

Peroral Endoscopic Myotomy: New Technique - Study in Pigs

Miotomia Endoscópica Per Oral: Nova Técnica - Estudo em Suínos

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ABSTRACT

OBJECTIVES: To propose a new technique for endoscopic dissection between the submucosa and the lower esophageal sphincter to enable myotomy. **MATERIALS AND METHODS:** Ten pigs underwent dissection of the internal muscle and submucosal layers of the esophagus and cardia, through a 15 cm tunnel in the space created by endoscopically injecting saline with a needle and inflating of a balloon-catheter. After insertion of the endoscope, dissection movements were to be used to advance, culminating with myotomy of 3 cm in the cardia and 5 cm in the esophagus. Eight animals of the ELECTRIC GROUP underwent myotomy with electrocautery at 10 watts and for the two pigs of the ARGON GROUP myotomy was performed with an argon scalpel argon at 8 watts. Feasibility of dissection and myotomy, visualization of the sphincter, operative time and complications were analyzed. **RESULTS:** In all the animals it was possible to do the following: dissection, visualization of the sphincter, and myotomy. Blood loss was negligible. Operative time: ELECTRIC GROUP, 8 to 12 minutes with two perforations, and ARGON GROUP, 12 to 14 minutes without perforations. **DISCUSSION:** Peroral endoscopic access offers advantages over videolaparoscopic surgery of achalasia. Studies have shown good results and effectiveness in animals and humans, however the procedure is considered difficult and time consuming and there is no consensus regarding indications of clinical applicability. With this technique fast and safe dissection, visualization, and myotomy of the sphincter are feasible, however, with complications in 25% of the ELECTRIC GROUP. **CONCLUSION:** Despite the good results with regard to access, visualization, sphincter and short surgical time, more trials are needed to study the effectiveness of myotomy with pre- and post-operative manometry and to generate complication rates and outcomes data.

Key words: Achalasia. Megaesophagus. Cardiomyotomy. Myotomy. Peroral Endoscopic Myotomy. Therapeutic Endoscopy, Endoscopic Treatment.

INTRODUCTION

Achalasia of the lower esophageal sphincter is a disease that is prevalent in the countries of South America, especially Brazil, where the principal cause is Chagas Disease. Destruction of Meissner's and Auerbach's plexuses by *Trypanosoma cruzi* results in disturbances of esophageal contractility and of lower esophageal sphincter (LES) relaxation. In Europe and the United States – where Chagas Disease is only seen in immigrants from endemic areas – the disease has no known cause, and thus is called idiopathic achalasia.^{1,2}

Rezende's classification divides patients into four groups – Groups I, II, III and IV – based on the degree of dilatation and elongation of the esophagus, disorders of peristalsis, lower esophageal sphincter hypertonia, and retention of contrast.³

Except for Group I, the preferred treatment is surgery, provided patients meet cardio-pulmonary criteria. For Group I patients, treatment is basically endoscopic, ranging from the infiltration of the LES using botulinum toxin to dilation with balloon-catheters. In various European and U.S. services surgical treatment for Groups II and III involves sectioning of the lower esophageal sphincter with or without fundoplication. In Brazil, preventive fundoplication to prevent gastroesophageal reflux disease (GERD) resulting from relaxation of the lower esophageal sphincter after surgical section of its muscle fibers has been widely described and studied, mainly by the Esophageal Surgery Service of the University Hospital of the University of São Paulo (USP). One of these techniques which has yielded satisfactory results is called the Heller's Cardiomyotomy with Pinotti's fundoplication, which encircles 270 degrees of the circumference.^{4,5,6,7,8,9,10}

In some European and American centers the surgery for idiopathic achalasia consists of cardiomyotomy without fundoplication, and the authors claim that there is no need to take additional measures to prevent reflux, because other natural anti-reflux factors such as the angle of His, the tortuosity of the abdominal esophagus, and the diaphragmatic hiatus are not adversely affected.^{11,12} Worldwide, over the last 20 years these procedures have been performed by laparoscopy, with better results than open surgery, especially as regards the incidence of incisional hernias and aesthetic aspects, as well as the rapid recovery of patients with shorter hospital stay and an earlier return to normal activities.^{13,14,15,16}

