Comparing the Operational Related Outcomes of a Robotic Camera Holder and its Human Counterpart in Laparoscopic Ovarian Cystectomy: a Randomized Control Trial

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Article info:
Received: July 28 2013
Accepted: October 14 2013

Keywords:

Laparoscope holder,
Robot-assisted surgery,
Cameraman robot, RoboLens.

A B S T R A C T

Purpose: Robotic camera holders have provided new prospects for more successful endoscopic surgeries. In this study we aimed to assess the operational subjective and objective outcomes of a newly developed camera holder, RoboLens, in comparison with a human camera holder, during laparoscopic ovarian cystectomy.

Methods: The study was performed as a randomized, single-blind, placebo-controlled, parallel-group trial. Forty patients with single ovarian cyst were randomized to laparoscopic ovarian cystectomy with robotic (RoboLens) or human camera holder.

Results: Results indicated that the surgeons felt less fatigue (P=0.047) and surgeries concluded sooner (P=0.001) in robotic assisted groups. Also, the image quality during operation with robotic camera holder was either superior or equal to what obtained with human assistant. However, mastery of the difficult situations, which were defined after the commencement of study, was significantly poorer in robotic group (P=0.001).

Conclusion: It was concluded that RoboLens, as a low cost robotic camera holder, is a safe, time and energy saving system which helps to obtain an improved vision from the surgery site.

1. Introduction

Laparoscopic surgery is often preferred to laparotomy for getting access to abdomen due to the faster recovery with shorter hospitalization, decreased blood loss, improved cosmetics and reduced post operative pain [1, 2]. However, in spite of the technical advancements, it is still faced with several limitations, e.g., poor perception of depth by surgeon due to the two dimensional visual field, indirect perceptual and visual feedbacks, and ergonomic difficulties [3].

Application of assistant robots in laparoscopic surgery has demonstrated promising results in comparison with the conventional laparoscopic surgery. Well designed robots can assist laparoscopic surgeons without limiting their human capabilities, while the robot's extra benefits could be utilized to enhance the quality and outcomes

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of surgery [4]. An important area of application for surgery assistant robots is manipulation of the endoscope. Considering the fact that both hands of the surgeon are engaged with the surgical instruments, the endoscope must be manipulated by an assistant. However, the degree of coordination between the surgeon and the assistant is a matter of concern. Since handling an endoscope is a static activity, it results in faster fatigue compared to dynamic activities [5]. Hence, the assistant becomes tired faster than the surgeon, leading to hand tremor, wrong or unwilling image motions, and poor surgeon-assistant coordination [6]. Moreover, the complexity of the counterintuitive hand movements can aggravate the problem based on the fulcrum effect of the incision site [7]. On the other hand, the surgery assistant is usually a surgeon who could be involved in other surgical tasks with his/her other hand. Therefore, it often happens that the lens of the endoscope hits the tissues and gets dirty, due to the poor attention of the assistant. In general, the poor quality of the image would affect the surgeon's performance, especially during fine hand motions such as suturing [8]. Furthermore, the workspace could be cumbersome for the surgeon because of the space occupied by the assistant [6].

A number of different robotic camera holders have been developed recently to overcome the aforementioned problems. Previous studies have shown that utilization of robotic holders resulted in more stable images, lower camera motions, lower number of lens cleaning actions and more accurate camera placements [9]. It has been also suggested that with robotic camera holders, surgeons are more efficient and feel less fatigue, and the surgeries are concluded sooner [10]. The majority of the previously developed camera holders were bulky which could impose maneuvering limitations on the surgeons [9]. On the other hand, the complexity of their design, in conjunction with their redundant degrees of freedom, caused high manufacturing and maintenance cost which made them impractical in some cases [11-13]. Moreover, the axial rotation which disorients the image, is an inevitable problem in a majority of well designed camera holder robots [10]. To overcome these problems a camera holder robot, RoboLens V2.2, had been developed and validated [14] in the Robotic Surgery Lab of Research Center of Biomedical Technology and Robotics, Tehran, Iran. The aim of this study was to evaluate the efficacy of RoboLens in laparoscopic surgery and to identify its potential advantages/disadvantages in comparison with a human camera holder. We studied the subjective and objective operational related outcomes of ovarian laparoscopic cystectomy in two groups of patients that were treated with and without the robotic camera holder.

