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Original Article

Comparison Between Single Trocar Access (SITRACC) Cholecystectomy and Conventional Laparoscopic Cholecystectomy - One year follow-up

Comparação entre Colecistectomia laparoscópica Single Trocar Access (SITRACC) e Colecistectomia laparoscópica Convencional - Seguimento após um ano

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ABSTRACT

Objective: To describe the data obtained after one year follow-up of patients who underwent Single Trocar Access (SITRACC®) cholecystectomy, compared to conventional endoscopic cholecystectomy. **Patients and Method:** Twenty patients who underwent SITRACC cholecystectomies and twenty patients who underwent conventional videocholecystectomy were questioned using the SF-36 instrument one year after the procedure to evaluate quality of life. The incidence of hernias in the trocar site was also studied. **Results:** There was no statistically significant difference between the groups with regard to quality of life and the trocar hernia rate. There were no major complications in either group**. Discussion:** The SITRACC device is a new platform for a novel surgical approach. The literature is limited regarding several important comparative questions, particularly whether this kind of approach truly offers benefits to patients. Studies which compare the SITRACC approach to the conventional laparoscopic approach in term of clinical outcomes (quality of life) and complications (the trocar hernia rate) are needed. **Conclusions:** One year after surgery the SITRACC cholecystectomy group had the same outcomes – in terms of quality of life as measured by the SF-36 – as the conventional laparoscopic cholecystectomy group, at least. There was no increase of trocar hernia cases in the SITRACC group. New studies are necessary, using larger series, to compare this new approach to the conventional endoscopic surgery procedures, especially concerning operative trauma and the metabolic response.

Key words: Videosurgery. Cholecystectomy. Surgery by Single Portal, SITRACC.

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INTRODUCTION

Since the 1987 introduction of videosurgery and the concept of minimally invasive surgery into the surgical field, it has been amply demonstrated that this approach offers patients less suffering, milder metabolic changes, faster recovery, and superior aesthetic results, and these advances have disseminating to operating rooms around the world quickly and enthusiastically.

With constant improvements in the optics and the instruments available for the performing videosurgeries, new and more complex procedures are being carried out successfully using the minimal invasion approach.

Simultaneously, new technologies and Minimum Access Surgery approaches have emerged, such as Natural Orifice Transluminal Endoscopic Surgery (NOTES), Needlescopy, and Surgery by Single Access, whose common goal is the search for minimal operative trauma and faster postoperative recovery, with the fewest complications.

Several platforms for performing Single Access Surgery have emerged in recent years[1]. One

of them is the Single Trocar Access – abbreviated SITRACC[2,3] – from the EDLO Company, Brazil, (Figures 1 and 2), that is a disposable single trocar which uses specially designed instruments (Figures 3, 4 and 5).

The literature lacks studies comparing classic videosurgery techniques with these new approaches. This paper reports the first comparative data, measured one year after the procedures, comparing SITRACC cholecystectomies and those done by conventional videosurgery.

METHODS

The Surgeries were performed at the Red Cross-Positivo University Hospital, in Curitiba, Brazil, between November 22, 2008 and October 30, 2010, after the study protocol was approved by the Ethics in Research Committee of the institution.

Twenty patients who had undergone SITRACC cholecystectomies and 20 patients who had undergone Standard Laparoscopic (SL) cholecystectomies were enrolled. All were at least one year out from their cholecystectomies.

All patients had had symptomatic cholelithiasis as the indication for surgery. The patients ranged in age from 18 to 65 at the time of surgery. Approximately three-quarters of each group – 15 in the SITRACC group and 14 in the SL group – were women.

Transumbilical access was established using the four channel Single Trocar Access (SITRACC®) platform (EDLO, Brazil). 5 mm trocars were used in three channels; the fourth channel typically had a 10 mm trocar, which could be converted to 5 mm with the use of a reducer. Flexible or articulated instruments, appropriate for the method, as well as a 5 mm 30

