Effectiveness of a reusable low-cost balloon trocar dissection device in the creation of preperitoneal space during endoscopic surgery. An experimental study in swine[1]

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ABSTRACT

PURPOSE: To evaluate a new, low-cost, reusable balloon trocar device for dissection of the preperitoneal space during endoscopic surgery.

METHODS: Twenty swine (weight: 15–37 kg) were randomized to two groups, according to whether the preperitoneal space was created with a new balloon device manufactured by Bhio-Supply (group B) or with the commercially available OMSPDB 1000® balloon device manufactured by Covidien (group C). Quality and size of the created preperitoneal space, identification of anatomic structures, balloon dissection time, total procedure time, balloon resistance and internal pressure after insufflation with 300 mL of ambient air, balloon-related complications, and procedure cost were assessed.

RESULTS: No significant differences in dissection time, total procedure time, or size of the created preperitoneal space were found between the groups. Balloons in group B had a significantly higher internal pressure compared to balloons in group C. None of the balloons ruptured during the experiment. Three animals in group C had balloon-related peritoneal lacerations. Despite a higher individual device cost, group B had a lower procedure cost over the entire experiment.

CONCLUSION: The new balloon device is not inferior to the commercially available device in terms of the safety and effectiveness for creating a preperitoneal space in swine.

Key words: Hernia, Inguinal. Laparoscopy. Retroperitoneal Space. Swine.

Introduction

The treatment of inguinal hernias has been the subject of controversy in surgical practice since it was first conceived in ancient time[1]. Although the procedure provides satisfactory results and is considered safe and relatively simple, the risk of recurrence with the procedure is as high as 10%. Patients may require a long recovery period, with late return to work. Therefore, inguinal hernias not only affect the patient individually, but also have major socioeconomic impacts, with annual costs exceeding USD 28 billion in the United States[2]. Surgical treatment of inguinal hernias is the most frequently performed procedure by general surgeons in the United States. In that country, approximately 700,000 hernia operations are performed annually, accounting for 15% of all surgeries[3]. Across the globe, 20 million hernia repairs are performed each year[4].

According to the Brazilian Institute of Geography and Statistics in 2010 annual sense, approximately 5.4 million people in Brazil have hernias[5]. Abdominal wall hernias accounted for about 500.000 of the operations that were performed by general surgeons between 1993 and 1996 in the Brazilian Unified Health System (Sistema Único de Saúde, SUS), ranking second among the most frequently performed procedures. These surgeries comprised a total public cost of about USD 40 million at that time[6].

The success of laparoscopic cholecystectomy in the 1990s motivated the development of endoscopic techniques for the treatment of inguinal hernias[7,8]. In addition to the classic Lichtenstein open tension-free approach, the transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP) endoscopic techniques are currently recommended as best evidence-based treatment options[4,9]. However, these techniques are dependent on surgeon training. Compared to open techniques, endoscopic repairs tend to be associated with lower rates of infection, chronic pain, numbness, and loss of work activity. Furthermore, they are more cost-effective and have been related to better quality of life[9].

The Brazilian Unified Health System database (DATASUS) reflects the state of the Brazilian public health-care system. For instance, in 2012, 74.9% of the Brazilian population had no supplemental health insurance[10]. According to the DATASUS, only a very small percentage of inguinal hernioplasties in Brazil are performed by endoscopic techniques[11]. Specifically, 162.008 laparoscopic cholecystectomies were performed in Brazil from 2008 to 2012, compared to 3.982 laparoscopic inguinal hernioplasties. From January to October 2013, a total of 94.150 unilateral and 11.858 bilateral inguinal hernioplasties were performed in the public health system, of which only 657 employed endoscopic techniques[11].

Strategies for expanding the use of endoscopic hernioplasty in the treatment of inguinal hernias in Brazil could bring important benefits for patients and society. Within this setting, the aim of the present paper was to evaluate a new, reusable, low-cost balloon trocar device, manufactured for the creation of preperitoneal space during endoscopic surgery.