2. Methods

A randomized patient blind controlled clinical trial was performed to compare the operation related subjective and objective outcomes of patients who underwent ovarian cystectomy in Arash Hospital in Tehran, Iran, with a robotic or a human camera holder, during November 2010 to June 2011. The trial was performed in accordance with the declaration of Helsinki and subsequent revisions and approved by the ethics committee of Tehran University of Medical Sciences. Written informed consent was obtained from the patients before entering the study. Eligible patients were 40 women with single small or moderate size (3 to 10 cm) sonographically benign ovarian cyst with normal tumor markers. Patients with large size cysts, increased tumor markers and medical and surgical contraindications for laparoscopic surgery were excluded from the study.

Randomization was in a 1:1 ratio of robotic camera holder and its human counterpart. Permuted block randomization was employed by using random numbers table and randomly assigned block size of four. The generated sequence of allocation was concealed in sequentially, sealed, opaque envelops. Just after the patient was anesthetized and before the operation, the corresponding envelop was opened by an assistant to determine the kind of surgery. The surgeries were performed by two surgeons, based on their availability on the time of surgery, with no consideration on who operates the consecutively enrolled patient.

Laparoscopic ovarian cystectomy was performed by entering laparoscope through three 5 mm incisions on the abdomen; then, cyst wall was removed and bleeding sites were controlled. In Robotic assisted surgery group, camera was held and manipulated by RoboLens V2.2 (RCBTR, Tehran, Iran), based on surgeon's orders, while it held by an expert human assistant in the control group. RoboLens is a newly developed robot that employs an effective low cost mechanism with a minimum number of actuated degrees of freedoms to hold and manipulate the laparoscopic lens under direct supervision of the surgeon. The detailed features of the robot and its development and validation procedure are provided elsewhere [14]. Briefly, the robot has one linear and two orthogonal rotary actuators and one passive encoded rotary joint, configured serially. The vertically oriented linear actuator is mounted on the trolley and is attached through a rigid horizontal arm to the head of the robot, where the two rotary actuators are located. This architecture allows the head of the robot to be located over the incision point on the patient's body, at a higher level than the surgeon's head. Two rotary actuators at the head of the robot connected to a thin detachable rod which comes down and holds the laparoscope stem via a passive encoded rotary wrist and a miniaturized autoclave-able quick release gripper (Figure 1). With the above configuration, the possible movements of the robot include Up/Down and Left/ Right movements in the screen plane and Zoom In/Out perpendicular to it. During these movements, no axial rotation occurs in the laparoscope stem, so the orientation of view is not disturbed. Two user interfaces are implemented to control the robot, including a voice command recognition system and a six-button foot pedal [14].

