DOI: 10.1590/0100-6991e-20192231 Original Article

Pneumostomy: an operative proposal for the treatment of severe diffuse pulmonary emphysema.

Pneumostomia: uma proposta operatória para o tratamento do enfisema pulmonar difuso grave.

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A B S T R A C T

Objective: to evaluate a new operative technique for the treatment of advanced pulmonary emphysema. **Methods:** we conducted a prospective analysis of nine patients with severe pulmonary emphysema submitted to pneumostomy. The procedure was performed under local anesthesia, in the anterior thoracic wall, hemiclavicular line, in the second intercostal space, through an anterior thoracotomy of 5cm for access to the upper lobe, whose anterior segment was pinched and fixed to the parietal pleura. We carried out the pneumostomy with electrocautery and blunt insertion of an intrapulmonary drain. To assess the procedure, we performed pulmonary function tests, imaging tests, six-minute walk test, and applied quality of life questionnaires, all measured preoperatively and 30 days after the procedure. **Results:** no deaths occurred related to the procedure. Imaging studies showed a decrease in lung volume. The pulmonary function showed a significant reduction in the residual volume. The six-minute walk test showed an increase in the distance covered in the postoperative period. There was significant improvement of the quality of life as demonstrated through questionnaires Medical Outcomes Study 36 Item Short-Form Health Survey (SF-36), Saint-George Respiratory Questionnaire (SGRQ), Medical Research Council scale (MRC), and Eastern Cooperative Oncology Group Performance status (ECOG). **Conclusion:** the proposed technique is feasible, safe, easy to perform and to maintain.

Keywords: Pulmonary Emphysema. Thoracic Surgery. Ostomy.

INTRODUCTION

The American Thoracic Society defines chronic obstructive pulmonary disease as a chronic and progressive obstruction to airflow associated with chronic bronchitis and emphysema[1]. Chronic bronchitis is defined as a clinical syndrome characterized by chronic cough with mucus or mucopurulent expectoration lasting at least three months for two consecutive years in patients who have had other causes of coughing excluded. Pulmonary emphysema is an alteration characterized by abnormal enlargement of the air spaces distal to the terminal bronchus, accompanied by destructive alterations of the alveolar walls.

Severe diffuse pulmonary emphysema (SDPE) is one of the major public health problems worldwide. It affects 1.8% of the world's population, or 65 million people, and it is the third leading cause of death in developed countries[2]. It kills three million patients annually. Its treatment includes hygiene and dietetic guidelines, antibiotic therapy, bronchodilators, oxygen therapy, corticoids, mucolytics, immunization, and respiratory rehabilitation. Despite the maximum clinical therapeutics, the functional capacity decline leads, when in advanced stages (severe pulmonary emphysema), to incapacitating dyspnea, with respiratory failure[3]. These patients lose the ability to exhale properly, which leads to hyperinflation (air trapping) of the lung.

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The debilitating effect of the hyperinflation is an extreme respiratory effort and disability to conduct gas exchanges in a satisfactory proportion. For these patients the only option is the operative treatment: lung volume reduction surgery and/or lung transplantation[4].

In a previous study, we proposed a protocol to test a new operative treatment of patients with severe diffuse pulmonary emphysema, based on the concept of collateral ventilation[5]. The concept of collateral ventilation is not new, having been described in 1930[6]. In normal ventilation, the inhaled and exhaled air travels through the respiratory airways, as there is no obstruction to prevent flow. However, in emphysematous patients, there is obstruction of these same airways, preventing optimal expiratory flow. As a consequence, there is an increase in the intra-alveolar pressure, forcing airflow to the neighboring alveoli through passages or channels (pores of Khon, Lambert and Martin) that deflect it from the natural airway. The circulating air between the alveolar sacs (collateral ventilation) causes pulmonary hyperinflation and remains trapped in the parenchyma, causing all its known consequences. Based on this concept, it was proposed in 1978[7], potentially clinically applicable, the artificial creation of air passages (spiracles) from the lung to the external environment, that is, outside the chest wall, which would allow the trapped air an alternative outlet, with decreased hyperinflation and improvement of respiratory mechanics.