Methods

The study was approved by the Graduate Research Group and the Animal Experimentation Ethics Committee of Universidade Positivo (protocol no. 121, of August 2012). The study was conducted in accordance with Brazilian and international guidelines for biomedical research involving animals, including the policies and principles established by the Animal Welfare Act and the NIH Guide for Care and Use of Laboratory Animals.

This randomized, noninferiority experimental study was carried out at the Laboratory of Experimental Surgery of Universidade Positivo. An animal model (swine) was designed to compare a new balloon trocar dissection device developed by Bhio-Supply (Esteio-RS, Brasil) to the commercially available and widely used OMSPDB 1000® balloon trocar dissection device manufactured by Covidien (Mansfield, MA, USA). The aim of this study was to determine the noninferiority of the new device compared to the commercially available product in terms of safety and effectiveness in the creation of preperitoneal space.

Bhio-Supply balloon trocar device

Figure 1 shows a computer rendering of the new device designed by Bhio-Supply. The device comprises a cannula (internal diameter: 10 mm, length: 15 cm), a seal port, and a bidirectional valve for filling and emptying the balloon and for CO_2 insufflation, if necessary. The cannula is fabricated from AISI 303 and 304 stainless steel. The control valve is made from chromed brass. The internal seals are made from medical-grade silicone. The device includes a blunt-tip trocar (diameter: 10 mm, length: 15 cm), fabricated from AISI 303, 304, and 420 stainless steel.

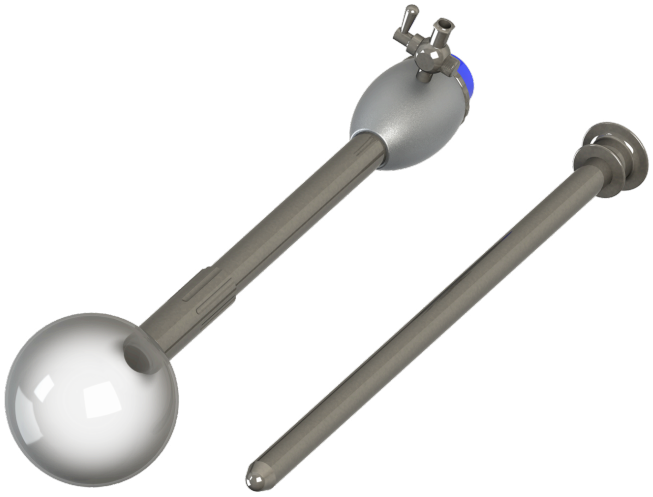

FIGURE 1 - Computer-aided design rendering of the new balloon trocar device designed by Bhio-Supply.

The elastomeric balloon is made from autoclavable transparent medical-grade silicone. The balloon is shaped like the finger of a surgical glove. When insufflated with 300 mL of ambient air, the balloon measures 44 mm in width and 65 mm in length. The balloon is fixed to the cannula by a threading adaptor (Figure 2), which is also made from stainless steel. The balloon is insufflated with ambient air with the aid of a pear-shaped bulb, similar to the bulb used to inflate sphygmomanometer cuffs, or through a 60-mL syringe connected to the bidirectional valve. The entire device is reusable, except for the disposable balloon. The device allows the internal monitoring of the anatomic dissection from within through the laparoscope inserted in the cannula and balloon.

FIGURE 2 - Image of the stainless steel threading adaptor, used to fix the balloon to the cannula in the Bhio-Supply device.

Sample

Twenty cross-breed swine (*Sus scrofa domesticus*), weighing between 15 and 37 kg, were randomly allocated to one of two groups. Swine were used as the animal model for the creation of preperitoneal space using either the balloon trocar dissection device developed by Bhio-Supply (group B) or the OMSPDB 1000® balloon trocar dissection device manufactured by Covidien (group C). The minimum sample size was calculated with consideration of the noninferiority study design and the use of a continuous variable (balloon dissection time). For a significance level of 95% ($p<0.05$), statistical power of 90%, variance of 10% (120 seconds, as established in a preliminary pilot study), and noninferiority limit of 15% (180 seconds), the minimum sample size was calculated to be 16 swine (eight swine/group). The random number sequence used in group allocation was obtained from the internet (http://www.randomization.com). Randomization was made in blocks of four swine.

