

Safeness and reproductivity of a laparoscopic colorectal program in two tertiary care academic centers of South America

Seguridad y reproducibilidad de la cirugía colorrectal laparoscópica en dos centros académicos de tercer nivel en Sudamérica

Martín Andrada*, Natalia P. Bollati, Franco J. Signorini, Pablo S. Maldonado, Federico Moser, Lucio R. Obeide and Alejandro M.C. Rossini

General Surgery Department, Hospital Privado Universitario de Córdoba, Córdoba, Argentina

Abstract

Objective: To evaluate the feasibility and safeness of a colorectal laparoscopic program in two centers from South America.

Method: We retrospectively review the records of patients who underwent laparoscopic colorectal surgery from 2012 to 2018 in two tertiary care academic centers. Surgical indication, operative time, conversion rate, lymph nodes harvested, surgical margins and complications were analyzed. These results were then compared to the open approach. **Results:** We collected data from 505 patients, mean age 63.4, 50.9% male. The most frequent indication was colon cancer, mean operative time was 175 minutes. Conversion rate was 9.5%, mean nodes harvested was 15.9 with free resection margins in every case. Morbidity was 35.4% at 30 days, most of them were minor complications. The leak rate was 11.7%. The 30-day mortality was 2.5%.

Conclusion: The laparoscopic approach for colorectal surgery might represent a safe and feasible option in a tertiary care hospital from a developing country.

Keywords: Colorectal cancer. Laparoscopic surgery. Colon. Rectum.

Resumen

Objetivo: Evaluar la reproducibilidad y la seguridad de un programa de cirugía colorrectal laparoscópica en dos centros de Sudamérica. **Método:** Se realizó un estudio analítico-descriptivo. Se revisaron retrospectivamente los registros clínicos de pacientes sometidos a cirugía videolaparoscópica colorrectal desde el año 2012 hasta el año 2018, en dos centros académicos de tercer nivel argentinos. Se analizaron datos demográficos, indicaciones y tiempos quirúrgicos, tasa de conversión, evolución posoperatoria, morbilidad y resecabilidad oncológica, y se comparó con el abordaje convencional. **Resultados:** Se realizaron 505 cirugías. La edad media de los pacientes fue de 63.4 años y el 50.9% eran hombres. El tiempo operatorio medio fue de 175 minutos. La principal indicación fue cáncer de colon. La incidencia de conversión fue del 9.5%. El promedio de ganglios por pieza quirúrgica en patología neoplásica fue de 15.9. La morbilidad fue del 35.4%, en su mayoría complicaciones menores. La tasa de fístulas fue del 11.7%. La mortalidad a 30 días fue del 2.5%. **Conclusión:** La cirugía colorrectal laparoscópica podría representar una opción segura y reproducible en un centro de tercer nivel de un país en desarrollo.

Palabras clave: Cáncer colorrectal. Cirugía laparoscópica. Colon. Recto.

*Correspondence:

Martín Andrada

Naciones Unidas, 346

C.P. 5000, Córdoba, Argentina

E-mail: martin.andrada.d@gmail.com

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Introduction

Since video-assisted laparoscopy was first used for cholecystectomy in 1985¹, it has developed rapidly and has been used in most fields of traditional surgery.

The first video-assisted laparoscopic colectomy was carried out in 1991 by Jacobs et al.² in Miami, Florida. Since then, numerous randomized controlled trials have shown the association of laparoscopic colorectal surgery with shorter hospital stay, less postoperative pain, and intestinal transit early recovery in comparison with the open route³⁻¹⁰.

However, acceptance of the technique as a treatment modality for colorectal pathology has not been the same in comparison with other laparoscopic abdominal procedures (cholecystectomy, Nissen surgery, appendectomy, adrenalectomy, etc.). This phenomenon is associated with a steeper learning curve, longer operative times, need for a multidisciplinary perioperative approach and occurrence of more serious complications^{11,12}. On the other hand, initially there were suspicions with regard to oncological safety of the procedure¹³⁻¹⁵.

Currently, numerous prospective randomized multicenter trials have shown that there are no differences in short- and long-term outcomes, oncological radicalness, overall survival, disease-free survival, and recurrence rates when the laparoscopic approach is compared with the conventional procedure¹⁶⁻²⁸. However, the results found in the literature originate from world-class centers, with broad access to material and human resources, which generate conditions that are not always replicable in developing countries.

