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Clinical strategies to aim an adequate safety profile for patients and effective training for surgical residents: The laparoscopic cholecystectomy model

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HIGHLIGHTS

- Practical training is an essential part in postgraduate programs for Residents.
- Laparoscopy represents a challenging procedure in terms of mentoring.
- Our Program seems to be economically sustainable and clinically feasible.

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ABSTRACT

Background: Training programs for resident surgeons represent a challenge for the mentoring activity. The aim of the present study is to investigate the impact of our training program for laparoscopic cholecystectomy on patient's safety and on the modulation of the residents' exposure to clinical scenario with different grades of complexity.

Material and methods: This is a retrospective study based on a clinical series of laparoscopic cholecystectomy performed in a teaching hospital. Study population was grouped according to the expertise of the attending primary operator among resident surgeons. Four groups were identified: consultant (C), senior resident (SR); intermediate level resident (IR); junior resident (JR). The intraoperative and postoperative outcomes were confronted to evaluate the patient's safety profile.

Results: 447 patients were submitted to LC: 96 cases were operated by a C, 200 by SR, 112 by IR and 39 by JR. The mean operative time was the longest for the JR group. A statistically higher rate of conversion to open approach was registered in C and IR groups in comparison to JR and SR groups. However, in C and IR groups, patients had worse ASA score, higher BMI and more frequent past history of previous abdominal surgery, cholecystitis or pancreatitis. Overall, it was not registered any statistically significant difference among the groups in terms of length of hospital stay and prevalence of major postoperative complications.

Conclusion: Applying an educational model based on both graduated levels of responsibility and modulated grade of clinical complexity can guarantee an high safety profile.

1. Introduction

Since William Halsted elaborated the concept of graduated levels of surgical resident responsibility based on years of experience, the debate on the most appropriate management for balancing resident education and patient safety has been always active and intense. Practical training is an essential part in the postgraduate program for surgical specialties but this must be in line with ethical, legal and economic requirements.

Laparoscopy represents a challenging procedure in terms of mentoring since the supervision is often just vocal or requires major changes in the operative settings such as changing the

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operator's position or interruption of the camera shooting. The tutor has less opportunity to manipulate the ongoing procedure compared to open approaches. This could potentially threaten the patient safety.[1].

On the other hand, the laparoscopic approach has become a standard of practice for many interventions nowadays and is routinely performed even at primary-level hospitals. Thus, the development of laparoscopic skills is mandatory in a surgical residency program. Laparoscopic Cholecystectomy (LC) is among the first and the most frequent laparoscopic experience that a trainee attends. The associated outcome may represent a consistent parameter to evaluate the performance of a teaching Surgical Unit in terms of education and patient care.[2,3].

The creation of standardized and structured training program with a detailed job description for each postgraduate year (PGY) has helped to guarantee a better supervision on the step progression of the resident's learning curve; this particularly in view of the aquisition of “validated” skills and “responsible” autonomy.

The aim of the present study was to review the active training program for LC at our Institution, investigating in particular the related impact on the patient's safety and the modulation of the residents' exposure to clinical scenario with different grades of complexity. This analysis was based on the confront of the intraoperative and postoperative clinical outcomes among groups of patients operate by resident surgeons of different grade of experience/PGYs.

2. Methods

This is a retrospective study based on the clinical series of LC performed at the General Surgery Unit of the Academic Hospital of Udine, in the period 2010–2014.

Demographic (gender, age) and clinical data (Body Mass Index (BMI), American Society of Anesthesiology Score (ASA Score), previous medical history of the patient, surgical records (Operative time duration, conversion rate, primary operator and assistant) and postoperative outcomes (hospital length of stay, major postoperative complications) were reviewed from the electronic database and recorded.

A history of cholecystitis, gallstone pancreatitis or previous abdominal operations were selected to classify the clinical case as a potentially complex LC.

LC was always performed according to a standardized technique. The patient was positioned in stirrups with the primary operator standing between the legs. A blunt Hasson trocar was positioned with an open technique. After exploration of the peritoneal cavity other 2–3 trocars were inserted under vision. The dissection of the Calot's triangle was performed to reach the “critical view of safety” with the aim to identify and dissect the cystic duct and cystic artery. Clipping and division of the structures was then carried out. Intraoperative cholangiography was not routinely performed. Retrograde dissection of liver bed was then completed and the gallbladder removed by using an endobag. Drainage was not routinely placed.

Unless specific indications, on POD 1 patients were allowed to eat solid meal and were checked clinically and with laboratory blood test including hemocrome and bilirubin serum level. If the pain was well controlled, the diet was tolerated and the blood tests were within normal value, the patient was discharged on the same day or the following according to the age, other comorbidities or patient's preferences.

The postoperative outcome was evaluated and compared among the different groups in terms of length of hospital stay, prevalence of postoperative complications requiring a second surgical operation or of a radiologic/endoscopic procedure.

To investigate the impact of the different level of technical skills of the resident surgeons on the outcomes the study population was thus divided in groups according to the experience/PGY of the primary operator.