Recently, several procedures have been described for treatment of achalasia using a peroral endoscopic approach to perform myotomy of the lower esophageal sphincter. These endoscopic techniques seek to section the lower esophageal sphincter through the esophageal lumen, either by including the mucosa or by the formation of a tunnel by dissection of the esophageal submucosa. The results of these studies, whether in animals or in humans, with or without fundoplication, are the most varied possible. However, the technical difficulty and operative time are still considered excessive when compared with the preferred approach performed by most authors, which is laparoscopic.^{17,18,19,20,21,22,23,24,25}

The authors describe a peroral endoscopic approach to the lower esophageal sphincter, carried out in swine, which, in an extremely short time, creates a space between the circular muscle and submucosal layers of the esophagus through which it is possible to access and perform cardiomyotomy.

MATERIALS AND METHODS

At the training center of the Immersion Courses in Surgery and Endoscopy of Goiás, the procedure was performed in ten animals – five females and five males – weighing around 18 to 20 kg, which had fasted (both food and water) for 24 hours. These animals were divided into two groups referred to as the ELECTRIC GROUP and the ARGON GROUP:

ELECTRIC GROUP: eight animals – four females and four males – underwent myotomy using electrocautery, at a power of 10 watts, and monopolar current.

ARGON GROUP: two animals, one female and one male, underwent myotomy using an argon scalpel, at a power of 8 watts.

The two groups were evaluated according to: technical feasibility of submucosal dissection of the entire length of the lower esophagus and cardia, visual identification of the musculature, feasibility of selectively sectioning muscle fibers, operative time, and complications such as bleeding and perforation.

All animals were euthanized immediately after the withdrawal of the endoscope from the animal's mouth.

Surgical Technique

1. The male or female pig is placed in the left lateral decubitus position with extremities anchored

to the operating table by bandages, with venous access in the right ear. The pig is sedated with acepromazine, intubated, ventilated with pure oxygen using Takaoka equipment, and anesthetized by veterinarians using thionembutal. The endoscopist is to the left of the animal, the videoendoscopy apparatus is also to the left and close to the head (Figure 1).

2. The snout is anchored using a modified 20 ml disposable syringe in the recesses of the pig's mouth, with transfixing sutures of 2-0 cotton thread mounted on a cutting needle, in order to protect the passage of the gastroscope through the mouth and pharynx until reaching the animal's esophagus (Figure 1).

3. After introduction of the insertion tube of the 8.9 mm diameter Fujinon Series 2500/530 gastroscope through the mouth, pharynx, cricopharyngeal muscle, and upper esophageal sphincter into the esophagus, a complete endoscopy of the esophagus, stomach and duodenum of the pig is performed (Figure 1).

4. The distance from the cardia to the upper dental arch of the pig is measured. A point 12 cm proximal to the esophagogastric transition is identified, where one plans to start the procedure.

4. Medida da distância de cárdia até a arca-da dentária superior do suino e identificação de um ponto cuja distância foi de 12 cm proximal à transição esôfago-gástrica, onde se planejou iniciar o procedimento.

5. Once this point is identified, the submucosal layer of the esophagus is punctured with an endoscopic sclerosing needle and 10 ml of 0.9% saline solution is injected, creating a liquid-filled blister between the circular muscle and submucosal layers of the esophagus, in the anterior curve of the organ (Figure 2).

6. The blister is perforated with an endoscopic needle knife, crossing the mucosal and submucosal layers that form the wall proximal to the blister, until it reaches its liquid content (Figure 3).

7. A three channel balloon-catheter – normally used to extract gallstones from the biliary tract – is introduced into the orifice of the blister, which is inflated with 1 ml of 0.9% saline solution (Figure 4A and B).

8. The inflated balloon is advanced along the longitudinal axis (back and forth) and from left to right as the gastroscope is gently advanced.