The purpose of this study is to report the feasibility, safety, and oncological results, as well as morbidity and mortality, of laparoscopic colorectal surgery at two tertiary care academic centers in a developing country.

Method

A retrospective, analytical-descriptive study was carried out, in which the medical records of patients undergoing laparoscopic colorectal surgery were reviewed at the Private University Hospital of Córdoba and at Raúl A. Ferreyra Hospital, within the period comprised between January 2012 and October 2018.

All patients who consecutively underwent laparoscopic surgery within the aforementioned period were

included, with scheduled or emergency surgeries being considered. Exclusion criteria for laparoscopic surgery were: 1) hemodynamic instability; 2) intestinal perforation with generalized peritonitis; 3) hostile abdomen due to significant adherence-related compromise; 4) anesthetic contraindication; 5) tumor adhered or fistulized to neighboring organs or viscera (T4); and 6) surgeon or patient preference.

Analyzed variables were: 1) demographic (gender, age, body mass index [BMI], comorbidity categorized according to the American Society of Anesthesiologists [ASA]²⁹; 2) preoperative (surgical indication and distribution between benign and malignant pathologies); and 3) intraoperative (type of procedure, surgical time, intraoperative complications and conversion rate). In addition, evolution of the indication for laparoscopic approach in relation to the conventional procedure over the years was examined. On the other hand, postoperative variables were assessed, from surgery through the 30 subsequent days, such as oral tolerance, morbidity, hospital stay, mortality and reoperation and readmission rates. Postoperative complications were graded according to the Clavien Dindo classification³⁰; grades I and II were considered minor complications, and those corresponding to grades III and IV were regarded as major complications. Finally, the rate of fistula development was also analyzed, which included the appearance of anastomotic leakage, abdominal sepsis, and intra-abdominal abscesses. In procedures for malignant disease, surgical margins and the number of resected lymph nodes were evaluated.

Conversion was defined as the situation in which an incision larger than that required for removing the surgical specimen or for conventional performing maneuvers had to be made.

Finally, the results obtained in this sample were compared with our historical series of cases approached by the conventional route, with no patient being excluded. Both groups were statistically compared using the chi-square test for qualitative variables and ANOVA for quantitative variables. The SPSS program (IBM SPSS Statistics 25.0, Chicago, IL) was used for data processing.

Results

A total of 505 colorectal surgeries were performed by video-assisted laparoscopy between January 2012 and October 2018. Patient mean age was 63.4 years (range: 15-89); 50.9% were males, and average BMI

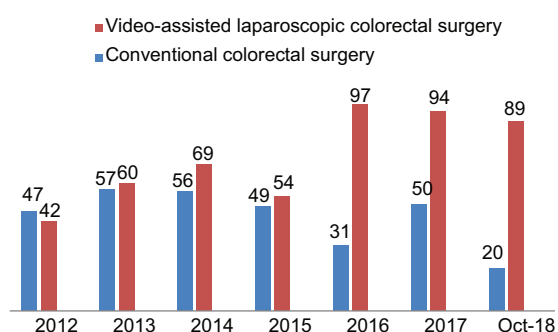


Figure 1. Colorectal surgeries per year.

was 27.4. Most patients were on ASA physical status class II (66.1%).

In 2012, 47% of colorectal surgeries were performed by video-assisted laparoscopy, and in 2018, 81% (Fig. 1). In 113 cases (22.3%), surgery was indicated for benign processes, and in 392 cases (77.6%), for neoplasms (Table 1). Of the procedures, 73.8% were in the colon and 26.1% included resection of the rectum (Table 2). Mean operative time was 175.4 minutes (range: 47-560).

The incidence of intraoperative complications was 1.9% (in 10 procedures); in six cases, conversion was required for resolution. Overall conversion incidence was 9.5% (48 cases), mostly due to excessive adhesions or poor exposure due to intra-abdominal obesity (Table 3). The need for conversion was statistically significantly associated with higher morbidity and mortality ($p = 0.017$ and $p = 0.002$, respectively) (Table 4).