The term "arway bypass" was first proposed in 2003[8] for procedures that would allow extra-anatomical communication between this trapped air (collateral ventilation) and the main airway, allowing the trapped air to escape from the lung, thereby reducing hyperinflation. In 2007[9], severe emphysematous patients were treated with endoscopically-inserted paclitaxel-eluting stents, promoting the airway bypass, thus creating a new passageway between the respiratory tree and adjacent lung tissue. It was concluded that this procedure reduces hyperinflation and improves lung function and dyspnea in selected patients with severe pulmonary emphysema.

Based on these concepts, the *Santa Casa de São Paulo* Chest Surgery Group proposed an alternative operation for the treatment of patients with severe pulmonary emphysema: pulmonary parenchyma drainage, communicating the lung to the outside environment (spiracle).

In order to show the results obtained, we describe the clinical and laboratory evolution of the patients who have undergone this therapeutic procedure that may alleviate the debilitating effects of emphysema, with low morbidity and mortality, and low cost.

METHODS

The research project was approved by the Ethics and Research Committee of the Faculty of Medical Sciences of the *Santa Casa de São Paulo*, opinion 1,796,323, and awarded a grant by the CAPES Foundation. Since we used a device (foreign body) that was inserted in the pulmonary parenchyma, ANVISA (National Agency of Sanitary Surveillance) was also consulted, releasing the procedure under the "Compassionate Use" of the technique. It was understood that selected patients were at risk of death and the proposed technique would be an opportunity for emergency treatment, with the condition that up to ten patients be operated at this stage. We present in this study the results of nine patients treated by the proposed method, seven males and two females.

Inclusion criteria were patients with severe emphysema, with chest X-ray on inspiration and expiration, and high resolution chest tomography showing diffuse emphysema with pulmonary hyperinflation; age up to 75 years; presence of disability, despite maximum clinical treatment for at least six months (pulmonary rehabilitation); FEV-1 (forced expiratory volume in the first second) after bronchodilator <30% of predicted; total lung capacity greater than 100%; cessation of smoking at least six months before the procedure; and candidate for lung transplant or pulmonary volume-reducing operation. We chose the following exclusion criteria: previous myocardial infarction within six months; ventricular ejection fraction below 45%; interstitial or pleural disease that could prevent the procedure; giant bubble; pulmonary hypertension ≥35mmHg; and evidence of systemic disease or neoplasia, with reduced life expectancy. We obtained an informed consent from all individuals included in the study.

In order to evaluate the proposed procedure, the selected patients were submitted to imaging, plethysmography, six-minute walk test, and to quality-of-life questionnaires. The following questionnaires were included: Medical Outcomes Study 36 - Short-Form Health Survey, Saint George's Respiratory Questionnaire, Medical Research Council scale, and Eastern Cooperative Oncology Group Performance status.

The proposed and performed operative technique, validated in previous work[10], was as follows (Figure 1): 1) The patient was taken to the operating room, kept in supine position, and submitted to local anesthesia in the sixth intercostal space in a 2cm extension, with the objective of performing conventional chest drainage, in the hemithorax that was chosen to perform the lung drainage. This procedure prevents any pneumothorax that may occur; 2) Next, a 4cm or 5cm incision is made in the chosen hemithorax, under local anesthesia, in the second intercostal space;