Experiment

Animals were subjected to a 12-hour fast of solid foods and a 4-hour fast of liquids. Animals were weighed immediately after the end of each surgical procedure. Anesthesia was administered by a veterinary physician, in accordance with the anesthetic protocol recommended by the Animal Experimentation Ethics Committee of Universidade Positivo[12–14].

Preanesthetic medication consisted of ketamine hydrochloride (dosage: 14 mg/kg; Vetnil, Louveira, SP, Brazil), xylazine hydrochloride (dosage: 2 mg/kg; Agener União Saúde Animal, Pouso Alegre-MG, Brasil), and 1% acepromazine (dosage: 0.4 mg/kg; Vetnil). Preanesthetic drugs were administered intramuscularly 15 min before anesthesia induction. Animals were maintained under continuous venous infusion of 0.9% saline (Solução Fisiológica, Baxter, São Paulo-SP, Brasil) until the end of the procedure. Anesthesia was induced with intravenous 2.5% thiopental (dosage: 10 mg/kg; Cristália, Itapira-SP, Brasil) and maintained with inhaled 3% isoflurane (Cristália), which was vaporized at a flow rate of 2.5 L/min of oxygen.

Oxyhemoglobin saturation, heart rate, body temperature, and mean arterial pressure were monitored throughout the surgical procedure in all animals. Values were obtained every 10 min throughout the procedure by using a previously calibrated multiparameter monitor (Hewlett-Packard, Germany). After each procedure was completed, the animals were subjected to a painless, assisted death, according to the same anesthetic protocol.

With the animal under deep anesthesia, 2.5% thiopental (dosage: 10 mg/kg; Cristália) and 19.1% potassium chloride (SAMTEC Biotecnologia, Ribeirão Preto, SP, Brazil) were administered as a 20-mL bolus injection.

Technique

Regardless of group allocation, the surgical procedure followed the same sequence after preoperative preparation. The animal was placed in a supine position. Anesthesia was induced, and the operating field was prepared using a 0.1% solution of iodinated alcohol. Access was gained to the preperitoneal space through a 15-mm incision made 2 cm laterally to the umbilical scar, to the right. Following identification and longitudinal exposure of the aponeurosis of the rectus abdominis muscle and transversalis fascia, digital dissection was used to create a small space near the pubic symphysis, but not beyond the midline. The right preperitoneal space was dissected by placing either the Bhio-Supply or Covidien dissection device, according to random group allocation.

The balloon dissector was insufflated with 300 mL of ambient air by a 60-mL syringe. The filling process was monitored externally through visualization and palpation of the anterior abdominal wall, followed by visualization with a 10-mm laparoscope (angled at 0°) placed inside the balloon. The internal pressure of the balloon (insufflated with 300 mL of air) was measured with a previously validated and calibrated sphygmomanometer, which was coupled to the bidirectional (group B) or unidirectional (group C) valve of the cannula with the aid of a catheter connector. Subsequently, the balloon dissection device was deflated and replaced with a 10-mm trocar. The preperitoneal space was insufflated with CO_2 to 12 mmHg. The laparoscope was introduced into the trocar. The right preperitoneal space was visualized for identification of any peritoneal injury and of anatomic structures.