Overall morbidity of the series was 35.4% (228 complications in 179 patients), mostly minor complications: 132 Clavien Dindo I and II complications in 112 patients. Among them, the most common were 38 surgical wound infections (7.5%), 31 fistulas that were resolved with medical treatment (6.3%), 12 ilei (2.3%), 11 urinary tract infections (2.1%) and 7 cases of high ileostomy output (1.3%).

The incidence of major complications was 13.8%: 70 patients with Clavien Dindo III and IV complications (Fig. 2). Overall fistula development rate was 11.7% (59 cases); 34 (58%) corresponded to minor complications, and out of these, 27 were self-limiting fistulas and 7 collections that were resolved with antibiotic treatment. Major complications secondary to anastomotic fistulas accounted for 4.9% of total (25 cases): 6 collections requiring percutaneous drainage, 14 fistulas requiring reoperation, out of which 2 required

Table 1. Surgical indications

Pathologies	Patients (n)	%
Colon-rectum cancer	392	77.6
Colon-rectum polyps	60	11.8
Diverticular disease	40	7.92
Other	13	2.5

Table 2. Performed surgical procedures

Procedures	n	%
Left hemicolectomy	154	30.5
Sigmoidectomy	51	10
Right hemicolectomy	149	29.5
Extended right hemicolectomy	19	3.7
Total colectomy	8	1.6
Low anterior resection	107	21.2
Abdominal-perianal resection	17	3.3

Table 3. Causes and incidence of conversion

Cause	n	%
Tumor adhesions to neighboring tissues	19	39.5
Poor exposure (intra-abdominal obesity, redundant colon)	21	43.7
Adhesions from previous surgeries	3	6.2
Arterial injury, incoercible bleeding	3	6.2
Colonic ischemia	1	2
Anatomical variation	1	2

postoperative care in a closed unit with vasopressors and mechanical ventilation support needs (4 lavages and drainage placement, 6 conversions to Hartmann, 3 raphies, 1 case in which anastomosis was redone), and 5 cases that required reoperation and culminated in patient demise.

Forty-nine patients (9.7%) underwent reoperation, with 30-day readmission rate being 7.7% (39 patients) (Tables 5 and 6).

Thirty-day mortality of this series was 2.5% (13 patients): 5 cases of anastomosis dehiscence, 1 case of bleeding in a coagulopathic patient with chronic liver disease, 1 case of small bowel ischemia secondary

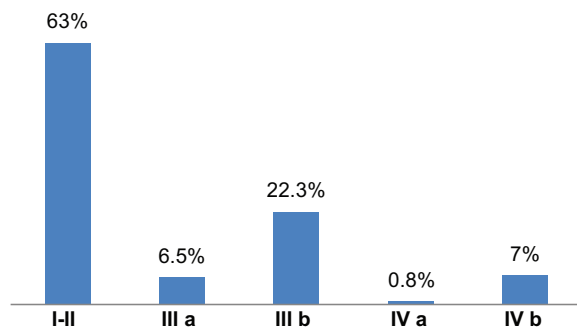


Figure 2. Percentage of complications according to Clavien-Dindo classification.

to superior mesenteric vein root injury, 1 patient who was readmitted to the hospital in septic shock and in whom an infectious focus of origin could not be found, 2 cases of pneumopathy, 1 patient who developed a cardiorespiratory arrest in the immediate postoperative period while being in hospital discharge conditions, and 2 patients who had a stroke.

As for intestinal function recovery, the first flatus occurred after 1.5 days, first bowel movement occurred at 1.7 days, and oral intake tolerance was accomplished at 2.5 days.

Overall hospital stay was 8.2 days on average, with a range from 2 to 69 days; for patients with major complications, it was 16.7 days on average, and for uncomplicated patients, it was 5.7 days on average.

As for surgical lymphadenectomy, in cases of surgery for malignant disease, average number of resected lymph nodes per surgical specimen was 15.9 ± 9.6 . Disease-free distal surgical margins were achieved in all cases. No disease recurrence was recorded at laparoscopic trocar sites.

In the conventional surgery group, 324 colorectal interventions were carried out within established time. Population mean age was 65.7 years (range: 18-91), 58.6% were males, and average BMI was 28.3. Most patients (48.9%) were at ASA class III. No significant differences were established vs. the laparoscopic surgery group.