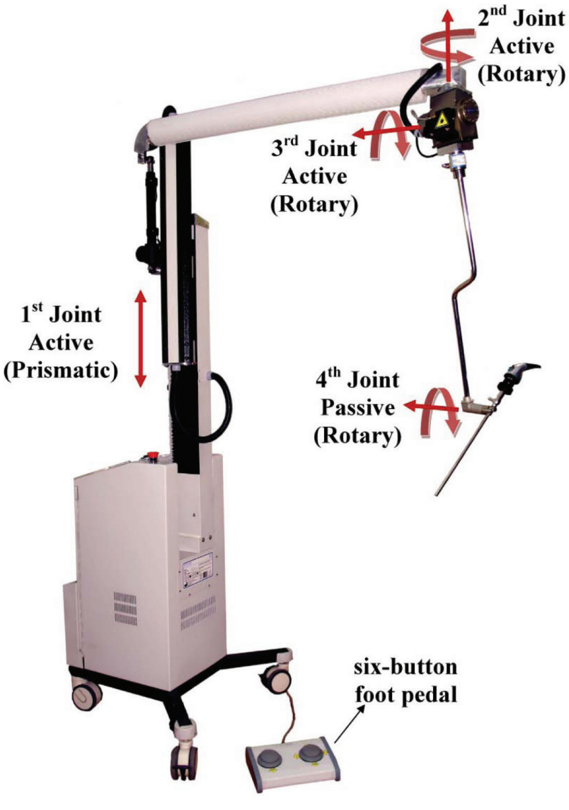

Figure 1. Newly developed camera holder robot: RoboLens V2.2 (Courtesy of Robotic Surgery Lab., RCBTR)

Objective outcomes were recorded by a trained operating room technician during each surgery. Subjective outcomes of operation were assessed by the surgeon based on a questionnaire after the surgery. The experience of the surgeon in laparoscopic surgery in years, the BMI of the patient, the location of the cyst, the kind of the cyst and the level of difficulty of the surgery were used for baseline comparisons. The level of difficulty of surgery was defined by a categorical variable containing three levels of easy, hard and very hard, and scored by the surgeon after the surgery. The primary outcomes included the fatigue of the surgeon after the surgery (defined by categorical variable with three levels of little, medium and much) and the time duration of the operation. The secondary outcomes included the frequency of changing the assistant, the occupied space of the room, the frequency of the undesired movements of the lens, the frequency of the lens focus correction, the frequencies of the camera head cleaning, the responding quality to the surgeon's orders, and the maneuvering limitation imposed to the surgeon by the assistant. We also defined a new variable during the trial which was the mastery of difficult surgical situations defined by excessive bleeding or organ perforations.

The frequency of changing the assistant was evaluated in two distinct categories: (1) the conversion to human assistant due to the hardware failure of RoboLens compared with conversion to another assistant because of physical problems, and (2) the conversion to human assistant due to software failure of RoboLens compared with conversion to another assistant due to inadequate expertise. The occupied space in the operating room was evaluated by a categorical variable with three levels (little, medium and much). The frequency of undesired movement of the lens was further divided into two groups (1) the frequency of undesired movements, and (2) the frequency of complete view correction. The responding quality to the surgeon's orders was defined by categorical variable with three levels (poor, acceptable and good). The maneuvering limitation imposed on the surgeon by the assistant was also defined by a categorical variable with three levels (little, medium and much).

Statistical analyses were performed using two-sided tests of significance using SPSS version 13. For continuous or ordered baseline and outcome variables, the normality of variables was examined using KS test, firstly. If assumption of normality was not markedly violated, T test was used to compare the means. For categorical variables Chi square and Fisher exact test were used. The level of significance was considered as 0.05.

3. Results

There were no significant difference between the baseline characteristics of the two groups, including the age (P=0.212) and the BMI of the patients (P=0.113), the experience of the surgeons (P=0.324), and the difficulty level of operations (P=0.236). Three kinds of single cysts (simple, dermoid, endometrioma) were operated and the kind of cyst was not significantly different between the robotic and the human camera holder groups (P=0.519). Generally, right cysts were more common but the side of the cyst was not significantly different between the two groups (P=0.507). The baseline characteristics are presented in Table 1.

