

Single-site laparoscopy in gynecology: preliminary study of a series of 50 cases

ADMÁRIO SILVA SANTOS FILHO¹, MAURÍCIO BECHARA NOVIELLO¹, RACHEL CRUZ FRAGA DAMASCENO¹, EVILANE DO CARMO PATRÍCIO¹, LARA RODRIGUES FÉLIX¹, PAOLA GASTON GIOSTRI¹, AUGUSTO HENRIQUES F. BRANDÃO^{2*}

¹Gynecologist, Hospital da Baleia – Benjamin Guimarães Foundation, Belo Horizonte, MG, Brazil

²PhD - Visiting Professor UFMG Women's Healthcare Post-Graduate Program, Gynecologist Hospital da Baleia – Benjamin Guimarães Foundation, Belo Horizonte, MG, Brazil

SUMMARY

Objective: to describe the initial experience of a gynecology team, at a tertiary care center, when performing single-port laparoscopic surgery.

Method: this is a retrospective study reviewing the medical records of 50 patients treated at the outpatient gynecology clinic of our institution between June 2012 and July 2013 who underwent single-port laparoscopic surgery. This study was approved by the institution's Ethics in Research Committee.

Result: the mean age of patients is 37.8 years, ranging from 18 to 70 years, and the most frequent surgical indications were adnexal mass (72%) and chronic pelvic pain (24%). The mean operative time was 94.4 minutes with a mean hospital stay of 25.8 hours. There were no perioperative complications. We recorded two conversions to laparotomy due to technical difficulties during the procedure. All cases of conversion had pelvic adhesions. All operative complications were successfully treated and none were considered severe.

Conclusion: this is one of the largest case series in the literature regarding surgical treatment by single-port laparoscopy in gynecology and presents evidence on reduction of surgical morbidity and satisfactory cosmetic results. We conclude that single-port laparoscopy is a viable minimally invasive technique, and that it contributes to the construction of a new scenario in modern gynecological surgery.

Keywords: laparoscopy, endoscopy, gynecologic surgical procedures.

Hospital da Baleia – Benjamin Guimarães Foundation, Belo Horizonte, MG

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*Correspondence:
Rua Juramento, 1464, Saudade
Postal Code: 30285-000
Belo Horizonte – MG
Phone: +55 31 3489-1500
augustohfbrandao@hotmail.com

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INTRODUCTION

Laparoscopy emerged as a promising surgical technique in the 1970s, as a less invasive method than a laparotomy in propedeutics and treatment of illnesses of the abdominal and pelvic cavities. It brought various benefits, such as better and quicker post-operative recovery, a lesser need for pain relievers, a shorter duration for the surgical procedure and early hospital discharge.^{1,2}

With the evolution of surgical techniques, minimally invasive procedures such as single-port laparoscopy make headway in medical practices and emerge as a challenge to modern medicine. Both patients and healthcare professionals are constantly seeking better functional and esthetic results, with a focus on the quality of life in the post-operative period and in the long term, without compromising the efficiency of the surgical treatment.

Single-port laparoscopy consists in performing only one incision for access to the peritoneal cavity, commonly located on the umbilical scar, different from a conventional laparoscopy, in which two to four ports are created. The use of a single port would allow reducing operative morbidity in relation to conventional laparoscopy, since making each port brings with it the inherent risk of bleeding, injury to adjacent organs, the formation of hernias and compromised esthetic results.³

The dissemination of the single-port surgical technique, as well as the technological innovations to the surgical materials, has made it the new global trend in relation to the propedeutics and approach to benign gynecological illnesses, especially cases of adnexal tumors.

The concept of a single port is not new to gynecology, despite being only recently recognized and used in other areas, especially urologic and gastrointestinal procedures such as nephrectomies, appendectomies and cholecystectomies.^{4,5} Some 150 years ago, Wheelless et al.^{6,7} reported more than 4000 cases of women who had successful tubal ligations through “single-trocar laparoscopy.” In 1991, Pelosi performed the first single-port hysterectomy.⁸

Even after the successful introduction of the technique,^{6,7,8} it did not become widespread as a standard procedure for reasons that range from lack of specific access systems (such as articulated instruments with rotational abilities), to the need for improvement of the optics used.⁹

Despite the strong focus on the topic these days, there are still only a few papers available about the use of a single port in gynecology, which comprise mainly case series and reports. Few are randomized studies and have a sufficient number of patients that encourage the dissemination of the technique.

