

Institutional report - Thoracic non-oncologic

Robotic versus human camera holding in video-assisted thoracic sympathectomy: a single blind randomized trial of efficacy and safety

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Abstract

Our objective is to compare surgical safety and efficacy between robotic and human camera control in video-assisted thoracic sympathectomy. A randomized-controlled-trial was performed. Surgical operation was VATS sympathectomy for hyperhidrosis. The trial compared a voice-controlled robot for holding the endoscopic camera robotic group (Ro) to human assisted group (Hu). Each group included 19 patients. Sympathectomy was achieved by electrodissection of the third ganglion. Operations were filmed and images stored. Two observers quantified the number of involuntary and inappropriate movements and how many times the camera was cleaned. Safety criteria were surgical accidents, pain and aesthetical results; efficacy criteria were: surgical and camera use duration, anhydrosis, length of hospitalization, compensatory hyperhidrosis and patient satisfaction. There was no difference between groups regarding surgical accidents, number of involuntary movements, pain, aesthetical results, general satisfaction, number of lens cleaning, anhydrosis, length of hospitalization, and compensatory hyperhidrosis. The number of contacts of the laparoscopic lens with mediastinal structures was lower in the Ro group ($P < 0.001$), but the total and surgical length was longer in this group ($P < 0.001$). Camera holding by a robotic arm in VATS sympathectomy for hyperhidrosis is as safe but less efficient when compared to a human camera-holding assistant.

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1. Introduction

Several recent technologic advances allow minimally invasive operations with a high precision level [1]. Although successful robot-assisted procedures series has been published, high costs can be prohibitive to its widespread use [2–5].

Despite studies comparing results of conventional operations to those using robotic devices [6–9], in general thoracic surgery case reports and small series are the most common publications [10–15]. Advantages in using robotic devices compared to traditional VATS are easily observed when precise and articulated movements are required to dissect deeply located anatomic structures in the thoracic cavity. Surgical maneuvers' precision that can be restricted when using traditional VATS devices through narrow ports, can be recovered when using robotic arms.

Our objective is to compare efficacy and safety between robotic (Ro) and human (Hu) camera holding in video-assisted thoracic sympathectomy.

2. Material and methods

2.1. Study design

It is a prospective randomized trial following CONSORT Statement 2001 [15].

2.2. Settings and locations where the data were collected

Thoracic Surgery Department of The São Paulo University Medical School Hospital.

2.3. Eligibility criteria for participants

Patients eligible for VATS sympathectomy due to axillary/palmar hyperhidrosis.

2.4. Protocol approval and informed consent

Both approval of the protocol by the hospital's human studies committee and patient informed consent were required to include patients in the study.

2.5. Inclusion criteria

Eligible patients.

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2.6. Exclusion criteria

There were seven exclusion criteria.

Preoperative exclusion criteria: body mass index higher than 25, previous thoracic surgery, current infection, malignancies, pregnancy and inflammatory diseases.

There was one intraoperative criterion (pleural adhesion). Randomized patients who had intraoperative pleural adhesion were excluded from the study.

Obesity and pleural adhesions were exclusion criteria because they become difficult with sympathetic chain visualization and could interfere in the uniformity between groups. Furthermore, pleural adhesions could require additional dissection that could predispose lung parenchyma to air leak, and, thus, result in chest tube drainage. A chest tube could interfere in the uniformity between groups regarding pain and aesthetical evaluation.

2.7. Randomization

Sequence generation: 20 sealed envelopes contained the indication of Hu group and another 20 the indication of Ro group.

Randomization allocation was performed by a shuffled, sealed envelope technique. Implementation: Envelopes were opened in the operating room, only after the patient was unconscious; aiming to blind patients about whose group they were included in.

Neither the patient nor assistants who applied the questionnaires could know in which group the patient was included. Patients could know it only after answering the last questionnaire.

2.8. Initial casuistic after randomization

From May to December 2005, 40 patients (27 female and 13 male) were initially included before two intraoperative exclusions. Final randomization recruited 20 patients in Hu and 20 patients in Ro.

2.9. Final casuistic after intraoperative exclusions

Intraoperative exclusions resulted in a final casuistic of 38 patients. Age average was 24.98 years with a standard

deviation of 7.90 years. Body mass index (BMI) average was 20.91 (kg/m²) with a standard deviation of 2.15 (Table 1).

2.10. Surgical team and pre trial training

All the surgeons were previously trained to perform both robotic and human camera holder video-assisted thoracic sympathectomy.

The human camera holder had performed more than 500 VATS sympathectomies. Specific robotic training consisted in performing 10 robotic arm-assisted simulated procedures, followed by 24 real sympathectomies performed in 12 patients, but without quantifying safety and efficacy end points.

2.11. Interventions intended for each group

All the procedures were performed by the same surgical team.