Table 1. The baseline characteristics of the operations

Variable	Measure	Case	Control
Patients' Age	Years (mean ± SD)	29.35 ± 8.85	33.25 ± 10.503
Patients' BMI	<25,25-30,30-35,>35	2,10,7,1	0,7,10,3
Type of cyst	Simple, Dermoid, Endometrioma	4,9,7	3,8,9
Location of cyst	Right, Left	14,6	12,8
Surgeon's Experience	Years (mean ± SD)	19.6 ± 2.019	19 ± 1.777
Difficulty of surgery	Easy, Hard, Very hard	4,14,2	1,13,6

The results found for the primary outcomes of the study indicate a higher efficacy for the robotic camera holder in comparison with its human counterpart. The surgeons generally felt less fatigue when operating with the robotic system (P=0.047), with a little level of fatigue in all robotic operations (Table 2). The set up time took less than 7 minutes in all cases which was negligible compared to the endoscopic time which ranged from 25 to 180 minutes (mean ± SD=80.82±34.12). Although the mean set up time was significantly longer in robotic assistant group (P=0.003), the endoscopic surgery time and the total time of surgery were significantly lower in robotic assistant group (P=0.001). The total surgery time and the endoscopic surgery time reduced by an average of about 35.5 and 34.5 minutes, respectively, when the robotic camera holder was used (Table 2).

Table 2. The comparison of the primary outcomes between RoboLens and human assistant groups

Variable	Measure	Case	Control	Statistical Test values
Surgeon's fatigue	Little, Medium, Much	20,0,0	15,4,1	P=0.047[1,2]
Set up time	Minutes (Mean ± SD)	5.90 ± 0.191	4.90 ± 0.250	t=3.179 df(38), P=0.003
Endoscopic time	Minutes (Mean ± SD)	63.15 ± 5,713	98.50 ± 7.345	t=-3.799 df(38), P=0.001
Total surgery time	Minutes (Mean ± SD)	69.05 ± 5.777	103.40 ± 7.475	t=-3.636 df(38) ,P=0.001

1) Obtained from Fisher exact test

2) Obtained from 2 × 2 table

The results found for the secondary outcomes of the study are somewhat inconsistent (Table 3). The mean number of complete view corrections and camera head cleanings were significantly lower in robotic group (P<0.001 and P=0.028, respectively). However, the undesired camera movement and the need to lens focus corrections were similar in both groups. On the other hand, in most cases, the space occupied by an assistant scored "little" by the surgeon (18 compared to 16 cases for robotic and human assistant groups, respectively). In both groups, the assistants, either human or robot, did not cause much maneuvering limitation for the surgeon (Table 3). Also, in both groups, changing to an alternative assistant was so rare and occurred in less than four times in each group. As a result, the two sub outcomes of (1) conversion to human due to hardware failure/physical problems and (2) conversion to the human assistant due to software failure/inadequate expertise were not significantly different between the groups (Table 3). Finally, in most cases, the coordination between the surgeon and assistant were sufficiently good and there was no significant difference between the two groups concerning appropriate response to the surgeons' orders (coordination). However, the mastery of difficult surgical situations was significantly better in human assistant group (P=0.001).

Table 3. The comparison of secondary outcomes between RoboLens and human assistant groups

Variable	Measure	Case	Control	Statistical Test Values
Complete view corrections	Numbers (Mean ± SD)	1.45 ± 0.153	4.45 ± 0.234	t=-10.543 df(32.797), P<0.001
Camera head cleanings	Numbers (Mean ± SD)	1.7 ± 0.179	2.25 ± 0.160	t=-2.283 df(38), P=0.028
Undesired camera movements	Numbers (Mean ± SD)	1.35 ± 0.264	1.30 ± 0.105	t=0.176 df(24.865), P=0.862
Lens focus corrections	Numbers (Mean ± SD)	1.55 ± 0.223	1.30 ± 0.105	t=0.250 df(27.028), P=0.320
Provision of optimal view	Poor, Acceptable, Good	0,0,20	1,1,18	P=0.487[1,2]
Coordination between assistant and surgeon	Poor, Acceptable, Good	0,2,18	2,1,17	P>.999[1,2]
Mastery of difficult situations	Poor, Acceptable, Good	1,15,4	1,5,14	$\chi 2$=10.101 df(1), P=0.001[2]
Space occupation by the assistant	Little, Medium, Much	18,2,0	16,3,1	P=0.661[1,2]
Maneuvering limitation for surgeon	Little, Medium, Much	16,4,0	19,1,0	P=0.342[1,2]
Change to an alternative assistant	Software failure or inadequate expertise (YES/NO)	1,19	2,18	P>.999[1]
Change to an alternative assistant	Hardware failure or physical problem (YES/NO)	2,18	1,19	P>.999[1]

