according to the Clavien classification. In the CLS group, there was one conversion to OS due to an obesity-related limited overview.

Fig. 1 Box-and-whisker plot of the measured operating time in the three different groups operated for PEH (RAS robotic-assisted surgery, CLS conventional laparoscopic surgery, OS open surgery). $p=0.057$ for comparison of the three groups, $p=0.785$ for RAS vs. CLS, and $p=0.052$ for RAS vs. OS

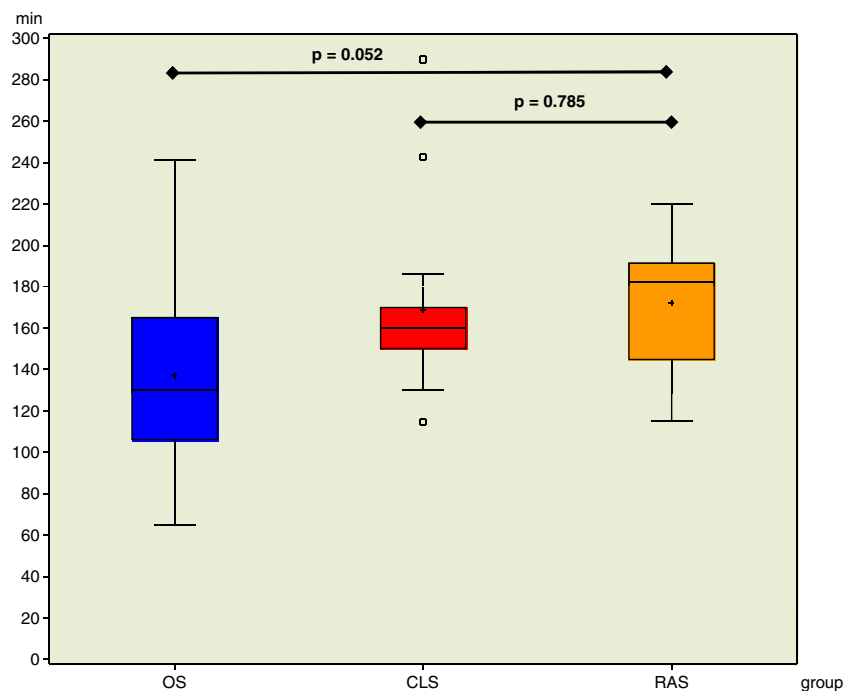
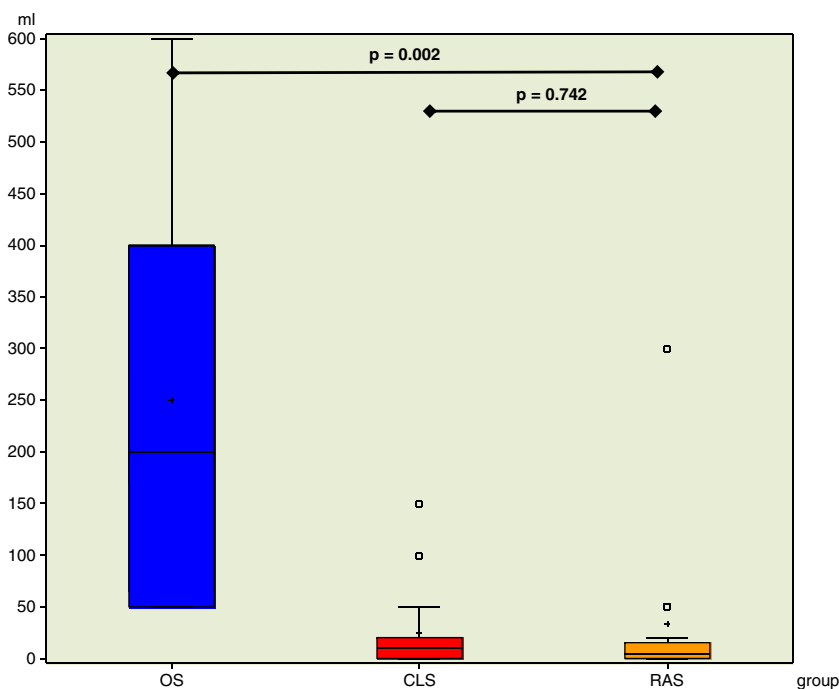


Fig. 2 Box-and-whisker plot of the measured intraoperative blood loss in the three different groups operated for PEH (RAS robotic-assisted surgery, CLS conventional laparoscopic surgery, OS open surgery). $p < 0.0001$ for comparison of the three groups, $p = 0.742$ for RAS vs. CLS, and $p = 0.002$ for RAS vs. OS



Postoperative data

The postoperative complication rate in the RAS group was significantly lower than in the OS group, though again similar to the CLS group ($p = 0.035$, $p = 0.765$, and $p = 0.028$; Table 2). In the RAS group, one patient generated postoperative bleeding, which needed a laparotomy to be stopped. Additionally, the patient developed pneumonia. Consequently, the hospital stay was prolonged to 19 days. In the CLS group, postoperative delayed gastric emptying was recorded in two patients. These patients could be treated conservatively and no reoperation was necessary. In the OS group, three patients generated pulmonary atelectasis, one patient had a wound infection, and one patient experienced delayed gastric emptying. These patients did not require reoperation and could be treated conservatively. One patient in the OS group generated a dehiscence of the abdominal fascia requiring reoperation. The intra- and postoperative

complication rate of RAS together was 16.7 %. The rates for CLS and OS were 17.6 and 58.3 %, respectively ($p = 0.097$, $p = 1.000$, and $p = 0.0649$). According to the Clavien classification, we had one Grade IIIb complication in the RAS and OS groups. Additionally, two Grade I complications in the CLS group and five Grade I complications in the OS group. The patients who were operated on with RAS had a hospital stay of 8 ± 3.9 , range 5–19 days. The hospital stays of CLS and OS were 7 ± 1.6 , range 5–10 days, and 12 ± 3.7 , range 6–20 days, respectively ($p = 0.009$, $p = 0.272$, and $p < 0.0001$; Table 2). There was no mortality in any of the three groups.