In 92 cases (28.4%), surgery was indicated for benign processes, and in 232 cases (71.6%), for neoplasms (p-value not significant). Mean operative time was 188.1 minutes (range: 30-600) ($p = 0.03$).

Overall morbidity of the series was 60.8% (197 patients had complications). When this result was compared with that obtained in the laparoscopic surgery group, the difference was significant ($p = 0.001$).

Table 4. Morbidity and mortality associated with conversion

	n	Overall morbidity	Major morbidity	Mortality
Non-converted	457	36.7% (166)	12.6% (58)	1.9% (9)
Converted	48	60.4% (29)	20.8% (10)	8.3% (4)
p		0.017		0.002

Table 5. Reoperation causes

Causes	n	%
Fistula or anastomosis dehiscence	19	38.7
Bleeding	10	20.4
Internal hernia	3	6.1
Evisceration	6	12.2
Ileostomy plasty	2	4
SI perforation due to inadvertent injury	2	4
Ostomy necrosis and dehiscence	3	6.1
Volvulus at ileostomy level	1	2
Intestinal ischemia	2	4
Perianal SSI cleansing	1	2
Total	49	9.7%

SI: small intestine; SSI: surgical site infection.

When minor complications were analyzed, 101 patients had Clavien Dindo I and II complications. Among them, the most common were 63 surgical wound infections (19.5%), 14 fistulas that were resolved with medical treatment (4.3%), 11 ilei (3.4%) and 20 urinary tract infections (6.1%).

The incidence of major complications was 31.5%; 102 patients had Clavien Dindo III and IV complications. When compared with the laparoscopic surgery group, the difference was significant ($p = 0.002$). The rate of fistulas that generated major complications was 4.3% (14 cases), which was lower than in the laparoscopic surgery group, without the difference being statistically significant ($p = 0.67$).

Reoperation was carried out in 14.9% of patients vs. 9.7% in the laparoscopic surgery group ($p = 0.02$), and 30-day readmission rate was 8.7% vs. 7.8%, with no statistical significance ($p = 0.63$).

Thirty-day mortality of this series was 5.9% (19 patients), with a statistically significant difference in comparison with the laparoscopic surgery group ($p = 0.01$).

Table 6. Readmission causes

Causes	n	%
Fistula	12	30.7
Dehydration due to ostomy high output	5	12.8
Ileus	5	12.8
Self-limiting lower digestive bleeding	4	10.2
Evisceration	3	7.7
Urinary tract infection	3	7.7
Fever with no focus	3	7.7
Fecaloma	1	2.5
Urethral fistula	1	2.5
Thin volvulus	1	2.5
Internal hernia	1	2.5
Total	39	7.7%

Overall hospital stay was on average 12.8 days $\pm$ 12.1, with a statistically significant difference vs. the laparoscopic surgery group ($p = 0.01$).

Discussion

Laparoscopic colorectal resection has undergone significant development since the first case reported in 1991, evolving until it became the approach of choice for many colorectal surgeons. However, widespread use of this technique was initially hampered by a steep learning curve and oncologic safety concerns¹¹⁻¹⁵. In recent years, the results of several randomized trials have confirmed laparoscopic colectomy oncologic safety for cancer, and have also shown that long-term results are equivalent to those of open surgery¹⁸⁻²⁸. All over the world, there has been an increase in the performance of laparoscopic colorectal surgery procedures, and the same has occurred in our institution in recent years³¹⁻³³.

Our group began to sporadically carry out elective laparoscopic colorectal surgery since 2008, with the number of cases and complexity gradually being increased. Since 2012, with electronic medical record implementation, an accurate record of all the surgeries performed by the department is kept, which facilitates data collection.

Adaptation to laparoscopic colorectal surgery demands a complex multidisciplinary learning curve and, initially, it is not applicable to all types of patients;

however, broadening the spectrum of indications is feasible as the number of operated patients increases. In our case, the number of annually-operated patients progressively increased, with up to 81% of colorectal interventions currently being performed with the laparoscopic approach. This increase can be attributed to higher acceptance of the procedure by health professionals, a higher number of trained surgeons, and public awareness on the advantages of minimally-invasive surgery. Furthermore, both are effective procedures, and one technique does not invalidate the other; the choice of the most suitable procedure will depend on the professional, on his experience, patient characteristics and those of his pathology.

