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What is the major public health problem: the morbid obesity or bariatric surgery coordinated for health system single? (Part I)

Qual o maior problema de saúde pública: a obesidade mórbida ou a cirurgia bariátrica no Sistema Único de Saúde? (Parte I)

FERNANDO DE BARROS – TCBC-RJ

Today we are witnessing a real pandemic of overweight, morbidly obese (MO) and metabolic syndrome. According to the World Health Organization (WHO), the prevalence of overweight patients is 1.9 billion, and of obese ones, 600 million¹. Currently, MO is the second factor of preventable death in Brazil, surpassed only by smoking. The way of life of our contemporary world certainly has a big share of the blame. We cannot, however, fail to reflect on the health policies and the current model of public management assistance created to reference centers for the treatment of MO in the country. We note that policies and guidelines are much more focused on solving this problem through bureaucratic measures, inefficient and difficult to perform in practice, rather than developing effective preventive and care actions that render the treatment of obesity feasible. We do not underestimate the scale of the problem, which is undoubtedly a major challenge for managers and specialists of our country public health, nor is our intention to point the way to “win” this battle, but we believe that, as doctors, is our duty and commitment to analyze some important mechanisms currently in the system for the comprehensive care of the morbidly obese patient.

According to VIGITEL (Risk and Protective Factors for Chronic Diseases Surveillance Through Telephone), for the first time in Brazil more than half of the population over 18 has a diagnosis of overweight (51%)². Should nothing be done, there are going to be, in 2030, amazing three billion morbidly obese in the world.

Let us stop and think, we are discussing a poorly controlled epidemic, of significant number, which does not distinguish race, economic status, gender, age, ethnicity or level of education. It affects everyone gradually, without mercy, chronically, deleteriously, overwhelmingly and, to make matters worse, there is a complex understanding of the health-disease process. Further compounding the disaster framework, treatment of MO requires qualified staff, adapted infrastructure, high cost and the recognition as an urgent public health matter. The issue is the complexity

involved in the situation of being obese. The lack of adequate information, prejudice, stigma – individual, social and cultural barriers – are undoubtedly the first aspect to face; often the obese patient is seen in a distorted way by the whole society. The population, the media and even some healthcare components do not see the morbidly obese as a sick person, but as a sedentary, gluttonous and undisciplined individual. The result often is a refusal to host these patients in the public hospital. Other barriers add up, this time structural and physical. On the day-to-day of public service, it is common to find the following limiting situations to the attention that an obese patient requires: overcrowded clinics, emergencies and image sectors; lack of adequate facilities; inefficient reference and counter reference; lack of adequate staff; lack of knowledge about the disease; prejudice on the patients’ condition; and ineffective management priorities.

It is interesting to note at this time how the contemporary world we live in is paradoxical, especially Brazil. We exhaustively watched the employment of government policies of “Zero Hunger” while our population reaches record statistics of overweight and obesity in recent years. We live in a culture of sculptural perfection – a body worshipping era – idealizing the perfect “contours”, searching for numerous aesthetic resources, without worrying about the “base” of this iceberg: the metabolic syndrome.

Have not we reached the time to be concerned about the obesity health-disease process?

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REVISTA DO COLÉGIO BRASILEIRO DE CIRURGIÕES

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Evaluation of outpatient discharge in patients with cutaneous melanoma

Avaliação da alta ambulatorial em pacientes com melanoma cutâneo

NURIMAR C. FERNANDES¹; FLAUBERTO DE SOUSA MARINHO¹

A B S T R A C T

Objective: to evaluate discharge in a group of patients with cutaneous melanoma according to recently established criteria. **Methods:** we conducted an observational, cross-sectional study with 32 patients at the Hospital Universitário Clementino Fraga Filho (HUCFF) / Universidade Federal do Rio de Janeiro (UFRJ), between 1995 and 2013, in the following stages: IA (17 cases, 53.12%), IB (4 cases, 12.5%), IIA (3 cases, 9.37%), IIC (1 case, 3.12%), IIIB (1 case, 3.12%), IIIC (3 cases, 9.37%), melanomas in situ (2 cases, 6.25%), Tx (1 case, 3.12%). **Results:** the follow-up time varied from one to 20 years (stage IA), five to 15 years (stage IB), six to 17 years (stage IIA), 20 years (stage IIC), 23 years (stage IIIB) and 14 to 18 years (stage IIIC). One melanoma in situ (subungueal) was discharged in the fourth year of follow-up and the other was promptly discharged. The Tx melanoma was followed for 12 years. We observed no relapses or recurrences in the period. **Conclusion:** although a controversial issue, it was possible to endorse the discharge of the patients since our follow-up time had already exceeded the one recommended by the other authors.

Key words: Prospective studies. Melanoma. Melanoma/epidemiology. Follow-up studies. Neoplasm staging.

INTRODUCTION

Literature data show that, among patients with cutaneous melanoma (CM), 75% detect their own recurrences and 50% detect their second primary tumors; it is possible that professional monitoring visits are scheduled more often than necessary^{1,2}.

The risk of recurrence is highest during the first year of follow-up; reports suggest that recurrence tends to a plateau, with low percentages, after the first ten years³. To date, there is no international consensus on the follow-up time of CM⁴⁻⁶.

Marsden *et al.*⁶ proposed follow-up times for each of the CM stages based on evidence levels: IA (evidence obtained from meta-analysis of randomized controlled trials or meta-analysis of epidemiological studies); IB (evidence obtained from at least one randomized controlled trial); IIA (evidence obtained from at least one well-designed, non-randomized, controlled study); IIB (evidence obtained from at least one other type of well designed quasi-experimental study); III (evidence obtained from well-designed descriptive studies, such as comparative studies, correlation studies and case studies); IV (evidence obtained from experts committees' reports or opinions and / or respected authorities' clinical). They then proposed the coming follow-up periods⁶: IA (one year); IB to IIIA (five years); IIIB and IIIC (ten years).

This study aims to carry out the evaluation of discharge in a group of patients with cutaneous melanoma in accordance with the criteria adopted in the Dermatology Service of the Clementino Fraga Filho University Hospital, Federal University of Rio de Janeiro (HUCFF/UFRJ).

METHODS

We used a multidisciplinary protocol^{7,8} to evaluate 32 patients with cutaneous melanoma in the Dermatology Service at HUCFF / UFRJ, between 1995 and 2013.

Histopathological Staging – Excisional biopsy is the technique of choice to confirm the clinical suspicion of melanoma; incisional punch biopsy is indicated in lesions located on the face, hands, feet and subungual region, with diameter greater than 1.5cm or in those in which an excisional biopsy would demand an extensive procedure. The Breslow thickness in the histopathological examination of the specimen (excisional biopsy) defines the optimal margins: d" 1mm (1cm margin) and > 1mm (2cm margin), establishing the need for re-excision to expand the margins. Breslow thickness in incisional biopsy is considered temporary. **Clinical staging** - A) search for evidence of metastatic disease: fever, headache, anemia, weight loss, bone pain, neurological and respiratory

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signs and symptoms. B) physical examination of the skin (transit metastasis: lesions in the lymph drainage area, more than 5 cm distant from the origin of the primary tumor; satellitosis - lesions around the tumor at a 5 cm radius C) physical examination of regional lymph nodes: Impalpable (clinically hidden) – tomographic evaluation and / or ultrasound of the lymph node is performed when doubts arise on palpation; palpable: macrometastasis, clinically detectable, is confirmed by therapeutic lymph node dissection; the commitment is classified according to the number of metastatic lymph nodes, 1, 2-3 and e"4 being the cutt-off limits. D) general physical exam: liver, spleen and especially the central nervous system; and laboratory tests – in the absence of signs and symptoms of metastasis: blood count, ESR, glucose, urea, creatinine and lactate dehydrogenase (LDH), liver function tests, x-ray of pleuropulmonary fields; in patients with metastases detected by clinical examination, the following tests are added: CT scan of chest, abdomen, pelvic cavity, and bone scintigraphy. Skeletal radiography is added if the bone scan reveals changes.

RESULTS

We evaluated 32 patients, predominantly female (21) and white (28), aged between 40 and 70 years old (29). The lesions were most commonly found in the head (8 cases) and trunk (11) (Table 1).

The cases were grouped into the following stages: IA (17 cases, 53.12%); IB (4 cases, 12.5%); IIA (3 cases, 9.37%); IIC (1 case, 3.12%); IIIB (1 case, 3.12%); IIIC (3 cases, 9.37%) (Tables 2 and 3).

Outpatient follow-up ranged from one to 20 years (stage IA), five to 15 years (stage IB), six to 17 years (stage IIA), 20 years (stage IIC), 23 years (stage IIIB) and 14-18 years (stage IIIC).

DISCUSSION

The routine for CM used to be based in the staging and follow-up indefinitely, except for in situ melanomas that were discharged (Table 2). In 2013, the retrospective analysis showed: the Breslow thickness was not determined (Tx) in one patient. In some circumstances, this evaluation index is partially damaged or becomes less accurate. The AJCC 2002/2009 does not define the conduct in melanomas Tx⁹. Follow-up lasted 12 years (Table 2).

According to our protocol^{7,8}, those with in situ melanoma (isM) are discharged, a conduct also recommended by Marsden *et al.*⁶. We observed two such patients (6.25%): one white, 46 years old, with a lesion located on the back; and one black, 40 years old, with dystrophy and overall darkening of the nail plate of the second right finger (subungual melanoma), evolving from a striated melanonychia; this patient underwent biopsy of the proximal nail fold and nail matrix. Amputation was indicated, since the excision with safety margins and the preservation of the finger functionality are not always feasible. The surgical specimen revealed melanoma in situ. Although our conduct in patients with melanoma in situ is discharge, we followed the observations of Tan *et al.*¹⁰, who studied the initial stage of the subungual melanoma in 121/124 cases: 11 (9%), stage 0 ; 16 (14%), stage I; 50 (41%), stage II; 30 (32%), stage III; and five (4%) stage IV. Nine of the 11 patients with isM were followed on average for 35 months. Our patient was discharged on the fourth year of monitoring (Table 2). Tan *et al.*¹⁰ pointed out that the accurate measurement of Breslow thickness may be difficult in acral melanoma and, in particular, the subungual melanoma, since the healthy nail matrix does not have a granular layer and the subcutaneous fat may be absent in the subungual area.

Among the 17 stage IA patients, five had new isM after one, two, four, six and 11 years of the initial

Table 1 - Distribution of cutaneous melanoma by age group, sex, color and location.

Age Group	Gender		Color		Location					
	F	M	W	NW	Head	Trunk	Upper Limb	Lower Limb	Foot	Hand
20-30 years old	-	1	1	-	-	1	-	-	-	-
31-40 years old	2	-	1	1	1	1	-	-	-	-
41-50 years old	4	4	7	1	2	3	-	2	-	1
51-60 years old	6	2	6	2	1	2	1	1	3	-
61-70 years old	6	1	7	-	3	1	1	1	1	-
71-80 years old	2	3	5	-	1	2	1	-	1	-
81-90 years old	1	-	1	-	0	1	-	-	-	-
TOTALS	21	11	28	4	8	11	3	4	5	1

Source: HUCFF/UFRJ (1995-2013)

Conventions: W - white; NW - not white; F - female; M - male.

Table 2 - Distribution of cases according to staging and follow-up (HUCFF).

Stage	Number of cases	Outpatient Follow-up Routine	Time
Tx	1	▪ not-defined	12 years
Tis	2	▪ resection with a 0.5 cm margin ▪ discharge	Discharge 4 years
I A	17	▪ Resection: 1.0 cm margin ▪ dermatological and lymph node examination: every six months (first two years) and then annually	1,2,4,5,7,10, 12 14,15,16,20 years
I B	4	▪ Resection: 2,0 cm margin ▪ Dermatological and lymph node examination: every two months (two years) and thereafter, every six months ▪ X-ray of chest and liver function tests: every six months (two years) and then annually	5, 5, 11, 15 years
II A	3	I B	6, 15, 17 years
II C	1	▪ Resection: 2,0 cm margin ▪ Dermatological and lymph node examination: every two months (two years) and thereafter, every six months ▪ X-ray of chest and liver function tests: every six months (two years) and then annually	20 anos 20 years
III B	1	▪ Clinical examination every four months ▪ X-ray of chest and liver function tests: every six months ▪ Imaging tests targeted to the region where there is relapse every four months ▪ Resection of limited locoregional and visceral metastases ▪ individualized chemotherapy	23 years
III C	3	III B	14, 18 years

diagnosis, respectively. The follow-up ranged from one to 20 years (Table 2). One patient (stage IB) submitted a new cutaneous melanoma two years after the first diagnosis. The four patients with stage IB were followed for five years (Table 2).

Considering the three patients included in the IIA stage, there were two acral lentiginous melanomas and one located in the chest. One of the acral lentiginous melanomas showed a neurotropic histological type – white female patient, 80 years old, left plantar region, evolution of 30 years. The neurotropic variant is composed of spindle cells with a pattern like a neuroma and tendency for circumferential distribution around small nerve fibers in the deep dermis and hypodermis. As a unique clinicopathological variant, it presents in the form of a pigmented or amelanotic nodule of rapid growth. The follow-up ranged from six to 17 years (Table 2).

One IIC patient (white, male, 50 years old, with nodular melanoma in his left knee and positive left inguinal sentinel lymph node) underwent lymph node dissection and then followed for 20 years without recurrence or relapse (Table 2). One IIIB patient (white, male, 26 year old, with

nodular melanoma on the back) was followed for 23 years without recurrence or relapse (Table 2).

Stage III melanoma is associated with high risk of recurrence and mortality. A retrospective study showed five-year survival without disease in the percentages of 63% (IIIA) and 32% (IIIB)¹¹. Early recurrence sites were: local / regional transit (28%), regional lymph node (21%) and systemic (51%).

Three patients were classified as IIIC: a) non-white, female, 63 years old, with acral lentiginous melanoma in the left plantar region, positive sentinel lymph node, submitted to inguinal lymph node dissection, monitored for 14 years without recurrence or relapse (Table 2); b) white, male, 76 years old, melanoma in the sternal region with metastatic lymph node in the right axillary region; lymph node dissection, followed for 14 years without recurrence or emergence of a new tumor (Table 2); c) white, male, 51 year old, acral lentiginous melanoma on the right heel. He showed two lymph node metastasis in the right inguinal lymph node chain and one in the right aortoiliac chain, having been followed for 18 years, without recurrence or appearance of new tumors (Table 2).

Table 3 - Staging of cutaneous melanoma (AJCC 2002/2009)⁹.

Stage	Tumor (T)	Lymph nodes (N)	Metastasis (M)
I A	< 1mm Clark II/III without histological ulceration	Ø	Ø
I B	< 1mm Clark IV/V with histological ulceration 1,01 – 2 mm without histological ulceration	Ø	Ø
II A	1,01 – 2 mm with histological ulceration 2,01 – 4 mm without histological ulceration	Ø	Ø
IIB	2,01 – 4 mm with ulceration > 4mm without ulceration	Ø	Ø
II C	> 4mm with histological ulceration	Ø	Ø
IIIA	<1mm a >4mm without ulceration <1mm a >4mm Without ulceration	Ø 1 micrometastasis 1 a 3 micrometastases	Ø Ø Ø
III B	<1mm a >4mm with or without histological ulceration transit metastasis satellitosis	1 a 3 micrometastases 2 a 3 macrometastases	Ø
III C	<1mm a >4mm histological ulceration any thick ness satellitosis transit metastasis	Confluent lymph nodes 1 macrometastasis 2 to 3 or more than 4 macrometastases	Ø

Local recurrences are defined as tumor relapse within 3 to 5 cm from the primary closure or graft and are considered to be rare (3.2%). The ulceration and the thickness of the primary tumor, as well as the location in the head and neck, are considered predisposing factors ⁷.

Although the subject is controversial and our monitoring time exceeded the period adopted by some centers^{6,12}, we concluded that it was possible to endorse the discharge of patients in stages IA, IB, IIA, IIC, IIIB and IIIC.

R E S U M O

Objetivo: realizar a avaliação da alta em um grupo de pacientes com melanoma cutâneo de acordo com critérios recentemente estabelecidos. **Métodos:** estudo observacional de corte transversal de 32 pacientes com melanoma cutâneo atendidos no HUCFF/UFRJ, entre 1995 e 2013, nos seguintes estágios: IA (17 casos/53,12%), IB (4 casos/12,5%), IIA (3 casos/9,37%), IIC (1 caso/3,12%), IIIB (1 caso/3,12%), IIIC (3 casos/9,37%), melanomas in situ (2 casos/6,25%), Tx (1 caso/3,12%). **Resultados:** o tempo de seguimento ambulatorial variou de um a 20 anos (estágio IA), cinco a 15 anos (estágio IB), de seis a 17 anos (estágio IIA), 20 anos (estágio IIC), 23 anos (estágio IIIB) e de 14 a 18 anos (estágio IIIC). O melanoma Tx foi acompanhado por 12 anos, um melanoma in situ teve alta imediata e outro, subungueal, permaneceu em acompanhamento por quatro anos. Não foram observadas recidivas ou recorrências. **Conclusão:** houve adequação do procedimento de alta nos estágios IA, IB, IIA, IIC, IIIB e IIIC.

Descritores: Estudos prospectivos. Melanoma. Melanoma/epidemiologia. Seguintes. Estadiamento de neoplasias.

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Importance of flexible bronchoscopy in decannulation of tracheostomy patients

Importância da broncoscopia flexível na decanulação dos pacientes traqueostomizados

LEONARDO BRAND RODRIGUES^{1,2}; TARCIZO AFONSO NUNES¹

A B S T R A C T

Objective: To evaluate the importance of flexible bronchoscopy in tracheostomy patients in the process of decannulation to assess the incidence and types of laryngotracheal injury and compare the presence of such lesions with clinical criteria used for decannulation. **Methods:** We studied 51 tracheostomized patients aged between 19 and 87 years, with tracheal stent for a mean of 46 ± 28 days and with clinical criteria for decannulation. They were submitted to tracheostomy tube occlusion tolerance test for 24 hours, and then to flexible bronchoscopy. We described and classified the diagnosed laryngotracheal changes. We compared the clinical criteria for decannulation indication with the bronchoscopy-diagnosed laryngotracheal injuries that contraindicated decannulation. We identified the factors that could interfere in decannulation and evaluated the importance of bronchoscopy as part of the process. **Results:** Forty (80.4%) patients had laryngotracheal alterations. Of the 40 patients considered clinically fit to decannulation, eight (20%) ($p = 0.0007$) presented with laryngotracheal injuries at bronchoscopy that contraindicated the procedure. The most frequent laryngeal alteration was vocal cords lesion, in 15 (29%) individuals, and granuloma, the most prevalent tracheal lesion, in 14 (27.5%) patients. **Conclusion:** flexible bronchoscopy showed a large number of laryngotracheal injuries, the most frequent being the vocal cords injury in the larynx and the granuloma in the trachea, which contributed to increase the decannulation procedure safety.

Key words: Bronchoscopy. Tracheostomy. Tracheal diseases. Tracheomalacia. Intubation, Intratracheal.

INTRODUCTION

Tracheostomy is performed in about 20% of patients who are on mechanical ventilation in the intensive care unit¹. It is indicated to increase comfort and facilitate weaning², reducing the rate of laryngotracheal complications caused by the long permanence of the orotracheal tube³, and as a safe airway in cases of obstruction of the upper airways. However, the presence of tracheostomy causes bronchorrhea, changes in the swallowing mechanism⁴, increased risk of airway infection and bleeding and hampers vocalization^{5,6}. Late complications are diagnosed in 65% of patients, the most frequent being the granuloma, followed by lesions with high morbidity and mortality such as malacia, stenosis, and vascular and esophageal fistulas^{7,8}. To avoid these complications, the patient decannulation should be performed as early as possible.

Proper patient assessment before the removal of the cannula has been neglected^{5,9}, and the literature is lacking in studies that indicate the criteria and the best time to carry this out¹⁰. Decannulation failure is characterized when it is necessary to reintroduce the artificial airway in the 48 hours following the removal of the tracheal cannula.

This occurs in up to 5% of cases and may be associated with acute respiratory failure^{6,10}.

The stringent multidisciplinary clinical evaluation associated with anatomical and physiological assessment of the larynx and trachea contributes to select patients who may be decannulated with more chances of success. The examination by flexible bronchoscopy is important to help decide on the time of decannulation, but is little used and without a detailed protocol^{10,11}.

This study aimed to evaluate the importance of flexible bronchoscopy in tracheostomy patients in the process of decannulation to know the incidence and types of laryngotracheal injuries and to compare the presence of such lesions with the clinical criteria used for decannulation.

METHODS

This was a prospective study in patients in tracheostomy decannulation process at the Hospital Odilon Behrens, in Belo Horizonte – MG. The study was approved by the Departmental Board of the Department of Surgery of FM-UFMG and by the Ethics in Research Committee of

1. Faculty of Medicine, Universidade Federal de Minas Gerais; 2. Hospital Odilon Behrens.

the Odilon Behrens County Hospital (FR 301247). All patients agreed to participate and signed a free and informed consent.

Sample calculation

To calculate the sample size, we used the records of the Department of Thoracic Surgery at the Odilon Behrens Hospital. We analyzed data of patients who met clinical criteria for decannulation and were referred to bronchoscopy to evaluate decannulation. Eighteen (72%) tolerated the occlusion of the cannula, and in three, bronchoscopy diagnosed laryngotracheal injuries contraindicating decannulation (16.6% failure). So we used the hypothesis test for a proportion that considers the binomial distribution for sample power calculation¹², considering a power of 80% with a 5% significance level and estimated the total size of the sample patients.

Sample characterization

We studied patients over 18 years, from March 2010 to January 2011, who met the following inclusion criteria: clinical stability, spontaneous ventilation for at least 48 hours; absence of infection at the time of decannulation indication; absence of new surgical procedure in the same hospital; effective coughing and swallowing; Glasgow coma scale > 8. The patients were examined by a multidisciplinary team including physicians, physical therapists, speech therapists and nurses. In order to be uniformity in the assessments of patients, the multidisciplinary team attended a continuing education program, which extended throughout the period of the survey data collection. The sample comprised 51 patients, 26 female and 25 male, median age 55 years (19-87 years), 22 brown, 19 white and ten black.

Four (7.8%) patients reported using illicit drugs. Associated diseases were diagnosed in 45 (88.2%) patients, with prevalence of diabetes mellitus (23.5%). Only seven (13.72%) patients had complications related to tracheostomy and overcame the cannulation difficulty (11.8%). The most prevalent clinical condition that led to tracheal intubation or tracheostomy was stroke (27.5%), followed by pneumonia (19.6%), surgery, trauma, sepsis and airway obstruction (each corresponding to 4% of patients). Periods of tracheal stent and mechanical ventilation can be seen in figure 1.

Composition of groups

Patients who met the inclusion criteria underwent placement of a standard number 4 metal cannula, Fadel-Med® brand, with an 7.5 mm internal diameter of, 10mm external and 7cm length, regardless of the cannula they were previously using. The cannula remained occluded for 24 hours, during which the patients were evaluated for chest expansion, breathing frequency and pattern, lung auscultation, heart rate, pulse and blood pressure. Patients should present with parameters better or equal to the ones

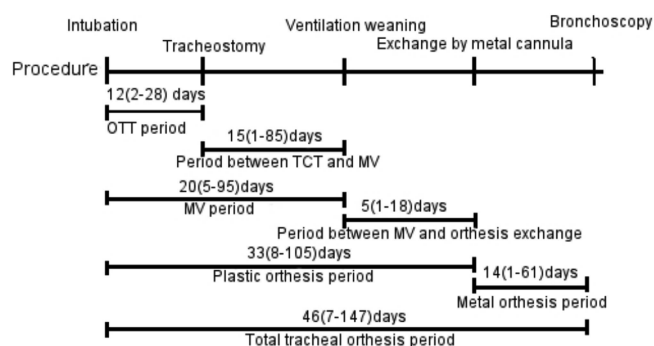


Figure 1- Periods of tracheal cannula and mechanical ventilation.

