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Time-action analysis of instrument positioners in laparoscopic cholecystectomy

A multicenter prospective randomized trial

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Abstract
Background: Instrument positioners can position and lock a laparoscopic instrument. This study uses time-action analysis to evaluate objectively whether IPs can substitute for a surgical assistant efficiently and safely.
Methods: In four hospitals, 78 laparoscopic cholecystectomies were randomly assisted by a surgical assistant or an instrument positioner (AESOP and PASSIST). The efficiency and safety of laparoscopic cholecystectomies were analyzed with respect to time, number and type of actions, positioning accuracy, and peroperative complications. A questionnaire evaluated the difficulties for each operation and the comfort of instrument positioner use.
Results: The PASSIST and AESOP were able to replace the surgical assistant during laparoscopic cholecystectomies without significantly changing either the efficiency or the safety of the operation. The questionnaire showed that the surgeons preferred to operate with an instrument positioner.
Conclusion: This study assessed objectively that instrument positioners can substitute for a surgical assistant efficiently and safely in elective laparoscopic cholecystectomies.

Key words: Time-action analysis — Instrument positioners — Laparoscopic cholecystectomies — AESOP — PASSIST

Various supporting instruments have been developed to facilitate laparoscopic surgery. An example of a supporting instrument is the instrument positioner (IP), which can help to lock a laparoscopic instrument and yet allow for adjustment of position. Usually, during a laparoscopic procedure, a surgical assistant controls the laparoscope and, when needed, an additional grasper. Consequently, the surgeon has no direct control over his viewing direction, and the laparoscopic image often is unstable because of tremor and sudden movements of the surgical assistant. Furthermore, the positioning task is a relatively static and tiresome task for the surgical assistant. Instrument positioners could assume the task of the surgical assistant, return camera control to the surgeon, and stabilize the laparoscopic image.

Instrument positioners are divided into two main groups: passive positioners, (manually repositioned by the surgeon) and active positioners (repositioned by a robotic device). An example of a passive positioner is the PASSIST. An example of an active positioner is the AESOP (computermotion, Santa Barbara, CA, USA) [4, 8, 9]. Laboratory experiments with IPs show that observation and manipulation tasks can improve when the surgeon has direct control over his viewing direction in laparoscopic procedures [12]. A clinical experiment indicated that the use of an active IP does not increase the total operation time [8].

The aim of this study was to analyze objectively whether IPs can substitute for a surgical assistant efficiently and safely in a clinical situation. Laparoscopic cholecystectomies (LCs) performed with a surgical assistant and LCs performed with an IP instead of an assistant were composed. This study analyzed the efficiency of the procedure in terms of time and actions needed per phase, using time-action analysis. To determine safety, the incidence of peroperative complications, the positioning accuracy of the image, and the judgment of the surgeons, were analyzed.

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Table 1. Exclusion criteria

Age younger than 18 years
Quetelet index less than 40
Pregnancy
Previous upper abdominal surgery
Recent pancreatitis
Clinical, chemical, or radiologic suspicion of cholestasis/stones in the ductus choledochus
Cholecystitis
Other infection in the right upper abdominal quadrant
Suspicion of perforation or empyema of the gallbladder
Porcelain gallbladder
Diagnosed cancer
Bleeding disorders

Methods

Patients and procedure

A multicenter, randomized, prospective clinical trial was used to compare LCs performed with a surgical assistant (AS group) and LCs performed without an assistant using IPs (IP group) instead. Patients in American Society Anesthesiology (ASA) stages I to III undergoing elective LC for symptomatic cholelithiasis were included in the study. Patients were excluded if they met at least one of the exclusion criteria listed in Table 1. These inclusion and exclusion criteria generally were used in the participating hospitals to select patients for LC, and therefore were sustained in this study. Acute cholecystitis was excluded because this study was a multicenter trial and procedures had to be planned in advance. In four hospitals 78 laparoscopic cholecystectomies were performed by four surgeons experienced in performing LCs and one resident. Laparoscopic cholecystectomy was selected for this study because LCs are performed on a regular basis in accordance with a standard protocol. All the surgeons randomly performed LCs in the AS or IP group as decided by the drawing of lots. An equal number of lots were distributed between the AS and IP groups for each surgeon to compensate for any variations caused by differences in individual surgical techniques and hospital policy. The study protocol was approved by the local ethical committees of the participating hospitals.