In this series, which involved a 7-year period, from 2012 to 2018, we were able to observe that laparoscopic colorectal resections carried out at two tertiary care academic centers in South America can have acceptable results in the short term. Although the number of patients included in our series is similar to that of large prospective randomized trials^{5,7,9,18,34}, ours is a study that has the limitation of its retrospective nature. However, since it is a consecutive series of patients that has included all scheduled or emergency laparoscopic colon and rectum surgeries performed for all types of colorectal pathologies, the selection bias is reduced.

Mean surgical time of 175 minutes was within the range of other international studies, which report approximately from 142 to 268 minutes. On the other hand, a similar result was obtained when intestinal transit restitution time and hospital stay were analyzed^{5-9,18,23,34}. These times did not show marked differences with those obtained in the conventional surgery group. Operative time showed some statistical advantage with regard to the laparoscopic surgery group, which could be explained by laparotomy and closure times, a higher number of emergency or advanced cancer surgeries in the conventional group, as well as by a higher participation of surgeons not specialized in colorectal pathology and residents, which corresponds to the academic profile of the participating institutions.

Postoperative morbidity in colorectal surgery ranges, according to numerous publications, from 11 to 47.9%^{3-10,18,23,34}; these large variations are essentially due to heterogeneous inclusion criteria, follow-up and definitions of different complications. In our series, 30-day overall postoperative morbidity was 35.4%. Although this percentage may be considered to be high, it should be noted that 63% were minor

complications that responded to medical treatment and did not require any endoscopic or radiological surgical intervention to be resolved. The conventional surgery group had a larger number of complications, but this is associated with the higher complexity of the cases in this group.

Anastomotic leakage after colorectal surgery is a common and feared complication that results in increased morbidity and mortality^{35,36}. We cannot fail to mention that this was the complication we encountered most often, which also constituted the main cause of reoperation and death. Although the fistula incidence of 11.7% reported in this series can be considered relatively high, most reports only include anastomotic dehiscence and evaluate the rate of intra-abdominal abscesses or abdominal sepsis separately, while not all include rectal surgeries^{6,7,18,23}. Denost et al.³⁴ include anastomotic fistula criteria similar to those reported in this work, which resulted in a leakage incidence of 17%; however, only rectal resections are included in this series and this would explain the higher number. On the other hand, being a retrospective work, our study included both colonic and rectal pathology, scheduled and emergency surgeries, which generates a less homogeneous sample. However, an objective analysis of the results of this experience provides a reference point that has not been described in the region for this type of surgeries. On the other hand, consecutive inclusion of all operated patients also provides a real reference of the results obtained throughout our experience, which could serve to other centers immersed in similar health realities when implementing this type of programs.

A low conversion rate has been suggested to contribute to a reduced operative morbidity; although conversion to open surgery is not a complication by itself, it should be taken into account, given that the benefits of laparoscopic surgery decrease as the conversion rate increases³⁷. A subgroup analysis carried out by the authors of the COST trial showed that patients who required conversion experienced more complications than those whose surgery was completed by laparoscopy (7.8 vs. 2.9%). Five-year overall survival was also lower in these patients (69 vs. 80%)³⁸. In the CLASICC trial, converted surgery was associated with a hospital stay up to 2 weeks longer than laparoscopic surgery, and with a higher complication rate (93 vs. 50% after open surgery and 59% after laparoscopic surgery)⁵. In the studies included in this review, conversion rates ranged from 5 to 33%, whereas in our series it was 9.5%^{3-10,18,23,28}. In our experience, we

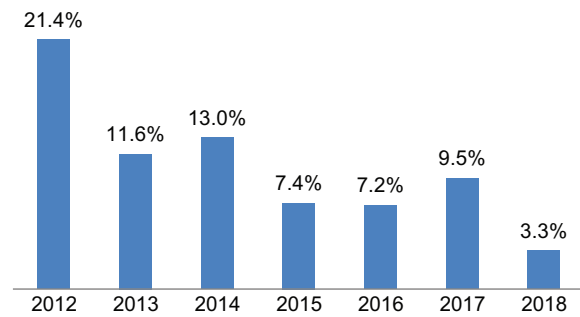


Figure 3. Conversion rate per year.