* OTT - tracheal tube, TCT - tracheostomy, MV - mechanical ventilation.

found before cannula occlusion. Thus, we divided patients in two groups, based on the results of the tracheostomy cannula occlusion: Group A – tolerated; and group B – non-tolerated. We considered that patients of group A met the clinical criteria of decannulation and group B did not present these criteria.

Bronchoscopy





We subjected patients in Groups A and B to laryngotracheobronchial endoscopy by the same examiner after 24 hours of cannula occlusion. The average period between cannula occlusion and the procedure was 1.7 days (1-7 days). The procedure was performed in the bronchoscopy room, with a flexible bronchoscope (Olympus, model BF-P60, optical, 4.9mm working channel external diameter) and local anesthesia with 10% lidocaine spray at a dose of 30mg, 5ml of lidocaine jelly in the nasal cavity and 1% lidocaine without vasoconstrictor. The cannula was removed to facilitate tracheal examination, as well as to dynamically assess of forced expiration and inspiration. For dynamic obstructions, such as tracheomalacia, we considered the lowest tracheal diameter during forced expiration. To assess the obstruction of the tracheal lumen, we employed the Cotton classification¹³. Patients with vocal cords bilateral lesions in adduction or subglottic or tracheal obstruction grade II Cotton or higher (Figure 2) were considered endoscopically unfit for decannulation¹¹.

Upon completion of bronchoscopy, and based on clinical evaluation, groups A and B were subdivided into four groups: A1, B1, A2 and B2. Patients in group A1 were decannulated after bronchoscopy and remained in hospital under observation for at least 48 hours. Patients in the B1 group were reassessed after clinical improvement, with subsequent decannulation after they tolerated a new occlusion period. Patients in the A2 and B2 groups remained tracheostomized, with an appropriate cannula for each identified lesion, and were referred to the Thoracic Surgery Clinic.

Variables studied and statistical tests

We described and classified the laryngotracheal lesions identified at bronchoscopy and expressed the result

Table 2 - Cotton Classification¹³ according to the percentage of tracheal lumen obstruction.

Grade I	without obstruction– up to 50% obstruction	
Grade II	51% to 70% obstruction	
Grade III	71% to 99% obstruction	
Grade IV	complete obstruction	

as percentage. We then compared patients' groups formed by decannulation clinical and bronchoscopic criteria.

The highest decannulation failure rate described among patients who fulfilled the clinical criteria for decannulation is 5%⁹. Bilateral lesions of the vocal cords and / or tracheal obstruction greater than Cotton grade II at bronchoscopy are at higher risk of respiratory failure without the use of tracheostomy. Hence, we compared the evolution of groups A1, A2, B1 and B2 by employing Fisher's test¹⁴.

Bronchoscopy is the best test for diagnosing laryngotracheal changes that contraindicate decannulation, so we carried out the analysis of clinical efficacy criteria by comparison between the predictive value found after bronchoscopic validation and the one described in the literature – 95% decannulation success. We considered null hypothesis (H_0) the positive predictive value of clinical criteria equal or greater than 95%, and as an alternative hypothesis (H_A) the positive predictive value being lower than 95%¹⁵.

RESULTS

Nine (17.6%) patients had no laryngotracheal changes. In 42 (82.4%) lesions were diagnosed, 20 with (39.2%) one and 22 (43.1%) with two or more lesions, as described: paresis or paralysis of the vocal cord in adduction or abduction in 15 (29%) patients, eight (15.7%) having bilateral lesions. All of them were associated with paresis of the corresponding hemilarynx; scar tissue suggesting granuloma in 14 (27.5%) patients, all located in the tracheostoma, determining grade I obstruction; depression of the anterior wall of the tracheostoma in six (11.8%) patients, determining tracheal grade I obstruction; tracheostoma in improper anatomical position, lateral to the midline of the trachea anterior wall in ten (19.6%) patients; laryngotracheal obstruction in 22 (43.1%), tracheomalacia in 12 (60%), five (25%) laryngotracheomalacias and five (25%) stenoses. According to the Cotton classification, we found the following degrees

of obstruction: Nine (17.6%) grade I, nine (17.6%) grade II, two (3.9%) grade III and two (3.9%) grade IV.

Forty patients tolerated cannula occlusion, but bronchoscopy diagnosed laryngotracheal injuries in eight (20%), for whom we contraindicated decannulation. Of the 11 patients who did not tolerate occlusion of the cannula, bronchoscopy showed no injuries that prevented decannulation in two (18.2%). Ten (19.6%) patients benefited from bronchoscopy, since it decreased the risk of decannulation failure in eight and avoided cannula permanence in two (Table 1). By employing bronchoscopy as one decannulation criteria, we found 20% of laryngotracheal injuries that could determine failure in the decannulation process. Thus, considering the binomial distribution, we rejected the null hypothesis that 95% of patients who meet the clinical criteria tolerate decannulation ($p < 0.007$). The decannulated patients who met the clinical and bronchoscopic criteria for decannulation had no complications and required no new tracheal cannula.

DISCUSSION

In the period when we conducted the survey, 240 patients were submitted to tracheostomy and only 51 (21.3%) met the clinical criteria for decannulation^{6,10}. This variation can be explained by the difference in the method used for patients inclusion in the various studies, as there was difference in the number and types of clinical criteria used to define the patient as clinically fit to decannulation^{5,6,10,16}. While in these studies patients remained with tracheostomy for prolonged periods (average of up to 147 days)¹⁷, in this study the average time was 33 days.

Lesions that affect 50% or more of the tracheal diameter are a contraindication to decannulation. From this degree of obstruction on, marked changes in pulmonary function tests may occur, with clinical repercussions^{10,18,19}. One study, however, considers that obstructions are significant when affecting 20% of the tracheal diameter¹⁷.

Table 1 - Description of patients fit for decannulation through clinical criteria, but contraindicated by Bronchoscopy (n = 8).

Patients	Age (years)	Associated Diseases	Clinical conditions that prompted orotracheal intubation or tracheostomy	Plastic Orthosis Period (days)	Bronchoscopic laryngotracheal changes contraindicating decannulation
1	26	—	Convulsive crisis	74	Bilateral paresis of vocal cords in adduction
2	81	DM, SAH, COPD	Trauma	105	Grade II tracheomalacia
3	54	SAH, AMI	Airway obstruction	24	Grade II tracheomalacia
4	88	DM, SAH, COPD, CRF, CHF	STROKE	26	Grade II tracheomalacia
5	55	DM, SAH	Sepsis	41	Grade II tracheomalacia
6	53	DM, SAH, muscular dystrophy	Pneumonia	49	Grade II tracheomalacia
7	70	SAH, Obesity	STROKE	30	Grade II tracheomalacia
8	64	COPD, CHF	Decompensated CHF	25	Bilateral paresis of vocal cords in adduction

DM -diabetes mellitus; **SAH** -systemic arterial hypertension; **COPD** – chronic obstructive pulmonary disease; **AMI** -acute myocardial infarction; **CRF** – chronic renal failure; **CHF** -congestive heart failure; **STROKE** -stroke.

In adults, the tracheal diameter is 20 mm in women and 23 mm in men⁸, which is why we used a number 4 metal cannula with 10mm external diameter at the time of decannulation, since when occluded, it represents about 50% of tracheal lumen obstruction.

We consider flexible bronchoscopy necessary before decannulation, like other authors^{17,20}, due to the method's sensitivity in diagnosing laryngotracheal anatomical and functional lesions²¹ that are common in tracheostomy patients. This test is considered safe and its complication rates are less than 1%²². In the present study there were no complications that prevented laryngotracheal assessment or that worsened patients' clinical status.

Granulomas were found in 27.5% of patients, all in the tracheostoma region, without determining airflow obstruction (Cotton Grade I). We found laryngotracheomalacias and laryngotracheal stenoses in 33.3% and 9.8% of patients, respectively, regardless of the degree of obstruction they caused. Some authors have observed similar findings when using flexible bronchoscopy as a criterion for decannulation^{7,17}.

Lesions that determined Cotton grades II, III and IV obstructions were diagnosed in 25.5% of patients. We did not find fistulas or bulky bleeding, which is in accordance with the literature^{7,17}. We found changes in vocal cords in 29.4% of patients, in eight patients the lesions were bilateral, and in 87.5% of the lesions the vocal cords were in adduction.

Patients who met the decannulation clinical criteria, but not the bronchoscopic ones, could have been decannulated without evolving with respiratory failure. One should consider that patients confined to bed or who, for other reasons, did not perform physical exertion, and might not present respiratory failure, even with obstructions larger than 50% of the tracheal lumen or bilateral vocal cord

paresis in adduction. This fact may have contributed to explain the difference between the 20% considered as failure, found in this study, and 5% described in the literature¹⁷. However, we considered that the decannulation of specific cases would be better evaluated after prolonged follow-up of the patient and recovery of symptoms, which determined the alternative airway maintenance. Considering the clinical criteria for the decannulation, bronchoscopy benefited ten (19.6%) patients, since it contraindicated decannulation in eight and identified two who did not have lesions that would contraindicate decannulation by clinical criteria. One study¹⁸ found that only the clinical criteria would be sufficient and safe to indicate decannulation. However, the author has employed a method different from ours regarding the sample, the inclusion criteria, the cannula to be occluded with large diameter, the difference in the description of laryngotracheal injuries, as well as the different bronchoscopy diagnoses. Thus, the comparison of the results rendered inadequate.

Clinical circumstances which led to tracheal intubation or tracheostomy, associated diseases and age did not influence decannulation, which is in line with the results of the literature¹⁷. Nonetheless, the number of patients was insufficient for statistical evaluation on these relationships. Patients with diabetes mellitus, however, were more likely to decannulation contraindication by bronchoscopy, even when meeting the clinical criteria ($p = 0.04$). This fact can be explained by changes in scarring mechanisms, since the four diabetic patients with favorable decannulation clinical criteria had unfavorable bronchoscopic ones due to the presence of tracheomalacia. We did not find this data in the literature.

Among the 15 patients with vocal cord lesions and 22 who presented laryngotracheal stenosis, the average time they remained with the tracheal tube was 10.06 days.

the Odilon Behrens County Hospital (FR 301247). All patients agreed to participate and signed a free and informed consent.

Sample calculation

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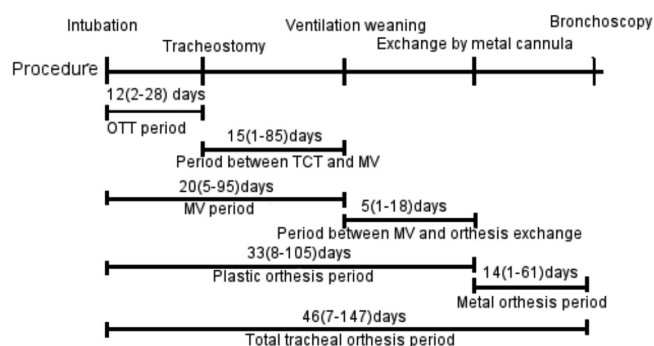


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RESULTS

Nine (17.6%) patients had no laryngotracheal changes. In 42 (82.4%) lesions were diagnosed, 20 with (39.2%) one and 22 (43.1%) with two or more lesions, as described: paresis or paralysis of the vocal cord in adduction or abduction in 15 (29%) patients, eight (15.7%) having bilateral lesions. All of them were associated with paresis of the corresponding hemilarynx; scar tissue suggesting granuloma in 14 (27.5%) patients, all located in the tracheostoma, determining grade I obstruction; depression of the anterior wall of the tracheostoma in six (11.8%) patients, determining tracheal grade I obstruction; tracheostoma in improper anatomical position, lateral to the midline of the trachea anterior wall in ten (19.6%) patients; laryngotracheal obstruction in 22 (43.1%), tracheomalacia in 12 (60%), five (25%) laryngotracheomalacias and five (25%) stenoses. According to the Cotton classification, we found the following degrees

of obstruction: Nine (17.6%) grade I, nine (17.6%) grade II, two (3.9%) grade III and two (3.9%) grade IV.

Forty patients tolerated cannula occlusion, but bronchoscopy diagnosed laryngotracheal injuries in eight (20%), for whom we contraindicated decannulation. Of the 11 patients who did not tolerate occlusion of the cannula, bronchoscopy showed no injuries that prevented decannulation in two (18.2%). Ten (19.6%) patients benefited from bronchoscopy, since it decreased the risk of decannulation failure in eight and avoided cannula permanence in two (Table 1). By employing bronchoscopy as one decannulation criteria, we found 20% of laryngotracheal injuries that could determine failure in the decannulation process. Thus, considering the binomial distribution, we rejected the null hypothesis that 95% of patients who meet the clinical criteria tolerate decannulation ($p < 0.007$). The decannulated patients who met the clinical and bronchoscopic criteria for decannulation had no complications and required no new tracheal cannula.

DISCUSSION

In the period when we conducted the survey, 240 patients were submitted to tracheostomy and only 51 (21.3%) met the clinical criteria for decannulation^{6,10}. This variation can be explained by the difference in the method used for patients inclusion in the various studies, as there was difference in the number and types of clinical criteria used to define the patient as clinically fit to decannulation^{5,6,10,16}. While in these studies patients remained with tracheostomy for prolonged periods (average of up to 147 days)¹⁷, in this study the average time was 33 days.

Lesions that affect 50% or more of the tracheal diameter are a contraindication to decannulation. From this degree of obstruction on, marked changes in pulmonary function tests may occur, with clinical repercussions^{10,18,19}. One study, however, considers that obstructions are significant when affecting 20% of the tracheal diameter¹⁷.

Table 1 - Description of patients fit for decannulation through clinical criteria, but contraindicated by Bronchoscopy (n = 8).

Patients	Age (years)	Associated Diseases	Clinical conditions that prompted orotracheal intubation or tracheostomy	Plastic Orthosis Period (days)	Bronchoscopic laryngotracheal changes contraindicating decannulation
1	26	—	Convulsive crisis	74	Bilateral paresis of vocal cords in adduction
2	81	DM, SAH, COPD	Trauma	105	Grade II tracheomalacia
3	54	SAH, AMI	Airway obstruction	24	Grade II tracheomalacia
4	88	DM, SAH, COPD, CRF, CHF	STROKE	26	Grade II tracheomalacia
5	55	DM, SAH	Sepsis	41	Grade II tracheomalacia
6	53	DM, SAH, muscular dystrophy	Pneumonia	49	Grade II tracheomalacia
7	70	SAH, Obesity	STROKE	30	Grade II tracheomalacia
8	64	COPD, CHF	Decompensated CHF	25	Bilateral paresis of vocal cords in adduction

DM -diabetes mellitus; **SAH** -systemic arterial hypertension; **COPD** – chronic obstructive pulmonary disease; **AMI** -acute myocardial infarction; **CRF** – chronic renal failure; **CHF** -congestive heart failure; **STROKE** -stroke.

In adults, the tracheal diameter is 20 mm in women and 23 mm in men⁸, which is why we used a number 4 metal cannula with 10mm external diameter at the time of decannulation, since when occluded, it represents about 50% of tracheal lumen obstruction.

We consider flexible bronchoscopy necessary before decannulation, like other authors^{17,20}, due to the method's sensitivity in diagnosing laryngotracheal anatomical and functional lesions²¹ that are common in tracheostomy patients. This test is considered safe and its complication rates are less than 1%²². In the present study there were no complications that prevented laryngotracheal assessment or that worsened patients' clinical status.

Granulomas were found in 27.5% of patients, all in the tracheostoma region, without determining airflow obstruction (Cotton Grade I). We found laryngotracheomalacias and laryngotracheal stenoses in 33.3% and 9.8% of patients, respectively, regardless of the degree of obstruction they caused. Some authors have observed similar findings when using flexible bronchoscopy as a criterion for decannulation^{7,17}.

Lesions that determined Cotton grades II, III and IV obstructions were diagnosed in 25.5% of patients. We did not find fistulas or bulky bleeding, which is in accordance with the literature^{7,17}. We found changes in vocal cords in 29.4% of patients, in eight patients the lesions were bilateral, and in 87.5% of the lesions the vocal cords were in adduction.

Patients who met the decannulation clinical criteria, but not the bronchoscopic ones, could have been decannulated without evolving with respiratory failure. One should consider that patients confined to bed or who, for other reasons, did not perform physical exertion, and might not present respiratory failure, even with obstructions larger than 50% of the tracheal lumen or bilateral vocal cord

paresis in adduction. This fact may have contributed to explain the difference between the 20% considered as failure, found in this study, and 5% described in the literature¹⁷. However, we considered that the decannulation of specific cases would be better evaluated after prolonged follow-up of the patient and recovery of symptoms, which determined the alternative airway maintenance. Considering the clinical criteria for the decannulation, bronchoscopy benefited ten (19.6%) patients, since it contraindicated decannulation in eight and identified two who did not have lesions that would contraindicate decannulation by clinical criteria. One study¹⁸ found that only the clinical criteria would be sufficient and safe to indicate decannulation. However, the author has employed a method different from ours regarding the sample, the inclusion criteria, the cannula to be occluded with large diameter, the difference in the description of laryngotracheal injuries, as well as the different bronchoscopy diagnoses. Thus, the comparison of the results rendered inadequate.

Clinical circumstances which led to tracheal intubation or tracheostomy, associated diseases and age did not influence decannulation, which is in line with the results of the literature¹⁷. Nonetheless, the number of patients was insufficient for statistical evaluation on these relationships. Patients with diabetes mellitus, however, were more likely to decannulation contraindication by bronchoscopy, even when meeting the clinical criteria ($p = 0.04$). This fact can be explained by changes in scarring mechanisms, since the four diabetic patients with favorable decannulation clinical criteria had unfavorable bronchoscopic ones due to the presence of tracheomalacia. We did not find this data in the literature.

Among the 15 patients with vocal cord lesions and 22 who presented laryngotracheal stenosis, the average time they remained with the tracheal tube was 10.06 days.

Even this being a long tracheal tube period, they showed no statistical difference when compared with patients without injuries. There are reports that the intubation time increases the number of laryngotracheal injuries and, therefore, the occurrence of decannulation failure, but there is controversy^{17,23} and the number of patients of this study was insufficient to contribute towards clarifying such doubts. Randomized studies are needed to better identify the factors that interfere in decannulation¹⁷. Whereas not only the tracheal tube, but any orthosis, can cause laryngotracheal damage, upon analysis of the periods of tracheal cannula use evaluated in this study, only the longest period of plastic orthosis use (tracheal tube plus tracheostomy plastic cannula) related significantly with the diagnosis of laryngotracheal injuries at bronchoscopy ($p = 0.04$). However, since this period interacts with other variables, such as the period between the tracheostomy and the end of mechanical ventilation, mechanical ventilation time, period of endotracheal tube use, period of tracheostomy plastic cannula use, and total orthosis period, including the period of metallic cannula (Figure 1), we used multiple logistic regression to the group of variables related to the period of tracheal cannula usage and which had significance less than 0.25²⁴. The goal was to determine whether one of the periods of total plastic orthosis alone could be related as cause and effect of the existence of laryngotracheal injuries contraindicating decannulation. The adjustment of logistic regression was affected by multicollinearity (positive correlation between the measured time variables) and none of the variables were significant.

One limitation of this study is the use of subjective criteria for classifying injuries that cause airflow obstruction. The Cotton classification¹³ is based on direct endoluminal observation, without a specific instrument to measure the area of tracheal lumen obstruction. Another limitation encountered was the difficulty of patients' monitoring after hospital discharge. However, most of the complications that cause decannulation failure occur in the first 48h^{9,25}, during which the patients in this study were hospitalized. The number of research subjects was sufficient to assess the benefit of performing bronchoscopy as a decannulation criterion. Nevertheless, we could not identify the factors that make bronchoscopy indispensable or dispensable for decannulation. In this paper we developed a protocol using clinical criteria that are consensus among most researchers, together with the most appropriate method for assessing the laryngotracheal region^{5,6,10,26}, aimed at providing safety to the patient at the time of decannulation. More prospective studies are needed to determine the usefulness of bronchoscopy in the evaluation of decannulation. Methods are needed to describe laryngotracheal injuries in an objective and standardized way, possibly altering the bronchoscopic decannulation criteria by identifying which ones can actually be cause of failure.

Flexible bronchoscopy showed a large number of laryngotracheal injuries, the more frequent being in the vocal cords, in the larynx and the tracheal granuloma, which contributed to increase the safety of the decannulation procedure.

R E S U M O

Objetivo: avaliar a importância do emprego, da broncoscopia flexível nos pacientes traqueostomizados em vias de decanulação para conhecer a incidência e os tipos de lesões laringotraqueais e comparar a presença destas lesões com os critérios clínicos utilizados para a decanulação. **Métodos:** foram estudados 51 pacientes, com idade entre 19 e 87 anos, traqueostomizados, com critérios clínicos de decanulação e com tempo médio de órtese traqueal de 46 ± 28 dias. Foram submetidos ao teste de tolerância à oclusão da cânula de traqueostomia por 24 horas, seguida da realização da broncoscopia flexível. As alterações laringotraqueais diagnosticadas foram descritas e classificadas. Comparou-se a indicação de decanulação por critérios clínicos com o diagnóstico de lesões laringotraqueais à broncoscopia que contraindicavam a decanulação. Identificaram-se os fatores que poderiam interferir na decanulação e avaliou-se a importância da broncoscopia como parte do processo. **Resultados:** Apresentaram alterações laringotraqueais, 40 pacientes (80,4%). Dos 40 pacientes considerados clinicamente aptos à decanulação, oito (20%) ($p=0,0007$) apresentaram lesões laringotraqueais à broncoscopia que contraindicaram o procedimento. A alteração laríngea mais frequente foi lesão de pregas vocais em 15 (29%) e o granuloma, a lesão traqueal mais prevalente em 14 (27,5%) pacientes. **Conclusão:** a broncoscopia flexível evidenciou um número elevado de lesões laringotraqueais, sendo mais prevalentes a lesão de pregas vocais na laringe e o granuloma na traqueia, que contribuiu para aumentar a segurança do procedimento de decanulação.

Descritores: Procedimentos Cirúrgicos Bronoscópicos. Traqueostomia. Traqueopatias. Traqueomalácia. Intubação Intratraqueal

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Ultrasonografic changes in the axillary vein of patients with lymphedema after mastectomy

As alterações ultrassonográficas na veia axilar de portadoras de linfedema pós-mastectomia

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A B S T R A C T

Objective: to determine the prevalence of sonographic abnormalities (SA) in the axillary vein of patients with and without post-mastectomy lymphedema. **Methods:** We studied a sample of 80 women, divided into two equal groups, with and without lymphedema, with B mode ultrasound, color and pulsed Doppler. The primary variable, SA, is defined as change in the venous diameter, parietal thickening, intraluminal images, compressibility, parietal collapse at inspiration and feature of the axillary venous flow on the operated side. Secondary variables were: stage of lymphedema, surgical technique, number of radio and chemotherapy sessions, limb volume, weight and age. The differences between the proportions in the groups were determined using the Chi-square test and / or Fisher's test. For continuous variables, we used the Mann-Whitney Test. To estimate the magnitude of the associations, we used the prevalence rate of SA in both groups as a measure of frequency, and as a measure of association, the prevalence ratio (PR) obtained as a function of relative risk (RR) and estimated by the test Mantel-Haenszel homogeneity test. We adopted the statistical significance level of 5% ($p \leq 0.05$). **Results:** only the criterion "parietal thickening" was strongly associated with the lymphedema group ($p = 0.001$). The prevalence of SA was 55% in patients with lymphedema and 17.5% in the group without it, with difference in prevalence of 37.5%. **Conclusion:** the prevalence of SA was higher in patients undergoing mastectomy with lymphedema than in those without lymphedema.

Key words: Breast cancer. Axillary Vein. Lymphedema. Ultrasonography.

