Original Article

Efficacy and safety of a new single-port model for appendectomy: Experimental study on swine

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Abstract

CONTEXT: With the cooperation of surgeons and the engineering division of the company Bhio supply© (Esteio-RS, Brazil), a permanent single port was developed. **AIMS:** An experimental study assessed the safety and efficacy of the device using a swine laparoscopic appendectomy model (right salpingo-oophorectomy). **SETTINGS AND DESIGN:** Experimental randomised study. **MATERIALS AND METHODS:** A total of 20 pigs were randomised for the conventional laparoscopic (CL) three-trocar technique or the single Centry port (CPort) with two working channels, aided by a transparietal thread. Operative times, surgical complications, CO_2 use, and pneumoperitoneal pressure were checked. Pressure and chromopertubation tests assessed the ligatures. **STATISTICAL ANALYSIS USED:** For quantitative outcomes, the Fisher's exact test analysed the samples to compare the surgeons in each group, the ANOVA test for parametric data (volume and pressure) and the Student's *t*-test for analysis of the fascial incision length. The binaries and isolated occurrence events were described in percentages. **RESULTS:** For all cases, pneumoperitoneum was maintained. The CPort group, however, resulted in higher CO_2 use (26.18 l; standard deviation [SD] ± 11.09) than CL group (5.69 l; SD ± 2.44) ($P < 0.01$). The mean pressure in CPort group (6.604 mmHg, SD ± 1.793) was comparatively lower than in CL group (7.382 mmHg, SD ± 1.833) ($P = 0.363$). There was no statistical difference between operative times, ligature safety or adverse surgical events between the different groups and surgeons. **CONCLUSION:** The surgical technique used with the single port showed no differences in safety and efficacy. Though it does require more CO_2 use, its working dynamics did not lead to increased operative times. The results were similar between the two surgeons in the study, suggesting that they can be reproduced.

Key words: Appendectomy, laparoscopic surgery, minimally invasive surgery, single port

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INTRODUCTION

In August 2009, our department began treating patients diagnosed with acute appendicitis using two-port laparoscopic technique. We used a 10 mm umbilical trocar for optical viewing and another of 5 mm for a grasper in the suprapubic region, aided by a transparietal thread in the right iliac fossa.[1] This procedure could serve as a training model to acquire the skills needed to perform single-access laparoendoscopic single-site surgery (LESS surgeries).[2,3] This possibility motivated our group to develop a single port model in order to reproduce the same steps by placing it at the level of the umbilicus.

The device would meet some requirements to serve as an alternative to the existing models.[4,5] For acute appendicitis, a reusable port would always be available to the surgeon and could be used in the public health system of Brazil. The sheath diameter should be introduced through an aponeurotic incision of 25 mm.[4,5] However, this size should allow suitable mobility of instruments and surgical ergonomics.

Following the development of the prototype, its efficacy and safety should be tested in order to compare it to the three-trocar conventional technique. Therefore, the pre-clinical study aimed to indicate the need for improvements to the device and standardize the operative technique, allowing its reproducibility.

MATERIALS AND METHODS

The project carried out between October 2010 and January 2012 in partnership with the company Bhio supply© (Esteio-RS, Brazil), resulted in the creation of the two-channel single port Centryport® (CPort), reusable after sterilisation in autoclave. Its conic body, made of stainless steel, has grooves to prevent it from inadvertently moving from its position. The distal end of the body has an inclined sinusoidal cut which increases the radius of the lateral displacement of the instrument. Its seal is made of silicone and equipped with "duckbill" valve orifices of 5 and 3 mm [Figure 1].

