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Anderberg, Magnus; Clementson Kockum, Christina; Arnbjörnsson, Einar

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Paediatric computer-assisted retroperitoneoscopic nephrectomy compared with open surgery

Magnus Anderberg MD, PhD, Christina Clementson Kockum MD, PhD, and Einar
Arnbjörnsson MD, PhD, Associate Professor. Department of Paediatric Surgery, Children's
Hospital Lund, Skåne University Hospital, Sweden and Lund University, Sweden.

Corresponding author:

Magnus Anderberg, Department of Paediatric Surgery, Children's Hospital Lund, Skåne
University Hospital, SE-205 02 Malmö, Sweden. Phone: + 46 46 171000 Fax: +46 46 178120
E-mail: magnus.anderberg@skane.se

Running title: Paediatric retroperitoneal robot-assisted laparoscopic nephrectomy

*Key words: robotic surgery; children; Paediatric surgery; da Vinci® Surgical System;
nephrectomy; computer-assisted*

Abstract

Purpose: Computer-assisted laparoscopic surgery (CALS) in children is increasingly used and has proven to be feasible and safe. However, its full potential remains unclear and clinical comparative studies hardly exist. The aim of this study was to prospectively evaluate our experience with CALS for performing retroperitoneal nephrectomies in children compared with controls undergoing open surgery in terms of safety, operative time, blood loss, opioid requirements, the duration of hospital stay and complications.

Children and methods: Computer-assisted retroperitoneoscopic nephrectomy was undertaken in ten consecutive children, mean age at the time of surgery 6.4 (SD \pm 4.5) years, and compared with a retrospectively collected control group of all other children, mean age 3.9 (SD \pm 4.6) years, who underwent the same procedure by conventional open surgery between the years 2005 and 2009. The endpoint of the study was one month postoperatively.

Results: Nephrectomies were performed in all the children and no child was excluded from the study. There was no per-operative complication in any of the groups. The median (range) operative time was 202 (128 – 325) and 72 (44 – 160) minutes for the CALS and open group, respectively. The blood loss was minimal (< 20 ml) for all the patients. The postoperative opioid requirements did not differ. The median (range) postoperative hospital stay was 1 (1 – 4) and 2 (1–7) days for the CALS and the open group, respectively. One complication in the form of an urinoma appeared five days after surgery in the CALS group.

Conclusion: Computer-assisted retroperitoneoscopic nephrectomy is a safe, feasible and effective procedure in children. Even though operative times are longer the patients benefit from the lower morbidity, improved cosmetics and shorter hospitalization associated with the minimally invasive approach.

Introduction

In the ever evolving field of surgery, laparoscopic instruments have been an option when performing surgery for almost twenty years. Thanks to the improvement for patients in terms of cosmetics, shorter hospital stay and less pain, laparoscopy is now considered the gold standard worldwide for many surgical procedures. However, its introduction in the paediatric surgery field has been somewhat slower than in adult surgery. The reasons for this might have been the diversity in diagnoses and size of the paediatric patients, the early lack of smaller instruments adapted for use in children, and the relatively long learning curve, which all complicate the introduction of a new technique. There have been many reports in the literature on the use of laparoscopy for relatively simple procedures in children, such as appendectomy, in diagnosing and treating impalpable, undescended testis, for cholecystectomy and hernia repairs. The clinical comparative studies show that this procedure is safe and valuable also for children [1]. Even if most paediatric surgical procedures are probably still performed with the open technique, minimally invasive surgery is well established in the paediatric population today.

However, for laparoscopic nephrectomy and more complex paediatric laparoscopic procedures such as partial nephrectomy, pyeloplasty and ureteral reimplantation, the number of comparative clinical reports is fewer, and contain smaller series of patients. The success rate is similar to that of open surgery but the low number of reports might indicate that this technique remains a challenge to perform and teach [2,3].

In recent years, robot-assisted laparoscopic surgery with the da Vinci® Surgical System from Intuitive Surgical® (Sunnyvale, CA, USA) has been increasingly used. It is a master-slave system where the surgeon, at a manoeuvre console, uses a computer to translate his hand movements into instrument movements at the surgical cart placed at the side of the patient.

Since the term robot should be saved for automated preprogrammed movements, the term computer-assistance is preferred by the authors for this surgical system. With an enhanced optic system and flexible instruments, it can be considered a definite improvement of the standard laparoscopic equipment. It has proven to be safe and efficient with results comparable to those of the conventional laparoscopic and open surgical procedures in adults. The literature on paediatric computer-assisted laparoscopic surgery (CALS) is very limited but demonstrates that it is safe, feasible and shows encouraging results also in children [4-9]. Very few paediatric comparative urological series have been reported and the role of CALS in children and its full potential remains unclear [10].