INTRODUCTION

Many authors believe in the participation of the venous system in the post-mastectomy lymphedema of the upper limb^{1,2}, which caused the phlebographic study of venous hemodynamics in post-mastectomy lymphedema (PML), with finding of 20% obstruction³. The flow measurement through the Doppler effect showed increased venous pressure in the upper lymphedematous limb⁴. The study of the axillary vein with color Doppler ultrasound and flow speed analysis found between abnormalities in 57% to 70%⁵. This noninvasive method is currently considered the one of choice to study the venous system, especially in patients with PML⁵⁻⁸.

However, some issues remain unclear, including the reasons for the wide variation in the incidence of PML over the postoperative years⁹ and whether the axillary venous disease relates to the PML.

Are there factors absent during surgery that present throughout the postoperative outcome that may influence the onset of post-mastectomy lymphedema? May there be venous factors of late onset? Would the individuals with PML also be suffering from axillary vein post-thrombotic disease? If the cause of venous involvement is associated with the surgical technique and the use of radiation therapy, and if there is a cumulative curve of incidence of the PML, how does the axillary vein behave in the presence of PML over time? Might the changes of the axillary vein have predictive value with respect to the development of PML? Can Ultrasound axillary vein patterns be established that correlate to the different degrees of installed PML?

Finally, is there a difference between the prevalence of changes in the axillary vein or around it detectable by axillary US in patients undergoing mastectomy with and without upper limb lymphedema?

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METHODS

This was a prevalence study conducted in 80 patients who underwent mastectomy and radiation therapy, who were attended sequentially and allocated into two groups: with lymphedema ($n = 40$) and without lymphedema ($n = 40$). Patients with the following conditions were excluded: bilateral mastectomy or non-neoplastic causes, lack of post-mastectomy radiotherapy treatment, history of central venous puncture, edema of upper limbs prior to mastectomy of venous or lymphatic origin, acute infection of the affected limb, psychiatric disorders, age lower than 18 years, indigenous people, pregnant women, prisoners and men. The study was approved by the Ethics in Research Committee of the Hospital Aristides Maltez (HAM) on 31/08/2009, Protocol 23/09, and all participants signed a free and informed consent.

We used ultrasound equipment model Sonoace X8 or SA 8000EX Prime, with a 5-12 MHz multifrequency linear transducer, both from Medison Co. Ltd., 1003 Daechi-dong, Gangnam-gu, Seoul 135-280 Korea. We searched the following sonographic abnormalities (SA) in the transverse and longitudinal directions: increase in venous diameter, parietal thickness, echogenic material inside the vein, compressibility, decrease or loss of collapsing capacity of venous walls upon deep breathing, and loss of phasic blood flow rate^{5,10-12}.

As secondary variables, we studied the stage of lymphedema, surgical technique, number of radio and chemotherapy sessions, limb volume, weight and age. Lymphedema stadium was clinically defined by inspection and palpation, and later revised to verify that it agreed with the findings of volume and classified according to the standard adopted by the International Society of Lymphology¹³.

The volume of the limb was indirectly obtained by calculation of the cone section volume¹⁴. To obtain the volume of each of the upper limbs, we represented each one as a succession of cone sections (Figure 1A), exemplified on a right upper member¹⁵. The calculation of the volume of each cone section was obtained with the measures of the radii of the circles at the bottom and at the top of the section and their heights, which correspond to the length of the represented limb segments, defined as the distance between two circumferences on the selected points. We measured the circumference of the hand, lower third of the forearm 2 cm above the wrist, middle third midway between the wrist and the elbow, upper third of the forearm, 2 cm below the elbow fold, lower third of the arm and to 65% of distance from the elbow to the shoulder. Additionally, we measured the total distance between the lower (hand) and top (upper arm) measurements by proportionality dividing this total value by the lengths of the segments, obtaining with the h values (Figure 1B). As it was not possible to obtain the radius of the circle directly in the studied member, we used the measurement of the

circumference, and with this value we calculated the radius: $R=C/2\pi$, where C is the circumference.

Results were imputed to the mathematical formula for calculating the volume of the cone sections, and the sum of the volumes obtained for each segment provided the measure of the total volume member. For calculating the volume we used the following formula:

$$V = \frac{\pi \cdot h}{3} \cdot (R^2 + R \cdot r + r^2)$$

where V is the volume, h is the height of the truncated cone, R is the radius of the larger base and r is the radius of the smaller base.

From the height and weight, we calculated the participants' body mass index (BMI).

The surgical technique and the operated side were searched by direct vision of the surgical area and by consulting the records. In the complete absence of the

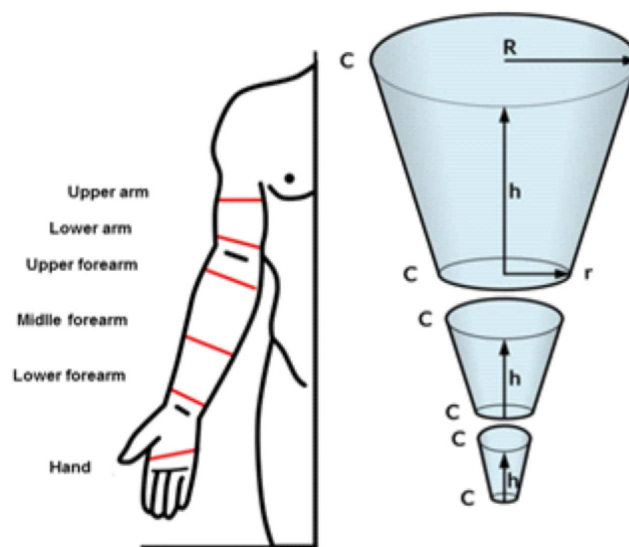


Figure 1A

Figure 1B

Figure 1 - A- Notable places or local measurements of the circumference to obtain the perimetry (c); b- cone sections and measures C, h, R and r to calculate the volumes: Where: h = height of the cone section, corresponding to the length of a given limb section, defined between two landmark points; R = Radius calculated on the cone base, which correspond to the calculated value of the circularity taken in one of two landmark points that define the limb's section; CR = cone base circumference, which corresponds to the value calculated for R ; r = radius calculated at the top of the cone, which corresponds to the calculated value of the circularity in the other two landmark points defining the limb section, opposite to where R is calculated; Cr = the cone top circumference, which corresponds to the value calculated for r .

breast, the operation was classified as a total mastectomy and the presence of a nipple, classified as partial. The postoperative time, age, number of sessions of radiotherapy and chemotherapy were obtained by direct research in the medical records.

Statistical method

The sample was calculated with the estimate of the presence of venous disease in people with lymphedema in the proportion of 20%, which was the lowest mean prevalence observed³, and in the population without lymphedema, 1%; we set the power at 80%, significance level of 5 % and two-tailed test. We obtained a convenience, non-probabilistic sample, composed of the first 80 patients who underwent mastectomy and consecutively referred to the ultrasound service that met the inclusion criteria. Descriptive and exploratory analyzes aimed to characterize the groups and verify the goals of the study through descriptive measures (mean, standard deviation and median), distributions of bivariate frequencies and measures of association. The differences between the proportions were verified by using the chi-square test of Pearson and Fisher's exact test (when necessary). To verify differences between continuous variables we used the Mann-Whitney test. To estimate the magnitude of associations we used, as a frequency measure, the prevalence of ultrasound changes (USC) in both groups and, as association measure, the prevalence ratio (PR) obtained as a function of the relative risk (RR) and estimated by the Mantel-Haenszel Uniformity test. In all analyzes, we adopted the level of statistical significance of 5% ($p \leq 0,05$).

RESULTS

The sample

The groups were proportionally similar in age, number of radiotherapy and chemotherapy sessions ($p > 0.005$) and differed with respect to BMI ($p < 0,005$) and postoperative time (Table 1).

The primary variable

We found that out of all the sonographic features used, the one statistically different in the two groups was the thickening of the vein wall ($p = 0.001$), although the collapse at inspiration has been present in greater proportion in those with lymphedema (57.5%), as well as the wall thick aspect (55%). Venous diameter showed little variation between groups. In both groups there was a predominance of phasic blood flow, compressible vein and absence of intraluminal images (Table 2).

Using only the feature "venous wall thickening" as a criterion for defining ultrasound changes due to its significance, there was high risk of such alteration in the group with lymphedema. The difference in prevalence was

37.5%. To estimate the association between the groups and the occurrence of ultrasound changes, we identified a statistically significant association and the increased risk of ultrasound changes of occurrences among those with lymphedema, which was 3.14 times higher compared with the group without lymphedema (Table 3).

We evaluated the gross association between the groups with and without lymphedema and the presence of ultrasound changes (USC) when all defined USC were used. Based on these characteristics, we set up the indicator "presence of ultrasound changes", and we found that the groups did not differ proportionally ($p = 0.762$). We observed a high prevalence of USC in both groups, 85.0% in the group with lymphedema and 82.5% in the group without it (Table 3).

We have not identified a statistically significant association between the groups and the presence of ultrasound changes, nor regarding the increase in the chance of occurrences among those with lymphedema (PR = 1.03; 95% CI: 0.85 to 1.25).

In the case of the ultrasound finding "venous wall thickening" (Figure 2), there is the lower thickness of the skin and normal subcutaneous aspect on the right axilla. The muscle has normal striated image and venous walls are thin and well defined. On the left side, which corresponds to the operated side, the skin is thicker and subcutaneous has a messy aspect, the muscle displays longitudinal lines that are more coarse and refringent, and the venous walls, proximal and distal to the transducer, are thickened with loss of the precise design of the wall.

Secondary variables

By analyzing the relationship between the groups with and without lymphedema and the presence of ultrasound changes (USC) and adjusting for clinical characteristics that define the secondary variables, we decided once again to use for the indicator "presence of USC" only the criterion "venous wall thickening". Regarding the groups with and without lymphedema, there was a 3.14-fold increased risk in the group with lymphedema compared with the group without lymphedema. By observing the prevalence of lymphedema by age group, there is a positive and statistically significant association between the occurrence of venous wall thickening and the clinical occurrence "aged between 47-57 years," after adjusting for age group, with increased risk of 3.82 times compared with other age groups.

With respect to BMI, there was a statistically significant association and increased risk of thickening of the vessel wall occurrences among people with overweight 3.49 fold higher when compared with morbidly obese patients (Table 4).

We also identified a positive and statistically significant association between the clinical occurrence "operated side", interchangeably, and the presence of thickening of the vessel wall. There was an increase in the

Table 1 - Clinical characteristics of patients with and without lymphedema.

Characteristics	With lymphedema n (%)	Without lymphedema n (%)	p value
Age group			
36 a 46 years old	7 (17.5)	6 (15.0)	0.430 ^a
47 a 57 years old	11 (27.5)	18 (45.0)	
58 a 68 years old	13 (32.5)	10 (25.0)	
>69years old	9 (22.5)	6 (15.0)	
Evolutionary stage			
Latent (0)	1 (2.5)	39 (97.5)	0.000
Mild (1)	8 (20.0)	1 (2.5)	
Moderate (2)	21 (52.5)	0 (0.0)	
Severe (3)	10 (25.0)	0 (0.0)	
Volumetric difference in cm ³			
Mean \pm standard deviation	915 \pm 746	84 \pm 56	0.093 ^c
Median	660	73	
BMI			
Overweight	22 (55.0)	32 (80.0)	0.17 ^a
Obese	18 (45.0)	8 (20.0)	
Surgical technique		1.000	
Partial	9 (22.5)	9 (22.5)	
Total	31 (77.5)	31 (77.5)	
Operated side		1.000	
Left	23 (57.5)	22 (55.0)	
Right	17 (42.5)	18 (45.0)	
Postoperative time			
Up to 5 years	14 (35.0)	27 (67.5)	0.007 ^b
6 to 10	14 (35.0)	10 (25.0)	
> 10 years	12 (30.0)	3 (7.5)	
Number of radiotherapy sessions			
Up to 19	2 (5.0)	4 (10.0)	0.220 ^b
20 to 25	24 (60.0)	16 (40.0)	
> 25	14 (35.0)	20 (50.0)	
Number of chemotherapy courses			
None	4 (10.0)	6 (15.0)	0.499 ^b
<5	6 (15.0)	2 (5.0)	
5 to 9	29 (72.5)	30 (75.0)	
10 or more	1 (2.5)	2 (5.0)	
Total patients in group	40 (50.0)	40 (50.0)	

Note: ^a Chi-square test; ^b Chi-square and Fisher's Exact tests; ^c non-parametric Mann-Whitney test.

risk of the independent occurrence "operated side", the increased risk being 3.11 times on the left, while on the right, 3.18 (Table 4).

Total mastectomy also displayed an increased risk of 3.17 times compared with partial mastectomy, with a statistically significant association (95% CI: 1.46 to 6.84).

The number of radiotherapy sessions proved to be positively associated with the presence of thickening of the vessel wall. We identified an increased risk of 9.33 among those with 20 to 25 sessions when compared with other categories, this association being statistically significant (95% CI: 1.36 to 64.15).

The number of chemotherapy sessions was positively associated with the presence of thickening of the vessel wall. There was increased risk of 3.31 times among those with five to nine sessions when compared with other categories, and this association was also statistically significant (95% CI: 1.39 to 7.86).

The lymphedema characteristics showed proportionally similar in age, but differed proportionally in relation to the evolutionary stage, predominantly in grade 2 ($p < 0.005$).

The volumetric study of the limbs revealed the average volume of 915 (\pm 746) ml with a median 660ml in

Table 2 - Characteristics of the groups regarding lymphedema and ultrasonographic criteria used to define the primary indicator variable "presence of ultrasound changes."

Characteristics	With lymphedema n (%)	Without lymphedema n (%)	p value
Changing in diameter			
No	27 (67.5)	24 (60.0)	0.321 ^a
Yes	13 (32.5)	16 (40.0)	
Wall Appearance			
Fine	18 (45.0)	33 (82.5)	0.001 ^a
Thick	22 (55.0)	7 (17.5)	
Intraluminal images			
Yes	1 (2.5)	0 (0.0)	0.500 ^b
Not	39 (97.5)	40 (100.0)	
Compressibility			
Yes	39 (97.5)	37 (92.5)	0.308 ^b
Not	1 (2.5)	3 (7.5)	
Blood flow			
Phasic	40 (100.0)	40 (100.0)	
Continuous			
Collapse at inspiration			
Yes	23 (57.5)	18 (45.0)	0.371 ^a
Not	17 (42.5)	22 (55.0)	
Total patients in group	40 (50.0)	40 (50.0)	

Note: ^a Chi-square test; ^b Chi-square and Fisher's Exact tests; ^c non-parametric Mann-Whitney test;

Table 3 - Estimates of gross association between ultrasound changes and groups with and without lymphedema.

Group	Venous Wall Thickening		
	Prevalence (%)	PR	95% CI
Without lymphedema	7 (17.5)	1.00	—
With lymphedema	22 (55.0)	3.14	1.51 - 6.51
Global prevalence	29 (36.2)		
Difference in prevalence	37.5		

Group	All Ultrasound Changes		
	Prevalence (%)	PR	95% IC
Without lymphedema	33 (82.5)	1.00	—
With lymphedema	34 (85.0)	1.03	0.85 - 1.25
Global prevalence	67 (83.8)		
Difference in prevalence Valor de p	2.5 (0.762)		

Note: PR: Estimated prevalence ratio based on the relative risk by the Mantel-Haenszel Uniformity Test.

limbs with lymphedema and 84 (± 56) ml with a median of 73ml in limbs without lymphedema.

With respect to BMI, we observed that the proportion of obese was twice among those with lymphedema (45%) compared with the group without lymphedema (20%). Therefore, there was a predominance

of women with lymphedema in the obesity range, in a statistically significant manner (p = 0.017).

As for post-operative time, in the group with lymphedema the postoperative period was longer than six years in 65% of cases, while in the group without lymphedema this time was less than six years in 67% cases.

Table 4 - Gross association between venous wall thickening and the groups with and without lymphedema, adjusted by clinical characteristics.

Risk Factor	Total Patients in Group n (%)		Venous Wall Thickening			
			Prevalence n (%)		PR ^a	95% IC
Group						
Without lymphedema	40	(50.0)	7	(17.5)	1.00	-
With lymphedema	40	(50.0)	22	(55.0)	3.14	1.51 - 6.51
Adjusted Association						
Age Group						
36 to 46 years old	13	(16.5)	2	(28.6)	0.86	0.17 - 4.37
47 to 57 years old	29	(36.2)	7	(63.6)	3.82	1.24 - 11.77
58 to 68 years old	23	(28.7)	9	(69.2)	3.46	0.95 - 12.59
> 69 years old	15	(18.7)	4	(44.4)	-	-
IMC						
Overweight	54	(67.5)	12	(54.6)	3.49	1.43 - 8.51
Obese	26	(32.5)	10	(55.6)	2.22	0.62 - 7.91
Left	45	(56.2)	16	(69.6)	3.11	1.19 - 8.09
Right	35	(43.8)	15	(88.2)	3.18	1.03 - 9.79
Total	62	(60.0)	26	(83.9)	3.17	1.46 - 6.84
Surgical technique						
Partial	18	(40.0)	5	(55.6)	3.00	0.38 - 23.7
Total	62	(60.0)	26	(83.5)	3.17	1.46 - 6.84
Postoperative time						
Up to 6 years	41	(51.3)	9	(64.3)	2.31	0.85 - 6.26
6 to 10	24	(30.0)	11	(78.6)	5.71	0.84 - 38.74
> 10 years	15	(18.7)	11	(91.7)	2.00	0.38 - 10.41
Number of radiotherapy sessions						
Up to 19	6	(7.5)	2	(100.0)	-	-
20 to 25	40	(50.0)	20	(83.3)	9.33	1.36 - 64.15
> 25	34	(42.5)	9	(64.3)	1.71	0.65 - 4.52
Number of chemotherapy courses						
None	10	(12.5)	3	(75.0)	-	-
< 5	8	(10.0)	5	(83.3)	1.34	0.30 - 5.96
5 to 9	59	(73.8)	22	(75.9)	3.31	1.39 - 7.86
10 or more	3	(3.7)	1	(100.0)	-	-

Note: PR: Estimated prevalence ratio based on the relative risk by the Mantel-Haenszel method.

The other characteristics were similar. The surgical technique and operated side were proportionally similar in both groups, as well as the number of radiotherapy and chemotherapy sessions ($p > 0.005$).

DISCUSSION

Discussion of the method

Ultrasonography is the diagnostic method of choice in suspected venous thrombosis of any kind in the upper limbs¹⁶. Compared to venography it showed 82% sensitivity and specificity¹⁷. It allows the vision of venous walls and its surroundings, the study of its flow and the effect of physiological maneuvers over it¹⁶, plus the ability

to identify tissue structures around the studied vein¹⁰, which is currently facilitated by the technical feature of the second harmonic, available in our equipment and not reported in previous studies. One can observe axillary vein stenosis by thrombus or post-thrombotic scar, extrinsic compression by adjacent mass and flow acceleration or turbulence. The indirect signs of disease are: the attenuation of the flow wave, reduction of the speed and loss of pulsatile characteristic transmitted by the respiratory and cardiac movement. All these findings should be compared with the contralateral side. Some errors are to be avoided, such as excessive compression with the transducer, which can change the shape and spectrum of blood flow from the vein, temporarily narrowing of the vein by deep breath, and reduced flow to between 3 and

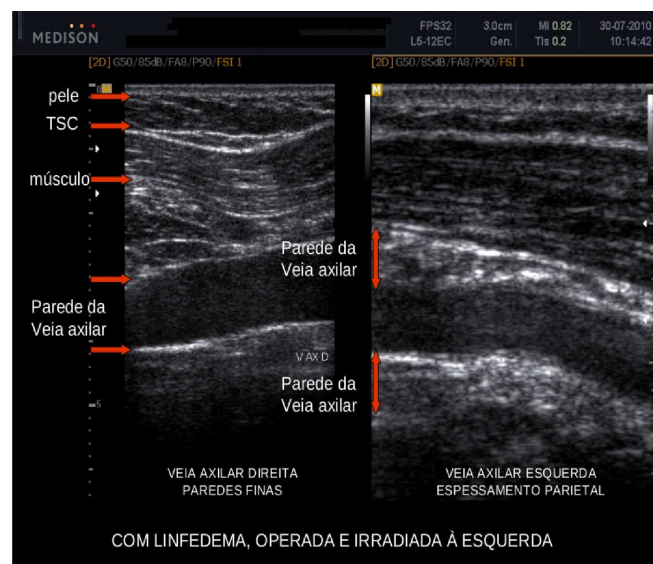


Figure 2 - Parietal thickness in the left axillary vein versus the right vein.

5 cm / s, which can produce absence of color and simulate lack of flow and cause confusion between a great collateral and the axillary vein itself¹¹. In our study there was no lack of vein identification or presence of collateral, and the maneuver to produce the collapse of venous walls was not reliable because obese participants had difficulty getting a deep breath and there was variation in the execution of the maneuver between the various subjects examined. With the surgical dissection and local irradiation, there is the possibility of development of fibrosis in the region, which may reduce the effectiveness of the maneuver¹⁸. The use of ultrasound to study the axillary vein specifically in patients with lymphedema arose from the need to study the possibility of a venous component in the post-mastectomy lymphedema (PML), since we already knew the thrombogenic effects of postoperative radiotherapy on the subclavian and axillary vessels¹⁹.

A preliminary study in four patients shows that the method can be used in patients with PML with advantages over venography, and describes a investigation sequence⁶, making room for a larger study with 81 PML patients and 28 without edema in the control group, which analyzed direct flow obstruction signs, such as the following: the presence of thrombus, no flow at Doppler, no identification of the vein, stenosis or absence of venous walls collapse with inspiration, and flow cessation with limb lifting or upper rotation. Indirect signals were the presence of collaterals, continuous flow pattern and loss of normal phasic movement of venous walls⁵, these parameters being analogous to those of this study.

The diagnosis of lymphedema is clinical. However, to quantify its volume is useful to assess the degree of lymphatic dysfunction, to classify it in evolutionary stages (Table 1) and to assess the results of provided treatment¹³.

The measure of the lymphedematous limb volume by the water displacement technique device is reliable and accurate, but operationally cumbersome, and unhygienic. Moreover, due to requiring advance preparation, being less available and difficult to transport, it may be underutilized, which helps to reduce the number of diagnoses and periodic measurements during treatment, with negative implications for the health of affected individuals. Thus, alternative ways of measuring lymphedema volume are searched and studied. A water displacement model for connecting pipes that skirted the issue of water overflow has been developed. However, we had no opportunity to use it, since this study was already completed²⁰.

Comparative studies between the water displacement method and the cylinder volume and cone section showed a strong relationship between the volume measured by water displacement and geometric measurements in the affected limb, especially with the truncated cone volume, the cylinder volume and even rectangular and trapezoidal solids. Although there is the possibility of variation in the measurement of the circumference with tape measure, the findings showed that the method is reliable, economical and, above all, practical¹⁴.

There are, however, various other ways to take these measurements. Two different ways were carried out, comparing the results of both. Taylor started from the end of the third chirodactyl up intervals of 30, 40 and 50 cm and 65% of the distance between the elbow and the shoulder, therefore obtaining four cone sections, whose combined volumes represent the limb volume. He also measured the distance from the fist to the half of the forearm, from the half of the forearm to the elbow, from the elbow to the half of the arm and then to 65% of the distance between the elbow and the shoulder, obtaining also four cone sections. He correlated the findings with the measured volume of water displacement and concluded that the circumference measures with the anatomical repair points were more accurate than those obtained at regular intervals from the digital end¹⁵. The method of obtaining limb volume through circumference measures ended up being the most widely used due to its simplicity and low cost, the one based on the anatomical repair points having better accuracy¹⁵.