Figure 1 – *SITRACC® – Single Trocar Access Platform, EDLO, Brazil.*

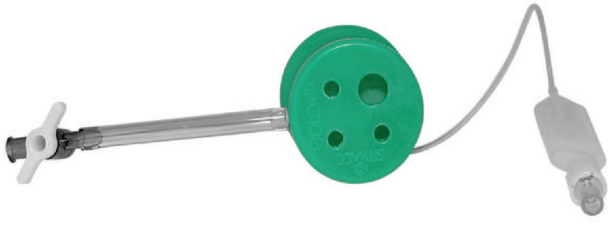


Figure 2 – *SITRACC – Note the three 5 mm and one 10 mm openings.*

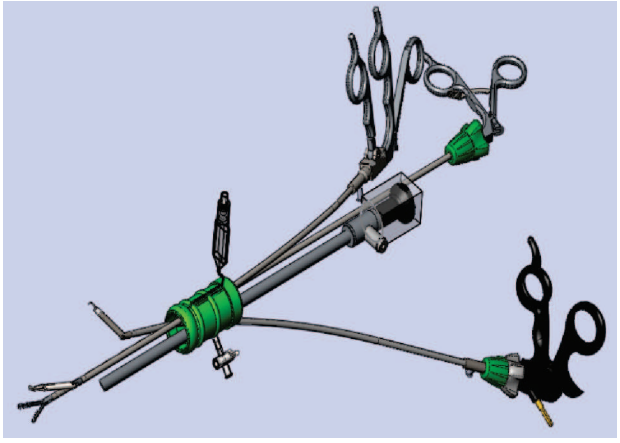
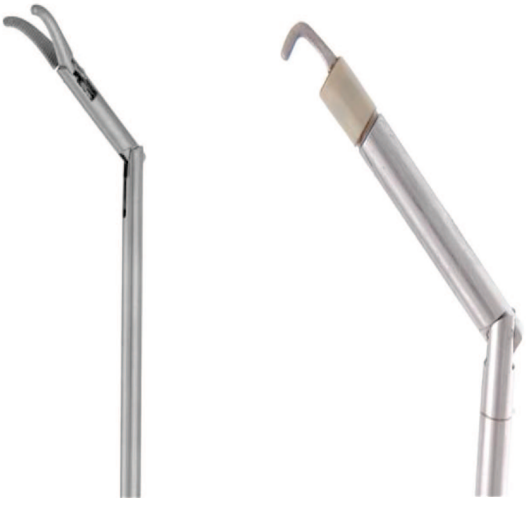


Figure 3 - *SITRACC platform, with the articulated instruments.*



Figures 4 and 5 - *SITRACC dissection forceps, with the articulated distal extremity and articulated hook, manufactured by EDLO, Brazil.*

degree optic were used. The "Standard Laparoscopic" cholecystectomies were performed following the classic steps.

Quality of life was measured using the Short Form (36) Health Survey (abbreviated SF-36) which was administered by an interviewer by telephone contact. The occurrence of incisional hernia at the trocar insertion site was also evaluated.

The SF-36 questionnaire measures health status. It consists of eight scaled scores (ranging from 0 to 100), which are calculated as the weighted sums of answers to the questions in each of eight domains:

1. Functional Capacity
2. Physical Aspects
3. Pain
4. General Health
5. Vitality
6. Social Aspects
7. Emotional Aspects
8. Mental Health

The results were tabulated and the group scores were compared by Mann-Whitney Non-Parametric Test; p values below 0.05 were considered statistically significant.

RESULTS

No incisional hernia was reported in either the SITRACC or SL group.

Analysis of the data shown in table 1 and figure 6 demonstrated that there was no statistically significant difference between the two groups on the SF-36 measures.

DISCUSSION

Since the groundbreaking publications of KALLOO[4,5] that initiated the study of the new

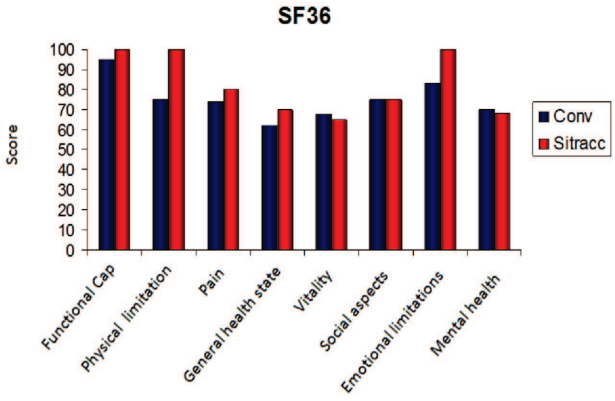


Figure 6 *- Mean scores obtained for the eight domains of the SF-36 health survey.*

Table 1 – *Results of the data collected by the application of the SF-36.*

SF-36 Domain	Technique	n	Average	Median	Minimum	Maximum	Standard Deviation	P Value
Functional Capacity	Conv	20	76.8	95.0	5.0	100.0	35.1	
	Sitracc	20	92.4	100.0	35.0	100.0	16.2	0.109
Limitations by Physical Aspects	Conv	20	62.5	75.0	0.0	100.0	42.5	
	Sitracc	20	92.6	100.0	25.0	100.0	19.3	0.071
Pain	Conv	20	62.1	74.0	20.0	100.0	25.0	
	Sitracc	20	76.8	80.0	30.0	100.0	20.2	0.138
General Health	Conv	20	58.4	62.0	10.0	80.0	17.8	
	Sitracc	20	64.9	70.0	20.0	80.0	14.5	0.215
Vitality	Conv	20	67.9	67.5	35.0	90.0	16.4	
	Sitracc	20	65.4	65.0	40.0	90.0	14.4	0.739
Social Aspects	Conv	20	68.2	75.0	5.0	100.0	30.5	
	Sitracc	20	76.5	75.0	25.0	100.0	19.2	0.570
Limitation by Emotional Aspects	Conv	20	71.4	83.3	0.0	100.0	36.7	
	Sitracc	20	92.1	100.0	66.6	100.0	14.6	0.138
Mental Health	Conv	20	66.6	70.0	24.0	92.0	20.0	
	Sitracc	20	68.7	68.0	40.4	96.0	12.8	0.860

approach now known as NOTES, several researches around the world have been conducting studies of the new equipment and instruments for this and even newer approaches, to determine their viability and practical application.