From February 16th to 19th, 2012, a randomised pre-clinical study was conducted, using a swine model for laparoscopic appendectomy to test the safety and efficacy of Cport as well as the operative technique approved by the Research and Graduate Studies Group.[6,7] As pigs do not have a cecal appendix, a right laparoscopic salpingo-oophorectomy was performed due to its pelvic location and the anatomic similarity.[8]

The animals undergoing anaesthesia protocol were placed in Trendelenburg position and the surgeon were positioned cranially to the operating table.[9] In the CPort group [Figure 2], a yin-yang-shaped skin incision was performed at the umbilicus, followed by open technique for creation of pneumoperitoneum.[10] A 5 mm 30° laparoscope was used in one of the working channels; the other was used for a 5 or a 3 mm instrument. The distal end of the uterine tube was secured with a transparietal monofilament in the right iliac fossa (2.0 polypropylene loop passed through a number 14 intravenous catheter), which also provided counter-traction by the assistant surgeon during dissection.[1]

In the conventional laparoscopic (CL) group, a longitudinal incision was performed at the umbilicus, followed by the use of the veress needle for subsequent puncture of a 10 mm metal trocar with a retractable blade (to use the 0° laparoscope). Two additional punctures were performed under laparoscopic visualisation with 5 mm metal trocars placed in the right and left lower abdominal quadrants. In both groups, the initial pneumoperitoneal pressure reached 10 mmHg using a CO_2 flow of 2 L/min, when it was increased to 9 L/min.

According to the guidelines for LESS surgery studies from the LESS Consortium for Assessment and Research consortium,[11] the characteristics of the CPort group can be summarised as follows: Incision length and site: 25 mm at the umbilicus; Approach: Peritoneal; Number and type of port: A rigid and resterilizable CPort® single port; Type of optics: 5 mm rigid laparoscope; Type of instruments: Straight, 3 and 5 mm; Aid for accessory ports: Transparietal traction suture in the right iliac fossa.

To analyse the efficacy and safety of the procedures, the primary outcomes were the successful procedure as defined by the randomisation, surgical complications, maintenance of pneumoperitoneum at 10 mmHg until safe removal of the surgical specimen, operative times, volume of CO_2 used, maintenance of ligatures during laparoscopy and their efficacy according to the chromopertubation and pressure tests.

The total operative time was measured, starting at the first abdominal incision and ending at the extraction of the surgical specimen. This period was divided into time to access the cavity (from the abdominal incision for the first trocar until the introduction of the laparoscope) and endoscopic time (from the introduction of the laparoscope to its final removal). At every minute, the prevailing pneumoperitoneal

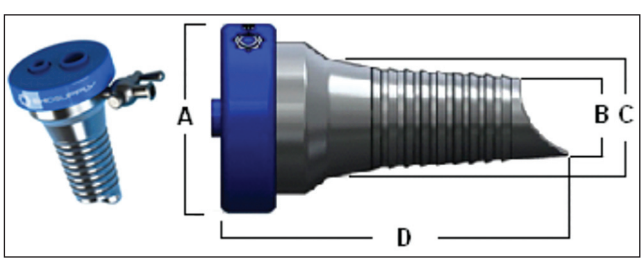

Figure 1: CentryPort®: (A) 5 cm, (B) 2 cm, (C) 2.2 cm, (D) 8.5 cm

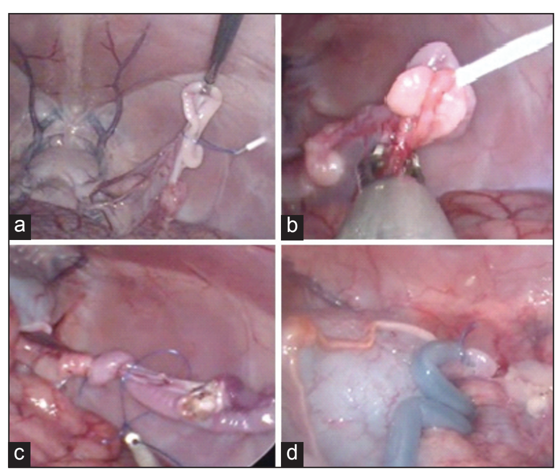

Figure 2: Centryport procedure. (a) Fixation of right uterine tube, (b) bipolar electrocauterisation of mesosalpinx, (c) distal ligature, (d) negative chromopertubation test

pressure and the volume of gas used were recorded as measured in the CO_2 insufflator. Equipment failures and surgical complications were quantified. At the end of the procedure, the umbilical aponeurotic lesion was measured with a centimetre ruler.

The efficacy of distal ligatures in the surgical specimens was assessed by a pressure test. A number six nasotracheal probe was introduced into the lumen of the uterine tube and secured with a simple knot. The specimen was then immersed in a water vessel to investigate the gas leak through the ligature. The probe was connected to the CO_2 insufflator at 30 mmHg pressure for 3 min.