1) Obtained from Fisher exact test

2) Obtained from 2 × 2 table

4. Discussion

The results of this study are generally in favor of the robotic camera holder in comparison with its human counterpart. Both primary outcomes, i.e., the surgeon's fatigue and the total time of operation, were scored higher in robotic group. Fatigue can be considered an important challenge in any surgery with a viscous cycle leading to more mistakes [15]. Although needs to be proved, reducing the surgeon's fatigue and the total time of surgery can be indirectly interpreted as decreased mistakes and improved clinical results [4].

Our results also indicate that the need to complete view correction and camera head cleaning were lower in the robotic assistant group. However, the quality of the image was similar in both groups. It might be suggested that, because of the small sample size, our study was not sufficiently high powered to detect the difference between the two groups in provision of the optimal view. Our raw data, however, shows that the image quality was higher in the robotic group. The other outcomes were similar in the robotic and human assistant groups. The coordination of the assistant with the surgeon was good in both and the maneuvering limitation imposed on the surgeon, the space occupation, and the rate of changing to an alternative assistant, were similar in them.

It might be concluded from the results that ovarian cystectomy with RoboLens provides either better or equivalent outcomes in comparison with ovarian cystectomy with human camera holder. In other words, the ovarian cystectomy can be performed by only one surgeon (solo surgery) [16] with equivalent or improved results for both time and energy costs. The only exception in the surgery outcomes that is in More favor of a human assistant is the mastery of difficult or special surgical situations. For example at unexpected situations such as bleeding or needle breakage an expert human assistant may work better and know what to do in comparison with a robotic cameraman. Also at special tasks such as camera maneuvering during the suturing task a human assistant know to zoom out when surgeon pull the suturing thread.

The newly developed cameraman robot, RoboLens V2.2 , is an effective, compact and low cost robotic assistant for laparoscopic surgery. The system is easy to use, portable, and fast to set up. It has a touch screen with a user friendly graphical interface and many useful guiding tips to work with safely. Unlike the other commercially available assistant robots its view orientation is always preserved, as the swivel motion of the laparoscope camera is physically impossible. Furthermore, using a passive wrist at the most distal joint of the robot makes it safer, since the robot may comply with the movement of the patient's body or surgical bed in the vertical direction. Finally, the architecture of the robot is such that during surgery the arms and all actuators are located out of the surgical workspace, and produce no limitation for the surgeon's maneuvers [14]. There is however, a concern about the efficacy of human – machine interface for the robot, similar to other robotic cameramen available. RoboLens is equipped with a voice command interface system to facilitate the human-machine interface. However, the safety observation of repeating the command in the headphone causes a considerable delay between the command and the resulting movement. As a result, in all operations of this study, the surgeons preferred to use the foot pedal interface. Nevertheless, this interface has also some disadvantages as the surgeon has to look away from monitor to find the appropriate pedal for commanding the robot. A better choice might be a small joystick on the surgical instrument handle. Herman et al. [17] used an especial joystick interface installed on the minor hand instrument to make the movements more natural reaching to the target in a straight line compared with stepwise horizontal and vertical movements. Although this design made the movements more natural, it is more complicated and there is a possibility of axial rotation in the up/down extreme borders. Future works should be directed to develope a robot with more efficient interface and also more natural movements while the axial orientation of the lens is still preserved.

Acknowledgement

The authors wish to thank K. Amini Khoei, S. Porsa, M. J. Shamsolahi, B. Ghanadi and H. Hashemi, from Robotic Surgery Lab of Research Center for Biomedical Technology and Robotics, for their valuable assistance.

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