9. Interspersed with movements of the balloon, saline is injected through the irrigation canal

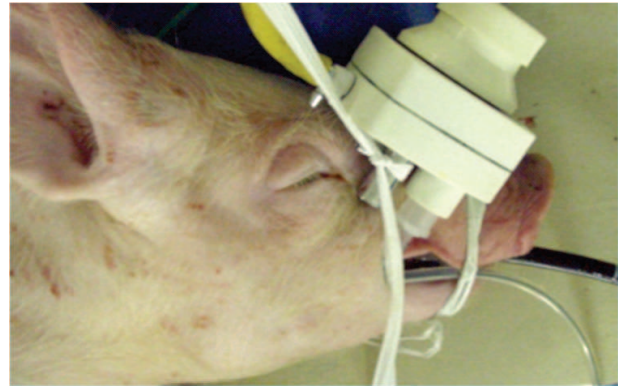


Figure 1 – Experimental animal anesthetized, intubated, mechanically ventilated with the placement of the insertion tube of the endoscope.

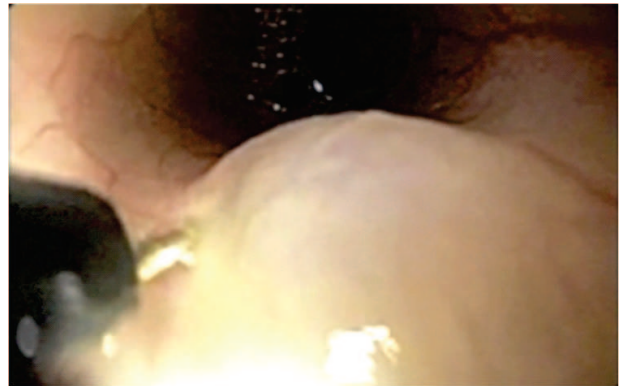


Figure 2 – Endoscopic sclerosing needle and the saline blister between the circular muscle and the submucosa of the esôfago.



Figure 3 – Orifice in the saline blister in the proximal wall.

of the balloon-catheter promoting the hydro-dissection, expanding the separation between the circular muscle and submucosal layers of the esophagus.

10. Withdrawal of the balloon-catheter after creating a space between the layers, a space which is large enough to permit penetration of the tip of gastroscope (Figure 5).

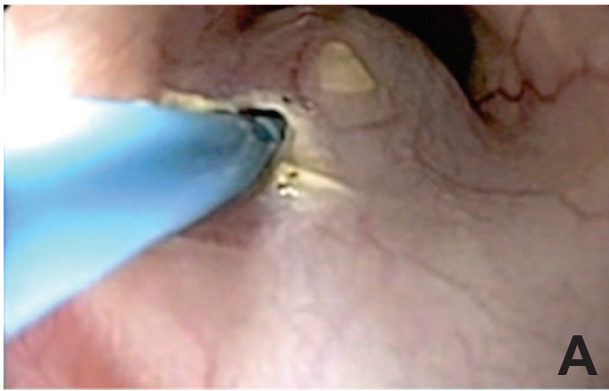


Figure 4 - A) View from the lumen of the esophagus: balloon inflated between the circular muscle and submucosal layers of the esophagus. **B)** View from the space created: inflated balloon between the circular muscle and submucosal layers of the esophagus.

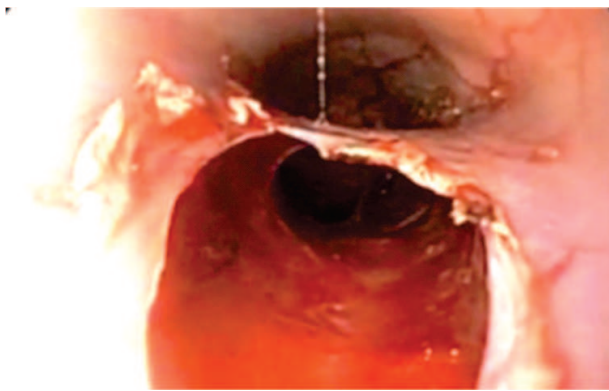


Figure 5 – Above, one observes the lumen of the esophagus. Below, one observes the proximal entrance of the space (tunnel) between the circular muscle and submucosal layers in the middle third of the esophagus.