Both groups were submitted to a new laparoscopy 24 h after the surgery by introducing a 10 mm trocar into the previous umbilical incision. The outcomes of interest were death, evisceration, presence of peritonitis or hemoperitoneum, fallopian tube ligature in place, and the chromopertubation test. This consisted of introducing a number 10 nasogastric probe into the urogenital sinus, connected with a 20 ml syringe containing methylene blue (1:20). After the manual closure of the urogenital opening around the probe, the solution was injected under pressure[12] [Figure 2].

For a standard deviation (SD) difference of 1.5 in the comparison of the operative times between the experimental group (CPort) and control (CL), it was estimated that 10 animals were required in each arm. It included 20 triple-cross sows (Sus scrofa domesticus) at the average weight of 15.04 kg ± 1.06 (Cport) and 15.01 kg ± 1.03 (CL) ($P = 0.953$). Randomisation was performed by sorting out five blocks of four procedures for the CL or CPort group and by the order in which the surgeries were performed by two surgeons. To reject the null hypothesis, a 90% power was used. The probability of a type I error associated with this null hypothesis test was 0.05.

The SPSS 19.0 software (Statistical Package for the Social Sciences, IBM Corp., Armonk, NY, USA) was used to make statistical calculations. For quantitative outcomes, the Fisher's exact test analysed the samples to compare the surgeons in each group, the ANOVA test for parametric data (volume and pressure) and the Student's *t*-test for analysis of the fascial incision length. The binaries and isolated occurrence events were described in percentages.

RESULTS

All of the cases selected for the CPort group underwent successfully completed procedures, requiring no conversion to CL or open surgery. In the CL group, an accidental puncture occurred during the introduction of the first trocar (10 mm, umbilical position). It was converted to a laparotomy, and a transfixing lesion was identified in the small bowel loop and a segmental enterectomy followed by a single-plane enteroenteroanastomosis were performed. A right salpingo-oophorectomy was performed according to the open appendectomy technique. This case was recorded as a loss. In two other cases in the CL group, it was necessary to insert the first trocar through direct visualisation of the cavity due to an inconclusive Palmer test.

In both groups, there was suitable maintenance of the pneumoperitoneum. However, in the CPort group, there was a higher mean for CO_2 use: 26.18 l (SD ± 11.09) versus 5.69 l (SD ± 2.44) in the CL group ($P < 0.01$).

The mean pressure was also comparatively lower in the CPort group (6.604 mmHg; SD ± 1.793); CL (7.382 mmHg; DP ± 1.833) ($P = 0.363$). The mean pressure curve, however, maintained oscillations without the occurrence of abrupt variations >2.0 mmHg (CL) or 3.0 mmHg (CPort). The lowest mean pressure recorded in the CL group was 8.7 mmHg. In the CPort group, it was 7.0 mmHg.

During the analysis of pressure curves [Figure 3], a pressure decline in the CL group was observed at three moments (a, b, and c). When the recordings were reviewed, the first (a) and second declines (b) were noted to correspond to the performance of proximal and distal ligatures, respectively. At this step, the slipknot kept the seal of the 5 mm trocar open, allowing gas to escape. During c time, a bag was placed for extraction of the surgical specimen. The same pattern was repeated in the CPort group (a', b', and c'). At the a' and b' times, the proximal and distal ligatures were also performed and the wire caused gas to leak through the port channels. The c' moment represents the extraction of the specimen by removing the seal.

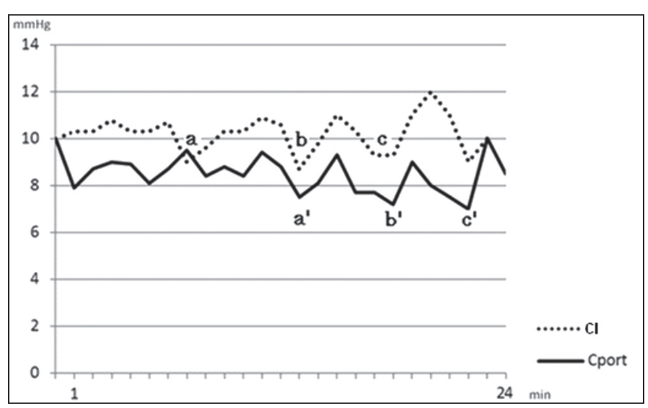

Figure 3: Graph showing mean pneumoperitoneal pressure values during the procedures