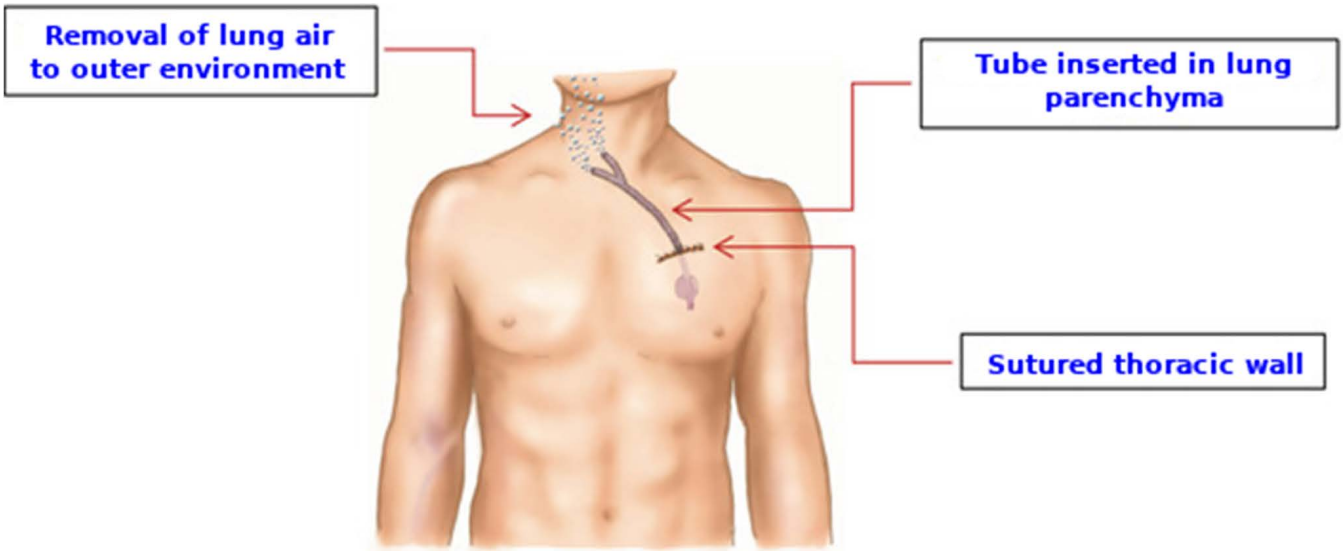

Figure 1. *Proposed surgical technique.*

3) Careful dissection is made by planes until we reach the pleural cavity; 4) Once in the pleural cavity, the pulmonary parenchyma is pinched, so that it can be safely opened. Four cardinal stiches are applied, securing the lung to the parietal pleura; 5) An opening in the lung of 2cm to 3cm is sufficient. Through this opening we insert a drain, which is fixed to the lung; e 6) It was not necessary to place this drain under water seal.

All patients had the proposed variables collected in two moments: MO- Preoperative: 20 days before surgery; e M1- Postoperative: between 20 and 30 days after surgery.

We compared all collected data for moments zero and one, which we consider fundamental for our analysis. The follow-up of the patients beyond 30 days postoperatively, although not the object of our study, was possible only for some patients who returned to the outpatient clinic after this period. At the end we will comment on this.

RESULTS

The mean length of hospital stay was 4.7 days. There was only one major complication during the procedure, contralateral pneumothorax, easily controlled. Minor complications occurred in two patients: chest wall cellulitis in one and subcutaneous emphysema in another. There was no operative mortality and no bleeding.

Image exams: chest radiography and tomography

These exams showed a fantastic result, as shown in figure 2, A and B (chest X-ray). Preoperatively, in all patients there were hyperinflated lungs, flattened diaphragm, increased pre-sternal space, and increased thoracic anterior-posterior diameter, as indeed are the findings of such patients. In the postoperative period, all these parameters returned to normal, showing that there was in fact a large air withdrawal from the lung parenchyma. We verified the same result with computed tomography of the thorax. In the chest X-ray, shown here, a tracheostomy cannula appears placed to mark the pneumostomy site.

Pulmonary function testing

The comparison between the data obtained in the spirometry and in blood gas analysis did not show significant statistical difference between the observed variables at any moment. As for the residual volume that was measured by plestimography, there was an important reduction in the postoperative period. There was a 66% reduction from M0 to M1. In the preoperative period, this mean value corresponded to 213ml, and after, 146ml, with Statistical significance.

Six-minute walk test

There was an increase in the distance covered in M1 in 89% of the patients, with statistical significance. In M0, the average distance walked by the patients was 272 meters. In M1, the average distance traveled was 322 meters, and one patient walked more than 400 meters.

Medical Outcomes Study 36 - item Short Form Health Survey (SF-36)

The SF-36 showed a statistically significant difference in the functional capacity domains, limitation by physical aspects, general health status, vitality and social aspects. No patient complained of worsened postoperative pain. There was improvement in quality of life by this questionnaire (Table 1).