In Italy, the residency training program is structured over 6 years. However to better differentiate the different skills levels among the resident surgeons in our specific training setting, 4 categories of primary operator were identified:

- Consultant MD (C): surgeon with advanced experience in laparoscopic surgery and tutoring;
- Senior Resident (SR): resident MD of PGY 5–6, with a personal surgical record of at least 16 LC as a primary operator; according to the specific job descriptions at our Department, they operate in association with Junior Residents both as primary operator or assistant;
- Intermediate Resident (IR): Resident MD of PGY 3,5, with a personal surgical record of between 5 and 15 LC as primary operator; according to the job description they attend LC as primary operator with the assistance of a C;
- Junior Resident (JR): Resident MD of PGY 2–3, with a personal surgical record of 4 or less LC as primary operator.

Thus, the study population was divided into 4 groups: C, SR, IR, JR.

The Resident MD of PGY 1 and 4 were not included in the study because our residency program schedules just a ward-based clinical training during the PGY 1 and a clinical/surgical training at different Regional Hospitals within the local District during the PGY 4.

Statistical analysis consisted of one-way analysis of variance among the 4study groups (C, SR, IR, JR). This was followed by independent sample tests with the Bonferroni correction for multiple comparisons. X2 and Fisher's exact tests were used for comparison of proportions with $P \leq 0.05$ considered significant throughout. Continuous data are presented as mean standard deviation.

Table 1
Demographic and clinical characteristics of patients.

Gender *(n°/percentage)*	
Female	246 55%
Male	201 45%
Age *(Years)*	
Mean ± DS	54.10 ± 15.42
BMI	
Mean ± DS	26.82 ± 5.16
ASA *(n°/percentage)*	
1	271 60.60%
2	135 30.20%
3	16 3.60%
missing	25 5.60%
Potential complexity *(n°/percentage)*	82 18.3%
Procedure years *(n°/percentage)*	
2010	96 21.50%
2011	100 22.40%
2012	88 19.70%
2013	85 19.00%
2014	78 17.40%
Operating Room Time *(minute)*	
Mean ± DS	77.91 ± 33.20
Conversion *(n°/percentage)*	24 5.40%
Hospital stay *(day)*	
Mean ± DS	2.12 ± 3.13
ERCP/Radiologic procedure *(n°/percentage)*	7 1.50%
Relaparotomy *(n°/percentage)*	7 1.50%

3. Results

During the study period 447 patients were submitted to LC. Their demographic and clinical data aresummarized in Table 1.

Overall the surgical procedure was performed by a C in 96 cases, SR in 200 cases, IR in 112 cases and JR in 39 cases. However, when comparing the period 2010/2011 with the period 2012–2014, it was registered a statistically significant decrease of the percentage of LC carried out by C in favor to SR and JR (P = 0.000). The surgical performance resulted in a mean operative time that was the longest for the JR group, but a statistically significant improvement was verified for every group on the learning curve when compared to the respective group with a lower grade of surgical skills (P = 0.000). Nevertheless a statistically higher rate of conversion to an open approach in the C and IR groups in comparison to the JR and SR groups (P = . 000) was registered. However no significant difference between the C and IR groups was found. The analysis of the clinical characteristics of the patients in each group showed that the C and IR groups were associated with a significantly worse ASA score (P = 0.000), higher BMI (P = 0.014) and more frequent potentially complex LC (P = 0.001).

Finally, the postoperative outcomes among the groups did not show any significant difference in terms of length of hospital stay (P = 0.307) and major complications rate (reoperation, P = 0.289; radiologic/endoscopic procedure P = 0.430). Comparison data are shown in Table 2.

4. Discussion

The performance of Surgical Residents attending LC (or other laparoscopic procedures) in terms of safety and effectiveness has been already demonstrated but still some concerns persist.[4,5] In accordance with other studies, we registered that the operative time was inversely correlated to the surgeon's experience, thus making the operations performed by a Junior Resident statistically longer.[1,6] In our experience however this was the only outcome that was negatively influenced by the activity of a trainee. Although intraoperative complications, length of hospital stay and morbidity rate, in our series were comparable among the groups, a lower grade of data agreement is reported in literature. [2,7] Nevertheless the overall reported feedback is that the differences between groups operated by C and those operated by Residents are not clinically significant. [1,5,8].

About the decrease percentage of LC carried out by C in favour to SR and JR in the period 2012–2014, this is the result of our instituion's policy to let Resident operate with higher independence's levels to improve their ability.

Thus, in our opinion, the crucial topic cannot be anymore whether to allow operate the Residents or not because of increased costs, or supposed potential increased risk of complications. [1,5,9,10].

What must be discussed is how the Teaching Hospitals can offer an educative training program which let the Residents go through a learning curve that is economically sustainable and clinically feasible. Also keeping in mind that the actual investment aims to guarantee the future benefit of a high standard of surgical practice. Under this perspective, there are some objective criticisms.