The objective of the present work is to describe the initial experience of the Gynecology team from the Benjamim Guimarães Foundation – Hospital da Baleia, in Belo Horizonte, when performing single-port laparoscopy. We describe the technique used, highlighting the profile of the patients treated surgically, as well as the intra-operative events and the post-operative results in the short and mid term.

MATERIALS AND METHODS

Study design

This is a retrospective study, descriptive of a case series, which evaluated the data from medical records of 50 patients cared for in the outpatient gynecology clinic of the Benjamim Guimarães Foundation - Hospital da Baleia, in Belo Horizonte (Minas Gerais/Brazil), from June 2012 to July 2013.

All the patients whose pelvic illness was treated surgically through single-port laparoscopy were included in the study.

In the analysis of the medical records, we identified that the criteria for indication and application of the technique were: adnexal tumor with average diameter below 9 cm, a malignancy risk index¹⁰ of less than 200, absence of prior umbilical hernioplasty with synthetic mesh. All the medical records consulted were considered eligible for the present study, since none of them presented a lack of any data that could be considered limiting.

The study was approved by the research ethics committee of the Benjamim Guimarães Foundation – Hospi-

tal da Baleia and is identified in the Brazil Platform with CAAE number 17036713.6.0000.5123.

Statistical analysis

The data was collected and stored in a database created with the IBM SPSS software program, version 2.0, which was also used for calculating statistics and building the graphs and tables. The distribution frequency of the categorical and ordinary variables taken from the medical records was analyzed.

Single-port laparoscopy

For the surgical procedure, all the patients underwent general anesthesia with tracheal intubation, indwelling bladder catheter and were placed in a decubitus dorsal position with their arms next to their body. Antisepsis was done with surface-active chlorhexidine solution. At the time anesthesia was induced, intravenous antibiotic prophylaxis with first-generation cephalosporin was established as routine.

The surgical technique was standardized as described below:

1. Periumbilical subcutaneous injection of 10mL of bupivacaine with a vasoconstrictor and, subsequently, a vertical or curved incision (in accordance with the anatomical characteristics of the patient) on the lower edge of the umbilical scar, with a length of around 2.5 to 3 cm. (Figure 1)
2. Dissection of the subcutaneous tissue and opening of the aponeurosis and parietal peritoneum under direct viewing.
3. Fixation of sutures at the angles of the aponeurosis, with a 1.0 Vicryl wire.
4. Introduction of the single access platform through the umbilical scar (Sitracc® - Edlo S/A Produtos Médicos). (Figures 2 and 3)
5. Insufflation into the abdominal cavity with carbon gas, reaching a maximum abdominal pressure of 15 mmHg. After the pneumoperitoneum is performed, a 10mm 0° optic is introduced into the orifice corresponding to the port.
6. Inventory of the entire abdominal and pelvic cavity is performed.
7. According to the characteristic of the pelvic disease and perioperative diagnosis, the forceps needed for the procedure were introduced through the other three 5mm access points of the port, with the availability of articulated 42cm Maryland forceps, 42cm flexible grasping forceps with a ring gear, 50cm

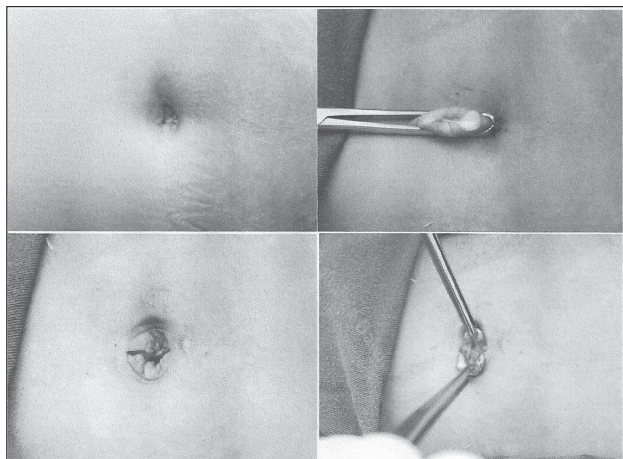


FIGURE 1 Umbilical incision for insertion of the Sitracc®.