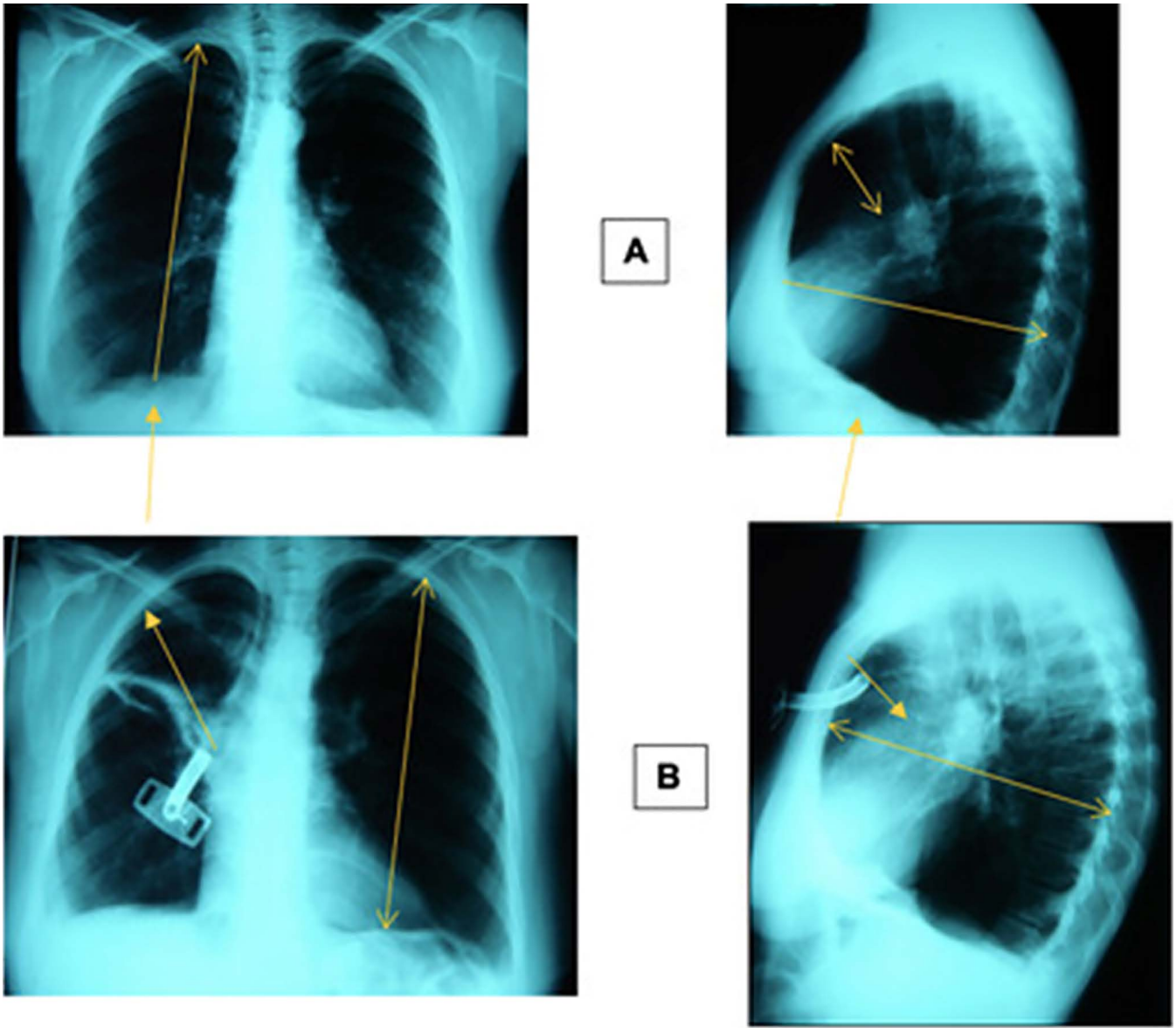

Figure 2. *Chest X-ray in AP and profile: A) preoperative; B) post-operative*

Saint George Respiratory Questionnaire 9 (SGRQ)

Through the SGRQ, there was a significant difference for activity, impact and total score. There was improvement in quality of life by this questionnaire as well (Table 2).

Medical Research Council (MRC) score

Preoperatively, all patients were classified as score 4. At M1, two patients were classified as score 2, six with score 3 and one with score 4. There was improvement in the sensation of dyspnea following the pneumostomy in 89% of the patients, with statistical significance (Figure 3).

Eastern Cooperative Oncology Group Performance status (ECOG)

In the preoperative period, all patients were classified as grade 4, that is, completely incapable of performing basic self-care.