Instrument positioners

In the IP group, one surgeon used the active voice-controlled AESOP because he was already experienced in using the AESOP to position the laparoscope. The other surgeons used the recently developed passive IP named PASSIST [6]. The PASSIST and AESOP allow movements in 4° of freedom: all three rotations around the incision point in the abdominal wall and one translation through this incision. None of the surgeons were experienced in solo surgery because residents had assisted with LCs performed with or without IPs as part of their surgical training.

The active voice-controlled AESOP was selected as a representative of the commercially available active positioners (Fig. 1a). The active IP can position and lock the laparoscopic camera using voice control, without interrupting the operating actions of the surgeon. Active IPs are rather expensive, are not sterilizable, and control only the camera.

The PASSIST (Fig. 1b) is a manually controlled mechanical arm, capable of locking the laparoscope and an additional grasper in the desired position, allowing for adjustments of position using one hand [6]. Because the PASSIST is slender, it does not interfere with the surgeon's actions, as some bulky active IPs do. In addition, the PASSIST can be mounted at the operating table rail next to or opposite the surgeon without interfering with the surgeon's actions, and is sterilizable. Two PASSISTs can be used at the same time. Thus, if a surgeon uses four trocars for LC, he can use two PASSISTs to position both the laparoscope and the gallbladder forceps.

Recording procedure

During the surgical procedures, the images from the laparoscope and the images from two additional external CCD cameras were recorded simultaneously using a four-channel mixing device. The small CCD cameras recorded one central overview of the surgical procedure and a detailed image of the surgeon's hands. In addition, an omnidirectional microphone recorded the comments of the surgeon during the operation. The equipment was placed outside the operating team's range of motion, and the recorded procedures were analyzed outside the operating theater to prevent interference with the peroperative procedure.

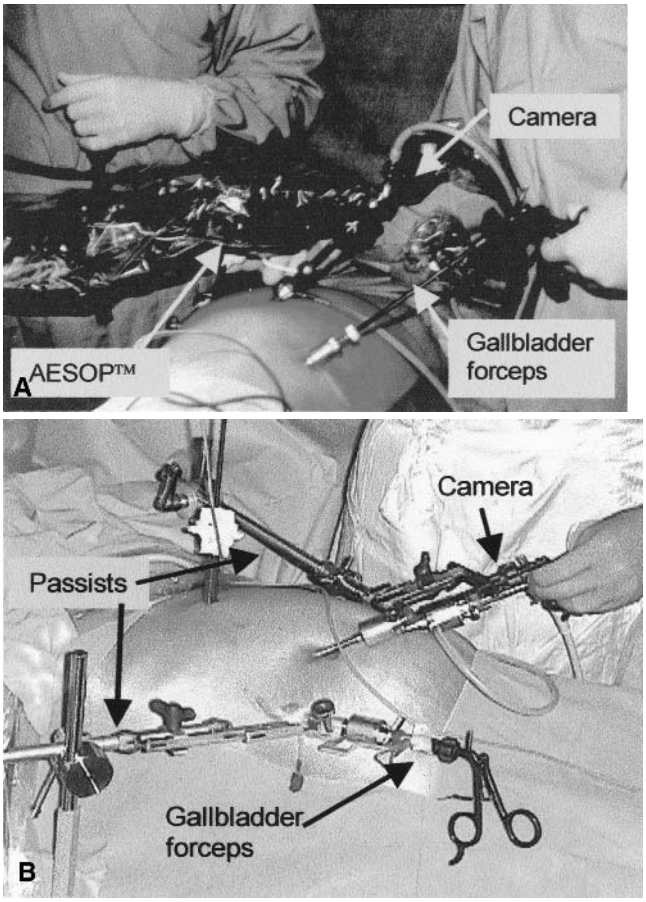

Fig. 1. A Active voice-controlled positioner: AESOP by computer motion. **B** Passive positioner: PASSIST. Two positioners are shown: one positioning the camera, the other positioning the gallbladder forceps.