A pen was used to demarcate lines on the skin of the anterior abdominal wall of each swine, as shown in Figure 3. A cross-sectional line connected the two anterior superior iliac spines to each another. A second line was drawn, connecting the right anterior superior iliac spine with the pubic symphysis. A 3-mm trocar was placed into the medial portion of the dissection in the preperitoneal space, on the line between the two iliac spines. The created space was measured laterally with a 3-mm graduated probe. Another 3-mm trocar was placed into the preperitoneal space at the center of the line demarcated between the right iliac spine and the midline. The created space was measured in the anterior-posterior direction with a graduated palpation probe. A third 3-mm trocar was placed at the palpation site, at the distal portion of the 10-mm cannula that was inserted totally in the abdominal wall. The created space was measured in the craniocaudal direction. The occurrence of complications (e.g., bleeding, peritoneal injury, visceral injury, etc.) was recorded.

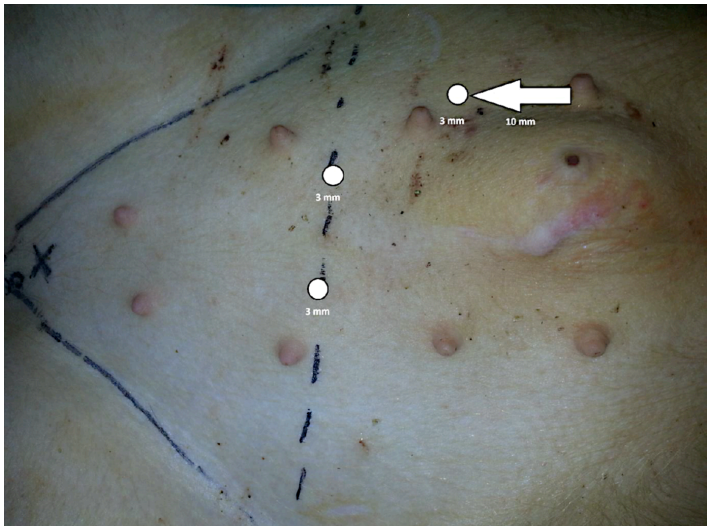

FIGURE 3 - Image of the skin of the anterior abdominal wall of a swine, with anatomic landmarks demarcated with pen. Circles marked with 3 mm indicate the position of the three trocars. Arrow marked with 10 mm indicates the location of cannula insertion in the abdominal wall.

Cost analysis

The cost of each procedure was calculated by considering the commercial price of the device, as provided by the manufacturer (Bhio-Supply or Covidien). All values were calculated in US dollars, according to the real-to-dollar exchange rate on March 7, 2014. In group B, the cost of the reusable device was calculated by dividing the total amount by 10 animals. Group B also included the individual cost of the disposable silicone balloon (one per animal). In group C, a disposable device was used, and the price of a single device was considered for each animal. Other surgical supplies were common to all procedures. A standard hourly cost of USD 51.32 was determined for the use of the operating room for medium-sized animals of the Laboratory of Experimental Surgery at Universidade Positivo. This value was multiplied by the number of hours spent on each procedure. One minute was added to the procedure time in group B, to account for the time required to couple the silicone balloon to the cannula tip.

Data and statistical analyses

Data from detailed reports and videos from each procedure were analyzed. The following variables were measured: quality

and size of the space created using the balloons, visualization of anatomic elements of the inguinal region, size of the preperitoneal space created after balloon dissection in the laterolateral, anterior-posterior, and craniocaudal directions, balloon dissection time (from cutaneous incision to balloon withdrawal), total procedure time, balloon resistance and internal pressure after insufflation with 300 mL of ambient air, transoperative events (e.g., peritoneal laceration, bleeding, or injury to visceral organs), and total amount of CO_2 used.

The Statistical Package for the Social Sciences (SPSS) software package, version 18.0, was used for statistical analysis. Categorical variables were described with the frequency and percentage. Normally distributed quantitative variables were expressed as the mean ± standard deviation. Non-normally distributed quantitative variables were expressed as the median (range). Normally distributed variables were compared by Student's *t*-test for independent samples, and non-normally distributed variables were compared by the Mann-Whitney test. The 95% confidence intervals (95% CIs) were calculated for the differences between means. Pearson correlation coefficients (r values) were used to assess the relationship between quantitative variables. Differences with a $p \leq 0.05$ were considered statistically significant.