Table 1. *Summary measures of the SF-36 score.*

Variable	Preoperative (M0)							Postoperative (M1)					
	N	Min*	Max**	Med***	Mean	SE#	SD##	N	Min*	Max**	Med***	SE#	SD##
Functional capacity	9	0	40	10.0	11.7	4.5	13.5	9	5	80	50.0	9.9	29.7
Physical aspects limitation	9	0	75	0.0	8.3	8.3	25.0	9	0	100	50.0	14.1	42.3
Pain	9	20	100	62.0	63.0	10.6	31.7	9	51	100	62.0	6.8	20.3
General health state	9	0	70	30.0	28.0	8.4	25.2	9	35	100	64.5	8.3	23.6
Vitality	9	0	65	15.0	26.1	7.9	23.7	9	30	90	60.0	6.3	18.9
Social aspects	9	0	50	12.5	23.6	5.7	17.1	9	25	100	68.8	10.8	30.4
Emotional aspects	9	0	100	0.0	33.3	16.7	50.0	9	0	100	100.0	15.21	45.5
Mental health	9	8	76	52.0	48.0	7.0	20.9	9	16	100	72.0	10.2	30.5

**Min: minimum; **Max: maximum; ***Med: median; #SE: Standard error; ##SD: Standard deviation.*

Table 2. *Summary measures of the SGRQ scores.*

Variable	Preoperative						Postoperative						¥p-value
	Min*	Max**	Med***	Mean	SE#	SD##	Min*	Max**	Med***	Mean	SE#	SD##	
Symptoms score	36.4	100.0	59.4	64.1	64.1	18.2	23.5	65.8	45.1	45.0	5.6	16.9	0.5
Activity score	92.5	100.0	93.3	95.9	95.9	3.9	23.1	92.5	53.2	57.7	8.9	26.8	<0.01
Impact score	60.9	100.0	73.7	76.3	76.3	13.1	16.7	68.8	40.1	39.2	5.8	17.4	<0.01
Total score	68.9	100.0	75.8	80.3	80.3	9.9	20.4	75.7	46.4	45.8	6.0	18.1	<0.01

**Min: minimum; **Max: maximum; ***Med: median; #SE: standard error; ##SD: standard deviation; ¥Wilcoxon test.*

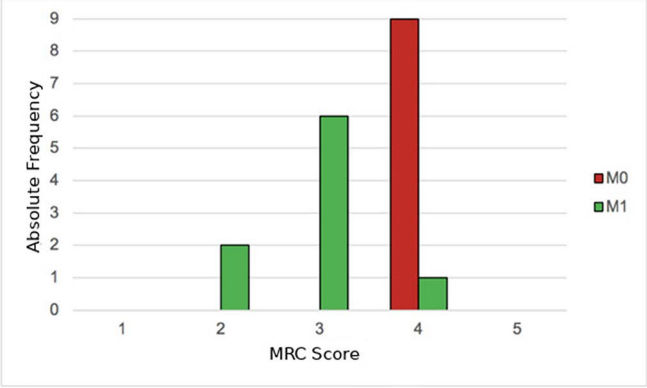

Figure 3. *Absolute frequency of the MRC score.*

In the postoperative period, 67% were classified as capable of limited basic self-care, 22% as capable of performing all self-care but unable to perform any work activity, and only 11% maintained the same initial situation. Thus, after surgery, there was an increase in autonomy in 89% of patients, which is statistically significant (Figure 4).