Data analysis

The efficiency and safety of IP use were determined for each procedure using the recently introduced time-action method to analyze the peroperative process objectively [1, 2, 5] The efficiency of the operation was analyzed by comparing the time and the number of actions needed for each operation phase between the AS and IP-groups. The types of actions were analyzed using a modified list of actions (Table 2) as defined by Claus et al. [5]. The outcomes of the AS group were used as the standardized reference for the IP group. For the AS group, the actions of the surgeon and surgical assistant were totaled and scored. For the IP group, the total number of the surgeon's actions were scored. Additionally, the actions that the scrub nurse took over from the surgical assistant also were scored in both procedures. For example, when the AESOP and four trocars were used, the scrub nurse sometimes had to hold the gallbladder forceps because the AESOP held only the laparoscope.

The efficiency of the procedure was analyzed in three phases (setup, dissection, and closure) as reported previously [1, 2, 10]. In short, the setup phase was defined to start after the last sterile sheet was placed and to end with the first intraabdominal dissection. The dissection phase was defined as the interval between the first intraabdominal dissection and the removal of the gallbladder from the abdomen. The closure phase was defined as the

Table 2. List of defined actions

Surgery	Instrument	Others
Dissect	Insert instrument	Waiting for personnel
Stretch	Remove instrument	Waiting for instruction
Coagulate bleeding site	Reposition laparoscope	Waiting for technical reason
Clip	Handle positioner	Command to reposition scope
Percussion/palpation	Reposition gallbladder forceps	Other verbal instruction
Irrigation/suction	Clean instrument	Apply bandage
Suture	Set up supporting systems	
	Use retrieval bag	

interval between removal of the gallbladder from the abdomen and placement of the last suture.

The safety of the procedure was evaluated by determining the peroperative complications (e.g., arterial bleeding, gallbladder leakage, bowel injury), the positioning accuracy of the image, and the difficulties assessed during the operation by the surgeons. Signs of mild cholecystitis that became apparent during the operation also were scored as a complicating factor because cholecystitis is regarded as a relative contraindication for elective LC, making the dissection more complicated.

Positioning accuracy was defined as the accuracy with which the laparoscope showed each dissecting action in the center of the image. Experienced surgeons were asked to indicate the field of the monitor image in which the actions should be performed for safe task performance. Accordingly, the center of the image was defined as a circle with a diameter two-thirds the height of the monitor (Fig. 2). The position of the manipulating instrument's tip was determined in the image as completely in the center of the image, at the border of the image, or partly outside the monitor (Fig. 2). For electrosurgical instruments, the tip was defined as the noninsulated part of the instrument. For other instruments, the tip was defined as the part between the hinge and the point. The position of the instrument tip was scored for each manipulating action of the experienced surgeons in the dissection phase. In addition, the number of times the laparoscope was repositioned (manually or by verbal command) was analyzed.

Difficulties during the operation and the comfort of IP use both were evaluated using a questionnaire, which was completed by the surgeon after each procedure (Table 3). The surgeons were asked to rate the answers on a scale ranging from 1 (not at all) to 5 (yes, absolutely). The average ratings of each answer were calculated to compare the AS group with the IP group.

The results of the residents and experienced surgeons were analyzed separately because the operation times for residents are significantly longer than those of experienced surgeons. In addition, a subanalysis was performed to analyze the outcomes of the AESOP and the PASSIST separately.