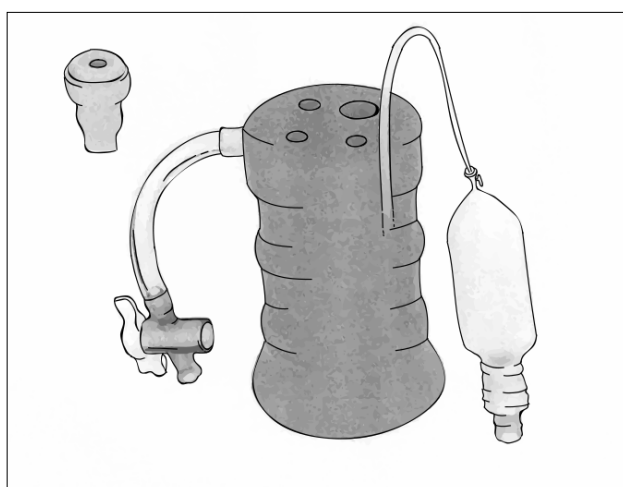


FIGURE 2 Sitracc®.

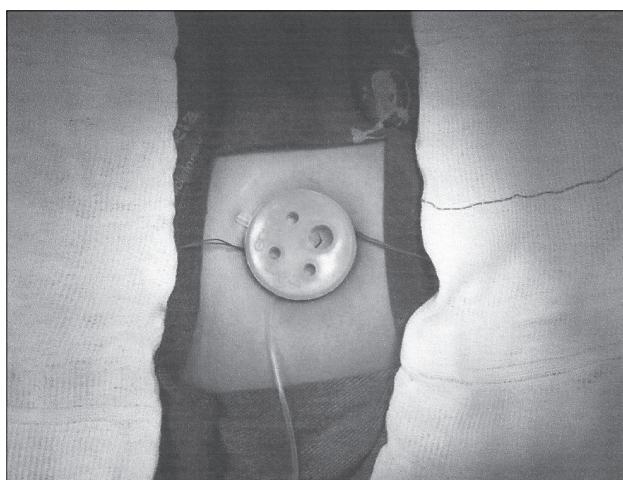


FIGURE 3 Sitracc® after insertion.

gallbladder grasping forceps with a curved ring gear and 42cm curved Metzenbaum-type scissors (Edlo S/A Produtos Médicos).

8. In the event of perioperative diagnosis of adnexal masses: grasping of the ovarian ligament by direct traction with the 42cm flexible grasping forceps through the 5mm orifice and ligation and sectioning of the pelvic infundibulum after identification of the ipsilateral ureter using a peritoneal x-ray. The resulting material from the excision, in all cases, was removed from the pelvic cavity through the umbilical orifice itself, used for the introduction of the port, where new incisions were not needed in the abdominal wall or at the bottom of the posterior fornix.
9. After excision, the pneumoperitoneum was undone and then the port was removed using direct traction.
10. Closure of the aponeurosis using continuous suture with a 1.0 Vicryl wire, hemostatis, skin suturing with a 4.0 Vicryl wire and localized bandage.

RESULTS

The average age of the patients included in the study was 37.8 years, ranging from 18 to 70 years. The age groups were distributed in the following way: 22% of patients were under 30 years old, 40% of the patients were between 30 and 40 years old, 24% were between 40 and 50 years old and 14% were older than 50 years old.

The most frequent surgical indications were adnexal mass (72% of cases) and chronic pelvic pain (24% of cases). Hydrosalpinx and surgical sterilization each accounted for 2% of the cases.

Thirty percent of the patients had a history of abdominal surgery, among them, 12% reported only one prior procedure and 28% reported two or more procedures.

The patients presented, predominately, a favorable surgical profile, having their anesthetic risk determined according to the classification from the American Society of Anesthesiology (ASA).¹¹ Seventy five percent were healthy and, therefore, classified as ASA I. Patients presenting light or moderate systemic disease (ASA II) made up 38% of the sample and 2% had a serious systemic disease, which limited their activities (ASA III).

The average time for duration of the procedure was 94.4 minutes, ranging from 20 to 218 minutes. Thirty two percent of the procedures lasted up to 60 minutes, 48% between 60 and 120 minutes and 20% lasted over 120 minutes.