The step improvement on the learning curve has not been standardized yet for Residents surgeons by Guidelines and the number of procedures required to advance to higher levels of autonomy is still chosen arbitrarily. [11] Moreover we believe that the progression in the training program must be set up not only on the number of procedures performed but also on the technical-clinical complexities and on the operative environment. The educational model applied at our Institution aims to empower these aspects. The SR as primary operators attend the procedure without any support (not even vocal) by a C and are assisted by a JR, who has limited experience and needs to be tutored. This setting creates a certain level of environmental pressure which is thus compensated by the selection of an “easier patient”. As reported by other Authors clinical elements that identify this category of patients are mainly low ASA score, low BMI and no history of upper abdominal surgery, cholecystitis or gallstone pancreatitis. [2].

The same approach is used when a JR operates with the assistance of a SR: a simpler case facilitates the mentoring process for the JR as trainee and for the SR as teacher, and minimizes the risks for the patients. In these situations the C is present in the operating room and can supervise and tutor the respective roles of the Residents. In accordance with other Authors we believe that the SRs as teaching Assistants are a powerful tool to implement the education since the SRs learn how to teach and the JRs learn how to operate without any increase of morbidity rate, as demonstrated by our results. [8].

The reported higher incidence of conversion in the IR group may apparently question the safety profile of this category group. However, according to our Residency Program, IR operate with a C

Table 2
Comparison data among different surgeon groups.

	Consultant (96)	Senior resident (200)	Intermediate resident (112)	Junior resident (39)	P Value
Gender					
F	46 47.90%	119 59.50%	61 54.50%	20 51.30%	0.187
m	50 52.10%	81 40.50%	51 45.50%	19 48.70%	
Age (years)	55.40 ± 17.05	53.60 ± 14.92	54.28 ± 14.28	52.60 ± 17.16	0.770
BMI (Kg/m$^{2)}$	25.99 ± 4.10	26.76 ± 4.65	28.14 ± 6.17	23.60 ± 3.57	0.014
ASA					
1	46 47.90%	140 70.00%	59 52.70%	26 66.70%	0.000
2	37 38.50%	51 25.50%	42 37.50%	5 12.80%	
3	7 7.30%	4 2.00%	3 2.70%	2 5.10%	
Missing	6 6.30%	5 2.50%	8 7.10%	6 14.40%	
Potential complexity	30 31.30%	23 11.50%	23 20.50%	6 15.40%	0.001
OR time	67.17 ± 25.67	72.20 ± 29.38	91.62 ± 40.53	93.08 ± 27.77	0.000
Hospital stay (day)	2.65 ± 3.35	1.96 ± 3.85	2.07 ± 1.46	1.84 ± 1.40	0.307
Conversion	13 13.50%	2 1.00%	8 7.10%	1 2.60%	0.000
ERCP/Radiology pts	2 2.00%	2 1.00%	3 2.70%	0	0.430
Relaparotomy	2 2.00%	3 1.50%	1 0.90%	1 2.60%	0.289
Procedure					
2010–2011	62 64.60%	54 27.00%	69 69.60%	11 28.20%	0.000
2012–2014	34 35.40%	106 73.00%	43 39.40%	28 78.80%	

Note: Continuous data are presented as mean ± SD and proportions as n (%).

as assistant who can consequently guarantee a more active supervision and therefore allows the IR to afford a more challenging surgical case. This implies that the tutoring process in this group was upgraded not only by enhancing the training but also increasing the grade of both control and education. As a result, it was not registered any significant difference in the rate of conversion between the C and IR groups. This outlines as well that in our series the patients selection was actually even influenced by the experience of the assistant. As a matter of fact, the presence of a C was associated with statistically more complex cases not only when the C was the primary operator but also when assisting. Therefore the statistically higher rate of conversion in the IR group in comparison to the other resident groups, but comparable to C group, should be interpreted as the result of the intrinsic clinical characteristic of the patients rather than as a disproportion between the resident skills and the case complexity. This is also in line with other previous studies. [1,12].

There are increasing evidences that identify the simulation as powerful educational method and tool in the surgical training programs. The major advantages include the absence of any risk for the patient, the capability to expose of the trainee to a wide range of clinical scenario including those less clinically frequent or those more catastrophic or extremes and the possibility of a structured debriefing. The environmental setting maximizes the possibility not only of testing the operative skills without any clinical risk, but also to supervise and guide the trainee during the process since the trainer can control and decide the inputs of the simulation. [6,13,14].

The major limit of the present study is represented by its retrospective modality. However, in our opinion, this might contribute to draw a more realistic picture of the routine LC's performance in a Teaching Surgical Unit with a residency training program, where the management must account and be tailored not only to the clinical characteristic of the patients but also to the develop skills of the trainee.

5. Conclusion

Our experience demonstrates that applying an educational model based on graduated levels of resident responsibility and autonomy, which are in turns adjusted and modulated according to the number of procedure performed, clinical complexities of the patients and the various mentoring systems, can guarantee an high safety profile. This system can be maintained and monitored just through the creation of standardized and structured training programs with a detailed job description for each postgraduate year. Moreover we believe that the simulation training will enhance and empower the surgical resident program.

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