The mean values and standard deviations were calculated for the time (in min), the number of actions, and positioning accuracy. The two-sided Student's *t* test was used to compare the outcomes. A p value less than 0.05 was considered significant.

Fig. 2. Positioning accuracy. The diameter of the circle in the center is two-thirds the height of the monitor image.

Results

No significant difference was found for patient characteristics (age, gender) or number of peroperative complications between the AS and IP groups (Table 4). No conversions to open cholecystectomy occurred. The surgeons performed 30 of the 78 LCs with and 30 without a surgical assistant. The resident performed 9 LCs with and 9 without a surgical assistant. One surgeon used the AESOP instead of the PASSIST (5 LCs in the AS and the 5 LCs in the IP group).

Efficiency

The total operation time did not differ significantly between the LCs performed with a surgical assistant (42 ± 21 min) and the LCs performed with an IP (49 ± 23 min; $p = 0, 18$) (Fig. 3). Moreover, the total number of actions also did not differ between the AS group (635 ± 251 actions) and the IP group (646 ± 265 actions; $p = 0.86$). The results per phase show that only the time for the setup phase was increased significantly in the IP group over that in the AS group. The number of actions did not differ between the two groups for any operation phase (Fig. 3).

Positioning of laparoscope

The number of times the laparoscope was repositioned during an operation decreased significantly when an IP was used (49 ± 27) instead of a surgical assistant (114 ± 54; $p <$ 0.001). Nevertheless, the positioning accuracy of the laparoscope did not differ significantly between the groups: 43% of all the dissections (80 ± 45 manipulating actions) were performed completely within the defined center in the As-group, as compared with 42% (86 ± 50) in the IP group ($p = 0,91$) (Fig. 4). Furthermore, 46% of all dissecting actions (72 ± 29) were performed outside the defined center in the As-group, and 11% (18 ± 16) took place outside the monitor image. In the IP group, this was 49% (92 ± 45) and 9% (13 ± 13), respectively. The gallbladder forceps, held by the surgical assistant in the AS group and by the PASSIST in the IP group, was repositioned 10 times per LC on the average in the AS group, and an average of 7 times in the IP group ($p = 0, 10$).

Table 3. Difficulties and comfort questionnaire[a]

Question	AS group (n = 39)	IP group (n = 39)
1. The operation was difficult.	2.3	2.0
2. The operation was efficient.	4.5	4.8
3. The installation of the positioners was easy.[b]		3.8
4. I was content with the laparoscope positioner.[b]		4.5
5. I was content with the forceps positioner.[b]		3.2
6. I can do this procedure without an assistant.[b]		4.9
7. I would have preferred to operate with an assistant.[b]		1.8
8. I was satisfied with the laparoscopic image.	3.9	4.2
9. Overall, the image centered correctly.	3.5	4.2
10. The video recording and persons involved bothered me.	1.0	1.0

[a] Mean rating score for each question per group, as expressed by the surgeons. The answer had to be scored on a range from 1 (no, not at all) to 5 (yes, absolutely)
[b] These questions were asked only in the IP group
AS, assistant; IP, instrument positioner

Table 4. Patient characteristics and perioperative complications

	AS group (n = 39)	IP group (n = 39)	t test
Males/females	11/28	6/33	NS
Mean age (years)	51 ± 15.3	51 ± 15.6	NS
Cholecystitis	8	5	NS
Arterial bleeding	4	1	NS
Gallbladder perforation	18	15	NS
Endobag used	8	9	NS

AS, assistant; IP, instrument positioner; NS, not significant

Subanalysis

Neither the AESOP nor the PASSIST effected a significant change in total operation time (33 ± 7 min and 53 ± 23 min, respectively) or total number of actions needed (489 ± 118 and 678 ± 275, respectively), as compared with LCs performed using a surgical assistant (42 ± 21 min and 635 ± 251 actions). The number of times the laparoscope was repositioned decreased significantly in both groups.