11. The insertion tube of the gastroscope is introduced into the space through the orifice in the wall of the blister. This orifice is intentionally widened by the withdrawal of the inflated balloon-catheter. From this point the dissection proceeds with delicate back and forth and left-right movements, interspersed with 5 ml injections of saline solution through the working channel. This hydro-dissection facilitates the progression of the tip of the gastroscope to the region of the cardia, and permits the identification of the circular esophageal musculature and oblique musculature of the cardia corresponding to the lower esophageal sphincter. The process creates a tunnel extending longitudinally for 12 cm in the esophagus and 3 cm in the region of the cardia (Figure 6A and B).

12. Once the tunnel is dissected in the submucosa of the final 12 cm of the esophagus and the first 3 cm of the stomach, a needle knife is introduced – as was done with the eight animals in

the ELECTRIC GROUP – through the working channel of gastroscope, to carry out the selective sectioning of the oblique layer of the cardia and circular layer of the esophagus that constitute the lower esophageal sphincter. For the two animals of the ARGON GROUP, an argon gas and electric current transmitting catheter were introduced through the working channel of the gastroscope to perform the sectioning of the same layers.

13. The eight animals of the ELECTRIC GROUP underwent sectioning with a needle knife of the musculature corresponding to the lower esophageal sphincter, extending 3 cm in the cardia and 5 cm in the esophagus, using electrocautery at a power setting of 10 watts, in a distal to proximal direction, with slow and gradual traction, from the set formed by the insertion tube and the needle knife. The two animals in the ARGON GROUP underwent sectioning of the fibers of the lower esophageal sphincter, also extending 3 cm in the cardia and 5 cm in the esophagus, with a gas and current transmitting catheter, in the same direction, and also with traction from the complex formed by the insertion tube and argon transmitting catheter with power setting of 8 watts (Figure 7A and B).

15. The euthanasia of the animal after the procedure is carried out by veterinarians by intravenous injection of 20 ml of 15% KCl.

RESULTS

The following items were analyzed: the technical feasibility of submucosal dissection of the entire length of the lower third of the esophagus and of the cardia, visual identification of these muscle

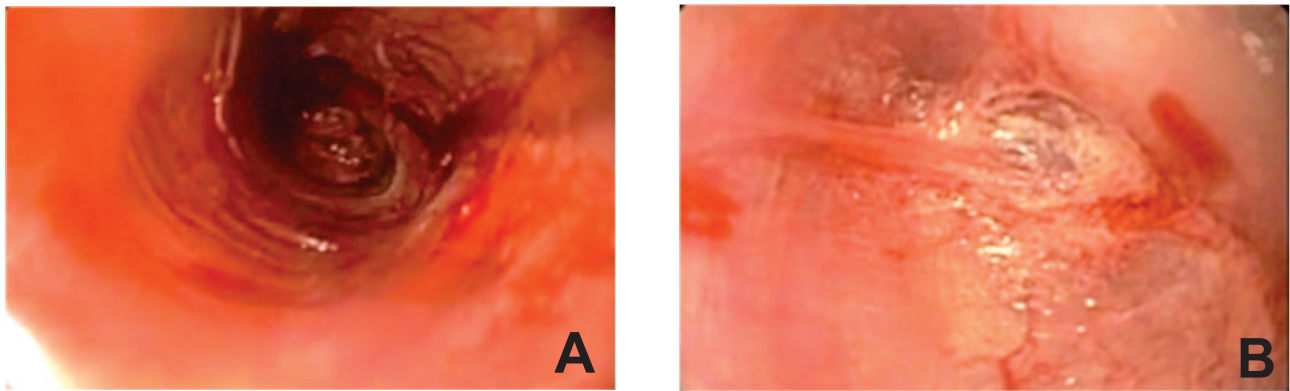


Figure 6 - A) circular musculature of the esophagus. **B)** oblique musculature of the cardia.