In the present study, this method was used with little variation, since there were no measurements in the joint line of the wrist or elbow. For anatomical reasons, these two regions vary in circumference less the rest of the limb, thus not representing the additions and decreases or fluid observed in lymphedematous limbs. Hence they are called skin folds. Therefore, we amended the measures at the points of anatomical repair to 2cm above the crease of the wrist and we named this measure as "lower forearm," 2 cm below and 2 cm above the elbow crease and labeled "higher forearm" and "lower arm", respectively, where

the circumference was less affected by cutaneous and subcutaneous folds (Figure 1).

Other methods for the diagnosis of lymphedema such as lymphoscintigraphy and MRI were not used in this study, since clinical diagnosis and the measured volume sufficed to select the participants of the two groups.

As for the axillary vein, this is classically defined as starting on the lower edge of the teres major muscle and extending to the lower edge of the first rib²¹. A reported biometric study in Brazil concluded that the axillary starts at the union of medial brachial and Basilica veins in 72.5% of cases and in another 20% at a single stem formed by the union of the medial and lateral brachial veins and the basilica, which is near the lower edge of the pectoralis major muscle. It stretches over 13,81cm on average, to cross the lower edge of the subclavian muscle, where it is then called subclavian vein. In the reported study, the found diameters were 0.69cm on its infrapectoral segment, 0.96cm on the retropectoral segment and 0.99cm on the suprapectoral segment²². Even if one takes into consideration such anatomic limits, this and other morphological studies have their basis in cadavers, whereas this study assessed living subjects and used ultrasound. For this reason, it was important to know the morphological study of the axillary vein in living and the use of ultrasound, which found minimum and maximum diameters of 0.35cm and 2.53 cm, respectively, with an average of 1.3 cm²³. Thus, studied veins were measured with ultrasound equipment and the best normality parameter would be the contralateral side and not absolute measures in diameter. Use of the contralateral side as parameter is a common rule in routine ultrasound studies¹¹. Therefore, we excluded from the study patients who underwent bilateral mastectomy or had been subjected to central venous catheterization, thus unfit for such comparisons at the reasonable expectation that the contralateral side did not remain unscathed. In our study, the best image definition venous contour occurred at approximately 4-2 cm outside the midclavicular line in the retropectoral and infrapectoral segments.

The exclusion of patients who had not undergone radiotherapy was due to the correlate lymphedema expectation of the upper limb with the damage to the vein wall that can be triggered by radiation, with the non-irradiated contralateral side as control. We also excluded patients with edema of upper limbs prior to mastectomy due to the possibility of introducing a confounding variable. We did not include patients with acute infection for ethical reasons.

For the calculation of our sample we used the hypothesis that ultrasound changes (USC) are 20% higher in women with post-mastectomy lymphedema (PML) than in individuals without it. Studies similar to ours reported 70% of global USC and 57% of obstructions⁵. Keeping the parameters used, if we used the estimated prevalence of 70%, we would get the total of six research participants for each group in the sample, and if we used 57%, we

would get only nine for each group. Studies with the use of equipment for flow measurement with CW Doppler plus venous occlusion reopletismography conducted in carriers of PML in sitting and lying positions shown that 31% of them had changes in two positions and 20%, changes in only one of the positions². When calculating an estimated 31%, the total survey participants found was 22, and with 20%, we obtained a total of 40 participants in each group with and without lymphedema. A study with venography³ also found 20% of venous obstructions and as we found no other anatomical study that addresses prevalence of venous changes in PML, we used the lowest observed prevalence, which was 20% despite coming from studies with methods different from ours, only with the aim of ensuring an ideal sample to obtain reliable results.

Discussion of results

The initial finding of overall prevalence of 83.8% of the axillary vein ultrasound of women with post-mastectomy lymphedema (PML) is higher than that found by other authors. We found 85% prevalence in the group with lymphedema and 82.5% in the group without lymphedema. A study previous to ours, with 81 patients with post-mastectomy lymphedema assessed by color Doppler ultrasonography (CDUs), found no evidence of venous obstruction in 57%, plus signs of venous congestion in 14%, totaling 71% of venous abnormalities. In that study, the author considered as lymphedema the increase in volume of the largest limb to 200ml calculated from multiple circumference measurements. He used, as criteria of abnormality, changes of the venous flow phasic characteristics, presence of thrombus, failure to observe the vein, reduction in its diameter or immobility of its walls during inspiration and presence of collaterals, criteria similar to those used in our present study⁵.

The highest prevalence rate in our study may be related to improving the quality of ultrasound images obtained by the current equipment, the use of second harmonic being an example.

In the present study, however, we observed, that the criterion "change in venous diameter" proved to be very similar in both groups, producing sample homogenization and contributing to the higher results. With the removal of this criterion and new analysis of the data, we found a decrease in prevalence to 77.5% in the group with lymphedema and 62.5% in the group without lymphedema, close to the results found by another author⁵.

With these data, the feature axillary "venous wall thickening" was significantly higher in patients with lymphedema compared with the group without lymphedema ($p = 0.001$). Discarding the other sonographic features due their low statistical significance and solely relating the characteristic "venous wall thickening" with the two groups, we found its prevalence to be 55% in the group with lymphedema and only 17.5% in the group

without it (PR = 3.14; 95% CI: 1.51 to 6.51). The cause of this thickening is not clear, and we can attribute it to the axillary vein thrombosis or to factors external to it such as surgery and radiotherapy.

The similarity of prevalence in both groups of other sonographic features, namely, change of diameter, presence of intraluminal images, compressibility, flow easiness and collapsing walls at inspiration, gave greater statistical value the unique feature that proved dominant in a given group, the one with lymphedema.

In reviewing the other sonographic features, we found that the flow was phasic in all sample cases, not being able to separate interest groups. In addition, the collapsing findings of the axillary vein similar to inspiration in both groups, and even slightly higher in patients with lymphedema, the venous diameter similar in both groups, and also the finding of just one intraluminal image in the whole sample, made us consider the possibility that the occurrence of thrombosis of the axillary vein can be infrequent, non-occlusive or quick resolution, or that the resulting impairment of venous function is of minor significance.

Furthermore, we observed that venous compression maneuver for venous thrombus was not as reliable, as some veins showed initially incompressible, though with normal flow demonstrable by Doppler. In most cases, venous occlusion obtained with the maneuver required more compression than on the contralateral control side. The compression caused by the equipment transducer promoted the movement of all the tissue block surrounding the vein, keeping it with its normal diameter or with small deformation, precisely in an area where sometimes the transducer's own weight is sufficient to occlude the vein. In patients submitted to total mastectomy, there is anatomical change in the chest wall at this location, which, associated with postoperative fibrosis, contributes to alter from convexity and typical softness to concavity and reduction of elasticity and thickening of the overlying skin. Subsequent radiotherapy may contribute to exacerbate this situation and this set of tissue changes makes the compressive maneuver difficult²⁴.

The maneuver to obtain venous collapsing at inspiration proved to be very dependent on the examined individual and appears to be hampered in overweight states and in the supine position. Moreover, pleuropulmonary lesions are common in this type of patients and we did not investigate their presence in our sample; their participation in the reported maneuvers is not known.

If we consider the set of signals that we deemed to be ultrasound changes for this work, we find that their occurrence is statistically similar in both groups, with and without lymphedema, except for the vessel wall thickening. We can also conclude that ultrasound changes are not associated with post-mastectomy lymphedema. It is possible that the adopted set of signals is not appropriate to separate the affected from the non-affected as for their local venous

circulatory function within the universe of patients exposed to mastectomy plus radiotherapy. However, it is also expected that the venous disease, usually correlated with ultrasound changes, is not an independent factor in the genesis of post-mastectomy lymphedema, but one amongst other contributory factors. We do not know the weight of this participation. Other factors related to the clinical and epidemiological aspects correlated with the presence of post-mastectomy lymphedema.

The groups with and without lymphedema were similar in many aspects, such as age, surgical technique, operated side, and number of radiotherapy and chemotherapy sessions, helping to give confidence in the correlation of the findings related to the risk of USC occurrence in some of the groups.

The age group between 47 and 57 years displayed increased risk of USC occurrence, of 3.82 times, moving far away from the risk seen in younger age groups and maintaining superiority, but closer to the age group above, a finding that suggests USC increased prevalence with increasing age. As the postoperative time did not confer increased risk, age appears to be an independent risk factor²⁵.

Total mastectomy showed 3.17-fold risk of increased USC prevalence compared with partial mastectomy, which is understandable due to the increased removal of affected lymph nodes and greater surgical aggression, with sequelae to the corresponding side, such as local fibrosis and limb mobility reduction, regardless of the operated side⁹. The risk of increased USC prevalence was also 9.33 times higher when the number of radiotherapy sessions ranged between 20 and 25. This is possibly due to all research subjects in our study underwent both therapeutic methods, and the association between PML and radiation is reported in the literature when associated with previous surgery, there being little evidence that it contributes to PML alone^{9,25}. This factor is well accepted in the literature as capable of aggravating local fibrosis, which can reduce the ability of spontaneous lymphatic compensation, contributing to the emergence or worsening of the post-mastectomy lymphedema²⁴⁻²⁶.

There were differences between the groups in the aspect lymphedema stadium, which was expected, since in the group without lymphedema would be the stage 0 participants, thus inevitably differing from the other group, where would be individuals with all the other developmental stages.

The aspect BMI also showed differences between groups, with overweight subjects predominating in the one without lymphedema, while in the group with lymphedema there was balance between overweight and obese individuals, suggesting, therefore, that with the BMI evolution from overweight to obesity, there is migration to the group with lymphedema. We also observed increased USC prevalence. This correlation between high BMI and lymphedema has been reported by other authors²⁵⁻²⁷. We

have not found participants with BMI compatible with ideal weight.

The association between increased USC prevalence and number of chemotherapy sessions was 3.31 times from as early as the fifth session on. There is doubt about the association between chemotherapy and PML, with acceptance, however, of its participation in postoperative painful morbidity²⁸.

During participants examination there were no limitations of movements that caused any restrictions, and we observed a wide freedom of movement of the upper limbs, whose amplitude seemed normal.

It was noteworthy the absence of venous collateral circulation in cases of recorded axillary vein thrombosis, which is described in studies involving axillary vein thrombosis due to effort, after catheterization, clavicle fracture, all without radiotherapy. Radiation therapy may have a role in it²⁴.

We recognize some limitations in this study. The lack of information on occupation, income and education did not allow correlating the prevalence of ultrasound changes and the presence of lymphedema with environmental risk.

Implications for clinical practice

This study allowed ultrasound changes to be detected in the axillary vein, showing its involvement with upper limb post-mastectomy lymphedema.

Since ultrasound alterations are easily found in post-thrombotic sequelae, this possibility should be aired in the postoperative period, and measures implemented, including prevention of venous thrombosis and early upper limb motor rehabilitation. Another aspect is that there must be caution with the axillary vein during surgery, plus postoperative care, in order to minimize the resulting scar.

The results of this study point to the need to reconsider some ultrasonographic signs found in the axillary vein when one wants to correlate them with the presence of post-mastectomy lymphedema. Changing in the diameter, presence of intraluminal images, compressibility as sign of thrombosis in the region and the absence of venous walls collapse seen at ultrasound as signs of post-thrombotic venous disease showed no reliability in our sample. As the venous wall thickening correlated strongly with the group with post-mastectomy lymphedema, this sonographic characteristic seemed reliable, rendering possible the correlation between the findings and high-risk patients, identifying those candidates for more often clinical follow-up.

Weight gain, with the research subject in the obesity range, correlated with the presence of PML. Efforts should be made in a multidisciplinary way for weight reduction when treating patients with post-mastectomy lymphedema.

The performance of total mastectomy is still a reality and this technique is related to increased risk of PML. There was increased USC prevalence in these cases

and effective measures of early diagnosis and treatment should contribute to the decline of such rates. Mastectomy, when held on the right side, does not seem to be a predisposing factor for lymphedema, although most people are right-handed and may put the dominant member to the effort, and consequently to the risk.

Implications for research

Many questions remain open on the subject venous disease and post-mastectomy lymphedema and specifically in its ultrasound assessment.

The presence of vessel wall thickening in 55% of cases with PML compared with only 17.5% in non-carriers correlates vein injury with post-mastectomy lymphedema. Nonetheless, we do not know if such injury precedes or follows the onset of lymphedema. Nor do we know whether such injury is the sequel of venous thrombosis or resulting from radiotherapy. Studies lack before and after mastectomy and before and after radiotherapy, with short, medium and long-term follow-up, to establish the natural history of venous repercussions and their relationship with lymphedema in patients undergoing mastectomy and radiotherapy for breast cancer.

We do not know if the venous walls collapse at inspiration can be influenced by the presence of pleuropulmonary injury secondary to radiotherapy and further research is necessary in this area.

The possibility of spontaneous postoperative lymphatic compensation to ensure the lymphatic outflow in the venous system is well established in the literature in living²⁹ and dead³⁰, which, of course, may be compromised by tissue aggression subsequent to surgery, such as infections and radiation.

The continuous study of the axillary vein and regional tissue changes in PML carriers by using complementary venous angiotomography or new ultrasound elastography techniques and magnetic resonance imaging can be important to select patients with the disease, since the ultrasound alone fails to diagnose it⁷. Elastography has emerged as an auxiliary tool for ultrasound diagnosis. Elastograms are images of tissue stiffness and may be colored, in shades of gray, or a combination of the two. Recent advances in elastography include quantification using voltage ratios, the acoustic radiation image, power boost, speed and wave cutting estimate. The first and most common elastography application is for the diagnosis of breast lesions and characterization of the focal masses such as liver cirrhosis of thyroid nodules, evaluation of lymph nodes for metastatic disease, detection of prostate cancer, among others. Promising applications include study of atheroma, assessment of venous and arterial wall and evaluation of characteristics and age of thrombi³¹. Studies with ultrasound elastography are conducted to select suitable locations for the employment of lymphatic-venous anastomoses³² and determination of the age of the thrombus³³, while other studies with magnetic resonance

elastography, investigate the tissue consequences of disease processes, such as inflammation and fibrosis³⁴. the use of these new technologies in a prospective study before and after mastectomy can help to better understand the factors that influence the installation of PML.

More studies are needed to assess the possibility of treatment of axillary venous hypertension with venous decompression by section of the pectoralis major¹⁸ or the suitability for venous flow unblocking or correction of stenosis and placement of a stent⁷ if the injuries are appreciable. However, this study is not conclusive in this direction.

Finally, other questions must be answered on the theme post-mastectomy lymphedema and, among those

that were addressed in this study, we highlight some, such as the need to deepen the study of the forms of limb volume measurement to lymphedema definition and staging. There is no standard way of measuring a lymphedematous limb and therefore to search correlation between the measured volume obtained by water displacement and the various forms of circumference measurement, which could help to clarify this question.

The prevalence of ultrasound changes was significantly higher in patients undergoing mastectomy and with lymphedema compared with those without lymphedema. These findings correlate with increased risk of developing post-mastectomy lymphedema.

RESUMO

Objetivo: verificar se existe prevalência de alterações ultrassonográficas (AUS) na veia axilar de pacientes portadoras e não portadoras de linfedema do membro superior pós-mastectomia. **Métodos:** uma amostra de 80 mulheres, alocadas em dois grupos iguais, com e sem linfedema foi estudada com ultrassonografia modo B, Doppler colorido e pulsado. A variável primária AUS foi definida como: alteração do diâmetro venoso, espessamento parietal, imagens intraluminares, compressibilidade, colapso parietal à inspiração e característica do fluxo venoso axilar no lado operado. Como variáveis secundárias: estágio do linfedema, técnica operatória, número de sessões de radio e quimioterapia, volume do membro, peso e idade. As diferenças entre as proporções nos grupos foram verificadas com o teste qui-quadrado de Pearson e/ou exato de Fisher. Para variáveis contínuas usamos o teste de Mann-Whitney. Para estimar a magnitude das associações utilizou-se como medida de frequência a prevalência de AUS em ambos os grupos e como medida de associação, a razão de prevalência (RP) obtida em função do risco relativo (RR) e estimada por meio do teste de homogeneidade de Mantel-Haenszel. Adotou-se o nível de significância estatístico de 5% ($p < 0,05$). **Resultados:** somente o critério "espessamento parietal" se relacionou fortemente com o grupo com linfedema ($p=0,001$). A prevalência de AUS foi 55% no grupo com linfedema e 17,5% no grupo sem linfedema, com diferença de prevalências de 37,5%. **Conclusão:** a prevalência de AUS foi maior nas pacientes submetidas à mastectomia e com linfedema do que naquelas sem linfedema.

Descritores: Neoplasias da mama. Veia Axilar. Linfedema. Ultrassonografia.

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Open abdomen management: single institution experience

Abdômen aberto: experiência em uma única instituição

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A B S T R A C T

Objective: to evaluate the outcome of abdominal wall integrity of both techniques. **Methods:** a retrospective study was carried out at the Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, identifying the patients undergoing temporary abdominal closure (TAC) from January 2005 to December 2011. Data were collected through the review of clinical charts. Inclusion criteria were indication of TAC and survival to definitive abdominal closure. In the post-operative period only a group of three surgeons followed all patients and performed the reoperations. **Results:** Twenty eight patients were included. The difference in primary closure rates and mean time for fascial closure did not reach statistical significance ($p=0.98$ and $p=0.23$, respectively). **Conclusion:** VAC and Bogota Bag do not differ significantly regarding the outcome of abdominal wall integrity, due to the monitoring of a specific team and the adoption of progressive closure

Key words: Peritonitis. Trauma. Sepsis. Negative-Pressure Wound Therapy. Abdominal Wound Closure Techniques. Intra-Abdominal Hypertension.

INTRODUCTION

Most of the time, at the end performing a laparotomy, the abdomen is closed with primary closure of aponeurosis. However, in some cases, the surgeon is forced to leave the open abdomen tactic that is associated with a mortality rate of 30%¹⁻³.

The open abdomen technique (AA) is a surgical strategy used in patients with related life-threatening intra-abdominal hemorrhage, prevention or treatment of intra-abdominal hypertension and treatment of intra-abdominal sepsis. It is a temporary measure to prioritize the control of bleeding, correction of metabolic disorders and hypothermia, and facilitate access to the abdominal cavity⁴.

In the 40s, leaving open abdomen after a laparotomy was considered technical failure. However, in the 70, the disseminated abdominal infections represented a major challenge, with mortality rates ranging from 30% to 80%⁵. Therefore, at that time, Hay et al.⁶ and Steinberg⁷ proposed to maintain the open abdomen to treat severe peritonitis. In the same period, Champault et al.⁸ advocated reoperations scheduled for cleaning the abdominal cavity.

Since 1981, the Department of General Surgery and Trauma Hospital of the Faculty of Medicine, Universidade de São Paulo (HCFMUSP), it was established that the open abdomen (AA) with planned reoperations would be

an option for the treatment of intra-infections abdominal with systemic repercussions, whose infectious focus could not be removed in one operation⁹. In the 90's was designed the Damage Control (DC). First described in 1993 by Rotondo *et al.* as an alternative to final laparotomy in patients with exsanguinating bleeding related to lesions of large vessels and multiple lesions intra-abdominal viscera¹⁰. It was later shown to initiate damage control early, before the patient's clinical conditions deteriorate to the extreme [massive blood loss, severe injury (ISS > 25), hypothermia (<34°C), acidosis (pH < 7.25) and blood coagulation (APTT > 19sec)], reduces mortality¹¹. Furthermore, keep the cavity open abdominal exposes patients to the risk of perforation of hollow viscera and increases the risk of developing complex hernias. Temporary abdominal closure techniques (FAT) with suture or skin closure Backhaus calipers reduce these complications, but increase the risk of abdominal compartment syndrome (ACS). After recognition of morbidity and mortality attributed to SCA, have been developed various methods to avoid this complication¹².

The ideal technique for the FAT was defined as one that contains the abdominal viscera, limit contamination, prevent the loss of abdominal fluid, avoid adhesions, allow easy access to the abdominal cavity, avoid damage and the retraction of the abdominal wall and stand in the way ACS¹³.

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The application of the Bogota Stock Exchange (BB) has become the most popular and effective method of temporary abdominal closure. It is still used in many hospitals in developing countries because of its low cost and easy handling. It was created by Oswaldo Borr  ez in 1984 and the name "Bogota bag" was created by Mattox, during a visit to a hospital in Bogota - Colombia, in 1997^{14,15}.

A decade ago, the negative pressure application concept was introduced by Barker et al. as a new means of temporary abdominal closure¹⁶. After the introduction of this vacuum closure technique, a more comprehensive method to manage negative pressure therapy to an open abdominal wound was developed: the closing assisted vacuum, the English "Vacuum Assisted Closure" (VAC). This technique enabled by the possibility of FAT drain peritoneal fluid, to minimize visceral edema, fascial apply greater tension in the abdominal wall and promoting the definitive abdominal closure in patients with open abdomen, one month after the initial laparotomy^{17,18}.

Today, despite advances in AA use with the development of vacuum therapy, the Bogota Stock Exchange (BB) is still widely used. In our institution and throughout Brazil, both techniques are used and the study's goal is to evaluate the morbidity and the result of the integrity of the abdominal wall after the use of both techniques.

METHODS

A retrospective study was conducted at HCFMUSP, identifying patients undergoing temporary abdominal closure (FAT) between January 2005 and December 2011. Data were collected through review of medical records. Data were compared in patients undergoing treatment with assisted closing the vacuum and the Bogota bag.

Inclusion criteria were temporary abdominal closure indication survival and the definitive abdominal closure. FAT indications included: abdominal trauma, severe abdominal sepsis and ACS. Data collected included age, FAT indication, the number of procedures in the operating room and the primary fascial closure rate. In the postoperative period, one group of three surgeons followed all patients and performed all reoperations. As soon as possible, the aponeurosis of the edges were subjected to progressive approach with careful not to cause abdominal hypertension.

The demographics of the two study groups (BB and VAC) were compared using the chi-square test of Pearson or Fisher's exact test for categorical variables and the Student t test for continuous variables.

RESULTS

During the study period, 59 patients require some kind of temporary abdominal closure (FAT), however, only 29 patients survived the final abdominal closure (52.5% mortality). One patient was excluded (subject to closure Backaus forceps). Thus, 28 patients were included, and, after two years of follow-up, none of them developed abdominal hernia or intestinal fistulas.

There was no statistical difference between the study groups with respect to age ($p > 0.05$) and a significant difference regarding indications for temporary abdominal closure ($p < 0.05$) (Table 1).

The primary closure rates were similar in both groups ($p = 0.98$). The average time (days) for fascial closure was 10.8 days for the BB group and 7.52 days in the group VAC (Table 2).

DISCUSSION

In this study, there was no statistical difference between the closing assisted vacuum and the Bogota bag (VAC and BB) when analyzed the number of operations, the primary closure, and the average time of closing. However, a previous study¹⁹ showed better results when using VAC BB was compared on the primary closure (50 to 70 % and 88% for BB VAC). The best approach to achieve the definitive abdominal closure in patients with open abdomen remains controversial. To improve the fascial closure rate, the excess volume resuscitation should be avoided, the water balance should be carefully implemented, not only on admission, but also throughout the course of treatment with open abdomen²⁰. The high rate of primary closure found in our patients, 80% for BB and 96% for the VAC, no statistical difference was due to the above mentioned guidelines and monitoring carried out by the same team of surgeons in all reoperations. This may also explain the same results of other variables analyzed with use of the BB or VAC.

Table 1 - Epidemiological data.

	Bogotá (n=10)	VAC (n=17)	p
Average age (years \pm SD)	39.5 \pm 14.8	33.17 \pm 16.6	0.17
Trauma	6 (60%)	6 (35.6%)	0.012
Non-trauma	4 (40%)	11 (64.7%)	0.01

Table 2 - Results.