There was no statistically significant difference between the times to access the cavity, the endoscopic time or total operative time between the two techniques [Table 1], as well as when the results were compared between the surgeons. However, during the analysis of the endoscopic time, surgeon B was observed to present 80% of his cases in the CPort group above the median, whereas the distribution for the CL group was symmetric ($P = 0.405$). surgeon A had 60% of his cases below the median for the endoscopic time in both groups ($P = 0.738$).

There was no difference in the occurrence of instrumental failures between the two groups with surgeon A ($P = 0.500$), but with surgeon B, there were more cases of instrumental malfunctioning in the CPort group ($P = 0.040$). The events included malfunctioning of the bipolar forceps, scissors, knot pusher, grasping forceps, optics, and light cable.

No statistical difference was found for surgical complications in either the general analysis between the groups or in the comparison between surgeons. The adverse transoperative events recorded were mesosalpinx bleeding, the need to use aspiration, maceration of uterine tube during dissection, wall hematoma at the puncture site, rupture of slipknot, displacement of trocar, and appearance of subcutaneous emphysema. The surgical specimen did not fall into the cavity during its extraction in any of the cases.

At the end of the procedures, the mean length of the umbilical aponeurotic incisions was 2.41 cm (SD ± 0.268) in the CPort group and 1.44 cm (SD ± 0.194) in the CL group ($P = 0.433$).

For the pressure test, a surgical specimen from each group was lost during the preparation. In the CL group, on the other hand, the specimen from the case in which there was a conversion to laparotomy was not used. One case among the eight cases included in the CL group had distal ligature leak; in the CPort group, there were no positive results in its nine samples.

At the time of the reassessment after 24 h, there were no deaths and no case had dehiscence or evisceration. During relaparoscopy, all ligatures were in place. A case in the CPort group showed a positive chromopertubation test. When the procedure was reviewed, the leak was observed not to occur because of a loose ligature, but due to a partial section of the wall as a result of excess force applied.

Table 1: Comparison data for CPort and CL techniques

Outcomes	CPort	CL	P
Operative times (min)			
Access time	05:00 (03:20-07:35)	4:42 (02:36-10:00)	0.395
Endoscopic time	18:18 (13:00-24:00)	17:07 (13:00-23:00)	0.414
Total time	30:37 (24:26-39:44)	26:47 (21:11-33:54)	0.128
Positive chromopertubation	1/10	0	—
Positive pressure test	0/9	1/8	—
Laparotomic conversion	0	1/10	—
Aponeurosis dehiscence	0	0	—
Mean aponeurotic incision (cm)	2.4 (2.0-3.0)	1.4 (1.0-1.7)	0.433
Mean CO_2 consumption (L)	26.18 (18.24-34.11)	5.69 (3.81-7.56)	0.000

CL: Conventional laparoscopic, Cport: Centryport

DISCUSSION

The first single port model described was the R-Port® (Advanced Surgical Concepts, Wicklow, UK), which had an interface made of gelatin. Subsequently, valved channels were included, which resulted in the TriPort® and Quadport® models.[13] This emerging technology aimed to offer patients a better cosmesis, decreased pain, faster return to normal activities and fewer surgical wound complications.

Currently, the surgeon's choice of device depends on factors that will make him decide on one of the different existing models. First, the cost will favour reusable ports, as the number of procedures will dilute the investment and will ensure the development of case studies by the medical staff. The surgeon will not need authorisation from health insurance plans for acquisition, which makes its use more viable in patients from the public health system. On the other hand, the equipment will be subjected to natural wear over time. Furthermore, as the device is made of hard material, triangulation will consequently be more difficult. The use of disposable models, which are made of flexible and complying materials, allow greater instrumental mobility.[14]