The aim of this clinical comparative study was to analyze our experience with CALS for performing nephrectomies in children compared with controls undergoing open surgery in terms of safety, operative time, blood loss, opioid requirements, the duration of hospital stay and complications. Our hypothesis was that these two procedures are comparable and can both be used in clinical practice. We are not aware of any similar reports.

Children and methods

We performed a case-control study of ten consecutive children undergoing computer-assisted retroperitoneoscopic nephrectomy with the da Vinci® Surgical System from Intuitive Surgical® between September 2007 and February 2010 due to a non- or malfunctioning kidney. This prospectively gathered consecutive group of children was compared with a retrospectively collected group of all other children who had undergone open nephrectomy for benign renal disease at our centre between 2005 and 2009. Nine out of the 21 children (10 of 23 nephrectomies) in the control group were operated during the time period when we also used CALS for nephrectomies. In the open control group two children underwent bilateral nephrectomy, one of which was performed in a single surgical procedure, but all CALS were

unilateral. All 33 nephrectomies were performed through the retroperitoneal approach. The patients' demographics and diagnoses are listed in Table 1.

Endpoints of this study were safety, the operating time, the number of postoperative doses of morphine, the length of hospital stay and the number of complications. Operative time was recorded as skin to skin in both groups, including docking time but not preoperative setup time for the surgical system in the CALS group, as this was done simultaneously with induction of anaesthesia and positioning of the patient. The length of hospital stay was recorded in days and determined by the computerized hospital admission and discharge records for all the patients. For the control group, all information was obtained from charts or the surgery planning database Provisio® (Provisio AB, TietoEnator Healthcare & Welfare, Sweden) but in the study group, the operative time was recorded prospectively. All postoperative doses of morphine were collected from the computerized chart system Melior® v.1.5 (Siemens Medical Solutions, Siemens, Germany) and counted manually. Data are presented as median (range) unless otherwise stated.

No randomization was done. Verbal, informed consent from all the children's guardians was obtained prior to surgery. The use of CALS instruments when performing paediatric surgery (Dnr 2009/59) and this study (2010/49) was approved by the Regional Ethical Committee. This study complies with the ethical standards laid down in the 1964 Declaration of Helsinki and with the current laws of the country in which it was performed.

Statistical considerations

SPSS statistical software, version 15.0 and the non-parametric Mann-Whitney U test were used for analyzing the data. $P < 0.05$ was considered significant.

Surgical techniques

The method to gain access to the retroperitoneal space for computer-assisted surgery previously described by Olsen et al. was used [11]. In brief: with the patient in the flank position and slight hip flexion with a gel cushion under the contralateral iliac crest, a 15 mm incision was made approximately 10 mm above the iliac crest in the anterior axillary line. After blunt splitting of the muscles, the lumbodorsal fascia was opened and the retroperitoneal space digitally created. The retroperitoneal working space was then fully developed with a home-made balloon inflated to 150 – 350 ml depending on the size of the patient. The two 8 mm instrument ports were placed under digital guidance, the lateral port just medial to the latissimus dorsi, 2 fingers above the iliac crest and the medial port just below the costal margin off the anterior axillary line. A 5 mm assistance port was used for one patient. A 12 mm balloon tipped trocar was inserted through the 15 mm incision and then secured by inflating the balloon, tethering of the trocar, and by 2.0 sutures in the fascia and skin. The insufflation pressure of CO₂ was maintained below 12 mm Hg and the flow rate was initially set at 1 L/min and progressively increased to 5 L/min if necessary. The surgical system was docked from behind at an angle of 45 – 60 degrees to the mid-axillary line and a 0-degree telescope camera was used. A DeBakey grasper and a monopolar cautery hook or scissors were used for dissection.

The kidney was approached from behind and the hilum was primarily exposed. The vessels were identified and divided with LigaSure TM (VallylabTM, Covidien, Boulder CO, USA), Harmonic Scalpel (Ethicon® Harmonic Scalpel, Soma Technology, Blomfield CT, USA) or the cautery hook with subsequent dissection, division and tying of the ureter as far distally as possible. Vascular control was excellent in all cases. The specimen was removed through the 15 mm incision. Fascia sutures were used in all holes and continuous, monofilament, absorbable sutures were used to close the skin.