	Bogotá (n=10)		VAC (n=17)		p
Average operations	2.4	(1-8)	2.05	(1-3)	0.3
Primary closure	8	(80%)	16	(94.1%)	0.98
Closure average (days ± SD)	10.8 ±	14.46	7.52 ±	9.03	0.23

A major obstacle to the abdominal closure is the retraction of the rectus abdominal muscles, which should be avoided at all costs. While the patient is open abdomen, the fascial edges are placed under tension by interrupted suture with nonabsorbable suture caliber. This strategy avoids the fascial retraction and facilitates the gradual approximation of aponeurotic edges in each reoperation until definitive abdominal closure²¹. These techniques also applied in our patients, reflect the high rate of abdominal closure, and reduced closing average time found that study, even when BB is the chosen method.

Another factor is the indication of the method used to implement the FAT. Some studies have shown the efficiency of the use of VAC in wounds that were not caused by trauma^{22,23}, results similar to those found in our study. Differences were found in the temporary abdominal closure indications: the Bogota bag was most appropriate in cases

involving trauma, while VAC was more indicated in cases of abdominal sepsis, abdominal compartment syndrome and mesenteric ischemia.

The absence of abdominal hernias and intestinal fistulas in patients undergoing FAT in our service is due to the technique used and the care adopted and applied by the same surgical team.

In our experience, the closing assisted vacuum (VAC) and the Bogota bag do not differ significantly with respect to the result of the integrity of the abdominal wall, although there is a tendency in our institution to use BB preferably in trauma and VAC in cases "no trauma". The monitoring of a specific team and the progressive closure of adoption are the factors that can explain the absence of difference between the groups and the high closing rate of the abdominal wall for both VAC and for the Bogota bag.

R E S U M O

Objetivo: avaliar o resultado da integridade da parede abdominal após utilização do fechamento assistido a vácuo e da bolsa de Bogotá. **Métodos:** um estudo retrospectivo foi realizado no Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP), identificando os pacientes submetidos à técnica de fechamento abdominal temporário (FAT) entre janeiro de 2005 e dezembro de 2011. Os dados foram coletados por meio de revisão de prontuários. Os critérios de inclusão foram indicação de FAT e sobrevivência até o fechamento definitivo da parede abdominal. No período pós-operatório, apenas um grupo de três cirurgias, seguiu todos os pacientes e realizou as reoperações. Além disso, independente da técnica de FAT utilizada, foi aplicada a tática de fechamento fascial progressivo durante as reoperações. **Resultados:** Vinte e oito pacientes foram incluídos. Não houve diferença estatística nas taxas de fechamento primário e tempo médio de fechamento fascial. **Conclusão:** O fechamento assistido a vácuo e a bolsa de Bogotá não diferem significativamente em relação ao resultado da integridade da parede abdominal após as reoperações. Isso se deve ao acompanhamento de uma equipe específica e a adoção de técnica de fechamento fascial progressivo.

Descritores: Peritonite. Trauma. Sepsis. Tratamento de Ferimentos com Pressão Negativa. Técnicas de Fechamento de Ferimentos Abdominais. Síndrome Compartimental Abdominal.

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Montreal classification of patient operated for Crohn's disease and identification of surgical recurrence predictors

Caracterização de pacientes operados por doença de Crohn pela classificação de Montreal e identificação de fatores preditores de sua recorrência cirúrgica

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A B S T R A C T

Objective: to evaluate Crohn's disease recurrence and its possible predictors in patients undergoing surgical treatment. **Methods:** We conducted a retrospective study with Crohn's disease (CD) patients undergoing surgical treatment between January 1992 and January 2012, and regularly monitored at the Bowel Clinic of the Hospital das Clínicas of the UFMG. **Results:** we evaluated 125 patients, 50.4% female, with a mean age of 46.12 years, the majority (63.2%) diagnosed between 17 and 40 years of age. The ileum was involved in 58.4%, whereas stenotic behavior was observed in 44.8%, and penetrating, in 45.6%. We observed perianal disease in 26.4% of cases. The follow-up average was 152.40 months. Surgical relapse occurred in 29.6%, with a median time of 68 months from the first operation. **Conclusion:** The ileocolic location, penetrating behavior and perianal involvement (L3B3p) were associated with increased risk of surgical recurrence.

Key words: Crohn's Disease. Classification. Recurrence. Risk factors.

INTRODUCTION

Crohn's disease (CD) is a chronic transmural inflammatory disease that can affect any segment of the digestive tract associated with intestinal manifestations and other immunological alterations. Its clinical presentation depends on the location and include diarrhea, abdominal pain, weight loss, fever, mucorrea or hematochezia. Clinical behavior comprises alternating periods of exacerbation and remission. The typical presentation is the involvement of discontinuous segments of the gastrointestinal tract. The inflammatory process can lead to the development of complications such as stenosis, abscesses and fistulas¹.

Among the many classifications proposed for CD, the Montreal², introduced in 2005, is the most used and aims to standardize the characterization of the disease, using reproducible clinical and epidemiological characteristics. Such categorization is desirable so that one can correlate particular disease phenotypes with possible clinical outcomes and prognosis, to select the best therapeutic strategy and the most appropriate follow-up for each patient.

Despite the increasing success with the clinical treatment of CD, about 75% of patients require surgical

intervention within 20 years of onset. Surgery, however, is not curative, postoperative recurrence being common³. This recurrence may be defined as clinical, endoscopic, histological, radiological or surgical. Often the disease is asymptomatic until the intestinal inflammation is severe, corresponding to the development of complications requiring a new operation⁴. Little is known specifically on surgical recurrence, there being few studies published in this respect.

The aim of this study was to characterize a cohort of patients with Crohn's disease treated at a tertiary referral center for intestinal inflammatory diseases, based on the Montreal classification, and to evaluate surgical recurrence and its possible predictors.

METHODS

We retrospectively analyzed data from 137 patients diagnosed with Crohn's disease (CD) who were followed-up at the Bowel Intestine Clinic of the Hospital das Clínicas, UFMG, and underwent surgical treatment between January 1992 and January 2012. Twelve were excluded due to loss of essential data for the preparation of the study, 125 patients operated remaining for evaluation.

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Data were collected from medical records and recorded in a specific protocol.

This study was approved by the Ethics in Research Committee of the Universidade Federal de Minas Gerais (CEP-UFMG - opinion ETIC 0156.0.203.000-11).

The variables studied were age, gender, clinical presentation according to the Montreal classification, time of disease evolution, smoking (smoking at diagnosis, regardless of the number of cigarettes smoked and the habit interruption after treatment start), clinical treatment performed before the first operation, progression of the disease until operation, surgical indication, type of surgery, postoperative complications, medications for maintenance of remission after operation, surgical recurrence, number of operations, type of new operation and date of performance.

Patients for whom the diagnosis of CD was perioperatively established, without previous medical treatment, were considered as receiving urgent surgical treatment.

Montreal classification

This classification subdivides CD according to three main phenotypic characteristics: age at diagnosis (A), topographic location (L) and clinical behavior (B)².

The age parameter takes account of the time when the diagnosis was definitely established. There are three possibilities: ≤ 16 years (A1); between 17 and 40 years (A2); and > 40 years (A3)².

Location is defined as the point of maximum anatomical extent of the disease at any time. There are four possibilities: the terminal ileum (L1, disease limited to the lower third of the small intestine, with or without the involvement of the cecum); colon (L2, anywhere between the cecum and the rectum, without involvement of the upper digestive tract); ileocolic (L3, terminal ileum disease and anywhere between the ascending colon and the rectum); and the upper gastrointestinal tract (L4, any location proximal to the terminal ileum, except the mouth). If there is concomitant proximal (L4) and distal (L1 to L3) involvement, the L4 category should be added as a modifier; if the distal condition is not found, L4 remains exclusively considered. This creates seven location possibilities: L1, L2, L3, L4, L4 + L1, L2 + L4 and L3 + L4².

Clinical behavior is classified as non-stenotic and non-penetrating (B1), stenosing (B2) and penetrating (B3). Non-penetrating, non-stenotic disease is defined as the presence of inflammation, without evidence of stenosis, or fistula. Stenotic disease is defined by the occurrence of luminal narrowing. Penetrating disease is defined by the occurrence of abdominal fistulas or inflammatory masses and / or abscess in any period of the disease. When there is perianal disease, this should be separately indicated by a marker (p), which must be added to the categories B1, B2 and B3. Thus, there are six possibilities: B1, B2, B3, B1p, B2p and B3p².

Statistical analysis

Data descriptions were based on frequency tables and graphs. For quantitative variables, we computed the average and standard deviation when they presented normal distribution, and median (interquartile range) when the distribution was not normal, after application of the Shapiro-Wilk test.

Initially we analyzed the association between the study variables and the number of operations (1 and ≥ 2) and subsequently we evaluated the association of the variables with the type of operation (elective and emergency) through the asymptotic or accurate Pearson chi-square tests. For the analysis of quantitative variables we used the Student t or Mann-Whitney tests, depending on the distribution's normality or not. The level of significance was 5% ($p < 0.05$).

We performed the multivariate analysis of the association between the number of operations and the study variables by the logistic regression model adjustment. The model was adequate when the p value was less than 0.05.

RESULTS

There were similar gender distribution, with a slight predominance of females (63 patients - 50.4%) and the mean age was 46.12 ± 12.2 years. Forty-eight patients were smokers (38.4%).

Six patients (4.8%) were diagnosed younger than age 16 (A1), 79 (63.2%) between 17 and 40 years (A2) and 40 (32%), over 40 (A3).

In 73 (58.4%) patients the terminal ileum was affected (L1); in 22 (17.6%), the colon (L2) and 29 (23.2%) had ileocolic disease (L3). The upper gastrointestinal tract (L4) was committed in six patients, one in isolation (0.8%), four (3.2%) in association with involvement of the terminal ileum (L1 + L4) and in one patient (0.8%), in combination with ileocolic involvement (L1 + L3).

Twelve patients (9.6%) had non-stenotic / non-penetrating disease (B1); 56 (44.8%) stenotic disease (B2) and 57 (45.6%) had penetrating disease (B3); 33 patients (26.4%) had associated perianal disease: five (4%) non-stenotic and non-penetrating (B1p), five (4%) stenotic (B2p) and 23 (18.4%) penetrating (B3p).

Fifty-four patients (43.2%) received preoperative clinical treatment (Table 1), the association of another type of medicine being common. Seventy-one (56.8%) patients underwent surgical treatment, usually of urgency, without prior medical treatment nor confirmed diagnosis.

The mean follow-up of patients was 152.4 months. The first surgery was performed on average 29 months after diagnosis. The most frequent surgical indications were acute inflammatory abdomen and ileal obstruction (Table 2).

The main surgical decisions during the first operation were ileocelectomy in 49 (39.2%) patients and

bowel resection in 46 (36.8%). The laparoscopic approach was applied in three patients. Anoperineal interventions were performed in 17 patients: simple fistulotomy, abscess drainage, placement of seton and excision of plicomas were the most common procedures (Figure 1).

Postoperative medication was used in 98 patients (78.4%), some patients receiving more than one drug; azathioprine was used in 61 (48.8%), mesalazine in 27 (21.6%), sulfasalazine in 25 (20%), infliximab in 16 (12.8%), methotrexate in two patients (1.6%) and adalimumab in one (0.8%) (Table 3).

Postoperative complications occurred in 23 patients (18.4%). Anastomotic leaks occurred in 15 individuals (12%), superficial surgical site infection in six (4.8%), pneumonia in one patient (0.8%) and deep vein thrombosis in one (0.8 %), which evolved to death due to pulmonary thromboembolism.

Surgical recurrence occurred in 37 patients (29.6%), on average 68 months after the first intervention, ranging from three to 204 months. In 27 patients (57.5%) recurrence ensued in the pre-anastomotic region, and in 20 patients (42.5%) it occurred in other places: proximal small intestine in nine (7.2%), terminal ileum in five (4%), perianal region in five patients (4%), colon in one (0.8%) and rectum in one patient (0.8%). Patients with symptoms recurrence required two or more operations. Fourteen patients (11.2%) underwent three operations, the second recurrence happening, on average, 47 months after the first. Four patients (3.2%) required four operations, 72 months being the average time of the third recurrence (Figure 2).

The ileocolic location (L3), the penetrating behavior (B3) and presence of perianal disease (B3p), as well as the time of disease progression, were significantly associated with surgical recurrence (Tables 3 and 4).

When the emergency operations were compared with the elective ones, we observed that there was no difference in relation to surgical recurrence. Regarding the Montreal classification, we observed that patients younger than age 16 and aged between 17 and 40 years at diagnosis underwent elective surgery more often. On the other hand, patients aged over 40 years underwent emergency surgery more frequently (Table 5).

Also regarding the type of operation, the main indication for surgery in the group undergoing emergency procedures was inflammatory acute abdomen in 30 patients (42.9%), followed by intestinal obstruction in 27 (38.6%). In the group of patients undergoing elective operations, the main indication was intestinal obstruction in 17 patients (30.9%), followed by perianal sepsis in 11 (20%) and clinical intractability in ten (18.2%) (Table 5).

DISCUSSION

The Montreal classification has been increasingly used in patients with Crohn's disease (CD) due to its

Table 1 - Preoperative clinical treatment (n = 54).

Previous Drug	n (%)
Sulfasalazine	25 (20)
Mesalazine	14(11.2)
Corticosteroids	42(33.6)
Azathioprine	27(21.6)
Mercaptopurina	1 (0.8)
Methotrexate	5 (4)
Infliximab	6 (4.8)

Table 2 - Main surgical indications (n=125).

Indication	n (%)
Acute Abdomen	36 (28.8)
Ileal Obstruction	35 (28)
Perianal Disease	17 (13.6)
Ileal Perforation	10 (8)
Clinical Intractability	10 (8)
Jejunal Obstruction	8 (6.4)
Enterocutaneous Fistula	4 (3.2)
Enterovesical Fistula	3 (2.4)
Enterointestinal Fistula	2 (1.6)
Colonic Perforation	2 (1.6)
Colonic Obstruction	1 (0.8)
Enterouterine Fistula	1 (0.8)
Refractory Bleeding	1 (0.8)

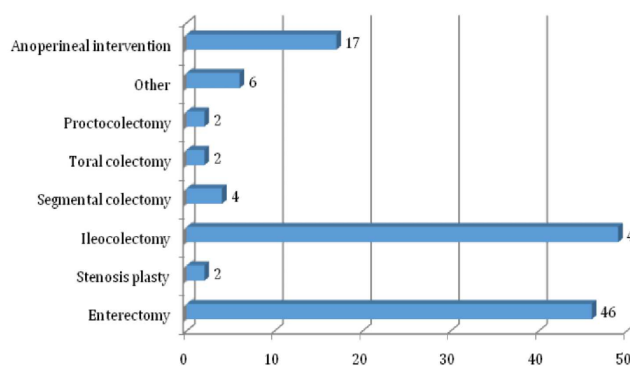


Figure 1 - Conduct adopted in the first operation (n=125).

diagnostic and therapeutic implications. However, despite its great utility, it is still little used in Brazil, especially when it comes to evaluating potential predictors of recurrence in a population of surgical patients. Its use in a cohort of patients with CD treated surgically, evaluated and monitored on a university reference center for treatment of inflammatory bowel disease can contribute to a greater understanding of the disease presentation and its response

Table 3 - Analysis of association between the number of operations in patients with Crohn's disease and the study variables (n = 125).

Variables n (%)	Number of Surgeries			p-value
	1 n=88 (70,4%)	>2 n=37 (29,6%)	Total n=125	
Age of diagnosis				
A1	3 (3.4)	3 (8.1)	6 (4.8)	0.319
A2	59 (67.0)	20 (50.1)	79 (63.2)	
A3	26 (29.5)	14 (37.8)	40 (32.0)	
Location				
L1	57 (64.8)	16 (43.2)	73 (58.4)	0.039
L2	15 (17.0)	7 (18.9)	22 (17.6)	
L3	16 (18.2)	13 (35.1)	29 (23.2)	
L4	0	1 (2.7)	1 (0.8)	
Behavior				
B1	8 (9.1)	4 (10.8)	12 (9.6)	0.001
B2	49 (55.7)	7 (18.9)	12 (9.6)	
B3	31 (35.2)	26 (70.3)	57 (45.6)	
Perianal Disease				
B1p	4 (4.5)	1 (2.7)	5 (4.0)	0.033
B2p	5 (5.7)	0	5 (4.0)	
B3p	11 (12.5)	12 (32.4)	23 (18.4)	
Smoking				
Yes	33 (37.5)	15 (40.5)	48 (38.4)	0.319
No	55 (62.5)	22 (59.5)	40 (32.0)	
Previous medication				
Sulfasalazine	17 (19.3)	8 (21.6)	25 (20)	0.769
Mesalamine	13 (14.8)	1 (2.7)	14 (11.2)	
Corticoids	32 (36.4)	10 (27.0)	42 (33.6)	0.313
Azathioprine	23 (26.1)	4 (10.8)	27 (21.6)	0.057
Mercaptopurine	1 (1.1)	0	1 (0.8)	1.000
Methotrexate	5 (5.7)	0	1 (0.8)	0.320
Infliximab	6 (6.8)	0	6 (4.8)	0.178
Postoperative medication				
Azathioprine	43 (48.9)	18 (48.6)	61 (48.8)	0.982
Infliximab	12 (13.6)	4 (10.8)	16 (12.8)	0.776
Other	44 (50.0)	15 (40.5)	50 (47.2)	0.334

to operative treatment. In the Brazilian literature, only a single study aimed to assess the factors of CD surgical recurrence⁵. In that study, Albuquerque et al. observed that penetrating clinical presentation and the presence of intestinal perforation are predictors of recurrence in surgical patients⁵. However, that article does not apply the Montreal classification and its prognostic implications.

Moreover, one may wonder whether CD would not be less frequently suspected in patients over 40 years of age, since inflammatory bowel diseases are considered to traditionally affect younger patients.

It is of paramount importance to study the concurrent involvement of the upper gastrointestinal and

other locations, a fact that was not contemplated by other classifications, with possible underestimation of the disease incidence in such topography. In this study, the involvement of the upper gastrointestinal (GIT) tract occurred in six patients (4.8%), 4% concurrent to other locations. This data are similar to the published by Thin et al., in that only 1% of the study population had an isolated upper GIT condition and 3.3% had concomitant involvement, L1, L2 or L3⁷. It has also been reported that the risk of recurrence is higher when the disease occurs in the terminal ileum and ileocolic regions^{8,9}. In this cohort, patients with L3 location had higher surgical recurrence, which had already been confirmed by other authors³

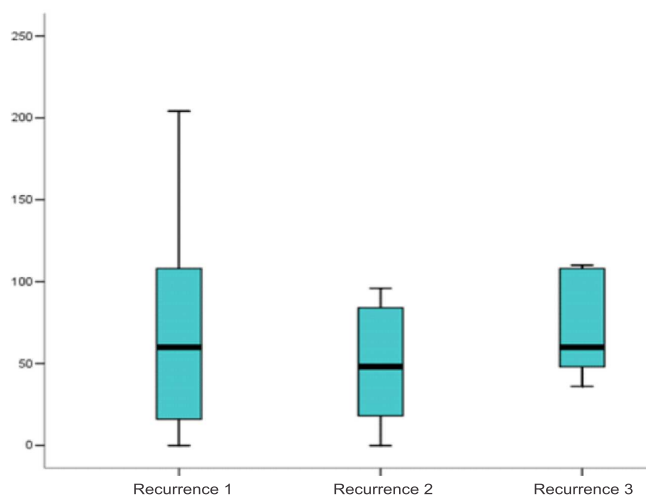


Figure 2 - Surgical recurrence time in patients operated for Crohn's disease (n=37).

It is well established that the penetrating behavioral features more aggressive clinical course and more recurrence index⁴, as well as the presence of perianal disease, often associated with colonic disease, which has also been considered an important marker of severe disease¹⁰. In this study, it was observed that B3 behavior patients had more surgical recurrence, which confirms the higher aggressiveness of this kind of CD behavior. However, despite the perianal disease is more associated with CD penetrating form, even grouped together with this form in the old Vienna classification¹¹, enteric fistula does not occur in up to 80% of patients with perianal disease², which is probably related to the genetic profile of the disease.

With regard to surgical treatment, ileocollectomy and enterectomy were the most common procedures, which conforms to the CD topographical location in the study population (L1 in 58.4% of patients). In this cohort, few patients underwent plasty of stenosis, always Heine-type Mickulicz, in segmental stenoses¹². This is because most stenoses were long, resulting in the realization of enterectomies or the need for more extensive plasties, type Jaboulay or Michelassi¹², which are not used in our service. Moreover, as most of the patients underwent emergency surgery, resection allowed the confirmation of CD by

histological analysis of the specimen in patients without prior diagnosis.

In this cohort, 12% of patients had anastomotic leak and 4.8% had superficial surgical site infection. These complication rates are high, since the reports of septic abdominal complication rates in the postoperative period of intestinal resection for CD range from 8% to 16%. These rates are higher than those recorded in patients undergoing bowel resection by other benign diseases¹³. It must be pointed out that this study was conducted in a reference center, at a hospital in tertiary complexity and therefore many of the operated patients are severely ill, with compromised nutritional status and in use of medications that lead to anastomotic dehiscence risk.

The obtained surgical recurrence rate of 29.6%, with a mean 68-month time onset, corresponding to 5.6 years, is consistent with the rates reported in the literature, which vary according to the definition of recurrence used: endoscopic, surgical or clinical¹⁴. Patients undergoing endoscopic ileocollectomy present relapse in 90% of cases in the absence of treatment, while clinical recurrence reaches 20-25% per year¹⁵. In what concerns surgical recurrence, reoperation rates range from, 11 to 32% in five years, 20-44% in ten and 46 to 65% in 20 years¹⁶.

Among the Montreal classification features, the factors most related to surgical recurrence in this study were the ileocolic location (L3) and the penetrating behavior (B3). In the national literature, in a paper published by Albuquerque et al., who also evaluated postoperative recurrence, penetrating behavior was also associated with higher recurrence rates⁵.

We also observed that the duration of the disease was more associated with recurrence, which conforms to CD's natural history, a chronic, progressive and almost invariably evolving into complications that culminate with surgical treatment. The long follow-up of this cohort in a university academic ambulatory-care character, averaging 152.4 months, accounting for more than 12 years, makes possible the proper assessment of a chronic disease with high morbidity but relative low mortality.

As for the analysis of other surgical recurrence predictors, smoking is widely deemed a negative prognostic factor, being recognized both as a risk factor for the onset

Table 4 - Multivariate analysis between the number of operations, the time of evolution and disease behavior.

Variables	Amount of operations			OR	IC95% OR	p-value
	1 N=88	>2 n=37	Total n=125			
Time evolution	133.8 ± 97.2	179.4 ± 81.1	147.3 ± 94.8	1.01	1.00 ; 1.01	0.031
Behavior						
B1	8 (66.7)	4 (33.3)	12	1		
B2	49 (87.5)	7 (12.5)	56	0.10	0.02 ; 0.54	0.686
B3	31 (54.4)	26 (45.6)	57	1.34	0.33 ; 5.48	0.007

Table 5 - Association between the type of operation (elective or emergency) in patients with Crohn's disease and the study variables (n=125).