2.12. Anesthetic technique

No epidural catheter was placed. Only intravenous anesthesia was used.

In our service, for thoracic sympathectomy of the third ganglion, we use a single lumen endotracheal tube. It is used because this ganglion can be easily visualized, dissected and fulgurated under single lumen intubation if the patient is placed in a seated position. In this position, lungs can be pushed down until reaching the third intercostals space.

2.13. Surgical technique

In the Ro group, camera holder robotic system AESOP (Automated Endoscopic System for Optimal Positioning, Computer Motion Inc, USA) was used. All the other surgical maneuvers were identically performed for both groups.

Patients were placed in a seated position with both arms opened.

Ports had 5 mm caliber and were identically placed in both groups. In each side, the first port was introduced in the periareolar region in male and sub-mammary region in female patients. Through this first port it the optical device

Table 1
Comparison between baseline demographic and clinical characteristics of each group

Variable	Group	n	Average	Standard deviation	P
Age (years)	Human	19	25.79	6.62	0.461*
	Robotic	19	24.11	7.30	
Gender (female/male)	Human	12/19			0.485*
	Robotic	14/19			
Weight (kg)	Human	19	58.01	8.15	0.708*
	Robotic	19	56.85	10.59	
Height (m)	Human	19	1.66	0.09	0.998
	Robotic	19	1.65	0.08	
BMI	Human	19	21.02	1.86	0.758*
	Robotic	19	20.80	2.46	

*Student t-test; **Fisher exact test.

BMI, body mass index.

was introduced in order to visualize pleural cavity, to survey the second port introduction under video visualization, and finally to identify sympathetic chain and its surgical fulguration.

Thoracic sympathetic chain was fulgurated by electrodesiccation of the third ganglion between the third and fourth rib levels.

At the completion of the surgery, lungs were re-expanded using positive intra tracheal air insufflations.

In our service we do not use chest tubes after sympathectomy as a routine. We place them only in the presence of air leak. Thus, in the absence of an air leak even under positive intra tracheal pressure, no chest tube would be placed. In case of any air leak, an ipsilateral chest tube would be placed.

2.14. Safety and efficacy criteria as outcomes

Safety criteria included the following intraoperative variables:

- Surgical accident;
- Frequency of involuntary movements (not target movements);
- Frequency of inappropriate camera contact of the laparoscopic lens with internal organs due to lens being moved onto the internal structures;
- Postoperative chest pain (in a numeric scale ranging from zero in the absence of pain to 10);
- Aesthetical features at the first postoperative day and at the sixth month (classified in three levels: unsatisfactory, good or excellent based on patients expected results). Patients were explained that excellent would be aesthetical results that exceeded their expectative, good if it was not unsatisfactory but did not exceed their expectative and unsatisfactory when not achieving the expected result.

Efficacy criteria included the following variables:

- Surgical duration and camera use duration in minutes;
- How many times lens camera were cleaned;
- Axillary/palmar anhidrosis during hospitalization (clinically evaluated as satisfactory or unsatisfactory);
- Compensatory hyperhidrosis and patient satisfaction level (classified in four levels: 0–50%; 51–75%, 76–90% and higher than 91%).

2.15. Image evaluation

Images were stored on DVD and were further independently analyzed by two observers. Images and discs were blindly identified.

2.16. Postoperative questionnaire

In the first postoperative day patients answered a questionnaire about postoperative pain and anhidrosis, and in the sixth month about postoperative pain, compensatory hyperhidrosis, aesthetical and general results satisfaction level.

2.17. Outcomes evaluation

Only professionals who did not know in whose group patients were allocated were eligible for DVD images evaluation, questionnaires application and statistical analysis.

2.18. Stopping rules

In the case of a surgical accident in the Ro group, the study should be interrupted and the accident cause should be evaluated.

2.19. Statistical analysis

Comparison tests between Hu and Ro groups were Student-*t*, Mann–Whitney, χ^2 and Fisher exact test. Significance statistical level of alpha was ($P < 0.05$).

3. Results

3.1. Flow of participants through each stage

Before randomization: one patient did not accept to be randomized. After randomization, 20 patients were included in each group.

Two patients, the 18th and the 19th included, out of 40 (one from Hu group and the other from Ro group) were excluded due to pleural adhesions identified intraoperatively, resulting in two groups, both of them composed by 19 patients. All the 38 remaining patients completed the postoperative follow-up until the sixth month.

Baseline demographic and clinical characteristics of each group are shown in Table 1. Uniformity between groups: Age, gender and BMI were similar between groups ($P = 0.461$; $P = 0.485$ and $P = 0.758$, respectively).

3.2. Intraoperative results

There was no surgical accident and no important adverse events or side effects in any group.

Surgical and camera use duration were lower in the Hu group (Table 2).