The patients remained hospitalized for an average of 25.8 hours, ranging from 19.9 to 68.8 hours. Eighty two percent of the patients remained in the hospital for up

to 24 hours, and only 18% for more than 24 hours. We recorded two conversions to laparotomy due to technical difficulties during the procedure. All the cases of conversion featured pelvic adhesions. Perioperative complications were not described.

The post-operative follow-up was done on at least two occasions, 15 and 45 days after the procedure. Two patients presented post-operative complications, which consisted of one case of infection at the surgical site and one case of an incisional hernia.

DISCUSSION

According to a review article published in 2013, there are approximately 66 studies in the medical literature aimed at single-port laparoscopic surgery in gynecology, being 17 case reports, 32 descriptive studies, 13 retrospective studies and 4 randomized studies.¹²

Fagotti et al. published one of the largest series of cases, with 125 patients submitted to single-port surgery in gynecology over a 3-year period.¹³

Although limited, there are already papers that cite the use of a single port in patients with malignant diseases, both for staging, and tumor excision and lymphadenectomy. In 2009, Fader et al. published a pioneering study on the use of a single port on patients with a diagnosis of gynecological malignant neoplasms, showing favorable results.¹⁴

We emphasize, however, that even with the growing interest in minimally invasive procedures, there is still no consensus about which criteria should be used for patient selection, or studies that define what the determining factors for better post-operative prognoses would be.

Important aspects should be considered when employing the technique. As a positive point, we point out that the introduction of the single system (Sitracc®), through direct viewing, may minimize the risk of injury to adjacent organs. We also emphasize the reduced surgical time and the fact that the technique does not require a large learning curve for surgeons that are already qualified to perform conventional laparoscopy.

On the other hand, we observed less freedom of movement of the instrument inside and outside the abdominal cavity, somewhat requiring greater surgical ability. To dodge this limitation, the literature cites auxiliary methods, such as the associated use of an intrauterine handing device, and a combination of long and short instruments, which reduces the friction between them.¹⁵

The results found up until now are positive even for patients with an unfavorable surgical profile, such as those who have had previous abdominal surgeries or who

have a high body mass index, whose surgical morbidity may be significantly reduced by the technique.

In our series, the average time for hospitalization of the patients was 25.8 hours in the post-operative area, being discharged in good clinical conditions, with no complaints of pain, and being able to continue their day-to-day functions. Early discharge was possible especially due to the absence of serious and immediate post-operative complications.

Similar results were described by Escobar et al.,¹⁶ and Kim et al.¹⁷ The first, in a paper published in 2010, evaluated 9 patients that underwent single-port laparoscopy, and stated that hospital discharge occurred, in all the cases, with less than 24 hours of hospitalization.¹⁶ Whereas the latter author prospectively followed 24 patients who had adnexal masses and underwent single-port laparoscopic surgery. In this study, there was no evidence of post-operative complications in any of the patients, and the average period of hospitalization was only one day (ranging from 1 to 3 days).¹⁷

When considering the post-operative outcomes of this study, we can see a reduction in the frequency of complaints of post-operative pain and a quicker return to daily activities. We point out, however, the fact that the evaluation was only done from information provided by the patients, without the use of objective parameters, such as visual pain scales. Nevertheless, our findings are compatible with the results from a recent study by Fagotti et al.¹⁵ In their series of cases, the authors demonstrated that the technique is safe and effective, resulting in a significant reduction of post-operative pain, associated with better esthetic results.¹⁵ The same author compared, in a randomized study, the rate of post-operative pain among patients who underwent single-port laparoscopy and multiple-port laparoscopy. This study included 60 patients with a sonographic diagnosis of benign adnexal mass and negative tumor markers, and found that the patients who underwent single-port surgery presented less pain, better recovery and lower hospitalization costs in relation to multiple-port surgeries.¹⁸

Cho et al.¹⁹ published a randomized study comparing single-port surgery with multiple-port surgery, when performing a cystectomy with ovarian preservation. The variables evaluated included the time for return to work after surgery, the level of satisfaction with the wound and level of post-operative pain in 63 patients, and the majority of them, when asked, would recommend the minimally invasive procedure to a friend or family member.¹⁹