Results

Surgical outcomes

There were no statistically significant differences between groups B and C in terms of the animal weight (21.8 ± 5.7 kg vs. 24.6 ± 6.2 kg, p = 0.304), dissection time (5.1 ± 1.1 min *vs*. 4.6 ± 1.0 min, 95% CI: -0.8–1.4, p = 0.359), or total operating time (12.1 ± 1.3 min *vs*. 12.0 ± 0.7 min, 95% CI: -0.8–1.2, p = 0.737). The surgical team considered the spaces created by both devices to be satisfactory in all animals. There were no statistically significant differences in the sizes of spaces created with the two devices, when analyzed in any direction or based on the total volume (Table 1). Analyses did not reveal any statistically significant correlation between the animal weight and the size of the created space in either group (r = 0.17, p = 0.475).

TABLE 1 - Mean size of the preperitoneal space created by each device.

Variables	Group B	Group C	P-valuea	95% CIb
Anterior-posterior measure (cm)	5.2 ± 1.3	4.9 ± 1.7	0.611	-1.07–1.77
Craniocaudal measure (cm)	11.2 ± 2.0	10.1 ± 1.2	0.130	-0.4–2.7
Laterolateral measure (cm)	7.6 ± 1.2	8.1 ± 1.3	0.381	-1.7–0.7
Volume (cm^3)	455.4 ± 182.0	402.6 ± 177.2	0.520	-116.0–221.5

[a] Student's *t*-test for independent samples.
[b] 95% confidence interval for the difference between means.

The mean internal balloon pressure was 199.1 ± 59.5 mmHg in group B, compared to 93.4 ± 16.0 mmHg in group C ($p<0.001$). None of the balloons ruptured during the experiment. There were no cases of device-related injury to the inferior epigastric vessels, bladder, intraperitoneal organs, spermatic cord elements, or iliac vessels in any animal. Blood loss due to balloon dissection was less than 1 mL in all animals.

Three animals in group C experienced peritoneal injury during balloon insufflation. In one of these animals, two lacerations were detected (measuring 3.5 and 1 cm). In another animal, it was not possible to identify the injury, but significant pneumoperitoneum was present. No cases of balloon-related peritoneal injury were observed in group B. However, in one animal, peritoneal injury occurred during digital dissection, before balloon insertion. The median volume of space created in animals with balloon-related peritoneal injury was 480.0 cm^3 (256.0–540.0 cm^3), compared to 237.5 cm^3 (82.5–693.0 cm^3) in animals with no injury (p = 0.517). This analysis was performed in group C only, because no animal in group B presented balloon-related peritoneal injury.

Cost analysis of the two devices

Total device costs were USD 388.02 for each Covidien device (http://www.brasindice.com.br/brasindice/index.php) and USD 212.87 for each Bhio-Supply device ([USD 1.278.80 per reusable device/10 animals] + [USD 423.43 per balloon kit/5 balloons]). The mean procedure costs (including hourly cost of the operating room (USD 51.32), with an extra 1 minute of total operating time in group B) were of USD 489.39 ± 6.20 and USD 323.73 ± 10.94, respectively ($p < 0.001$). Although the individual initial cost of device acquisition was lower in

group C, costs in group B became less than costs in group C from the fifth surgical procedure forward (Table 2). The median CO_2 volume used in group B was 9.7 L (6.5–44.6 L), compared to 13.7 L (7.6–52.0 L) in group C (p = 0.631). Therefore, the CO_2 volume used yielded low values that were statistically similar in both groups. Moreover, the cost of CO_2 was low. For these reasons, CO_2 was not included in the calculation of procedure cost.

TABLE 2 - Device costs over the study period (USD).