Although there was no difference between groups regarding the number of involuntary camera movements ($P = 0.165$) and how many times camera lens was cleaned ($P = 0.368$), inappropriate movements were more common in Hu group ($P < 0.001$) (Table 3).

No air leak was observed.

3.3. First postoperative day results

Anhidrosis was successfully achieved in all the patients, pain was similar between the groups ($P = 0.446$), average of 2.49 ± 1.86 for Hu group and 2.96 ± 1.55 for Ro group. All patients were discharged before the second day.

3.4. Sixth postoperative month results

Aesthetical results at the sixth month were similar between groups ($P = 0.440$; Fisher exact test). They were considered excellent or good by all patients in Hu group and 17 patients (89.47%) in Ro group. There was no differ-

Table 2
Comparison of surgical and camera use duration in minutes between human and robotic groups

Duration in minutes	Group	Average	Standard deviation	Min.	Max.	P*
Surgical	Human	9.89	2.96	7	22	<0.00
	Robotic	12.89	3.38	8	23	
Camera use	Human	4.58	1.99	2	12	<0.00
	Robotic	7.55	2.97	3	16	

*Mann–Whitney test.
Min., minimum; Max., maximum.

Table 3
Comparison of frequency of involuntary movements, frequency of lens cleaning and inappropriate movements between Human and Robotic groups based on image films analysis

Variable	Group	Average	Standard deviation	Min.	Max.	P*
Involuntary movements	Human	0.97	1.49	0	5	0.165
	Robotic	0.37	0.65	0	2	
Frequency of lens cleaning	Human	0.42	0.83	0	3	0.368
	Robotic	0.22	0.54	0	2	
Inappropriate movements	Human	4.18	4.32	0	16	<0.001
	Robotic	0.92	1.76	0	8	

*Mann–Whitney test.
Min., minimum; Max., maximum.

ence regarding general satisfaction and compensatory hyperhidrosis ($P=0.643$ and $P=0.749$, respectively).

3.5. Ancillary analysis

No subgroup analysis was performed.

4. Discussion

Surgical safety is a major end point before incorporating new technologies in the surgical practice. Experts base their conclusions on previous results, corroborating the need of studies in the robotic area.

Several studies have already evaluated surgical safety and efficacy of robotic devices [6–9]. Routine elective minimally invasive operations, with low operative risk were chosen to compare robotic and human arm performance. In general thoracic surgery, VATS sympathectomy for hyperhidrosis is a surgical operation that fills all of these criteria.

Safety was achieved in both groups. Although there was no difference between groups regarding the majority of safety criteria, inappropriate camera movements were less frequent in the Ro group.

We agree with Kondraske et al. [6] that the robotic arm is as safe as the human arm as a camera holder in VATS sympathectomy. Merola et al. [9] believe that surgeons can better coordinate operatory movements when controlling the robotic arm. Another advantage of the use of the AESOP system is that it is a good choice in services with a limited number of surgeons [7].

We agree with them, except in University hospitals where residents need to acquire experience in both simple and complex surgeries, where holding VATS camera is one of the expected skills. But in the case of non-University hospitals, or in cases where senior surgeons, with a large experience in holding VATS camera are needed for more

complex surgeries, AESOP can be located as a camera holder in more simple procedures, allowing senior surgeons to take part in more complex operations.

This was the case in our department. Besides sympathectomy, more complex thoracic surgeries are performed, requiring the allocation of several thoracic surgeons and residents. The use of the robotic arm to hold a camera in more simple VATS procedures, as sympathectomy or small pleural biopsies, allowed that even a single senior surgeon or resident could perform these procedures.

In spite of efficacy evaluation, results were similar between groups, except for duration time, that was longer in the Ro group. Some authors concluded that a robotic arm increases surgical length, while others conclude that it decreases surgical length [6], but it can depend on the learning curve.

Another factor that probably lengthened operations was the left to right repositioning of robotic devices. Robotic arm was first used in the left side and was replaced and reassembled in the right side. Although this replacement and reassembling duration was not quantified, it took at least one minute. Delaney et al. also attributed surgical lengthening in the robot-assisted procedures to their assemblage and repositioning when comparing to human assisted colorectal laparoscopic resections.

Unilateral procedures are most common in thoracic surgery. In this case, replacing or reassembling devices is not necessary. Therefore, additional surgical length could be not so dramatically increased.

Although robotic devices performing tasks in simple surgical procedures do not bring important advantages, its use increases surgical team experience and skills in robotic surgical use, improving the learning curve. These improvements can be applied in more complex surgical procedures, involving more complex robotic devices, and we believe

that this scenario is the unavoidable future of some thoracic surgery procedures.

In conclusion, although robot camera holding was as safe as human holding in VATS sympathectomy, it increased surgical length of time.

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