An important aspect to be considered is the learning curve. In a retrospective study on non-complicated appendicitis, a significant decrease in operative time was identified after 10 surgeries and 30 would be required to achieve the same time as the three-trocar conventional technique.[15] Nevertheless, the surgeon's skills will have to be adapted regarding the use of CL instruments and others specifically designed for this purpose. One of the difficulties that must be overcome is the restrained movement of instruments and the laparoscope. In our experiment, we found an alternative to optimize the workspace by using a 3 mm mini-laparoscopic forceps and a 5 mm laparoscope. The smaller size of these instruments is an advantage in confined surgical spaces, as occurs in laparoscopic total extraperitoneal hernia repair and in paediatric laparoscopic surgery.[16] Other options would be pre-bent and flexible forceps with articulated tips.[14]

The surgical technique used in the CPort group showed that there was no instrumental collision halting its progress or affecting the ergonomics of the surgeon. This can be explained by the virtually straight movements for dissection, haemostasis and ligatures, and the appendicular transparietal fixation wire had an undeniably decisive role. First described by Yeung in 1999, in addition to stabilising the structure, it is the best method to avoid traumatising the inflamed friable organ, with a lower probability of rupture and contamination of the peritoneal cavity.[17]

Regarding the material used in the manufacture of the CPort® model, the external grooves of the trocar body prevented its displacement. Its malleable silicone seal allowed the rods to slide freely, and its deformation ability satisfactorily accommodated them when lateralisation was required. However, we noted that this type of movement led to greater gas leak from the cavity. When we found that there was an increased use of CO_2 in the CPort group and lower mean pneumoperitoneal pressures, we realised that the duckbill-shaped access channels were not as effective as the permanent trocars in the CL group. However, this had no impact on the operative times as well as on the quality of the laparoscopic field. The distal end of the trocar body in the sinusoidal profile was also shown to help the range of lateral movements.

When analysing the results between the two surgeons for both arms, there was a tendency towards equality for the operative times, effectiveness of ligatures, and the number of surgical complications. The same was observed when comparing the two procedures for the same surgeon or even in the overall analysis between the cases of the CL and CPort groups, regardless of the operator. Although surgeon B showed a higher percentage of CPort procedures in which the endoscopic time was above the median, it was noted that more instrumental malfunctioning events occurred in his surgeries, and this may have interfered as a confounding factor. Despite this, the increased time was not significant when compared to surgeon A.

Regardless of the type of trocar used, the open technique for creating the pneumoperitoneum did not increase the time to access the cavity. Note that the only case of injury occurred in the CL group. One of the factors that may have influenced this event was the higher density of the aponeurosis in pigs compared to humans, which may have justified the use of excess force when the trocar was introduced.

In the CPort group, the aponeurotic incisions had an average length of 2.41 cm, similar to other models. When compared to the CL group, with an average of 1.41 cm, if we use the mathematical formula for the volume of a cylinder to calculate a parietal lesion on an abdominal wall in humans (typically 31.85 mm thick), we will have a volume of 33.60 cm^3 in the CPort group and 22.13 cm^3.[18] However, no case of evisceration took place within 24 h after the surgery.

As the secondary goals of the experiment, we identified relevant improvements to the CPort® model, although the design, internal angles, and materials should be maintained. Nevertheless, due to the high degree of freedom that we had in conducting the appendectomy model, the port could be smaller, mainly with the purpose of decreasing the length of injury. Consequently, a smaller model was manufactured, but the proportionality of the original one was maintained (new measurements: A = 4 cm, B = 1.5 cm, C = 1.8 cm, D = 7 cm). In a pilot case, we found that a 1.8 cm aponeurotic incision was needed, which resulted in a smaller injury of 28.26 cm^3 (5.34 cm^3 reduction). There was no increase in difficulty, collisions or operative time.

Despite the advantages that single ports aim to provide, there is no established evidence yet. Five meta-analysis studies that compared the CL technique (using three trocars) to the single port procedure were identified, concluding that only the operative time was significantly higher in the latter group.[19-23] For the CPort® experimental study, no difference was detected.

The CPort® with two working channels used to perform the two-port laparoscopic appendectomy technique in a swine model showed no difference in efficacy and safety when compared to the conventional three-trocar technique. It was also possible to reduce the dimensions of the device, causing less trauma to the abdominal wall.

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