The training and demand for new workstations, access to the abdominal cavity, closure of the stomach and other hollow viscera, the potential for infection, the development of new and necessary equipment, and the orientation difficulty because of the use of regular endoscopes have emerged as the principal challenges for the development of transluminal surgery. They need to be overcome to transform NOTES into a common option in clinical and surgical practice.

The transumbilical approach now presents itself as the most viable technology, because the visualization is similar to conventional videosurgery, and because the development and use of flexible and articulated instruments allows a degree of triangulation, facilitating surgical maneuvers.

WHEELEES is credited with being the first to use the principles of single-access surgery, in 1969, to perform tubal ligation.[6]

In 1997 NAVARRA[7] et al.[7] described cholecystectomy performed through two 10 mm trocars introduced via the umbilicus.

Single Access Surgery entered in a period of latency, resurfacing in 2007, when ZHU published his first experience using the umbilicus as a single access path into the peritoneal cavity, a technique he named *Transumbilical Endoscopic Surgery* (TUES).[8]

In 2008, ZHU et al.[9] published a study describing new cases of TUES: two cases of hepatic cyst fenestration, six cholecystectomies, and nine appendectomies, using a trocar with three working channels.

Also in 2008, Indian authors PALANIVELU et al.[10] published a study describing eight transumbilical appendectomies in which a standard flexible endoscope was used. The authors considered the technique as a preparatory step for NOTES.

Since then Single Access Surgery techniques have been developed for various procedures such a nephrectomy and pyeloplasty,[11,12,13] adrenalectomy,[14] right colectomy,[15] sleeve gastrectomy,[16,17] adjustable gastric band,[18] Roux-en-Y gastric bypass,[19] gastrostomy,[20] intracorporeal gastrojejunostomy,[21] and splenectomy,[22] among others.

Procedures in several surgical subspecialties have been successfully performed using single surgical access techniques. Data to date indicate that transumbilical surgery is feasible and safe,[23] but the literature is quite limited in terms of medium to long term follow-up and in terms of studies comparing single access surgery and so-called conventional videosurgery.

The SF- 36 quality of life health survey was developed in the USA in the 1980s, and have be widely used and validated by several studies. The SF-36 is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. Accordingly, the SF-36 has proven useful in surveys of general and specific populations, comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments. The experience to date with the SF-36 has been documented in nearly 4,000 publications, including surgical studies.[24,25,26,27,28]

The benefits of Single Access Surgery as compared to NOTES vary, but include from the principles of *Scarless Surgery* – operations that leave little or no scar – to the improved vision provided (which surgeons already use in regular laparoscopic procedures), and the low risk of infection.

We still need large double blind series, that compare similar procedures performed using single access surgery techniques with those performed by regular videosurgical methods. Data collected in this study begins to demonstrate that single access surgery has, in the medium and long term, outcomes that are at least comparable to outcomes obtained with the current "gold standard" approach for performing cholecystectomy, the videocholecystectomy.

Single access surgery procedures need to be viewed as part of an operative arsenal that extends from open surgery to videosurgery and NOTES. Each patient is unique, as is his or her illness. It is up to the experienced surgeon to determine the best approach that offers security and better surgical outcomes and aesthetic results.

RESUMO

Objetivos: Descrever os dados obtidos pelo menos um ano após a realização de colecistectomias pela abordagem Single Trocar Access (SITRACC®), comparadas àquelas realizadas pela abordagem laparoscópica convencional. **Pacientes e Método:** Foram estudados vinte pacientes SITRACC e vinte pacientes submetidos à colecistectomia laparoscópica convencional, todos eles pelo menos um ano após o procedimento, tendo sido submetidos ao questionário SF-36, classicamente utilizado como medida de aferição da qualidade de vida, bem como também foi avaliada a incidência de hérnia em sítio de trocater. **Resultados:** Não houve diferença estatística significativa entre ambos os grupos estudados, tanto com relação à qualidade de vida quanto sobre o montante de incidência da hérnia em local de trocater. Igualmente entre ambos os grupos não foram relatadas complicações maiores. **Discussão:** A plataforma SITRACC é um novo equipamento para uma nova abordagem, que necessita de estudos comparativos com a abordagem convencional mais aprofundados, bem como sobre a incidência de hérnia incisional. A literatura disponível é escassa na resposta de diversas questões comparativas, especialmente se este tipo de abordagem realmente representa benefício real para os pacientes. **Conclusões:** O grupo submetido a colecistectomia SITRACC apresentou o mesmo nível de satisfação, com relação a qualidade de vida, quando comparado ao grupo convencional, um ano após os procedimentos. Não houve aumento de incidência de hérnia incisional no grupo Single Trocar Access. Novos estudos são necessários, utilizando-se séries maiores, para comparar esta nova abordagem aos procedimentos videocirúrgicos convencionais, especialmente no que diz respeito ao trauma cirúrgico e à resposta metabólica.

Palavras chave: Videocirurgia. Colecistetomia. Cirurgia por Portal Único, SITRAC.

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