Variables	Types of surgery			p-value
	Urgency (n=70)	Elective (n=55)	Total (n=125)	
Number of surgeries				
1	46 (65.7)	42 (76.4)	88 (70.4)	0.195
>2	24 (34.3)	13 (23.6)	37 (29.6)	
Age at diagnosis				
A1	1 (1.4)	5 (9.1)	6 (4.8)	0.04
A2	42 (60)	37 (67.3)	79 (63.2)	
A3	27 (38.6)	13 (23.6)	40 (32)	
Location				
L1	43 (61.4)	30 (54.5)	73 (58.4)	0.084
L2	8 (11.4)	14 (25.5)	22 (17.6)	
L3	19 (27.1)	10 (18.2)	29 (23.2)	
L4	0 (0)	1 (1.8)	1 (0.8)	
Behavior				
B1	6 (8.6)	6 (10.9)	12 (9.6)	0.902
B2	32 (45.7)	24 (46.3)	56 (44.8)	
B3	32 (45.7)	25 (45.5)	57 (45.6)	
Surgical Indication				
Inflammatory acute abdomen	30 (40.2)	6 (10.9)	36 (28.8)	<0.0001
Jejunal Obstruction	4 (5.7)	4 (7.3)	8 (6.4)	1.000
Ileal obstruction	23 (32.9)	12 (21.8)	35 (28.0)	0.172
Colonic pseudo-obstruction	0 (0)	1 (1.8)	1 (0.8)	0.440
Refractory bleeding	1 (1.4)	0 (0)	1 (0.8)	1.000
Enterocutaneous fistula	1 (1.4)	3 (5.5)	4 (3.2)	0.319
Enteroenteric fistula	0 (0)	2 (3.6)	2 (1.6)	0.192
Enterovesical fistula	1 (1.4)	2 (3.6)	2 (2.4)	0.582
Enterouterine fistula	0 (0)	1 (1.8)	1 (0.8)	0.331
Ileal perforation	7 (10.0)	3 (5.5)	10 (8.0)	0.510
Colon perforation	0 (0)	2 (3.6)	2 (1.6)	0.192
Clinical intractability	0 (0)	10 (18.2)	10 (8.0)	<0.0001
Perianal sepsis	6 (8.6)	11 (20.0)	17 (13.6)	0.064

of the disease, and for recurrence after surgical treatment^{3,5}. Nonetheless, this was not confirmed in this study (Table 4).

We did not aim to evaluate clinical treatment, nor the association between the type of drug treatment with the need for surgical treatment. It is noteworthy that in this study most patients (56.4%) underwent surgical treatment without previous clinical treatment, ie, had suspected and confirmed diagnosis peri- and postoperatively. Importantly, patients belong to a reference clinic, which often receives individuals who were operated in various other services, often undiagnosed. One cannot say whether these patients had a more acute disease course or stopped seeking medical assistance at the start of symptoms, losing the opportunity to establish the diagnosis without the need for surgical intervention. Many may have been treated in emergency rooms, where the initial condition of acute inflammation of the ileocecal region was interpreted as

inflammatory acute abdomen, with strong suspicion of acute appendicitis.

The relationship between appendicitis, appendectomy and Crohn's disease is not well established. Many patients who present with acute ileitis can be submitted to appendectomy for suspected acute appendicitis, when the true diagnosis is Crohn's disease, which can be diagnosed in the perioperative period or a few months later. However, it is not yet confirmed if appendectomy is a risk factor for CD or previous appendectomy changes the natural history of the CD¹⁷.

We did not to evaluate postoperative prophylactic medication, as many of these patients were operated on other services, sometimes staying long periods without any medication, being referred only when they became symptomatic again. In any case, there was no relationship between preoperative clinical treatment and greater surgical

recurrence rate, nor regarding the use of prophylactic postoperative medication (Table 4).

In a study published by Latella et al.¹⁸, who evaluated CD's clinical course in patients undergoing surgical treatment for acute abdomen and had their diagnosis revealed at surgery, and observed that the risk of these patients being submitted to reintervention due to surgical recurrence was lower. The authors also found that patients with involvement of the terminal ileum and penetrating or stenotic behavior were at greater risk of being subjected to exploratory laparotomy without prior diagnosis. In another study¹⁹, in which they compared two groups who underwent early surgery (without medical treatment) and late surgery (along the course of the disease due to complications), patients who underwent early surgery had a longer clinical remission¹⁹. However, the reoperation rate was the same. In this cohort, there was no statistically significant difference between the two groups of patients regarding surgical recurrence. The most common indication for surgery in the emergency surgery group was laparotomy for suspected inflammatory acute abdomen, followed by bowel obstruction, whereas in patients undergoing elective surgery, the main indication was intestinal obstruction, followed by clinical intractability.

The perianal disease affects about 33% of patients with CD in ten years of evolution and has high morbidity due mainly to pain and drainage in the area,

which can lead to complications such as dermatitis, itching, among others¹⁰. We observed perianal involvement in 26.4% of patients. In a recent study, Eglinton et al. reported prevalence of symptomatic perianal disease in 26.6% of patients with DC¹⁰, much like the rate found in our cohort. In this, the most frequent type of injury was the perianal fistula, followed by abscess, fissure, plicoma and stenosis. The goal of treatment of perianal disease should be aimed to improve the quality of life and is determined by the complexity of involvement. Simple abscesses may be drained, always as close to the anal verge as possible. Simple fistulas can be treated by fistulotomy, as occurred in 12 patients in this study. The seton placement is indicated by the presence of complex fistula, to drain the perianal sepsis and to prevent the sphincter section, which can lead to fecal incontinence²⁰. This technique was used in six patients. It is known that the association of seton with immunobiological therapy provides better results in fistulas healing than each type of therapy alone²⁰.

In conclusion, surgical recurrence of Crohn's disease affects a significant portion of patients (29.6%), usually more than five years after the first intervention. The penetrating behavior, especially in the ileocolic topography, associated with perianal involvement most often lead to recurrence after surgical treatment, confirming the prognostic importance of the Montreal classification.

R E S U M O

Objetivo: avaliar a recorrência da doença de Crohn e seus possíveis fatores preditores em pacientes submetidos ao tratamento cirúrgico. **Métodos:** estudo retrospectivo de pacientes com doença de Crohn (DC) submetidos a tratamento cirúrgico entre janeiro de 1992 e janeiro de 2012, em acompanhamento regular no Ambulatório de Intestino Clínico do Hospital das Clínicas da UFMG. **Resultados:** foram avaliados 125 pacientes, sendo 50,4% do sexo feminino, com média de idade de 46,12 anos, a maioria (63,2%) com diagnóstico entre 17 e 40 anos de idade. O íleo terminal foi envolvido em 58,4%, sendo que o comportamento estenosante foi observado em 44,8% e o penetrante em 45,6% dos pacientes. Doença perianal foi observada em 26,4% dos casos. A média de tempo de acompanhamento foi 152,40 meses. Recorrência cirúrgica foi observada em 29,6%, com um tempo médio de 68 meses até a segunda operação. **Conclusão:** a localização ileocólica, o comportamento penetrante e o acometimento perianal (L3B3p) estão associados ao maior risco de recorrência cirúrgica.

Descritores: Doença de Crohn. Classificação. Recorrência. Fatores de Risco.

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Profile of hip arthroplasty patients in a teaching hospital

Perfil dos pacientes submetidos à artroplastia do quadril em hospital de ensino

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A B S T R A C T

Objective: to characterize the epidemiological profile of patients undergoing hip replacement, primary or revisional. **Methods:** we conducted a retrospective, descriptive study, including hip arthroplasties performed from January 2009 to June 2012 in a Belo Horizonte teaching hospital, Minas Gerais State – MG, Brazil. Data were analyzed using descriptive statistics. **Results:** orthopedic procedures represented 45% of the operations at the hospital in the period, 1.4% hip arthroplasties. There were 125 hip replacements, 85 total, 27 partial and 13 revisions. Among the patients, 40% were male and 60% were female. Age ranged between 20 and 102 years, mean and median of 73 and 76 years, respectively. The most frequent diagnosis (82%) was femoral neck fracture by low-energy trauma caused by falling from standing position. In 13 revision operations, 12 required removal of the prosthesis. The infectious complication led to revision in 54% of the time, followed by dislocation (15%), peri-prosthetic fracture (15%) and aseptic loosening (15%). The infection etiologic agent was identified in 43% of occasions. The average length of the prosthesis to a revision operation was eight months. **Conclusion:** patients undergoing hip arthroplasty are elderly, with femoral neck fracture caused by falling from standing position, affecting more women. The incidence of hip prosthesis loosening was 10%. The main cause of the infection was loosening. The incidence of revisional hip arthroplasty was 10% and the incidence of hospital mortality in patients undergoing hip arthroplasty was 7.2%.

Key words: Orthopedics. Hip Arthroplasty. Reoperation. Surgical Wound Infection.

INTRODUCTION

Currently, the use of biomaterials in orthopedic implants is well known. This application has the prospect of becoming more and more intense when considering the high life expectancy of the population in recent decades. Among the obstacles faced in the implementation of these prostheses, there is the rejection of the body to the materials used and infections resulting from surgical procedures. Biocompatibility studies that assess the tolerance of the body to the presence of a foreign body and its toxicity has been made¹.

Hip arthroplasty represents an advance in surgical procedures of the modern era and, after five decades since the first total hip replacement surgery, the scientific literature data prove the success, between 90 and 95% for 10 to 15 years, of an operation that relieves pain and corrects deformities^{2,3}.

The failure of implants can occur by mechanical or biological reasons. The mechanical ones includes excessive use of the prosthesis, its displacement or misalignment, physical stress and peri-prosthetic bone

fracture. The biological failure, on its turn, basically includes inflammation, which can occur as an infectious response or a consequence of the presence of particles in the site. In general and in practice, any of these events requires surgical revision. Infectious complication causes approximately 1.5% of prosthesis loosening. However, the non-infectious complication is the main cause of surgical revision, for the so-called aseptic prosthesis loosening. In the United States approximately 500,000 arthroplasties take place a year and over 40,000 revisions for aseptic loosening are carried out³⁻⁵.

Epidemiological studies evaluating the surgical procedures and the performance of implants are important, especially to identify postoperative complications, as well as their causes. The Brazilian Society of Orthopedics and Traumatology (SBOT), similar to what occurs in many countries, proposed a national arthroplasty registry in 2007, when a pilot project was initiated in some Brazilian cities. The partnership with the National Agency of Sanitary Surveillance (ANVISA) was established and soon the national registry will be extended to all health establishments⁶.

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Considering the magnitude of the loosening, whether septic or aseptic, of hip joints with regard to increased morbidity, care costs of such complications and also the absence of national data on the subject, it is necessary to produce knowledge that will assess current care practices. Also noteworthy is the contribution to nursing assisting patients in the perioperative period and processing surgical materials.

This study aims to characterize the epidemiological profile of patients undergoing hip arthroplasty.

METHODS

We conducted a retrospective study, with descriptive approach, for the analysis of hip arthroplasties performed in a public teaching hospital from January 2009 to June 2012. The hospital performs an average of 500 operations per month, 45% orthopedic and of these, 1.4% hip arthroplasties. The team of orthopedic surgery consists of 24 surgeons, six of them hip experts, operating weekly and leading all arthroplasties in the institution during the study period.

We used a specific instrument for collecting data through query to the electronic medical records of all patients undergoing hip replacement, primary or revisional, from January 2009 to June 2012. The exclusion criteria were: electronic records unavailable or incomplete filling. The interest collected variables were: gender; age; dates of hospitalization, surgical procedure and outcome (discharge, transfer or death); admission diagnosis, presence of fracture, its cause; the type of surgical treatment (partial, total or revisional arthroplasty); surgeon; type of prosthesis; in the case of surgical revision: time of prosthesis and cause of the review; postoperative complications; and clinical care. We created a database and the variables of interest were analyzed at first, by using descriptive statistics. All incidence rates were calculated using point estimate and 95% confidence intervals⁷. We applied the Garden classification⁸ to determine the types of fracture

The research project was approved by the Ethics in Research Committee of the Federal University of Minas Gerais – UFMG, Opinion No ETIC 0300.0.203.000-10 and its conduction was authorized by the Teaching, Research and Extension Nucleus of the Risoleta Tolentino Neves Hospital.

RESULTS

During the period from January 2009 to June 2012 19,233 operations were carried out in the hospital, 8,701 orthopedic, corresponding to 45% of the procedures. Among these, 125 were hip replacements, which corresponds to 1.4% of the orthopedic operations.

Among patients undergoing hip arthroplasty, 50 were male (40%) and 75 (60%) female. Patient age ranged between 20 and 102 years, mean and median of 73 and 76 years, respectively. The sample of patients had a standard deviation of 14.6 years and 20% coefficient of variation, which indicates an intermediate variability (Table 1).

Most patients had femoral neck fracture as admission diagnosis, its main cause being the low-energy trauma by falling from standing position. Regarding the type of operation, the majority was total hip replacement (68%). As for the type of prosthesis, in the 27 partial arthroplasties the femoral prosthesis was cemented. Among the 85 total arthroplasties with acetabular and femoral prosthesis, both were cemented on 18 occasions, both were non-cemented on 56 occasions, only the femoral one was cemented in six and only the acetabular was cemented on five. Two orthopedic surgeons were responsible for the absolute majority of the procedures (77%).

Of the 102 patients with hip fracture diagnosis, 53 had the Garden classification defined: two Garden type II fractures, complete fracture without deviation (4%), 17 Garden type III, partially varus deviation (32%) and 34 Garden IV, completely deviation, with displacement of the femoral head (64%). The two patients with fractures classified as Garden II had symptomatic coxarthrosis prior to the fracture.

Of the 13 surgical revisions, infectious cause was observed in 54%, requiring prosthesis removal. The surgical site infection was classified as deep, whose etiologic agent was identified in only 43% of patients (Table 1). Seven other patients underwent reoperation, on three occasions to the repositioning of the prosthesis due to dislocation and four times for surgical cleaning due to superficial infection. In one, culture examination was performed, and the etiologic agent was *Staphylococcus aureus*.

Also in the 13 reviews the average time of prosthesis to the revision operation was eight months, ranging from 10 days to 48 months. Among the revisions, 38% occurred within 45 days after arthroplasty. The frequency of prosthesis loosening was observed in 12 patients, with an incidence of 9.6% (95% CI = 4.4% to 14.8%). The incidence of prosthetic loosening of infectious cause was 5.6% (95% CI = 1.6% to 9.6%). Of the 125 patients studied, nine died during hospitalization, with a hospital mortality of 7.2% (95% CI = 2.7% to 11.7%).

DISCUSSION

Hip arthroplasty is considered a successful surgical procedure for treating diseases that manifest in a more advanced stage of life. In this study, only 12.8% of patients were younger than 60 years, the majority (63%) consisting of individuals aged between 70 and 90 years. The elderly population has increased both in developed and developing

Table 1 - Characteristics of patients undergoing hip arthroplasty between the years of 2009 and 2012.

Variable	Categories	Frequency	Percentage
Age	< 60 anos	16	12,8%
	60 – 69	21	16,8%
	70 – 79	40	32,0%
	80 – 89	39	31,2%
	90 – 99	8	6,4%
	>100	1	0,8%
Admission diagnosis	Femoral neck fracture	102	81,6%
	Secondary osteoarthritis	8	6,4%
	Infection	7	5,6%
	Peri-prosthetic fracture	2	1,6%
	Prosthesis dislocation	2	1,6%
	Osteonecrosis	2	1,6%
	Prosthesis aseptic loosening	2	1,6%
Etiology of femoral neck fractures (n = 102)	Low-energy trauma	94	92%
	High-energy trauma	6	6%
	Other	2	2%
Surgery type	Total hip arthroplasty	85	68%
	Partial hip arthroplasty	27	22%
	Revisional arthroplasty	13	10%
Reason for reoperation (n = 7)	Superficial infection	4	57%
	Prosthesis dislocation	3	43%
Reason for revisional operation (n=13)	Infection	7	54%
	Peri-prosthetic fracture	2	15%
	Prosthesis dislocation	2	15%
	Prosthesis aseptic loosening	2	15%
Prosthesis removed after review (n=13)	Yes	12	92%
	No	1	8%
Identification of the etiologic agent (n=7)	Yes	3	43%
	No	4	57%
Etiological agent (n=3)	<i>Enterococcus faecalis</i>	1	33%
	<i>Escherichia coli</i> , <i>Proteus mirabilis</i>	1	33%
	<i>Staphylococcus aureus</i>	1	33%

countries. In Brazil, data from the the Brazilian Institute of Geography and Statistics (IBGE) show 23.5 million people over 60 years of age, that is, 12.1% of the population⁹.

Femoral neck fracture in the elderly affects men and women. In this study, the vast majority of patients undergoing hip arthroplasty had femoral neck fracture and 60% were women. A study carried out in an orthopedic hospital in the state of Mato Grosso identified the incidence of 11% of elderly patients with hip fracture, 63% of them women. Most underwent fracture surgical correction¹⁰. Another study, conducted in São Paulo, identified the predominance of women among elderly hip fracture victims¹¹.

Researchers have conducted investigations to search beyond the incidence and prevalence of falls among the elderly, institutionalized or not, and assess their causes and predisposing factors. A study in Goiania with institutionalized elderly found a prevalence of 38% in falls¹².

In Belo Horizonte, among the elderly enrolled in a health center, the prevalence of falls was 59%, and half fell from standing position¹³. Fall from standing position was also the most common mechanism of injury among elderly patients from the emergency department of the São Paulo Holy Home¹⁴. In the present study the main cause of hip replacement surgery was femoral neck fracture caused by falling from a standing position, in 92% of cases.

Infectious and non-infectious complications can cause loosening of the hip prosthesis. In this study, the infection was identified as the leading cause of surgical intervention in 54% of revisional cases, resulting in prosthesis removal. The literature brings different results, with the infectious complication accounting for 8% of the revisional cases in a retrospective US study that evaluated more than a thousand records of patients undergoing hip arthroplasty surgical revision. Aseptic loosening is the cause of 51% of revisions; however, infection has become a major cause of

prosthesis loss after the surgical intervention for 30% of patients¹⁵. Other studies showed similar results^{16,17}.

Understanding the interaction between microorganisms, prosthesis and host is necessary to establish the best approach for both diagnosis and treatment of infections associated with the implants. Although infection in hip arthroplasties are not so frequent, when it occurs it has devastating effects, with high morbidity and significant cost. Although the skin colonizing microorganisms are associated with implants infection, their diagnosis is complex and has been studied by many researchers. Conventional culture methods must be combined with other laboratory tests, since studies show negative culture results in 20% of cases of prostheses infection. In addition, it is estimated that over 10% present false positive results¹⁶⁻¹⁹.

In this study, microbiological investigation was performed in less than half of the cases of infection by standard clinical methods. Identification of gram-positive bacteria was consistent with the literature, which describes the gram-positive cocci as responsible for approximately 65% of infections in orthopedic prostheses¹⁸.

Infections in implants caused by virulent microorganisms, such as *S. aureus* and gram-negative rods, typically manifest themselves as acute infection in the first three months after surgery^{17,18}. In this study, almost half of surgical revisions occurred up to three months after hip replacement, and infection was the main cause. It is worth mentioning that reoperations due to infection for surgical cleaning were not effective, requiring surgical revision approach for prosthesis replacement.

Considering the recent developments with regard to the diagnostic investigation of infection associated with orthopedic prostheses, and also to prevention and treatment, despite the hospital has a team of orthopedic surgeons, two held the vast majority of procedures, a fact that enables the extensive discussion and review of techniques and procedures related to the perioperative period. People involved in infection control, perioperative nursing and surgeons must work together to discuss best practices to be implemented, as well as reviewing those being applied.

R E S U M O

Objetivo: caracterizar perfil epidemiológico de pacientes submetidos à artroplastia do quadril, primária ou de revisão. **Métodos:** estudo retrospectivo, descritivo, incluindo artroplastias do quadril realizadas no período de janeiro/2009 a junho/2012 em hospital de ensino de Belo Horizonte, MG. Os dados foram analisados por estatística descritiva. **Resultados:** as operações ortopédicas correspondem a 45% das realizadas no Hospital e 1,4% à artroplastias do quadril. No período, foram realizadas 125 artroplastias do quadril, sendo 85 totais, 27 parciais e 13 revisões. Dentre os pacientes, 40% pertenciam ao sexo masculino e 60%, ao feminino. A idade variou entre 20 e 102 anos, com média e mediana de 73 e 76 anos. O diagnóstico mais frequente (82%) foi fratura de colo de fêmur por trauma de baixa energia causado por queda da própria altura. Em 13 operações de revisão, 12 necessitaram a remoção da prótese. A complicação infecciosa motivou a revisão em 54% das ocasiões, seguida de luxação (15%), fratura periprótese (15%) e soltura asséptica (15%). O agente etiológico de infecção foi identificado em 43% das ocasiões. O tempo médio de prótese até a operação de revisão foi oito meses. **Conclusão:** os pacientes submetidos à artroplastia do quadril são idosos, com fratura de colo fêmur, causada por queda da própria altura, que acometeu mais as mulheres. A incidência de soltura de prótese do quadril foi 10%. A principal causa de soltura foi a infecção. A incidência de revisão cirúrgica de artroplastia do quadril foi 10% e a incidência de mortalidade hospitalar nos pacientes submetidos à artroplastia do quadril foi 7,2%.

Descritores: Ortopedia. Artroplastia de Quadril. Reoperação. Infecção da Ferida Operatória.

Although this study answered the questions previously established, it has some limitations. The first is the retrospective data collection, from the electronic medical records, which has a variability related to forgetting in recording important details about the patient in the perioperative period. The second limitation is related to the creation of a heterogeneous group that included total and partial arthroplasties, making it impossible to draw meaningful conclusions, only allowing to know the reality of the scenario in question. The partial hip arthroplasty is indicated for more severe patients with worse clinical state, low life expectancy and low functional demand when compared with total arthroplasty. The third limitation is the inclusion of revisions of those undergoing primary arthroplasty in other services.

The concern with improving the quality of care leads us to reflect on strategies to minimize risks and enhance security of the elderly patients undergoing arthroplasty. The results suggest a careful evaluation to assess the risk of falls in hospitalized elderly as a measure to prevent fracture and complications arising from it. An important aspect to be investigated is the adhesion of assistance professionals to infection prevention protocols in arthroplasties, that being the most important complication identified in this study. Considering the aseptic loosening, they have been associated with the presence of endotoxins and its origin may be due to both the excessive use of the prosthesis and the presence of gram negative bacteria. Therefore, investigating the presence of bacteria in surgical instruments that are reprocessed using drinking water becomes essential in order to reset guidelines for reprocessing.

Patients undergoing hip arthroplasty in the study hospital are elderly, with femoral neck fracture caused by falling from standing position, affecting more women than men. The incidence of hip prosthesis loosening was 10%, and infection, 5.6%. The main cause of loosening was infection. The incidence of hip arthroplasty surgical revision was 10%. The hospital mortality in patients undergoing hip arthroplasty was 7.2%.

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Efficacy of varicose vein surgery with preservation of the great saphenous vein

Eficácia do tratamento cirúrgico das varizes com preservação de veia safena interna

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A B S T R A C T

Objective: To evaluate the efficacy of surgical treatment of varicose veins with preservation of the great saphenous vein. **Methods:** We conducted a prospective study of 15 female patients between 25 and 55 years of age with clinical, etiologic, anatomic and pathophysiologic (CEAP) classification 2, 3 and 4. The patients underwent surgical treatment of primary varicose veins with great saphenous vein (GSV) preservation. Doppler ultrasonography exams were carried out in the first and third months postoperatively. The form of clinical severity of venous disease, Venous Clinical Severity Score (VCSS) was completed before and after surgery. We excluded patients with history of deep vein thrombosis, smoking or postoperatively use of elastic stockings or phlebotonics. **Results:** All patients had improved VCSS ($p < 0.001$) and reduction in the diameter of the great saphenous vein ($p < 0.001$). There was a relationship between VCSS and the GSV caliber, as well as with preoperative CEAP. There was improvement in CEAP class in nine patients when compared with the preoperative period ($p < 0.001$). **Conclusion:** The varicose vein surgery with preservation of the great saphenous vein had beneficial effects to the GSV itself, with decreasing caliber, and to the symptoms when the vein had maximum caliber of 7.5 mm, correlating directly with the CEAP. The decrease in GSV caliber, even without complete abolition of reflux, leads to clinical improvement by decreasing the reflux volume.

Key words: Venous insufficiency. Saphenous vein. Varicose veins. Saphenous vein/ultrasonography. Saphenous vein/surgery.