The open nephrectomy was performed with the patient in the flank position and through a sub costal, transverse incision. After the mobilization of the ureter and vascular control with braided, absorbable 4-0 ligatures the kidney was removed. The ureter was transected and tied as low as possible. The fascia and skin were closed as previously described.

Local anaesthetic with bupivacaine 2.5 mg/ml+adrenaline 5 µg/ml or ropivacaine 2 mg/ml in a dose of 1 ml/kg was injected in the wound(s) for postoperative analgesia in all the patients. A drain was normally not used. An epidural catheter was never used. A Foley catheter was used during the surgical procedure and routinely removed at the end of the anaesthesia. All the nephrectomies were performed by the same team.

All the patients received paracetamol (15 mg/kg) every sixth hour postoperatively.

Postoperative pain was evaluated by the registered nurse on duty according to the visual analogue scale (VAS). Morphine (0.05 mg/kg) was ordered by the surgeon on call after evaluation of the patient's pain. The administration of morphine was stopped when the patient indicated on the lowest third of the scale. The discharge home criteria were the same for all 31 patients in the two groups; adequate pain control without requiring intravenous medications, two normal meals, return of bowel movement and appropriate patient/family education by the staff.

The last endpoint, postoperative complication, of the study was collected at the standard clinical follow-up in the outpatient clinic one month after each operation. Further diagnostic imaging examinations were performed only if clinically indicated.

Results

There was no difference in age, weight or length of the patients in the two groups (Table 1).

The mean age was 6.4 (SD ± 4.5) and 3.9 (SD ± 4.6) years, the mean weight 26.4 (SD ± 16.8)

and 16.6 ($SD \pm 12.7$) kg and the mean length 114 ($SD \pm 35$) and 94 ($SD \pm 33$) cm in the CALS and open group respectively. The diagnoses of the patients were all benign renal disease, as listed in the Table 1. All the operations were performed without peroperative complications and in the CALS group without conversion to open surgery. The operating time in the console was 100 ($65 - 180$) minutes. The total operating time was longer for the CALS group, 202.5 ($128 - 325$) minutes than for the open group, 72 ($44 - 160$) minutes (Table 2). The mean console operating time was 118 ($SD \pm 48$) minutes and the mean open operating time was 87 ($SD \pm 32$) minutes. The time for placing trocars for the surgical system, positioning, docking and undocking of the da Vinci® and finishing the procedure was 71 ($60 - 145$) minutes. Four out of ten patients in the CALS group had total operating times within the range of the operating time for an open procedure (Figure 1). The blood loss was minimal (< 20 mL) in both groups. The number of postoperative doses of morphine did not differ, 0 ($0 - 2$) for the CALS group and 0 ($0 - 7$) for the open group but the hospital stay was shorter for the CALS group, 1 ($1 - 4$) day compared to 2 ($1 - 7$) days for the open group (Table 2). The only complication seen at follow-up was a retroperitoneal urinoma that appeared on the fifth postoperative day in the first patient operated with computer-assistance.

Discussion

Our study showed a significantly longer operating time for the computer-assisted retroperitoneoscopic nephrectomy compared with the open procedure but also a shorter length of hospital stay. The median and mean number of doses of morphine, 0 ($0 - 2$), 0.2 ($SD \pm 0.6$) and 0 ($0 - 7$), 1.4 ($SD \pm 2$) in the CALS and open group, respectively, were lower in the CALS group but not significantly so. Only one out of 10 patients in the CALS group received morphine postoperatively as compared to nine out of 21 patients in the open group. More patients are needed to make this significant.

We have not found any other comparative studies between computer-assisted laparoscopic nephrectomy and open nephrectomy in children. Najmaldin and Antao report a series of four computer-assisted laparoscopic nephrectomies, console time 103 (55 – 110), total operating time 162 (114 – 170) minutes, length of hospital stay 2 (1 – 2) days and four nephroureterectomies, console time 96 (58 – 180), total operating time 172 (132 – 235) minutes and length of hospital stay 1 (1 – 2) days [7]. Passerotti and Peters describe how to perform a robot-assisted nephrectomy but do not report any results from their series [8,9]. In a recent publication by Lee RS et al. robot-assisted laparoscopic nephrectomy with contralateral ureteral reimplantation was performed in four patients and this combined procedure had a mean total operating time of 291 (243 – 380) minutes and a mean length of hospital stay 2.3 (1.9 – 2.9) days [12].