With respect to the duration of the surgical procedure, there are various results described, with times ranging

from 42¹ to 79.6 minutes.¹⁵ The average surgical time observed in our study was 94.6 minutes, a value higher to that found in the literature. There are various factors that influence this data. Since this is a technique that has been recently implemented in the service, there was the need to train all the professionals involved, from the surgeons to the anesthesia and nursing teams. We highlight that the study was developed at a teaching institution in which there are medical residency training programs, and these knowingly have a higher learning curve compared to experienced surgeons. Furthermore, the procedures were done without the assistance of surgical technicians, professionals that can contribute to the optimization of the surgical time.

The low rate of conversion to laparotomy found in our work is consistent with the majority of the studies available. Even for diseases that may have a greater technical difficulty, single port surgery has been used successfully. We cite, as an example, a series of 20 cases of single-port salpingectomy due to ectopic pregnancy published by Yoon et al.,²⁰ in which there was no need for conversion to laparotomy in any of the patients.²⁰ Among the 13 cases of hysterectomies, with or without lymphadenectomy due to malignant gynecological disease described by Fader et al., there was also no description of surgical conversions.¹⁴

Another parameter commonly used as an operative morbidity indicator is the estimation of blood loss during the procedure. Lee et al. evaluated the blood loss of 24 patients that underwent a video-assisted, vaginal, single-port hysterectomy, and found an average value of 400 milliliters (mL).²¹ Whereas Yoon et al., in a study that included 7 cases of subtotal hysterectomies done using morcellators, showed an average blood loss of 200 mL.²² The values are exciting; however, in a single randomized study that evaluated this parameter, Cho et al. reported that the drop in hemoglobin levels was statistically higher in patients that underwent single-port surgery (2.0 0.7g/dL) compared to those who underwent multiple-port video-laparoscopy (1.7 0.6g/dL). The authors believe that this difference may be reduced with an increase in the surgeons' experience performing the less invasive procedure.¹⁹

In our series of cases, an objective evaluation of blood loss was not done, but none of the patients needed a post-operative blood transfusion, since neither acute anemia symptoms nor hemodynamic instability symptoms were identified.

The purpose of this study was not to compare the aesthetic results of single-port laparoscopy with those of

conventional surgery, just as with any other type of comparison between two techniques. Nonetheless, during the post-operative follow-up interviews, we noted that this was a positive impact factor in the patients' satisfaction with the surgical procedure.

Some works, such as the one by Song et al., published in 2013, have already confirmed better aesthetic results and, consequently, higher levels of post-operative satisfaction with the single-port surgery as compared to the multiple-port laparoscopy.²³ In a recent, randomized study published by Yoo and Shim, 73 patients were evaluated for pain and satisfaction associated with surgical scarring 1 month, 6 months and 1 year after the single-port surgery and compared with pain and satisfaction associated with multiple-port surgery. There was no difference found between the 1-month post-operative groups. However, for all the other time points evaluated, the patients that underwent single-port surgery showed better results.²⁴

Although relevant, all the randomized studies previously cited involve a small number of patients and there are some conflicting results, which have led to questioning by several researchers. The largest study about single-port laparoscopy in gynecology was then published by Muriji et al.²⁵ in April 2013, consisting of a meta-analysis that included 15 observational studies and 6 randomized studies, 10 of which on adnexal mass and 11 on hysterectomies, totaling 2,085 patients. The initial objective was to compare post-operative complications, classifying them as "major" and "minor." The secondary outcomes evaluated were surgical time, post-operative pain, objective blood loss (drop in hemoglobin levels), hospitalization time and aesthetic satisfaction with the scar. There were no statistically significant differences found concerning complications in the two groups. We observed a difference in surgical time of 6.97 minutes more for the single-port in adnexal mass surgeries in the randomized studies. In the studies involving hysterectomies, there was no difference in surgical time.

Among the secondary outcomes, post-operative pain could not be adequately evaluated due to various analysis criteria adopted by the different studies. Nevertheless, after a systematic review, the majority of the studies did not find a difference in the rate of pain after 24 hours of surgery.

No differences were found in hospitalization time between the two surgical approaches, however, this is a variable that is highly dependent on factors that are extrinsic to the surgical act itself, such as geographical and cultural factors, socio-economic conditions and conditions imposed by the public or private healthcare systems.