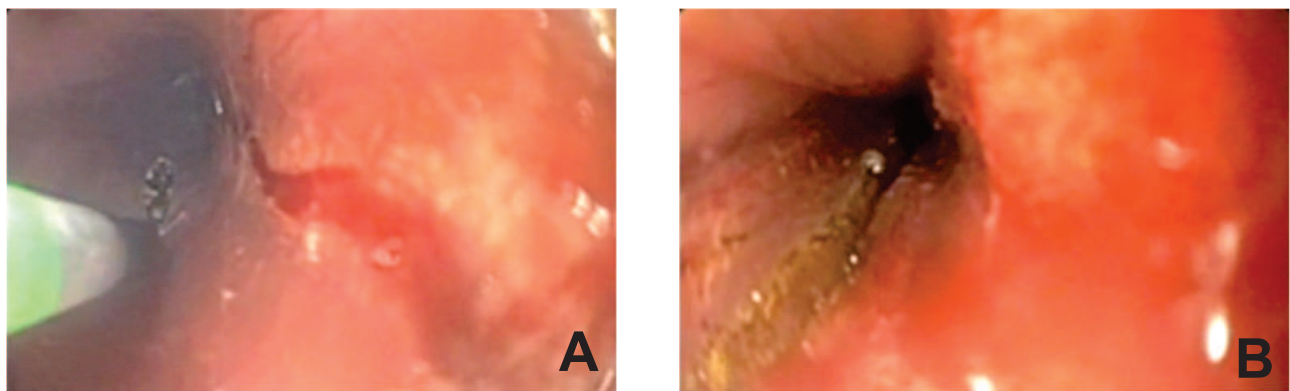


Figure 7 - A) Beginning of the myotomy at the distal end of the lower esophageal sphincter (cardia). **B)** Myotomy completed: viewed from the proximal end (esophagus).

fibers, feasibility of selectively sectioning only these fibers, operative time, and complications such as bleeding and perforation. The findings of this research for the two groups are presented in table 1. Results for each criterion follow:

TECHNICAL FEASIBILITY OF SUBMUCOSAL DISSECTION: the eight animals of the **ELECTRIC GROUP** underwent dissection between the submucosa and circular muscle layers of the esophagus, step by step as described above, in a span extending 12 cm in the esophagus and

continuing 3 cm between the layers of the oblique muscle and submucosa of the stomach, without an occurrence of perforation and with negligible bleeding. The two animals in the **ARGON GROUP** also underwent dissection step-by-step in the same plane between the layers, as described, without complications.

VISUAL IDENTIFICATION OF THE CIRCULAR MUSCULATURE OF THE ESOPHAGUS AND THE OBLIQUE FIBERS OF THE CARDIA: in the eight animals in the **ELECTRIC GROUP** and

Table 1 – Results of the evaluated items.

| Items Evaluated | Electric Group | Argon Group |
|----------------------------------|-----------------------|----------------------|
| Submucosal Dissection | Feasible | Feasible |
| Visualization of the Musculature | Circular and Oblique | Circular and Oblique |
| Sectioning of Muscular Fibers | Feasible | Feasible |
| Operative time | 8 - 12 minutes | 12 - 14 minutes |
| Complications | 2 Perforations | None Occurred |

in the two animals in the ARGON GROUP, the fibers that comprise the lower esophageal sphincter (LES) were perfectly and clearly identified visually on the monitor, through the lens of the Fujinon videoendoscope.

TECHNICAL FEASIBILITY OF SECTIONING THE FIBERS OF THE LOWER ESOPHAGEAL SPHINCTER: both in the eight animals of the ELECTRIC GROUP, and the two of the ARGON GROUP, fibers of the lower esophageal sphincter were sectioned, approximately 5 cm in the esophagus and 3 cm in the stomach.