Procedure no.	Device cost[a] in group B	Accumulated device cost in group B	Device cost[b] in group C	Accumulated device cost in group C	Difference
1	1,278.80 + 423.43	1,702.23	388.02	388.02	-1,314.21
2	-	1,702.23	388.02	776.04	-926.19
3	-	1,702.23	388.02	1,164.06	-538.17
4	-	1,702.23	388.02	1,552.08	-150.15
5	-	1,702.23	388.02	1,940.10	+237.87
6	+423.43	2,125.66	388.02	2,328.12	+202.46
7	-	2,125.66	388.02	2,716.14	+590.48
8	-	2,125.66	388.02	3,104.16	+978.5
9	-	2,125.66	388.02	3,492.18	+1,366.52
10	-	2,125.66	388.02	3,880.20	+1,754.54

[a] Value defined by Bhio-Supply.
[b] Brasíndice (www.brasindice.com.br/), March 2014.
Values calculated according to the real-to-dollar exchange rate on March 7, 2014 (source: Central Bank of Brazil).

Discussion

Expanding the use of endoscopic hernioplasty in the treatment of inguinal hernias in Brazil may improve employment, disability, and health-care costs. However, the techniques used for endoscopic hernioplasty must be reproducible, safe, and economically viable[15]. Using a balloon trocar dissection device can shorten the surgeon's learning curve in TEP endoscopic inguinal hernioplasty, especially for beginning surgeons and technically difficult hernias[16,17]. Although using a commercial balloon dissector adds direct costs to the procedure[17–24], these devices facilitate the procedure technically and decrease the operating time and complications—advantages that may ultimately reduce costs[22]. Use of a low-cost, reusable, and domestically manufactured balloon trocar could lower procedure costs and benefit a large number of patients in Brazil, especially in the Public Health System (SUS).

The use of hand-made indigenous balloon reduces the cost of TEP repair[24]. This low-cost balloon proved relatively effective[24,25]. However, these balloons do not allow internal viewing of the dissection. Even when they enable, partially visually impaired depends on the balloon material. They are generally made with latex surgical glove, material that is not design for the purpose of dissection of anatomical function spaces. Finally, handmade balloons tend to break easily and can cause fragmentation during its insufflation, which compromises their safety[25].

The initial cost of a Covidien device was lower than that of a Bhio-Supply device. However, the Covidien device became more expensive than the Bhio-Supply device after only five surgical procedures. If used in a larger sample, the cost of the Covidien device per procedure would remain unaltered because the device is designed for single use, whereas the proportional cost of the reusable Bhio-Supply device would become progressively lower. The costs of sterilization of the reusable devices as its durability should be also consider, but this fact probably doesn't have a significant influence on the cost-effectiveness of the device.

The model used to access the preperitoneal space was appropriate to test the balloon dissection devices in animals. Access by the open technique, balloon insertion, and dissection were easy to achieve with both devices, which behaved similarly with respect to dissection time and total procedure time (i.e., the time spent coupling the balloon to the cannula in group B was insignificant). The devices also created similarly sized and satisfactory preperitoneal spaces, suggesting that they were both effective in dissecting the anatomic space.

The higher balloon internal pressure found in group B was probably caused by the smaller size and greater thickness of the balloon in this group. Gaur[25] has recommended monitoring the

internal balloon pressure during insufflation as a method to predict balloon rupture. Moreover, the internal pressure may provide information on the position of the balloon in the abdominal wall, because it reflects the resistance offered by tissues surrounding the balloon. Pressure tends to be high when the balloon is located in the interfascial or intermuscular space, whereas pressure tends to be low when the balloon is placed in the peritoneal cavity. However, Gaur used this method only in the beginning of his learning curve. Provided that a safe margin is allowed when filling the balloon, routine measurement of the internal pressure during balloon insufflation is not necessary[25].