The indications for nephrectomy in children are mainly to remove a non- or malfunctioning kidney primarily or secondary to complicated congenital anomalies. The open procedure is often performed via a retroperitoneal approach and the minimally invasive procedure is either performed trans- or retroperitoneally. Previous reports comparing standard laparoscopic and open nephrectomy in children state that also the minimally invasive approach is safe and feasible. Ku et al. included 10 + 13 children undergoing nephrectomy and had similar median operating times, 150 (120 – 200) and 145 (90 – 200) minutes, but shorter median hospital stay, 2.5 (2 – 6) and 4 (3 – 14) days, in the laparoscopic and open group, respectively [13]. Lee RS et al. reported 9 + 9 children younger than two years undergoing laparoscopic and open retroperitoneal partial nephrectomy with similar mean operating times, 162 (116 – 244) and 175 (150 – 226) minutes, but shorter mean hospital stay, 1.8 (1 – 3.9) and 4.6 (3.8 – 7) days, in the laparoscopic and open group, respectively [14]. Their shorter hospital stay was supported by our study, but the operating time for CALS was significantly longer than for the open procedure. However, our operating times are not that different from those of others but

show less consistency with some very long procedures (Figure 1). This is partly because we are still in a learning phase. Our longest operating times were mainly caused by different technical problems such as conflicts of working arms on the outside, and a large kidney in case four and five, added time for instructing a new console surgeon and scrub nurse for case six, and bleeding from one port hole, seriously impairing visibility in case seven. Our tenth CALS patient weighed only 8.6 kg, which made retroperitoneal port placement more challenging and limited the operative field. However, we expect the operating time to decrease with the number of cases performed and consider a total of 120 minutes to be reasonable. Two of our last three cases come close to that time.

The retroperitoneal approach offers an access comparable to standard open renal surgery and has been our preferred approach for all computer-assisted renal surgery. The main theoretical advantages are a direct and rapid exposure of the kidney, minimization of the risk for injury of peritoneal viscera and for postoperative obstructive adhesions, and the confinement of a postoperative haematoma or urinoma to the retroperitoneum in the case of a complication.

Comparative studies on the trans- and retroperitoneal approach are only performed for conventional laparoscopy.

As Passerotti et al. and Casale et al. have pointed out, port placement with the retroperitoneal approach must be distinct [5,8] but operating times for conventional laparoscopy in children become shorter, with times approaching those for the open procedure and the learning curve is considered reasonable [15]. Castellan et al. report their experience with laparoscopic partial nephrectomy in the paediatric age group and conclude that there are no significant differences between the transperitoneal and retroperitoneal approach with regard to operating time, complication rates or hospital stay. Since the transperitoneal approach offers more space than the retroperitoneal, it has been advocated for children younger than one year but the

retroperitoneal approach is preferred in older patients [16]. McDougall et al. performed laparoscopic nephrectomies in adults with benign renal disease and small kidneys (< 100g) and reported that the retroperitoneal approach was associated with lower postoperative doses of morphine and quicker return to oral intake than the transperitoneal approach, but the total length of hospital stay was not affected [17]. To establish which approach is better for minimizing the risk for complications, further studies with larger series of patients is warranted in the future.

Our study showed that computer-assisted retroperitoneoscopic nephrectomy is safe and feasible since no peroperative complications occurred in either group, and this is supported by others [5,6]. One serious complication was noted at follow up in our first CALS patient, a one-year-old boy with a non-functioning kidney due to vesicoureteral reflux grade IV. He went home the day after surgery but returned on the fifth day due to general deterioration. Ultrasound revealed a retroperitoneal urinoma on the side of the nephrectomy. This insufficient closure of the ureter could also have happened in the open surgical group and is not specific for the computer-assisted procedure. The urinoma was drained through an open surgical procedure and the ureter was closed again. The patient then quickly recovered and presented with no further adverse events.

Minimally invasive surgery in paediatric urology is well established but the advanced laparoscopic skills needed at least for reconstructive surgery in children may limit its widespread application among paediatric urologists. The main advantage of the minimally invasive approach is improved cosmetics, less pain and possibly shorter hospital stay. Computer-assistance in the form of the da Vinci® Surgical System from Intuitive Surgical® has been available for some years. It offers improved 3-D vision and flexible instruments with a more natural and intuitive range of motion than conventional laparoscopic instruments, and

has the potential to facilitate laparoscopic surgery with the same advantages. Some surgeons have managed to perform procedures with these new instruments that they have never done before with the standard laparoscopic instruments [18]. Our team has performed a Morgagni Hernia repair in a small child, and a radical cystoprostatectomy due to a rhabdomyosarcoma in the bladder in a young boy with computer-assisted surgery, thus converting an open procedure to a minimally invasive one with excellent results [19,20].