INTRODUCTION

Chronic venous insufficiency (CVI) is defined as an abnormality in the functioning of the venous system due to venous hypertension caused by venous reflux, obstruction of venous flow, or by the combination of these two factors¹. CVI can affect the superficial venous system, the deep venous system, or both. Furthermore, the venous dysfunction may be the result of a congenital or acquired disorder²⁻⁴.

Reflux-induced venous hypertension can be caused by breakdown or damage to the venous valves; more recently, it is believed that the lesion and weakness of the vessel wall play a more important role in causing reflux and even in the genesis of valve disease^{1,5-7}.

The prevalence of chronic venous insufficiency in the population increases with age. In Europe, 5 to 15% of adults between 30 and 70 years of age have this disease, and 1% of them have varicose ulcers. In the United States, about seven million people have chronic venous insufficiency, which accounts for 70 to 90% of all lower extremity ulcers⁸⁻¹⁰. The prevalence of primary venous disease can reach 20% of the population¹¹. Maffei *et al.*¹²

conducted an epidemiological study on venous alterations of the lower limbs in the population of Botucatu / SP and found an estimated prevalence of 35.5% of varicose veins and 1.5% of severe forms of CVI, with active or healed ulcers. With the aging of the world population, this prevalence tends to increase.

Being a chronic, progressive and relapsing character disease, CVI is still far from being understood and treated properly, although several theories and methods may be employed with relative immediate success, but without proven long-term results¹³.

Histological results of the saphenous vein wall with marked valvular insufficiency in patients with altered lipid profile show clear resulting subintimal thickening of intense reflux, hypertension and inflammatory reaction similar to atherosclerosis¹³.

Several methods have been used to assess the degree of CVI, such as the Venous Clinic Severity Score (VCSS), air plethysmography and echo-color-Doppler¹⁴⁻¹⁶, but none of them proved reliable stratification when relating clinical, etiologic, anatomic and pathophysiologic (CEAP) classification, nor has been successfully used to demonstrate efficacy of treatment methods.

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The authors aimed to evaluate the importance of surgical treatment of lower limb varicose veins with preservation of the great saphenous vein in clinical regression of chronic venous disease.

METHODS

We evaluated a total of 22 lower limbs of 15 female patients with chronic venous insufficiency (CVI), according to the clinical, etiologic, anatomic and pathophysiologic classification. The patients underwent a preoperative protocol for surgical treatment of primary varicose veins of the lower limbs with preservation of the greater saphenous vein¹⁷. The VCSS form was completed before and after surgery to assess venous disease clinical severity.

The inclusion criteria adopted were: 1) female patient; 2) aged between 25 and 55 years; 3) diagnosis of chronic venous insufficiency (CEAP classification – clinical, etiologic, anatomic and pathophysiologic – between 2 and 4); 4) surgical treatment; 5) insufficiency in at least one of the saphenous veins; and 6) Maximum 7.5 mm diameter of the great saphenous vein. Exclusion criteria were: 1) history of lower limbs deep vein thrombosis; 2) smoking; 3) use of compression socks or phlebotonic medication postoperatively; 4) postoperative complications such as deep venous thrombosis or infection; 5) maximum diameter of the greater saphenous vein greater than 7.5 mm; and 6) prior saphenectomy.

Patients were treated at the Vascular Surgery clinic, Hospital Universitário Gaffree e Guinle, Hospital Universitário Pedro Ernesto and VASCLAR Clinic. The selection was made from the history and physical examination of each patient (CEAP classification and VCSS). All patients underwent examination with eco-color-Doppler to identify and classify the degrees of venous insufficiency, completing the CEAP classification.

Postoperatively, patients were followed with queries made at one week, one month and three months after surgery. Each evaluation consisted of clinical history, physical examination and venous echo-color-Doppler exam of the lower limbs. The comparative analysis was performed between the results of the three tests applied during the visits.

The varicose paths were marked in standing position. Patients received spinal anesthesia and sedation and underwent surgery in the supine and Trendelenburg positions. The varicose paths were resected after ligation of insufficient veins directly and indirectly communicating to the great saphenous vein, which was preserved.

The main indicators in the evaluation of the great saphenous vein by Doppler ultrasonography were: the diameter of the vein in the groin, thigh and leg; the presence of insufficiency and the location of the insufficiency. These indicators were evaluated preoperatively and

postoperatively, and subsequently compared.

The following parameters were evaluated: VCSS, diameter and insufficiency of the great saphenous vein (GSV), CEAP classification between the pre- and postoperative periods, as well as differences in individuals within the CEAP classification. For the statistical analysis we used the Student's t test ($p < 0.05$).

RESULTS

We operated, between August 2011 and August 2012, 15 female patients between 25 and 55 years of age, bearers of varicose veins. All patients (Figure 1) improved clinical criteria (VCSS) postoperatively ($p < 0.001$) and there was decrease in the diameter of the great saphenous vein ($p = 0.002$) (Figure 2).

We observed that there was no postoperative improvement of the CEAP class in 11 patients, one patient showing improvement of CEAP classification in one of the limbs ($p < 0.001$) (Table 1). There was restoration of the flow of the great saphenous vein in seven operated legs, with statistical significance ($p = 0.001$) (Table 2). There was a directly proportional relationship between the VCSS and the great saphenous vein diameter, and the preoperative clinical, etiologic, anatomic and pathophysiologic classification (Table 3).

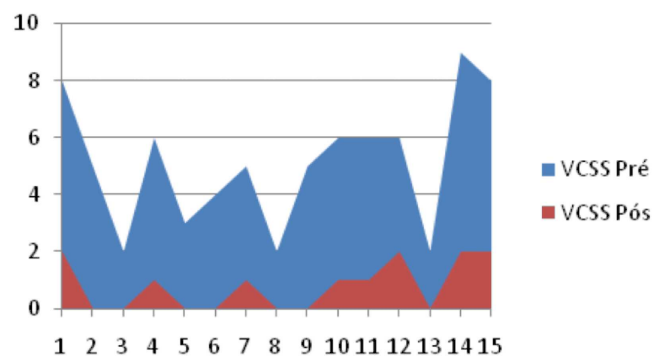


Figure 1 - Pre- and postoperative VCSS (Venous Clinic Severity Score) values.

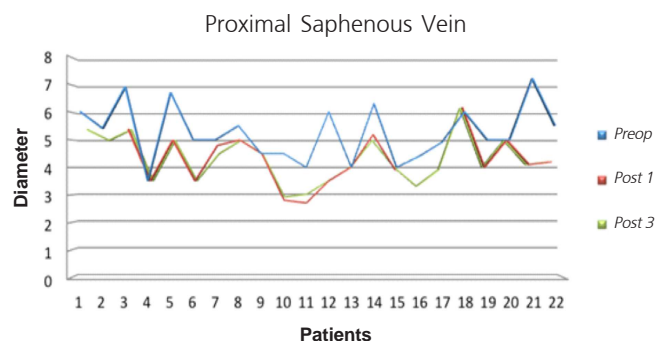


Figure 2 - Diameter of the great saphenous vein.

Table 1 – Classification according to CEAP and VCSS criteria.

Patients	Limb studied	Age	Pre RLL CEAP	Post RLL CEAP	Pre LLL CEAP	Post LLL CEAP	Pre VCSS	Post VCSS
TMLT	RLL/LLL	51	3	2	3	1	8	2
TLS	RLL	47	3	2	-	-	5	0
TPA	RLL	35	2	1	-	-	2	0
MS	RLL/LLL	48	3	2	3	2	6	1
MJNS	LLL	55	-	-	2	2	3	0
MCAN	RLL/LLL	53	2	2	2	2	4	0
LSS	LLL	28	-	-	2	1	5	1
LN	RLL	29	2	1	-	-	2	0
DFFP	RLL/LLL	50	3	2	3	2	5	0
ASI	RLL/LLL	40	3	2	2	2	6	1
RML	RLL/LLL	48	2	1	3	2	6	1
MCA	RLL/LLL	49	3	2	4	2	6	2
MAG	MIE	34	-	-	1	1	2	0
EPM	MIE	34	-	-	2	1	9	2
COC	MIE	47	-	-	4	4	8	2

CEAP – clinical, etiologic, anatomic and pathophysiologic; RLL - right lower limb; LLL – left lower limb; VCSS – Venous Clinic Severity Score.

DISCUSSION

Radical saphenectomy plays a role in the treatment of chronic venous disease, but with increasingly limited indication, given its importance as a vascular substitute for various beds of the circulatory system. Associated with this, Pittaluga *et al.*¹⁷ showed that the great saphenous vein, when presenting with a diameter of approximately 7.5 mm, shall, after the withdrawal of collaterals and the ligation of the perforating, decrease in diameter, with improvement or complete abolition of

reflux, associated with improvement of clinical parameters, confirming the effectiveness of the proposed method. Nonetheless, it might be questioned that the diameter of the saphenous vein may have no direct correlation or be the only significant predictor¹⁸ associated with the symptoms.

Resection of varicose veins with preservation of the saphenous vein and venous reservoir resection¹⁷ restores venous flow, resulting in the beneficial effects to the saphenous vein, reducing signs and symptoms, and therefore the degree of venous disease of the patients thus operated.

Table 2 – Restoration of flow in the greater saphenous vein (GSV).

Patients	RLL Preoperative reflux	RLL Postoperative reflux	LLLPreoperative reflux	LLLPostoperative reflux
TMLT	P	P	P	A
TLS	P	P		
TPA	P	A		
MS	P	P	P	A
MJNS	P	P		
MCAN	P	P	P	P
LSS			P	A
LN	P	A		
DFFP	P	P	A	A
ASI	P	A	A	A
RML	A	A	P	P
MCA	P	P	P	P
MAG		P	P	
EPM		P	P	
COC		P	A	

Legends: RLL - right lower limb; LLL – left lower limb.
P- present; A- absent

Table 3 - Preoperative CEAP, VCSS and saphenous vein diameter.

Patients / Parameter	Pre RRL CEAP	Pre LLL CEAP	Pre VCSS	SVD right arch	SVD thigh	SVD right leg	SVD left arch	SVD left thigh	SVD left leg
TMLT	3	3	8	6		4.2	5.4		3
TLS	3	2	5	6.9	4.7	3.5			
TPA	2	2	2	3.5	3.2	3.7			
MS	3	3	6	6.7	5	4	5	3.5	3.5
MJNS	2	2	3				5	4.5	2.5
MCAN	2	2	4	5.5	3.7	3	4.5	2.5	2.5
LSS	2	2	5				4.5	2.5	2
LN	2	2	2	4	3.5	2.5			
DFFP	3	3	5	6	4.5	4.5	4	2	2.2
ASI	3	2	6	6.3		4.7	4		2.3
RML	2	3	6	4.4		3	4.9		3.1
MCA	3	4	6	6	5.5	5	5	5	4
MAG	2	1	2	6			5	3	3
EPM	4	2	9				7.2		3.6
COC	4	4	8				5.5	4.5	4

CEAP: clinical, etiologic, anatomic and pathophysiologic; RLL: right lower limb; LLL: left lower limb; VCSS: Venous Clinic Severity Score; SVD: saphenous vein diameter.

The decrease in diameter of the great saphenous vein without completely abolishing reflux can lead to clinical improvement by decreasing the volume of reflux¹⁸⁻²⁰, since this is in direct proportion to its diameter.

Recently, less invasive methods with laser and radio frequency and even dense foam opened new horizons in the treatment of chronic venous disease with less invasive techniques, an outpatient basis and results comparable to conventional surgery²¹.

Prospective studies with longer follow-up are needed to define the method to be used in cases of dilation and greater saphenous vein insufficiency and in cases of venous symptoms recurrence in patients with chronic venous insufficiency.

The long-term follow-up of these patients may help elucidate the most effective method in the treatment of lower limb varicose veins, its success and recurrence rates, bringing a new, less invasive proposal, with fewer comorbidities, to the therapeutic arsenal of lower limbs varicose disease.

In the authors' view, the preservation of the great saphenous vein, even if dilated and insufficient, is possible. It provides improvement of symptoms and also preserves the best autologous vascular conduit replacement. The aging population and the emergence of new instruments may influence the choice of radical treatment of the great saphenous vein, but not modify the surgical outcome in the short term.

R E S U M O

Objetivo: avaliar a eficácia do tratamento cirúrgico das varizes de membros inferiores com preservação da veia safena magna.

Métodos: estudo prospectivo realizado em 15 pacientes do sexo feminino entre 25 e 55 anos com a classificação clínica, etiológica, anatômica e patofisiológica (CEAP) 2, 3 e 4. Os pacientes foram submetidos ao tratamento cirúrgico das varizes primárias dos membros inferiores com preservação da veia safena magna (VSM). Foram realizados exames com eco-Doppler no primeiro e terceiro meses de pós-operatório. O formulário da gravidade clínica da doença venosa, Venous Clinical Severity Score (VCSS) foi preenchido no pré e pós-operatório para graduá-la. Foram excluídos pacientes com história de trombose venosa profunda, tabagismo, uso de meia elástica ou flebotômicos no pós-operatório. **Resultados:** todos os pacientes obtiveram melhora do VCSS ($P < 0,001$) e redução do calibre da veia safena magna ($P < 0,001$). Houve relação do VCSS com o calibre da VSM, assim como, com o CEAP no pré-operatório. Houve melhora da classe CEAP em nove pacientes comparado com o pré-operatório ($P < 0,001$). **Conclusão:** a operação de varizes com preservação da veia safena magna teve efeito benéfico à própria VSM, com a diminuição de calibre, e à sintomatologia quando a veia apresentava calibre máximo de 7,5mm, correlacionando-se diretamente com a CEAP. A diminuição do calibre da VSM mesmo sem abolição total do refluxo leva a melhora clínica por diminuição do volume de refluxo.

Descritores: Insuficiência venosa. Varizes. Veia safena. Veia safena/ultrassografia. Veia safena/cirurgia.

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Influence of preoperative supplementation of omega-3 fatty acid in the healing of colonic anastomoses in malnourished rats receiving paclitaxel

Influência da suplementação pré-operatória com ácido graxo ômega-3 na cicatrização das anastomoses colônicas em ratos desnutridos que receberam paclitaxel

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A B S T R A C T

Objective: To evaluate the effect of preoperative supplementation of omega-3 fatty acids on the healing of colonic anastomoses in malnourished rats receiving paclitaxel. **Methods:** we studied 160 male Wistar rats, divided in two groups: one subjected to malnutrition by pair feeding (M) for four weeks, and another that received food ad libitum (W). In the fourth week, the groups were further divided into two subgroups that received omega-3 or olive oil by gavage. The animals were submitted to colonic transection and end-to-end anastomosis. After the operation, each of the four groups was divided into two subgroups that received intraperitoneal isovolumetric solutions of saline or paclitaxel. **Results:** mortality was 26.8% higher in the group of animals that received paclitaxel ($p = 0.003$). The complete rupture strength was greater in well-nourished-oil Paclitaxel group (WOP) compared with the malnourished-oil Paclitaxel one (MOP). The collagen maturation index was higher in well-nourished-oil saline group (WOS) in relation to the malnutrition-oil-saline group (MOS), lower in malnourished-oil-saline group (MOS) in relation to malnourished-omega3-saline one (M3S) and lower in the well-nourished-omega3-saline group (W3S) compared with the malnourished-omega3-saline (M3S). The blood vessel count was higher in the malnourished-oil-saline group (MOS) than in the malnourished-oil-paclitaxel group (MOP) and lower in the malnourished-oil-saline group (MOS) in relation to the malnourished-omega3-paclitaxel group (M3P). **Conclusion:** supplementation with omega-3 fatty acids was associated with a significant increase in the production of mature collagen in malnourished animals, with a reversal of the harmful effects caused by malnutrition associated with the use of paclitaxel on the rupture strength, and with a stimulus to neoangiogenesis in the group receiving paclitaxel.

Key words: Anastomosis, Surgical. Malnutrition. Omega-3 Fatty Acids. Paclitaxel.

INTRODUCTION

Ovarian cancer is the second most common gynecological cancer in Brazil, with an annual mortality of about 15,000 cases¹. It is often diagnosed at a stage when there is peritoneal dissemination, and has surgery as its initial treatment approach with the aim of ideal cytoreductive resection, i.e., residual disease that is less than 0.5cm². To this end, intestinal segments resection and performance of colonic anastomosis are frequently required. Early chemotherapy containing paclitaxel is an important treatment element³. The healing process of these colonic anastomosis takes place in an adverse environment, under the effects of malnutrition, which is very common in patients with ovarian cancer with peritoneal dissemination, and of the immunosuppressive effects of chemotherapy⁴.

Preoperative food intake is crucial to ensure that the postoperative healing process will properly occur⁴⁻⁶. Although preoperative adequate renutrition is difficult in such patients, supplementation with specific nutritional elements in small volumes can be an alternative to accomplish it, especially if the substrate has a nutritional modulatory role in the healing process, enabling it to elapse with smaller effects of malnutrition⁷.

Experimental studies conducted to evaluate the effect of paclitaxel in colonic anastomosis in rats showed that when administered in the postoperative period, this drug hampers the healing process^{8,9}. In this scenario, the omega-3 fatty acids have been proposed as a nutritional element that allow caloric intake and favorable modulation of the inflammatory process and healing^{4,10,11}.

This study evaluated the effect of preoperative supplementation of omega-3 fatty acids on the healing of

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colonic anastomoses in malnourished rats receiving intraperitoneal paclitaxel.

METHODS

Experimental design and administered solutions

We used 160 male Wistar rats (*Rattus norvegicus* albinos, Roentia Mammalia) with body weight ranging from 200 to 330 grams (288.76 ± 4.45 g) from the vivarium of the State University of Maringá. The animals were housed in individual boxes and divided into two main groups: W - well-nourished rats ($n = 80$) who received food and water *ad libitum*; M - malnourished rats ($n = 80$) who received half the amount of the diet that their well-nourished pairs had received the previous day (malnutrition process, pair feeding method). Each group was divided into four subgroups with 20 animals each, according to lipid supplementation and the administration of saline or paclitaxel.

The lipid solutions were extra-virgin olive oil emulsion and omega-3 fatty acids consisting of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in a ratio of 80:20 and concentration of 20mg / ml. The administration comprised a single daily dose of 100mg / kg via orogastric gavage without anesthesia.

The drug used was paclitaxel at a dose of 3.5 mg / kg diluted in isotonic saline solution at a concentration of 0.35 mg / ml. The administration of chemotherapy or 0.9% isotonic saline solution was carried out with intraperitoneal injection, immediately after the surgical procedure.

The well-nourished rats (W) received chow *ad libitum* the four weeks prior to the procedure and were divided into four subgroups, being supplemented with: WOS – olive oil and saline; W3S – omega 3 and saline; WOP - olive oil and paclitaxel; and W3P – omega 3 and paclitaxel. The malnourished rats (M) were divided into four subgroups and were supplemented with: MOS – olive oil and saline; M3S – omega 3 and saline; MOP – olive oil and paclitaxel; and M3P - omega-3 and paclitaxel.

Surgical procedure and evolution

The surgical procedure, conducted under general anesthesia with a combination of 10 mg / kg xylazine and 50 mg / kg ketamine, consisted of two colon transections (colostomies), one at the colon proximal segment, 4.0 cm from the ileocecal valve, and one at the distal colon segment, 3.0 cm above the peritoneal reflection of the rectum. The reconstructions were performed in total single plane end-to-end anastomosis with interrupted suture using eight stitches of 6-0 monofilament, synthetic, nonabsorbable suture (Ethicon?). After anesthetic recovery all animals received food and water *ad libitum* until the time of death.

We observed and weighed the animals daily, and those which died underwent necropsy to evaluate the presence of fistula or peritonitis. Euthanasia, with a lethal dose of ketamine and xylazine association, was taken on the fifth day after surgery. After death, the animals underwent celiotomy for evaluation of the following: presence of wound infection, adhesions (by the Knighly index)¹² and anastomotic complications (dehiscence or stenosis). Then we excised the proximal and distal colon segments containing the anastomoses. The proximal segments, about 2.0 cm long, were named proximal specimen (PS) and used for pathological and immunohistochemical study. The distal segments, 4 cm long, were named distal specimen (DS) and subjected to tensile test.

Tension trial

The distal specimen was subjected to tensile test, using a computerized mechanical testing machine (EMIC®). Tension was applied with a 50 mm / minute speed. We used a 1Kg load cell with a sensitivity of 50 grams for a 4500 gf strength limit, until complete anastomotic rupture. The variables evaluated were the maximum tensile strength (MTS) and the complete rupture strength (CRS), measured in Newtons (N), and the maximum tension (MT), measured in N / cm².

Histological evaluation

The proximal specimen was fixed in buffered 10% formalin and sent for histological processing and evaluation by hematoxylin-eosin (HE), picosirius-red (PSR) and immunohistochemistry.

HE staining was used to assess the degree of inflammatory reaction (poly and mononuclear infiltrate), interstitial edema, vascular congestion, granulation tissue and fibrosis. The data were classified as severe, moderate, mild or absent, and transformed into quantitative variables by assignment of indexes to the histological findings, as follows: absent, index 0; discrete, index 1; moderate, index 2; and severe, index 3.

The staining with F3BA picosirius-red was made to identify the mature and immature collagen fibers by microscopy technique with polarized light and computerized morphometric analysis. Each section was assessed by optical microscopy at 200x magnification using a polarized light source (C-SP simple polarizer). We analyzed two fields, proximal and distal to the anastomotic line, containing the entire thickness of the colonic segment. The images were captured by a Nikon DS-FI1C camera and transmitted via the D-DA simple system analyzer, to the G205HV® color LCD monitor, frozen and scanned. We then performed image analysis using the Image Pro-plus™ software. In the RGB ("Red, Green, Blue") system, we quantified areas of mature collagen fibers – collagen type I (shades of red, yellow and orange) – and immature ones – type III collagen (green tones). We computed the between the area

percentages of collagen type I and collagen type III, determined as collagen maturation index (CMI).

Immunohistochemical evaluation

By immunohistochemical method, we evaluated CD31 (Monoclonal, JC70 code, Cell Marque, Moleenstraat, NL), calponin (Monoclonal, code CALP, Cell Marque, Moleenstraat, NL) and Ki-67 (Monoclonal, SP6 code, Cell Marque, Moleenstraat, NL), on separate slides. We used these markers to evaluate neoangiogenesis, research for myofibroblasts, and for cells in the replication phase (other than G0) present in the healing process area. We carried out antigen retrieval by exposing the materials to heat and pressure. Development of the slides was made by Diaminobenzidine (DAB) brown chromogen; the detection technique, by HRP-polymer (free biotin). We used positive and negative controls to validate the reactions. We examined the slides under 200x magnification to count vessels and 400x to count myofibroblasts and proliferating cells. The images were made using the pictures OPT 5000 Power Opticam® capture system, of 5.0 megapixels, connected to a computer with image analysis software (VMS 3.5 Measuring Software HPower®). We performed quantitative analysis of the number of vessels, fibroblasts and proliferating cells in the area of the anastomosis, as well as 10mm proximal and 10mm distal to it, in four randomly selected different fields.

Statistical analysis

We carried out the statistical analysis according to the nature of the data. We used parametric tests for quantitative variables with normal (Gaussian) distribution. For comparison between all groups, was applied the analysis of variance (ANOVA), and for the pair-wise comparison of groups, we used the Student's t test. For quantitative variables without normal (Gaussian) distribution, we used non-parametric analysis. For comparison between all groups, we applied the Kruskal-Wallis test, and for pair-wise analysis, the Mann-Whitney test (Wilcoxon test for independent groups). We evaluated dichotomous variables, such as a fatal outcome, presence of wound infection and anastomotic complications (dehiscence or stenosis) by the chi-square test and the Cochran test. The level of significance was $p < 0.05$.

RESULTS

Of the initial 160 animals experiment on, 117 survived until the day of euthanasia, with an overall mortality rate of 26.8%. Of the 43 deaths, 42 were for anastomotic complications, 15 in the animals receiving saline and 28 in groups receiving paclitaxel, significantly higher in the latter ($p = 0.03$).