The results from the LCs performed by the resident did not differ significantly between the AS and IP groups (p = 0.58). Naturally, the average total operation time (AS group, 86 min; IP group, 90 min; p = 0.69) and the total number of actions needed (AS group, 1081 ± 187; IP group, 1023 ± 211; p = 0.58) were higher for the LCs of the resident than for the LCs of the experienced surgeons.

Questionnaire

The results from the questionnaire (Table 3) showed that surgeons judged the operations as equally difficult and efficient for both groups. The surgeons indicated that an IP could replace the surgical assistant. Furthermore, the surgeons indicated that they preferred the use of an IP to the use of a surgical assistant, and finally, that they were more satisfied with the laparoscopic image if an IP positioned the laparoscope.

Discussion

This study showed that the use of IPs enables surgeons to perform elective laparoscopic cholecystectomy without a surgical assistant. The findings proved that there was no change in total operation time and number of actions needed when IPs were used instead of surgical assistants. In addition, the laparoscope was repositioned 60% less frequently when IPs were used, and the positioning accurateness of the image was retained. Furthermore, the occurrence of peroperative complications (Table 4) did not differ between the groups, and the complications that occurred did not have any consequences for the operative use of IPs or the outcome for the IP group.

The total operation time did not change significantly, but the average setup time did increase significantly by 6 min when IPs were used. This increase was caused by the time needed for the installation. The surgeons often waited to install the IPs until they were finished with their normal setup procedure. In the future, the setup time will be reduced if the surgeons become experienced in using the IPs and installing them during the pneumoperitoneum. Furthermore, the design of the PASSIST possibly could be improved to reduce the time needed for installation.

The surgeons in this study were not experienced in solo surgery, which possibly might have resulted in a bias. The results from the analysis showed that the average setup time was longer in the beginning and decreased during the 10 procedures performed with the PASSIST. The dissection and closing phases in the IP group did not decrease during the 10 procedures, and were not longer than those phases in the AS group. Therefore, the inexperience of the surgeons might have caused the efficiency of the setup phase of the IP group to be underestimated, particularly for the surgeons using the PASSIST.

This study showed that IPs can substitute for a surgical assistant. This is especially relevant in the setting of a nonteaching hospital. In the teaching setting, residents frequently assist LCs as part of their surgical training program. The use of IPs would deprive residents of this opportunity to learn laparoscopic skills. In fact, during our study, a surgical assistant often was present during LCs with an IP because of the educational aspect for residents. Sometimes, this resulted in the resident participating in a positioning task because he or she was at hand, although it was against the study protocol. In these cases, the actions of the assistant were added to the total number of actions for the IP group.

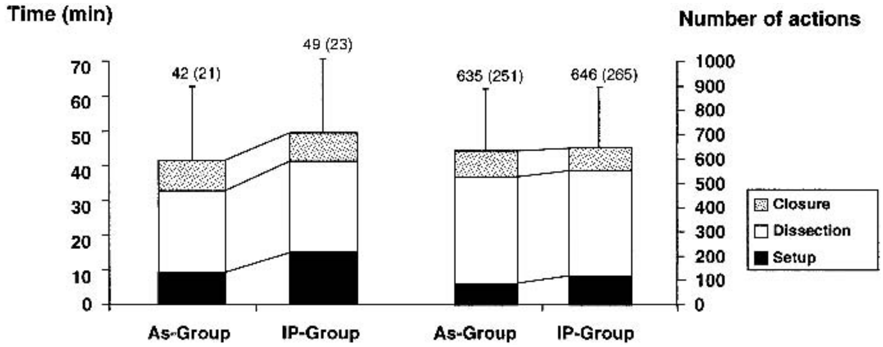

Fig. 3. Time-action analysis results. Average time and number of actions are shown per phase for the AS group and the IP group of the experienced surgeons. Total time (± standard deviation) in minutes and number of actions are shown on top.