Discussion

The results of the present case–control study suggest that RAS for PEH repair seems to be feasible and safe like CLS

Table 2 Intraoperative and postoperative complication rates and hospitalization

	RAS group (n=12)	CLS group (n=17)	OS group (n=13)	p value
Intraoperative complication rate	8.3 %	5.9 %	7.7 %	1.0 (3 groups) 1.0 (RAS vs. CLS) 1.0 (RAS vs. OS)
Postoperative complication rate	8.3 %	11.8 %	46.2 %	0.028 (3 groups) 0.765 (RAS vs. CLS) 0.035 (RAS vs. OS)
Hospitalization (days) ^a	7.8 ± 3.9 (5–19)	6.5 ± 1.6 (5–10)	12.4 ± 3.7 (6–20)	<0.0001 (3 groups) 0.272 (RAS vs. CLS) 0.009 (RAS vs. OS)

^aValues are mean plus/minus standard deviation and range

and OS. These findings are in line with other published data, showing that both RAS and CLS are safe alternatives to OS in many surgical procedures, such as gastric resection [6, 16], cholecystectomy [9, 17], hysterectomy [18, 19], as well as prostatectomy [20, 21].

Studies investigating the role of RAS in PEH surgery are scarce, and no randomized controlled trials have been done so far. In a case series of 40 consecutive patients with RAS for PEH repair, Draaisma et al. concluded that RAS for PEH repair was effective, with a relatively low midterm recurrence rate, and that the operating team experienced the support of the robotic system as beneficial, especially in the dissection of the hernia sac and extensive crural repair. In this study, median operating time was 127 min and median blood loss was 50 ml. Intraoperative complications occurred in two patients (5 %) and early postoperative complications in five patients (12.5 %). Furthermore, three patients had to be reoperated during 30-day follow-up (7.5 %). No patients died, and median hospital stay was 4.5 days [12]. Also, Braumann et al. described the feasibility and safety of robotic-assisted PEH repair and other variety of procedures in a pilot study. In this study, the population consisted of 280 elective patients who were submitted to a variety of robot-assisted laparoscopic or thoracoscopic surgery. Therefrom, 14 patients with a PEH were operated with the da Vinci® Surgical System. Average operating time was 134 min and the average hospital stay 6.5 days. There were no intraoperative surgical-related complications owing to the telerobotic system, and the patients' postoperative courses were uneventful. No specific robotic surgery-related complication has been detected [11].

The results of these two studies investigating the role of RAS in PEH surgery relate favorably to the findings of our case–control study. We also found a low blood loss, intraoperative and postoperative complications, as well as a short hospital stay of the patients in the RAS group. Only the operating time for RAS was 45 and 38 min longer as described in the mentioned two available studies. However, in these studies, it is not shown whether operating time included set-up time, docking time, or demounting time. In our study of the RAS group, the operating time only included the docking time of the da Vinci® telemanipulation system. Including the set-up time and demounting time of the robot would definitely increase the operating time of the RAS group. However, the operating time of the RAS group might be reduced by a consistent team, made up of specialized and experienced personnel [13]. But in our opinion, manipulation with the da Vinci® telemanipulation system in PEH is more complicated than with conventional laparoscopy due to the limited and hindered interaction between surgeon and assistant and the restricted visual field.

In addition to the only two published studies, we found in our case–control study a significantly lower intraoperative

blood loss, postoperative complication rate, and hospital stay for RAS and CLS compared to OS, while the intraoperative complication rate was similar. These results are in line with other authors who found a lower blood loss for RAS and CLS in radical hysterectomy [18, 22] and in total and partial gastric resection [6, 16]. The significantly lower postoperative complication rate and equally low intraoperative complication rate for RAS of our study is in line with other published data [23, 24]. However, according to the Clavien classification, there was one Grade IIIb complication in the RAS and OS group, with many more Grade I complications in the OS group. Further trials are necessary to confirm the trend of this data and to evaluate the clinical relevance of complications of each group. The significantly shorter hospital stay for RAS and CLS compared to OS has also been described in previous literature [16, 22, 25]. The operating time was not significantly different in our study, but with a clear trend in favor of the OS group. This is in accordance with several authors who described the same trend [23, 25]. A limitation of the study is its non-prospective character. However, the estimates obtained in the present study may be helpful for the design of future randomized controlled trials.

In conclusion, the present case–control study shows that RAS is feasible and can be used safely for PEH. Additionally, in comparison to OS, the use of RAS might lead to a reduction of intraoperative blood loss and less postoperative complications with reduced length of hospital stay. The results of our study show that RAS is superior to OS for PEH regarding the patients' perioperative course. Though, RAS is not superior to CLS; our results show that there is no significant advantage of the da Vinci® telemanipulation system over the conventional laparoscopic technique. However, further well-designed randomized controlled trials are necessary to confirm those results and to evaluate the further potential of RAS, such as better ergonomics and a shorter learning curve for the surgeon, as well as economy of human resources.

Conflicts of interest The authors T. Gehrig, A. Mehrabi, L. Fischer, H. Kenngott, U. Hinz, C. N. Gutt, B. P. Müller-Stich declare that they have no competing interests, financial or otherwise. No external funds were used to perform the evaluation, and all of the technology tested was separately purchased to complete the study. In addition, the authors had full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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