The other secondary outcomes were biased due to the scarcity of data, not being, however, considered significant to the publication.

In an article published in October 2013, Song et al.²⁶ prepared a meta-analysis from 6 randomized studies, comparing multiple and single-port surgeries in gynecology, being 3 on hysterectomies and 3 on adnexal masses. There were no statistically significant differences in relation to the rate of perioperative complications, conversion to laparotomy, drop in hemoglobin levels, time for elimination of flatus, surgical time and hospitalization time. It was concluded that single-port laparoscopy is comparable, in efficacy and safety, to conventional laparoscopy, but there were no proven advantages in terms of reduced post-operative pain and satisfaction with the surgical scar.²⁶

Through the present analysis, we can see that single-port laparoscopy in gynecology is a viable technique and shows good results in the short and medium term. Currently, minimally invasive laparoscopic techniques represent an evolution of the standard laparoscopy with respect to the needs of patients regarding the post-operative aesthetic and functional results. It also shows advantages for healthcare managers, through a reduced rate of complications and costs for hospitalization.

Its biggest contribution is related to the treatment of patients with adnexal disease and those with suspected endometriosis, but there are still many possibilities to be explored with the evolution of the technique and better training of the surgeons involved.

CONCLUSION

This is one of the biggest series of cases in the literature regarding single-port laparoscopy surgical treatment in gynecology. The data available up until now, including this series of cases, reaffirm the hypotheses that the technique offers an important contribution to reduced surgical aggression and better post-operative results, reinforcing the fact that difficulties found in the learning phase do not justify the low adherence of gynecologists to the procedure's regular use.

The data observed in this study is in line with the data available in the scientific literature, especially when we note the short hospitalization time, reduced morbidity and the small number of post-operative complications, highlighting the absence of complications considered serious, as well as the aesthetic results.

All the characteristics observed contribute to the increased quality of life of the patients, reducing unpleasant experiences, which is closely related to the overall sensation of well-being.

The findings accumulated up until now do not present any prominent advantage of the single-port over the multiple-port technique. However, single-port laparoscopy has already been shown to be a safe and viable option.

Even with these findings, new prospective and randomized studies are still needed to define the scope of the impact of this technique in the refinement of the aesthetic result, in the reduction of surgical morbidity and in the improvement of the patients' quality of life.

RESUMO

Laparoscopia por portal único em ginecologia: estudo preliminar de uma série de 50 casos

Objetivo: descrever a experiência inicial da equipe de ginecologia, em um centro de referência, na realização de cirurgia laparoscópica por portal único.

Métodos: trata-se de estudo retrospectivo, com a revisão dos prontuários de 50 pacientes atendidas no ambulatório de ginecologia do Hospital da Baleia – Fundação Benjamin Guimarães, entre junho de 2012 e julho de 2013, e que foram submetidas a tratamento cirúrgico laparoscópico por portal único. Este trabalho foi aprovado pelo Comitê de Ética em Pesquisa da instituição.

Resultados: a idade média das pacientes incluídas no estudo é de 37,8 anos, variando entre 18 e 70 anos, e as indicações cirúrgicas mais frequentes foram massa anexial (72%) e dor pélvica crônica (24%). O tempo médio cirúrgico foi de 94,4 minutos, com tempo de internação médio de 25,8 horas. Em nenhum caso ocorreu qualquer tipo de complicação perioperatória. Registraram-se duas conversões para laparotomia por dificuldade técnica durante o procedimento. Todos os casos de conversão apresentavam aderências pélvicas. Todas as complicações operatórias foram tratadas com sucesso e nenhuma delas foi considerada grave.

Conclusão: esta é uma das maiores séries de casos da literatura em relação ao tratamento cirúrgico por laparoscopia de portal único em ginecologia e apresenta resultados que sugerem a redução da morbidade cirúrgica e resultados estéticos satisfatórios. Concluímos que a laparoscopia por portal único é uma técnica minimamente invasiva viável e que traz importante contribuição à construção de um novo cenário na cirurgia ginecológica moderna.

Palavras-chave: laparoscopia; endoscopia; procedimentos cirúrgicos em ginecologia.

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