Laparoscopy was introduced at our department of paediatric surgery in the early 1990s and has been used as a diagnostic tool, for appendectomy, cholecystectomy, undescended testis, fundoplication and for placing gastrostomas. Our hospital purchased its first da Vinci® Surgical System in 2005, and our previous experience of conventional laparoscopic urologic procedures was very limited. Since the da Vinci® Surgical System became our preferred method for performing minimally invasive urology, and we never attempted any standard laparoscopic nephrectomies prior to that, we present our initial experience of CALS compared to the open procedure for nephrectomies. A comparison between computer-assisted laparoscopic and standard laparoscopic nephrectomies, which would be the preferred method for nephrectomies for many paediatric urologists today, is not possible at our department, since we have never used standard laparoscopic instruments for that procedure. By using computer-assisted instruments for all minimally invasive urological procedures, we gain maximum experience with that technique, since port placements and the technique with the instruments differ from standard laparoscopy. This experience is beneficial also in other, more complex procedures, as been pointed out by others [18] such as, in the case of urology, partial nephrectomy and pyeloplasty.

To our knowledge, no comparative report between CALS and either the open or standard laparoscopic nephrectomy in children exists. In our earlier report on computer-assisted and

standard laparoscopic funduplications in children no significant difference was seen between those two methods [4].

We have used the 8 mm instruments for all our CALS procedures since the existing 5 mm instruments demand more space inside the patient to work properly. The da Vinci software will not allow an instrument to function, unless the entire articulating length is external to the distal end of the trocar and the articulating length is paradoxically longer in the smaller instruments. The 12 mm endoscope used, give superior 3D vision compared to the 5 mm endoscope with 2D vision. The assistant 5 mm port used in one patient was unnecessary. The improved manoeuvrability and vision of the da Vinci system compared to standard laparoscopy, is of course most important in reconstructive surgery like pyeloplasties, but is also advantageous in simpler procedures as nephrectomies [8]. The use of the da Vinci® Surgical System, also for simpler cases, shortens the learning curve and increases the probability for succeeding with more complex procedures [18].

There are a number of limitations in our series. Selection bias with a tendency to include smaller children in the open group could be considered one. However, those nine children operated with an open procedure 2008 – 2009 were not different from the open group as a whole and more a reflection of limited access to the surgical system for laparoscopy. The smallest patient operated with CALS weighed 8.6 kg and only five out of 21 patients in the open group weighed less. Furthermore, with a larger number of patients and strictly prospective, age matched cohorts, the statistical analysis would be more robust and the evidence stronger. In the absence of such a study, our report is an attempt to add to the current literature and to set the basis for further studies.

A randomization of the children to either open or CALS was impossible for a number of reasons. First, we do not have unlimited access to the da Vinci® Surgical System and a

randomization would be difficult to handle for organizational reasons. The fact that nine children were operated with an open procedure even after we started using CALS is a result of this. Second, our catchment area of southern Sweden with two million inhabitants is not enough to include many patients in a study in a short time period. Furthermore, we cannot afford to exclude patients without counteracting the advantage of randomization by injecting bias into the study material in the form of historical data.

With the introduction of new instruments into clinical practice comes a great responsibility to thoroughly evaluate and compare with the reference standard procedure. An adoption of a new surgical technique can only be justified if it is at least equally safe and efficient and preferably comes with clear advantages for the patients and/or medical staff.

When introducing new instruments into clinical practice the cost is always an important issue, which is discussed in a recent report comparing the costs for open, laparoscopic and CALS by our group [21]. This report is only applicable for comparing the cost of CALS with open surgery since we do not perform conventional renal laparoscopic surgery. The higher cost for the surgical procedure itself was not as great as expected and could perhaps be motivated by benefits for the patient and the fact that the total in-hospital cost was lower than for open surgery, thanks to the shorter hospital stay. Furthermore, a simple procedure might not necessarily have to be cost efficient; if the team gains sufficient experience to be able to perform more complex procedures, these, at least, will certainly prove to be cost efficient.

In conclusion, our data show that computer-assisted retroperitoneoscopic nephrectomy in children is an effective and safe procedure. In spite of longer operative times compared with open surgery, the computer-assisted procedure significantly shortens the length of hospital stay and adds cosmetic advantages. Our results support the future use of computer-assisted minimally invasive surgery.