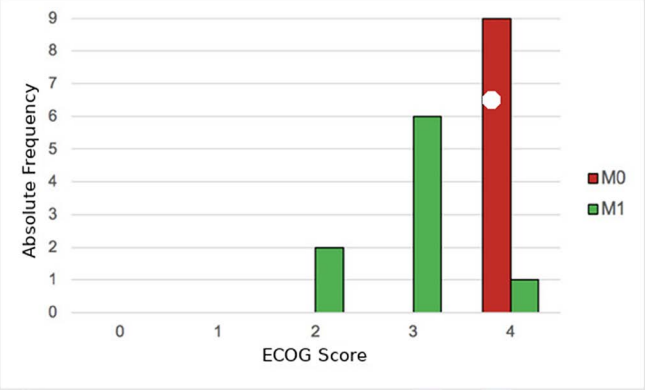

Figure 4. *Absolute frequency of the ECOG score.*

Late results of each operated patient

Patient 1- operated on September 11, 2006. Since then she has not needed oxygen for daily tasks. She is alive, 13 years later, with the pneumostomy still functional. She is the only patient who still attends our outpatient clinic. Patient 2- operated on October 26, 2006, in the course of evolution acquired tuberculosis and died 18 months after the operation. Patient 3- operated on December 21, 2006, the last contact with this patient was on July 12, 2016. He lived, therefore, for at least ten years. Patient 4- operated on January 20, 2007, died in December 2008 due to a severe respiratory infection, an expected complication of the original disease. Patient 5- operated on January 19, 2007, died in January 2010, as a result of respiratory infection, therefore three years after the operation. Patient 6- operated on July 25, 2007. Although with improved symptoms, died on July 25, 2008, due to a bladder cancer, and not respiratory problems. Patient 7- operated on July 24, 2007. This patient was addicted to heavy drugs and disappeared from the outpatient clinic in March 2008. Patient 8- operated on December 3, 2007. He was a patient who had acute myocardial infarction in 1989, treated with angioplasty. In 1991, he had a new ischemic event, and myocardial revascularization was performed. In 2003, he had implanted an internal defibrillator and performed correction of aortic aneurysm. He was also operated on for "acute cholecystitis" in November 2008. He left our clinic in January 2011, five years after the procedure. Patient 9- operated on April 11, 2009. Abandoned the outpatient clinic in October 2010.

DISCUSSION

In a previous publication[11], there has been experimental work on the lungs of patients who have undergone pulmonary transplantation. In the native lung, a small orifice was created, through which a silicone tube was inserted to create a spiracle. The lungs were then vented through the bronchial tree or through the transpleural pathway, and they measured the flow-volume curve, volume of air recovered from the lungs by the spiracle, and performed magnetic resonance to study the spatial distribution of helium administered through the nasal airway or spiracles. They concluded that due to the presence of collateral ventilation in the emphysematous lung, the direct communication between the pulmonary parenchyma and the environment improved respiratory mechanics and, consequently, ventilation. This study was the end result of several that began in 1930[6], 78 years ago, when the concept of collateral ventilation was first demonstrated by proving its existence in healthy lungs. In 1969, American authors[12], performing resistance measurements of the interalveolar canals, demonstrated that in the regime of hypertension (emphysema) the collateral ventilation becomes of fundamental importance in the net distribution of air in the parenchyma, and pulmonary hyperinflation appears with all its consequences. In 1978, the use of a new procedure for the treatment of emphysematous patients was suggested, based on the concept of collateral ventilation[7].

Besides these aspects, some authors defend the thesis that there are air passages between the pulmonary lobes, so that when severe emphysema is present, the collateral ventilation that appears keeps the alveoli of the pulmonary lobes in open communication[13]. Thus, in theory, a procedure that communicated the upper lobe, for example, with the environment, would enable not only the drainage of this upper lobe but also that of the lower lobe on the same side.

Since then, the procedure suggested in this context has been with the aid of bronchoscopy, creating a communication between the pulmonary parenchyma and the corresponding bronchus, by means of isolated stents or with pharmaceutical products with the aim of inhibiting the growth of inflammatory tissue around them, avoid obstruction. In this procedure, it is necessary to use general anesthesia and high technology; it has high costs, longer hospitalization and the risk of severe bleeding[8].

Currently, two other therapeutic methods for the treatment of severe pulmonary emphysema are the lung volume reduction surgery and lung transplantation. In all the methods it is necessary to make use of general anesthesia, intensive care unit, and there is prolonged hospitalization. They present high morbidity, mortality and cost.

According to the National Emphysema Treatment Trial[14] (NETT), the mortality at 90 days after the lung volume reduction operation was 7.9%. It is contraindicated in high-risk patients, those with FEV-1 below 20% of predicted. In selected patients submitted to this operation, the following results were described[15]: clinical and functional improvement after the operation with 30% decrease of RV, 50% increase in FEV-1, and 80% of patients stopped using supplemental oxygen. After two years, however, all patients returned to the same values displayed in the preoperative period.

Regarding lung transplantation[16,17], perioperative mortality is 6.2%, the survival of the bilateral transplantation is 86.4% in one year and 66.7% in five years. The most common complications in the first year after the operation are primary graft failure (10.2%), severe acute rejection (10.5%), infection (80%), pulmonary hypertension (51.1%), renal dysfunction (25.7%), dyslipidemia (17.7%), diabetes (21.5%), bronchiolitis obliterans (8.8%), and malignant neoplasm (3.9%).