OPERATIVE TIME: the time measured from the moment of introduction of the endoscope insertion tube to its withdrawal from the mouth of the animals ranged in eight pigs of the ELECTRIC GROUP from 8 to 12 minutes, with an average of 10 minutes. In the ARGON GROUP, the operative time of the two animals was 14 and 12 minutes.

COMPLICATIONS: In 25% of the ELECTRIC GROUP animals perforation occurred at the time of myotomy, using electrocautery of the fibers at a power of 10 watts. There were no perforations in the ARGON GROUP.

DISCUSSION

The idiopathic achalasia of unknown etiology and the achalasia caused by Chagas disease, have no curative treatment for the underlying diseases. Patients begin to experience motility abnormalities of both the body of the esophagus and the lower esophageal sphincter caused by injury or degeneration of Meissner's submucosal plexus and of Auerbach's myenteric plexus. Diminution of esophageal peristalsis and of LES relaxation lead to the symptoms of achalasia.^{1,2}

The main symptom is dysphagia, which ultimately leads to malnutrition due to increased tone of the lower esophageal sphincter with consequent installation and worsening of the dilatation and elongation of the esophagus, features called megaesophagus. (Figure 8^{26,27})

Treatment seeks to eliminate the dysphagia, allowing the patient to eat comfortably and have intake commensurate with adequate nutrition.

Cardiomyotomy is the treatment of choice for correction of achalasia of the lower esophageal sphincter in patients belonging to Groups II and III of the Rezende classification.^{3, 8,9,10,11,12}

LEHMAN et al³² (2001), proved that the squamous mucosa of tissue removed by esophagectomy in patients with end-stage achalasia shows significant changes, which are responsible for the increased risk of cancer in patients with this disease.

In patients with Group IV megaesophagus, many authors recommend the removal of the esophagus and its replacement with another organ, usually the stomach, because of the atony and aperistalsis of the esophagus, the near total loss of LES relaxation, and the risk of malignant degeneration.^{28,29,32}

Patients that undergo cardiomyotomy usually experience a significant decrease in sphincter pressure, improvement in the dysphagia, and are able to improve their food intake; many recover weight.^{8,9,10,11,12}

Open surgery with the attendant complications of laparotomies, such as dehiscence, infections, and incisional hernias, has been replaced over the last twenty years, by the videolaparoscopic approach with good results in terms of safety, comparable operative time, shorter hospital stays, rapid recuperation, more satisfying visualization of the lower esophagus a lower incidence of incisional hernias, and excellent cosmetic results.^{8,9,10,11,12,13,14,28,29,30,31}

Despite the current indisputable advantages of laparoscopic over open cardiomyotomy, laparoscopy is not without risks and complications.^{15,16,33}

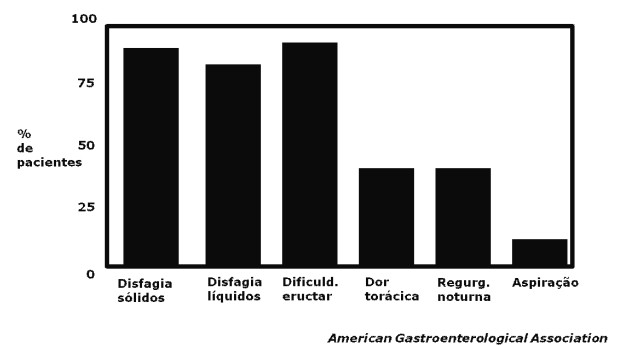


Figure 8 – Achalasia symptoms

Spechler SJ. *Gastroenterology*. 1999 Jul;117(1):229-33. ^{26,27}

Translation of chart axes:

Y-axis: % of patient

X-axis: Dysphagia with solids, Dysphagia with liquids, Difficulty Belching, Thoracic Pain, Nocturnal regurgitation, Aspiration

SOUSA et al^{16, 33,34} (1993-2011), report puncture and perioperative complications such as injury to the spleen, stomach, pneumothorax, and other organs.