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Competing interests

When performing this work, there were no external influences or conflicts of interest. None of the authors has received financial support of any kind from any of the manufacturers of the material used for the care of the reported patients.

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*Table 1**Demographic data of the patients. Median and (range) if not otherwise stated.*

	Surgical method		
	Computer-assisted	Open	Statistics
Number of patients	10	21	
Female/male	4/6	8/13	0.951
Number of kidneys	10	23	
Side left/right	8/2	10/13	0.105
Age at surgery, years	7.0 (1.2 – 13.7)	1.9 (4 days -14.2)	0.143
Weight at surgery, kg	24.0 (8.6 – 61.0)	12.9 (2.4 – 51.5)	0.074
Length at surgery, cm	120 (55 – 155)	85 (49 – 161)	0.180
Diagnoses			
• Hydronephrosis	1	4	
• Renal dysplasia	5	4	
• Multicystic dysplasia	2	3	
• Renal hypoplasia	1	2	
• Vesicoureteral reflux	1	2	
• Nephrotic syndrome		8	

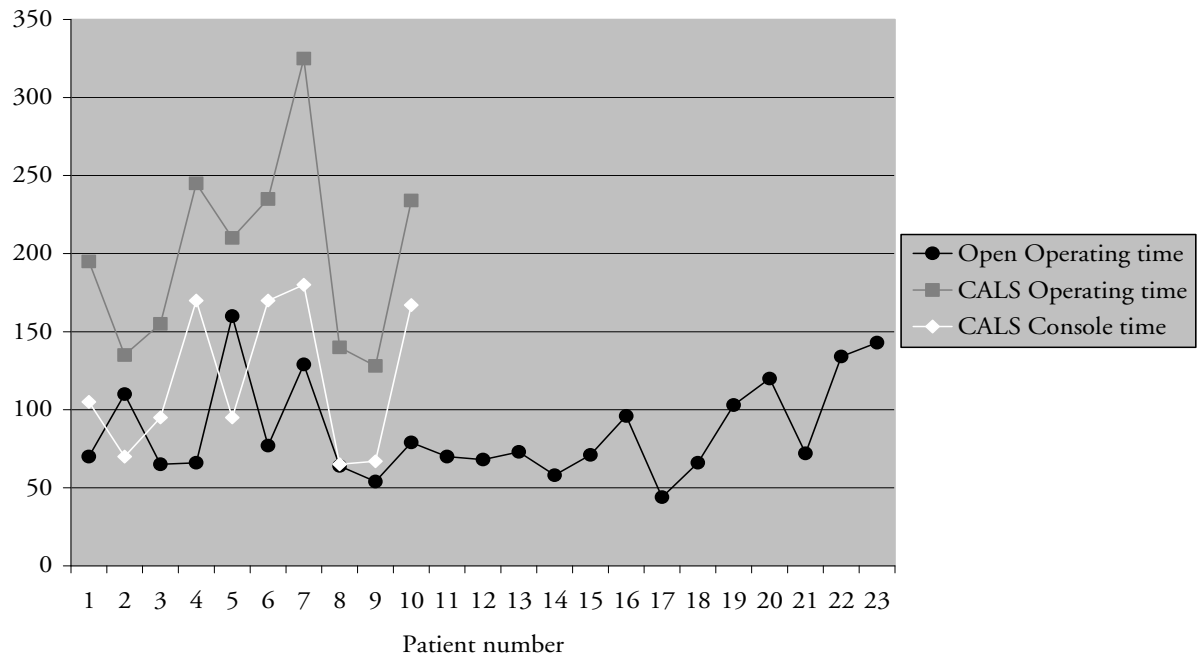
Table 2

Duration of operation, use of morphine analgesics, length of hospital stay and complications. Median and (range) if not otherwise stated.

	Surgical method		
	Computer-assisted	Open	Statistics
Operating time, minutes	202.5 (128 – 325)	72 (44 – 160)	<0.001
Morphine doses	0 (0 – 2)	0 (0 – 7)	0.081
Hospital stay, days	1 (1 – 4)	2 (1 – 7)	0.031
Complication	1		

Figure 1

Operating time for all patients and console time for the CALS group in minutes.



Time in minutes	Computer-assisted laparoscopic surgery			Open surgery
	Total operating time	Console time	Pre- and post console	
Median (range)	202.5 (128 – 325)	100 (65 – 180)	71 (60 – 145)	72 (44 – 160)
Mean (\pm SD)	200 \pm 63	118 \pm 48	82 \pm 28	87 \pm 32

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