were able to observe a high morbidity and mortality associated with conversion, concurring with the literature^{37,38} (Table 4). In the CLASICC trial, the conversion rate to open surgery for colorectal cancer decreased as more experience was acquired: from 38% in the first year to 16% in the sixth year⁵. This same phenomenon can be observed in our series (Fig. 3). We do not doubt that early conversion, in cases where improvement is not observed with the procedure or in case of intraoperative complications that are difficult to resolve, should be the behavior to be followed for reducing the high risk of complications conversion entails. Laboriousness of the procedure and prolonged time cause fatigue of the surgical team and exposes it to injuries more easily, but especially to wrong decision-making, biased by intraoperative exhaustion. Finally, mortality within the first 30 postoperative days ranges from 0.5 to 4% in the reviewed literature^{3-10,18,23,34}; in our work, it was 2.4% for the laparoscopic surgery group. Again, the conventional surgery group showed a poorer result due to the complexity of included cases.

The higher number of metastases to the abdominal wall, and in particular to the laparoscopic trocar sites, described in some of the first series published in the 1990s, caused great concern regarding the indication of minimally-invasive techniques for the treatment of gastrointestinal tumors¹³⁻¹⁵. However, subsequent randomized controlled trials have consistently shown a very low incidence of port site recurrence in the laparoscopic surgery group, effectively dispelling this initial fear. In our series, no metastases were recorded at laparoscopic trocar sites, contributing to the results already reported on this point. Currently, evidence has also shown that there is no significant difference between the number of examined lymph nodes and the resection margins between laparoscopic and

Table 7. Comparison of results with the main international trials

	BRAGA	BARCELONA	COST	COLOR	CLASICC	COLOR II	GRECCAR 5	LEUNG	HP-HF
Number of laparoscopic surgeries	136	105	435	536	526	699	469	203	505
Exclusion	Emergency, transverse, benign pathology	Emergency, rectum, transverse, benign pathology	Emergency, rectum, transverse, benign pathology	Emergency, rectum, transverse, benign pathology	Emergency, transverse, benign pathology	More than 15-cm anal margin, emergency, benign pathology	More than 15-cm anal margin, Miles, emergency, benign pathology	Emergency, lower rectum, benign pathology	Hostile abdomen, T4 tumor, intestinal perforation
Surgical time (min)	222	142	150	145	180	240	268	190	174
Conversion rate (%)	5.1	11	21	17	29	17	-	23.3	9.5
Hospital stay (days)	10.4	5.2	5	8.2	9	8	12	8.2	8.4
Resected lymph nodes (n)	14.8	11	12	10	13	13	-	11.1	15.9
Positive margins (%)	-	-	5	2	6	10	-	-	0
Morbidity (%)	20.6	11	21	21	33	40	47.9	19.7	35.4
Mortality (%)	0.7	0.9	0.5	1	4	1	1.1	2.4	2.4
Fistula (%)	5.9	-	-	3	10 R 3 C	13	17.1	0.98	11.7
Reoperation (%)	5.9	-	2	7	-	16	18	2.9	9.7

conventional open surgery methods¹⁸⁻²⁸. Most cases in our series (76%) were operated on for malignant disease. In these patients, we managed to achieve an overall resection average of 15.9 lymph nodes, with no compromised margins being obtained, which suggests that an oncologically safe approach consistent with the recommended minimum of 12 lymph nodes for accurate staging is feasible.

The results of a surgical series may exhibit variations secondary to the diversity of criteria for some concepts characteristic of the patient, the procedure, complications and even of the surgeon himself. On the other hand, direct extrapolation of the results of first-world experiences to centers in developing countries may establish a difficult-to-reach bar be due to known differences in access to resources. This bar can even represent a risk by itself, since it can predispose to an attempt to replicate processes without adequate means and, therefore, put the patient at risk. Therefore, it is important for each surgical department to know the results of its own experience, with the resources and population it is immersed in (Table 7).

Conclusion

In the light of these results, laparoscopic colorectal surgery could represent a safe and reproducible option in a tertiary care center of a developing country as long as its own results on the subject are known. It is possible that multicenter prospective trials conducted in underdeveloped countries may clarify this question.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this research.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors obtained informed consent from the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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