In light of these risks and complications that can occur with laparoscopic surgery, several minimally invasive methods have been developed in experiments with animals and humans.^{16,33,34}

Over the past seven years the idea of using natural orifices to gain access into thoracic and abdominal cavities stimulated various research initiatives around the world, all with the goal of permitting surgical procedures on thoracic and abdominal organs while minimizing the trauma to the chest or abdominal wall.

- In 2005, SWANSTRON et al³⁵ report the development of a new instrument for transgastric access to the abdominal cavity.
- In 2007, ZORRÓN et al³⁶ perform the first hybrid transvaginal cholecystectomy in the world, without complications.
- In 2009 SOUSA et al,^{37,38} published a report announcing that in June 2007 they had, after training with eight pigs, performed, in four women, the first surgeries anywhere in the world carried entirely through natural orifices – in these cases through the vagina – without abdominal wall puncture, using two flexible endoscopes.
- In 2008, SUMIYAMA et al³⁹ publish a pilot study of access to the mediastinum and coagulation of the epicardium through endoscopic submucosal dissection of the esophagus, and creation of a mucosal flap functioning as a safety valve.
- In 2008, GEE et al⁴⁰ access the pig mediastinum through submucosal dissection of the esophagus with flexible endoscopy.

Natural orifice surgeries continue to be performed and studied, but new means of sterilization, new platforms, and new accessories need to be developed to consolidate the benefits this type of access can offer.

The peroral endoscopic approach to reach the LES is a mode of access by natural orifices, although it does not penetrate the thoracic or abdominal cavity.

This route was used by Pasricha et al (2007) to perform myotomy in four pigs. The authors conclude that peroral endoscopic myotomy (POEM) is feasible and effective, and they are already suggesting it as a new treatment for achalasia.¹⁷

These results were corroborated by Perretta et al (2010, 2011), who after studies in animals also suggested this approach as a novel treatment for achalasia.^{18, 19}

It has been shown both in animals by Pasricha et al (2007) and Perretta et al (2010, 2011), and in humans by INOUE et al (2010) and VON RENTEIN et al (2011), that sphincter pressure decreases by 65% after (POEM) endoscopic myotomy, without significantly increasing the postoperative incidence of gastroesophageal reflux disease (GERD).^{17,18,19,20,22}

Although Pasricha et al (2007), INOUE et al (2010), ZHOU et al (2011) and SWANSTRON et al (2011) conclude that the procedure is feasible, safe, and effective in humans – and even suggest that it is a promising method to replace the prevailing laparoscopic treatment – the authors call for longer follow-up to establish the clinical applicability of their experiments.^{17,20,23,24}

Although these preliminary results are satisfactory in terms of technical feasibility, safety, effectiveness, the decrease in sphincter pressure, and the low incidence of post-operative GERD, there is no unanimity in advocating the implementation of the technique in humans.²⁵

ABU et al²⁵ (2011), performing POEM in humans, had a 25% death rate due to pneumothorax and mediastinal sepsis. In addition, two patients developed ischemic ulcers. The authors conclude their work stating the procedure should not be performed in humans.

The current trials of POEM have shown the procedure to be technically difficult and time consuming. In humans ZHOU et al (2011) reported operative times ranging from 23 to 180 minutes, while SWANSTRON et al (2011) reported operative times ranging from 120 to 240 minutes.^{23,24}

Further research in peroral endoscopic myotomy (POEM) is therefore justified, to improve submucosal dissection – which is considered technically difficult – and in this way avoid perioperative complications such as perforation, reduce the well-documented long operative time, and establish the effectiveness of the procedure as regards sphincter pressure reduction, and the absence or low incidence of post-operative GERD.

These results, if confirmed, should be compared with the results already known about laparoscopic myotomy. If advantages over the laparoscopic approach were demonstrated, then peroral endoscopic myotomy (POEM) could be recommended as an alternative treatment for achalasia in humans.

In this research in animals, carried out by the SOUSA GROUP, the authors report excellent results, particularly in relation to the items that most often limit the development and subsequent implementation of peroral endoscopic myotomy so it can be systematic in humans: technical ability and the operative time.