On the other hand, since the year 2000, the Group of Thoracic Surgery of the Faculty of Medical Sciences of the *Santa Casa de São Paulo* has been perfecting the treatment of drainage of giant bubbles with the use of local anesthesia[18]. Therefore, in the years after this first publication, we accumulated enough experience and confidence with this technique[19] to propose this type of procedure not only in patients with giant bubbles, but also in patients with diffuse pulmonary emphysema as proposed in 1978[7] and in the manner performed in native lungs of patients who underwent lung transplantation[11].

It is worth mentioning that the nine patients selected for this study were in the queue for lung transplantation and their life expectancy, if nothing was done, would be one year. And as we verified, all have lived for more than one year, and with better quality of life when compared with the preoperative status.

The first patient undergoing this procedure has been alive for 13 years. The second lived for 18 months and died from tuberculosis. The third, we followed for ten years and then he abandoned follow-up, the same happening with patient seven (followed for one year), eight (followed for five years) and nine (followed for one year). Patients four and five died of severe respiratory infection as a result of pulmonary emphysema.

We believe that the observed improvement in quality of life is mainly due to the improvement of respiratory mechanics. Reduction of the normal volume, with consequent diaphragmatic elevation, reduction of the anteroposterior diameter of the thorax and reduction of the sternal retro-space undoubtedly contributed to an increase in respiration efficacy. In a comparison, to illustrate, we can say that before the operation these patients were drowning in their own air. After the operation with relative lung emptying, this organ had better respiratory incursions, which allowed for an increase in gas exchange. As a result, these patients had their drug doses reduced, the amount of oxygen they needed to perform routine work decreased, etc. This study suggested that patients with the highest volume values were the candidates who most benefited from the operation. So in an upcoming work, we will include patients with a higher such parameter. Those who display this parameter as normal will not be included. Our goal is to "empty the lungs" of its air content, its hyperinflation (air trapping). A normal residual volume indicates that there is little amount of trapped air, so there is nothing to be emptied, thus these patients will benefit less from the proposed procedure.

Although the results obtained have shown a clinical improvement of the patients in the postoperative period, we can not yet conclude that the proposed operative technique actually brings benefits. However, we can say that this study persuaded us to continue to obtain data from a larger number of patients. And, even more, it proved to be an innocuous procedure, without mortality or serious morbidities, and could at least be a "bridge" procedure while waiting in the lung transplant queue.

R E S U M O

Objetivo: *avaliar uma nova técnica operatória para o tratamento do enfisema pulmonar avançado.* **Métodos:** *análise prospectiva de nove pacientes portadores de enfisema pulmonar grave, submetidos à pneumostomia. O procedimento foi realizado sob anestesia local, na parede torácica anterior, linha hemiclavicular, no segundo espaço intercostal, através de toracotomia anterior de 5cm para acesso ao lobo superior, cujo segmento anterior foi pinçado e fixado à pleura parietal. Realizada pneumotomia com eletrocautério e inserção romba de dispositivo (dreno) intrapulmonar. Para avaliação do procedimento, foram realizados os seguintes exames: testes de função pulmonar, exames de imagens, teste da caminhada de seis minutos e questionários de qualidade de vida, medidos todos no pré-operatório e 30 dias após o procedimento.* **Resultados:** *não houve mortes relacionadas ao procedimento. Exames de imagens mostraram diminuição do volume pulmonar. A função pulmonar mostrou significante redução do volume residual. O teste de caminhada de seis minutos mostrou um aumento na distância percorrida no pós-operatório. Houve melhora significante da qualidade de vida, demonstrada por meio dos seguintes questionários: Medical Outcomes Study 36 Item Short - Form Health Survey (SF-36), Saint-George Respiratory Questionnaire (SGRQ), Medical Research Council scale (MRC) e Eastern Cooperative Oncology Group Performance status (ECOG).* **Conclusão:** *a técnica proposta é viável, segura, de fácil realização e manutenção.*

Descritores: *Enfisema Pulmonar. Cirurgia Torácica. Estomia.*

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Received in: 05/04/2019
Accepted for publication: 05/20/2019
Conflict of interest: none.
Source of funding: Coordination Grant for the Improvement of Higher Education Personnel (CAPES).

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