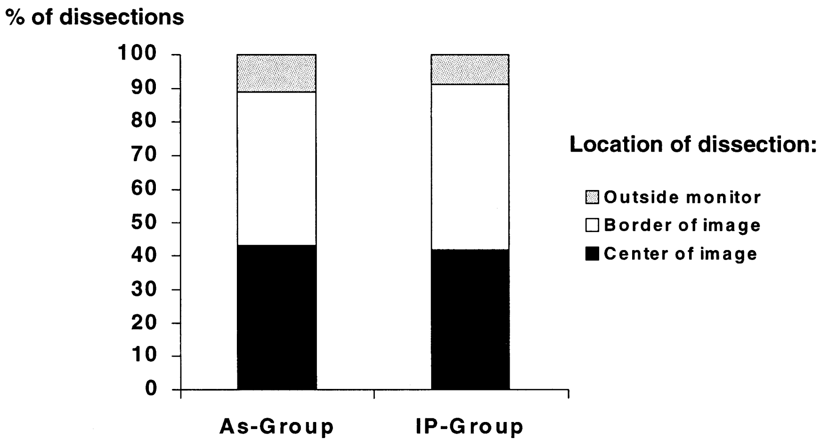

Fig. 4. Positioning accuracy. Percentage of actions performed inside the central circle, outside the circle, and totally outside the monitor are shown for the AS group and the IP group of the experienced surgeons.

The surgeons indicated afterward that they were fully convinced that these actions could have been performed either by themselves or by the scrub nurse. In other procedures, when no resident was present, the surgeons indeed proved that they could operate fully without a surgical assistant. Of the total actions performed per LC, the surgeon performed 74% of the surgical actions on the average in the AS group (471 ± 193), and 88% of the actions in the IP group (565 ± 229; $p = 0{,}10$). The number of actions performed by the resident decreased significantly (23% in the AS group and 9% in the IP group; $p < 0{,}001$) without increasing the number of actions performed by the scrub nurse (3% vs 3%; $p = 0{,}46$).

Positioning accuracy was assessed using a central circle. Experienced laparoscopic surgeons indicated that a safe diameter of the circle would be two-thirds the height of the monitor. However, more than 50% of the actions were performed outside the central circle. Apparently, in the clinical situation, the surgeons often preferred a decentralized view over an extrarepositioning action. In our study, the actions performed outside the central circle did not lead to an increase in complications.

This study was designed to compare the efficiency and safety of IPs with those of a surgical assistant in a clinical setting. The study was not designed to analyze erroneous task performance or postoperative complications in detail. Detailed data concerning the occurrence of complications in LCs can be found in the literature. For example, the study of Joice et al.[7] analyzes peroperative complications in detail. In addition, various clinical studies have assessed postoperative complications in LCs [3, 11].

The questionnaire showed that surgeons preferred to operate with an IP instead of a surgical assistant. The main reasons mentioned were the stable image, the absence of misunderstood verbal commands between the surgeon and the assistant, and the reduced need to clean the lens of the laparoscope. These reasons also are described in the literature [3]. Furthermore, the surgeon was able to concentrate more on his dissection task because less attention was required to position the laparoscope and the gallbladder forceps or to guide the assistant. In the case of the resident operating with the IP, supervising surgeons mentioned that they could focus better on the training aspect (e.g., by pointing out structures on the monitor) because they did not need to attend the laparoscope.

Conclusion

This study showed that the use of instrument positioners enables surgeons to perform elective laparoscopic cholecystectomy without a surgical assistant. Furthermore, replacing the surgical assistant with an IP does not result in a significant increase in the time and number of actions needed for LC. The use of instrument positioners reduces laparoscope repositioning without significantly changing positioning accuracy. Surgeons subjectively prefer to operate with an instrument positioner instead of a surgical assistant.

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