The surgical technique was performed in ten animals by a videolaparoscopic surgeon and an endoscopist accustomed to laparoscopic surgery and therapeutic endoscopy, including NOTES & TNOTES (TOTALLY NOTES). This experience demonstrates the feasibility of the submucosal approach with full visualization of the fibers of the lower esophageal sphincter, the adequacy of tools common to the day-to-day work of endoscopists, but with a perforation rate (25% in the ELECTRIC GROUP) that is still high for the small number of animals used in this study.

Bleeding was negligible and establishing the 15 cm tunnel was safe, fast, and easy, allowing access between the circular muscle and submucosal layers of the esophagus and between the oblique muscle layers and submucosa in the stomach, in the cardia region.

It seems likely that lower rates of perforation will accompany more training and the use of a greater

number of animals in future research, using instruments with types of energies that penetrate the muscular layer less.

CONCLUSION

Considering the variables that we propose to evaluate, in the case of experimental research for technical, surgical, and endoscopic development in animals that were not subject to the study of survival, the results of this study permits us to conclude that:

Peroral endoscopic myotomy (POEM) using the dissection technique between the internal muscle layer and the submucosa developed and proposed in this research is technically feasible, allowing clear visualization of the circular musculature of the lower third of the esophagus and the oblique muscle fibers of the cardia, making it possible to perform a cardiomyotomy with instruments routinely used by endoscopists, in much shorter time than that described for other techniques of peroral endoscopic myotomy, with negligible bleeding.

These results allow us to propose a novel technique for peroral endoscopic myotomy and stimulates us to perform the technique in a greater number of animals, in order to truly evaluate safety in relation to the true rate of esophageal perforation. Studies of survival in animals should be performed to evaluate pre- and post-operative sphincter pressures, and thus the effectiveness of myotomy in the correction of dysphagia.

RESUMO

OBJETIVOS: Propor nova técnica de dissecação endoscópica entre a submucosa e o esfíncter inferior do esôfago com realização de miotomia. **MATERIAL E MÉTODOS:** Dez suínos foram submetidos à dissecação entre as camadas muscular interna e a submucosa do esôfago e de cárdia, por um túnel de 15 cm iniciado em espaço criado endoscopicamente por injeção salina com agulha e insuflação de balão. Após penetração do endoscópio, procedeu-se movimentos de dissecação e miotomia de 3 cm em cárdia e 5 cm no esôfago. Oito animais do GRUPO ELÉTRICO submeteram à miotomia com bisturi elétrico a 10 watts. Dois do GRUPO ARGÔNIO, com bisturi argônio a 8 watts. Analisou-se: factibilidade da dissecação e miotomia, visibilidade do esfíncter, tempo cirúrgico e complicações. **RESULTADOS:** Em todos animais foram factíveis: dissecação, visão do esfíncter e miotomia. Sangramento desprezível. Tempo Cirúrgico: GRUPO ELÉTRICO, 8 a 12 minutos com duas perfurações e GRUPO ARGÔNIO, 12 a 14 minutos sem perfuração. **DISCUSSÃO:** Acesso endoscópico peroral objetiva vantagens sobre a videocirurgia da acalásia. Estudos têm demonstrado bons resultados e efetividade em animais e humanos, entretanto o procedimento é considerado difícil e demorado, não havendo unanimidade na indicação da aplicabilidade clínica. Nessa técnica foram factíveis dissecação rápida, segura, visão e miotomia do esfíncter, porém, ocorreram complicações em 25% do GRUPO ELÉTRICO. **CONCLUSÃO:** Apesar dos bons resultados quanto ao acesso, visão do esfíncter e curto tempo, sugere-se maior número de experimentos incluindo sobrevivência para conhecer a real taxa de complicações e estudar efetividade da miotomia com manometria pré e pós-operatórias.

Palavras chave: Acalásia, Megaesôfago, Cardiomyotomia, Miotomia, Miotomia Endoscópica Per oral, Endoscopia Terapêutica, Tratamento Endoscópico.

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