Although use of a balloon dissector for initial access to the preperitoneal space is a safe and well-established method[17,25], it is not free of complications[25,26]. Balloon malpositioning or misplacement in the abdominal wall musculature or fascial layers may hinder or block access to the preperitoneal space, preventing the procedure from being completed endoscopically. If the balloon is not inserted completely in the correct anatomic space, then the muscle fascia may tear, resulting in a hernia. Hemorrhage may occur from laceration of the muscle fibers or blood vessels[26]. Bladder lesions have been very rarely reported during TEP repair, especially in patients who underwent previous surgery[27]. In the present study, there were no cases of injury to the anatomic structures in any group. However, three animals in group C showed device-related peritoneal injury. Even though the balloon in group C was inflated with no more than 300 mL of ambient air, the larger balloon size (designed for use in humans) may explain the increased incidence of peritoneal injury in this group. The balloon in group B was smaller and well-fitted to the small preperitoneal space of swine. Additionally, the peritoneum of swine is much more fragile than that of humans. Therefore, we speculate that the chances of peritoneal injury caused by the devices investigated here would be lower in humans, provided that an adequate insufflation volume is observed.

In addition to potential injury to the peritoneum and internal organs and structures, balloon rupture (due to, e.g., high pressure during insufflation, hyperdistension, or a product defect) may cause fragmentation and fragment loss[25]. In this study, there were no cases of balloon rupture in either group. The high resistance of silicone balloons and the relatively low volume of air used for insufflation may have been the main factors responsible for this result. Balloon insufflation with ambient air increases the risk of rupture-related injury[28] comparing with filling the balloon with liquid; however, this risk has only been demonstrated in laboratory studies and does not seem to have clinical relevance[25]. Moreover, filling the balloon with air is practical, simple, and quick, and it decreases the time needed to inflate the balloon.

In terms of the essential characteristics of a balloon trocar dissection device, the devices used in group B and C may be considered as close to the ideal[25,28]. Both balloons have an oval (group B) or round (group C) shape when filled, with no sharp edges or corners, and are well-adapted for use in the preperitoneal space. Both balloons showed resistance to at least 150 mmHg during dissection of a virgin anatomic space. Both balloons are made of silicone, a biocompatible, resistant, transparent material. Both devices allowed the balloons to be inflated and deflated quickly. Both devices had cannulas that were sufficiently rigid to allow correct insertion into the space. Finally, both balloons allowed internal visualization of insufflation.

In the 1990s, BBraun, via its subsidiary Aesculap Endoscopic Technology (Tuttlingen, Germany), developed the Herloon Balloon® dissection device. This device consists of a blunt trocar, cannula (with a proximal metal and distal plastic portion), and transparent silicone balloon that allows internal visualization of the anatomic dissection. Except for the distal part of the cannula and the balloon, which are single-use, the device is reusable. The Bhio-Supply balloon has several similarities with the Herloon® balloon, even though there is no connection between the two companies and the Brazilian development team was not aware of the German balloon at the time of development. In terms of comparing the utility of the devices, the Herloon® device would need to be imported for use in Brazil, which would affect its cost-effectiveness ratio in the Brazilian setting. Furthermore, the Herloon® device is not very well-known in Brazil; its registry at the Brazilian Health Surveillance Agency (no. 80136990455) expired in October 2009, although it was renewed in March 2014.

Minimum sample size of 16 swine was calculated considering 10% of variance as established in a preliminary pilot study (120 seconds) and a non-inferiority limit of 15% (180 seconds). The calculated difference of 120 seconds refers to a total time of 20 minutes. However, operation time was only 12 minutes in mean. Based on that fact that both groups needed only 60% of the originally estimated operation time, the group sizes might have been underpowered. As refers to an experimental study with a well homogeneous sample, we believe that this difference did not have influence on the results of the study.

In addition to the limitations of the animal model (e.g., fragility of the swine peritoneum), the study design was limited in that a full hernioplasty was not included in the method. Nevertheless, in spite of these limitations, the model described here is an interesting option for training surgeons in accessing the preperitoneal space and TEP repair.

Conclusions

The balloon dissection device developed by Bhio-Supply was not inferior to the OMSPDB 1000® device manufactured by Covidien in terms of safety and effectiveness in creating a preperitoneal space in swine. Moreover, because of the significantly lower cost of the Bhio-Supply device over its lifetime, its use in humans should be assessed in clinical studies.

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