The average weight of the animals was $294.8 \pm 1,67g$. There was no difference between the groups average

weight on the first day (D1) of the experiment ($p = 0.8037$). The animals of well-nourished groups had an average weight gain of 23.1% between D1 and D28. The animals of the malnourished groups had an average weight loss of 16.6% between D1 and D28. Between the day of the operation and the euthanasia there was a mean weight loss of 18% in the well-nourished group and 10% in the malnourished group (Figure 1).

On the operation day (Figure 2), the average weight of the MOS group ($236.5 \pm 4.2 g$) was significantly lower ($p < 0.05$) than the average M3S group weight ($253.8 \pm 4.1 g$).

Anastomotic stenosis occurred in 14 rats of the well-nourished group and in 31 of the malnourished group, being significantly higher in this group ($p = 0.007$).

Full tensile strength (Figure 3) was significantly higher in the WOP group compared with the MOP group (1.28 ± 0.17 vs. 0.77 ± 0.07 , $p < 0.05$). There was no difference between the groups in terms of maximum tension ($p = 0.2119$) and for the maximum tensile strength ($p = 0.3638$).

The mean intensity of the inflammatory infiltrate (Figure 4) was significantly lower in the MOS group compared with the M3S group (1.61 ± 0.78 vs. 2.50 ± 0.63 , $p < 0.05$).

Regarding the collagen maturation index (CMI) (Figure 5), it was significantly higher in the WOS group than in the MOS one (1.45 ± 0.4 vs. 0.35 ± 0.08 , $p < 0.05$), significantly lower in the W3S group than in M3S one (2.08 ± 0.35 vs. 2.82 ± 0.33 , $p < 0.05$), and significantly lower in the MOS group than in groups M3S (0.35 ± 0.08 vs. $2.82 \pm$

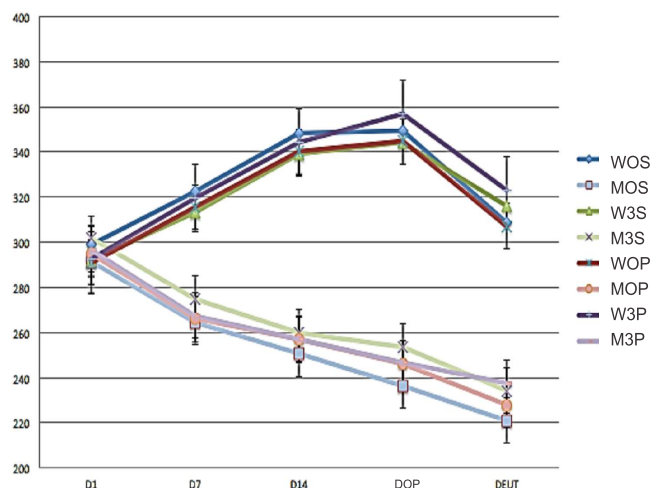


Figure 1 - Evolution of animal weight. X-axis: days of the experiment - D1: Day 1; D7: 7th day; D14: 14th day; DOP- day of operation; and DEUT: day of mice death (euthanasia). Y-axis: Weight (grams). WOS: well-nourished-oil-saline; W3S: well-nourished-omega-3-saline; WOP: well-nourished-oil-paclitaxel; W3P: well-nourished-omega-3-paclitaxel; MOS: malnourished-oil-saline; M3S: malnourished-omega-3-saline; MOP: malnourished-oil-paclitaxel; M3P: malnourished-omega-3-paclitaxel.

0.33, $p < 0.05$) and MOP (0.35 ± 0.08 vs. 1.58 ± 0.15 , $p < 0.05$).

The average blood vessels count (Figure 6) was significantly higher in the M3S group compared with the MOP group (12.64 ± 1.7 vs. 6.45 ± 0.28 , $p < 0.05$) and significantly lower in the MOP group in relation to the M3P group (6.45 ± 0.28 vs. 8.91 ± 0.88 , $p < 0.05$).

DISCUSSION

The overall incidence of deaths in this study was 26.5%, consistent with other studies using similar methodologies. Trubian observed 24.5% of deaths when assessing malnutrition with toxemia induction¹³. The mortality rate was higher in the groups receiving paclitaxel compared with the groups that received saline, most due to anastomotic postoperative complications.

The immunosuppressive action of chemotherapy drugs such as paclitaxel is one of the possible factors associated with higher death rates observed in the groups receiving this drug^{2,14}. Another possible explanation for this higher death rate is because such drugs act by inhibiting cell proliferation by different mechanisms of action. As such proliferation is essential in the healing process, they play an important attenuation of the fibroplasia process^{8,9,15}. The inhibitory action on fibroplasia results in higher anastomotic dehiscence rate, causing fistula and fecal peritonitis¹⁵, which is consistent with what was observed at the animals' necropsy.

The average starting weight of the animals in all groups was homogeneous. The induction of protein-energy malnutrition, by restriction to 50% of the standard diet, promoted progressive weight loss during the 28 days. The animals in well-nourished groups had an average weight gain of 23.1% between D1 and D28, while the ones in malnourished group had a mean weight loss of 16.6% between D1 and D28. The average weight of the malnourished group was lower compared with the well-nourished ones at the end of 28 days, showing the efficiency of the food restriction procedure on obtaining malnutrition. Similar results were found in other studies^{13,16}.

Relatively few studies have evaluated the role of supplementation of omega-3 fatty acids in post-anastomosis recovery of the digestive tract, most of them clinical studies. Clinical trials such as the ones of Farreras *et al.*, in 2005¹⁷, Torrinhas, 2013⁴, and Aoyama *et al.*, in 2013¹⁸, evaluated the effect of omega-3 fatty acids supplementation in patients undergoing digestive tract anastomosis. Only in the latter, the weight was evaluated as a nutritional recovery indicator, and the omega-3 fatty acids had an important role for nutritional recovery and weight gain in postoperative patients undergoing gastroenteric anastomosis for stomach cancer¹⁸.

We also observed that in the operation day, after one week of olive oil or omega-3 fatty acids administration,

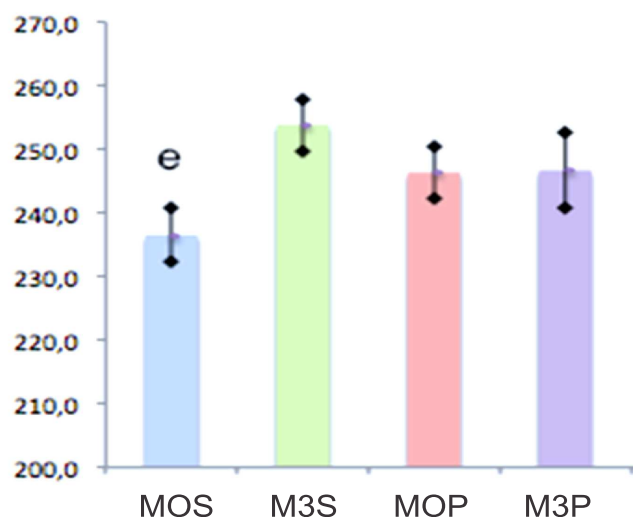


Figure 2 - Mean weights in malnourished groups on the day of operation. Y-axis: weight in grams; X-axis: groups: MOS - malnourished-oil-saline; M3S - malnourished-omega-3-saline; MOP - malnourished-oil-paclitaxel; M3P - malnourished-omega-3-paclitaxel; e - Average of MOS group weight is smaller than the average weight of M3S group ($p < 0.05$).

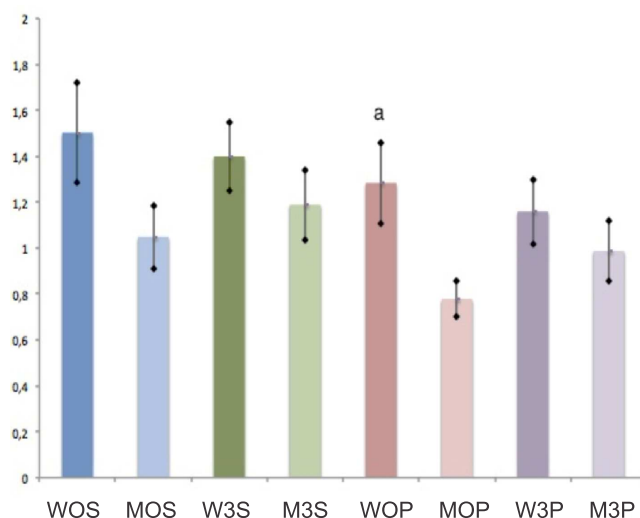


Figure 3 - Complete Rupture Strength (CRS) in groups. Y-axis: force in Newtons. X axis: groups; WOS: well-nourished-oil-saline; W3S: well-nourished-omega-3-saline; WOP: well-nourished-oil-paclitaxel; W3P: well-nourished-omega-3-paclitaxel; MOS: malnourished-oil-saline; M3S: malnourished-omega-3-saline; MOP: malnourished-oil-paclitaxel; M3P: malnourished-omega-3-paclitaxel. There was no significant difference between groups ($p = 0.3638$).

the MOS group mean weight was greater than the M3S group. This finding, consistent with the literature, suggests that supplementation with omega-3, besides favorably modulating the anastomotic healing process, also contributes as an important nutritional energy intake factor in the recovery from undernourishment¹⁸.

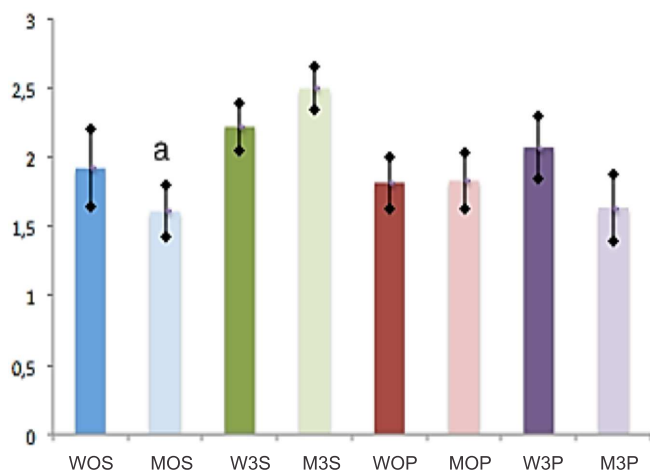


Figure 4 - Intensity of the inflammatory infiltrate at HE.

Y-axis: intensity index of inflammatory infiltrate.

X axis: groups. WOS: well-nourished-oil-saline; W3S: well-nourished-omega-3-saline; WOP: well-nourished-oil-paclitaxel; W3P: well-nourished-omega-3-paclitaxel; MOS: malnourished-oil-saline; M3S: malnourished-omega-3-saline; MOP: malnourished-oil-paclitaxel; M3P: malnourished-omega-3-paclitaxel; a- intensity of the inflammatory infiltrate of the MOS group significantly lower than of the M3S group ($p < 0.05$).

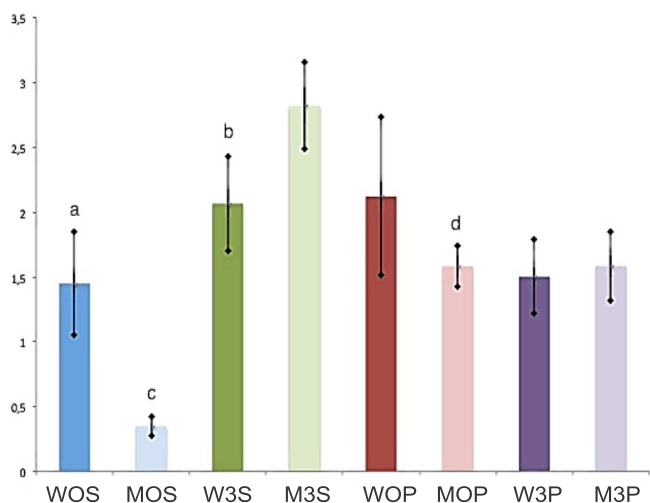


Figure 5 - Collagen maturation index.

Y-axis: collagen maturation index (CMI) average.

X axis: groups. WOS: well-nourished-oil-saline; W3S: well-nourished-omega-3-saline; WOP: well-nourished-oil-paclitaxel; W3P: well-nourished-omega-3-paclitaxel; MOS: malnourished-oil-saline; M3S: malnourished-omega-3-saline; MOP: malnourished-oil-paclitaxel; M3P: malnourished-omega-3-paclitaxel; a- WOS CMI was significantly higher than MOS ($p < 0.05$); b- W3S had significantly lower average CMI than M3S ($p < 0.05$); c- MOS had significantly lower average CMI than M3S ($p < 0.05$); and d- MOS had significantly lower average of CMI than MOP ($p < 0.05$).

Of the three measured tensile resistance strengths, the maximum tensile strength (MTS) and the maximum tension (MT) did not differ between groups. Concerning the complete rupture strength (CRS), it was

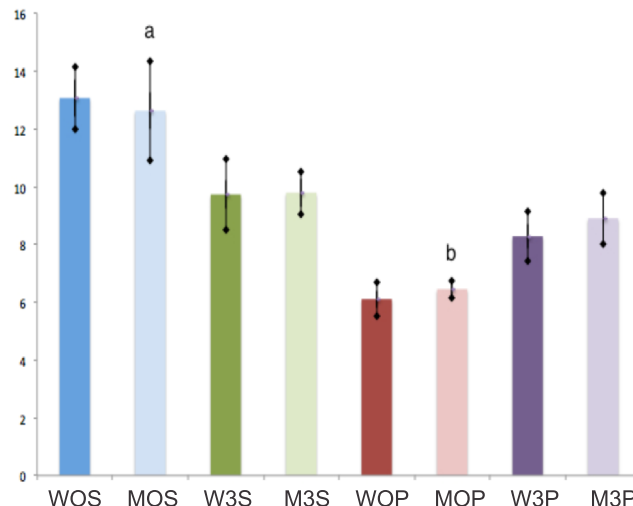


Figure 6 - Number of blood vessels according to the CD 31 marker.

Y-axis: number of vessels.

X axis: groups. WOS: well-nourished-oil-saline; W3S: well-nourished-omega-3-saline; WOP: well-nourished-oil-paclitaxel; W3P: well-nourished-omega-3-paclitaxel; MOS: malnourished-oil-saline; M3S: malnourished-omega-3-saline; MOP: malnourished-oil-paclitaxel; M3P: malnourished-omega-3-paclitaxel; a- number of vessels was significantly higher in MOS the group than in MOP ($p < 0.05$); b- number of vessels was significantly lower number in the MOP group than in M3P ($p < 0.05$).

lower in the MOP group when compared to the WOP. Malnutrition associated with paclitaxel played a deleterious role on the anastomotic tensile strength. In this sense, experimental studies that evaluated the effect of malnutrition^{13,16} and the use of chemotherapy¹⁵ on the on the rupture strength of colonic anastomoses in rats also observed its significant reduction due to harmful effects of such drugs on the healing process.

The induction of protein-energy malnutrition interferes systemically in protein synthesis. Possibly, this effect also occurs in the anastomotic site, hampering collagen synthesis. As the synthesis of collagen in the anastomosis is one of the major recovery factors of tensile resistance strength^{13,19}, disturbances in this synthesis are possibly associated with a reduction in tensile strength. This mechanism might explain the finding of reduced complete rupture strength (CRS) in the MOP group in relation to the WOP one. The also lower collagen maturation index (ratio between mature and immature collagen) in the MOP group when compared with the WOP, although not significant, corroborates this idea.

The action of chemotherapy on cell proliferation attenuates the fibroplasia process^{8,9,15}. Possibly this is an enhancer element of the malnutrition inhibitory effects on protein synthesis, especially collagen in the anastomotic site. These elements, malnutrition and paclitaxel administration, acting concurrently, probably explain the reduction of CRS in the MOP group in relation to the WOP

group, as this reduction was not observed in the group of animals submitted only to malnutrition without paclitaxel administration (MOS) in relation to the WOS group.

On the other hand, there was no significant difference in CRP between the M3P and W3P groups. This finding suggests that nutritional supplementation with omega-3 fatty acids can reverse the deleterious effects caused by the association of malnutrition and paclitaxel administration in colonic anastomosis CRS, for the significant reduction of this force, observed in the MOP group in relation to the WOP one, was not observed when the M3P group was compared with the W3P group. This finding is consistent with the ones of Ekçi *et al.*²⁰, who also observed a significant increase in the colonic anastomosis rupture pressure of rats receiving dietary supplementation with omega-3, although used in combination with ascorbic acid. The favorable modulation of omega-3 on collagen synthesis in the anastomotic site is one possible explanation for the observed recovery of the colonic anastomosis rupture strength.

We also noted an increase in cell activity in the anastomotic site, considered as inflammatory infiltrate, in the M3S group compared with the MOS one. This finding reinforces the idea that omega-3 has immunomodulating effects in inflammation and healing, by stimulating cellular activity, and corroborates the findings of McDaniel *et al.*²¹, who observed an inflammatory infiltrate increase of human healing skin wounds, as well as a significantly higher level of interleukin 1 α (IL-1 α) in the inflammatory lesion fluid in the group that received the administration of EPA and DHA. This finding may seem conflicting with that proposed in the literature, that the omega-3 fatty acids have less pro-inflammatory activity by replacing arachidonic acid (omega-6 fatty acid) in the cell membrane and increase, through its metabolism, the production of eicosanoids of lower inflammatory potential, such as leukotriene B₅ and prostaglandin E₃^{10,22}. Authors speculate that this increased cellular activity of the anastomotic environment is due to specific cell types, such as macrophages, fibroblasts, and myofibroblasts. It is possible that at the anastomotic site eicosanoids derived from the omega-3 fatty acids, although display an inhibitory effect on the inflammatory process in general, can stimulate the proliferation of specific cell types. The largest production of mature collagen (CMI) in the M3S group compared with the MOS one contributes indirectly to this idea, as this increased production is correlated with increased activity of cells producing collagen (fibroblasts and myofibroblasts) in the anastomotic environment.

The evaluation of collagen densitometry showed a significant reduction of mature collagen (type I) in relation to the immature one (type III), when assessed by the collagen maturation index (CMI), in the MOS group compared with the WOS group. This finding suggests that malnutrition is an important factor reducing the production of mature collagen in the healing anastomosis. Trubian also

observed a reduction of CMI in groups of malnourished rats compared with the group of well-nourished ones¹³.

The recovery of the tensile strength is more related to type I collagen than with type III one. The deposition and remodeling of type I collagen fibers is the main factor for recovery of anastomotic resistance¹⁹.

The M3S group showed an important gain of mature collagen in relation to the immature one when compared to W3S group, as the CMI of the former was greater than the one of the latter. This finding suggests that the administration of omega-3 in the week before the surgical intervention stimulates the production of mature collagen in malnourished animals. The CMI was also significantly higher in the M3S group compared with the MOS one. This finding supports the idea that preoperative administration of omega-3 can reverse the deleterious effects of malnutrition in the production of mature collagen in the healing anastomotic environment.

The migration and proliferation of fibroblasts and myofibroblasts in the healing environment, and consequently the production of collagen, is mediated by the action of inflammatory prostanoids (prostaglandins and leukotrienes) produced by inflammatory cells. Therefore, the higher CMI in the M3S group in relation to the MOS is possibly correlated with the higher level of cellular activity observed in the M3S group compared with the MOS group.

Another finding of this study that favors the concept of immunomodulation produced by omega-3 was the observation made in the number of blood vessels (neoangiogenesis) in the anastomotic healing environment. In immunohistochemistry, CD31 is mainly used to demonstrate the presence of endothelial cells in histologic tissue sections. This allows evaluating the degree of tissue angiogenesis²³. We observed a decrease in the number of blood vessels in the MOP group in relation to the MOS group, suggesting that the administration of paclitaxel, which is a drug with antiangiogenic action²⁴, is the causative factor of such reduction, agreeing with another study⁸ that showed significant reduction in neovascularization of colonic anastomoses of rats receiving paclitaxel. Supplementation with omega-3 in the M3P group was associated with recovery of the number of vessels, since this number was higher in this group compared with the MOP group. This finding suggests that the inhibition that paclitaxel causes on neoangiogenesis of the colonic anastomosis healing process can be reversed with the addition of omega-3 preoperatively. It is speculated that the eicosanoids produced by the metabolism of omega-3 fatty acids, such as prostaglandin E₃ and leukotriene B₅, stimulate the migration and proliferation of endothelial cells precursors in the anastomotic environment.

Myofibroblasts are (predominantly) type I collagen-producing cells, and its quantification can also be used as a healing evaluation method¹³. Fibroblasts start to appear in the wound around the third day after surgery, proliferate in response to growth factors and begin to

produce collagen²⁵. We observed a significant reduction in the average number of myofibroblasts in the M3S group compared with the W3S one. This finding suggests that malnutrition is a deleterious effect to the myofibroblasts production. Trubian also found a significant reduction in the number of myofibroblasts in colonic anastomosis in malnourished rats¹³.

Proliferating cells are the very hallmark of anastomotic healing. The Ki-67 antigen is present on all active phases of the cell cycle (G1, S, G2 and mitosis), but is absent on resting cells (G0)²⁶. In this study, there was no difference between groups in the number of proliferating cells when assessed by Ki67. Given the previously reported findings and hypotheses developed, one would expect to find more proliferating cells in the groups receiving omega-3 fatty acids, particularly in subgroups that did not receive chemotherapy, when compared with groups receiving olive oil, but we did not. We could not establish objective reasons for this. One suggested possibility is that proliferating cell types are different between the groups olive oil and omega-3 fatty acids. In the latter, with healing mediated by eicosanoids of lower inflammatory potential (prostaglandin E₃ and leukotriene B₅) derived from the metabolism of omega-3 fatty acids, cell types would be composed of myofibroblasts, fibroblasts, endothelial cells and their precursors; in the former group (olive oil), with healing mediated by prostanoid of more inflammatory potential, other cell types would prevail, like polymorphonuclear and mononuclear ones.

In agreement with the literature, the data presented here suggest that the use of omega-3 was associated with modulation of the inflammatory process, with stimuli to collagen production and to its quality in the anastomotic environment¹⁹. As already mentioned, the amount of mature collagen in relation to the immature, as measured by the CMI, was significantly higher in the M3S group compared with the MOS. Also in the M3S group, cellular activity represented by the inflammatory infiltrate in the anastomosis was higher than in the M3S group. These two concomitantly assessed findings support the idea that preoperative omega-3 administration in malnourished animals contributes positively to the healing process modulation of colonic anastomoses in rats, corroborating data from another work²⁰, which pointed to the beneficial action of fatty acids.

The supplementation of omega-3 was also an important energy intake nutritional factor, as it attenuated weight loss in the M3S group compared with the MOS. This supplementation also played an important role in the recovery of the deleterious effects of paclitaxel on neoangiogenesis, since the number of blood vessels in the M3P group was higher than in the MOP one.

The exact mechanisms by which omega-3 may have acted to produce this study's findings still need to be clarified. Omega-3 fatty acids have immunomodulatory activities, still under study, on the production of cytokines, activation of T lymphocytes and angiogenesis²⁷, which, when understood, can contribute to a better data comprehension.

RESUMO

Objetivo: avaliar o efeito da suplementação pré-operatória dos ácidos graxos ômega-3 sobre a cicatrização das anastomoses colônicas em ratos desnutridos que receberam paclitaxel. **Métodos:** foram estudados 160 ratos Wistar, distribuídos em dois grupos: um submetido à desnutrição pelo pair feeding (D) durante quatro semanas, e outro que recebeu ração ad libitum (N). Na quarta semana, os grupos foram subdivididos em dois subgrupos que receberam, por gavagem, ácido graxo ômega-3 ou azeite de oliva. Os animais foram submetidos à transecção colônica e anastomose término-terminal. Após a operação, foram distribuídos em dois subgrupos que receberam soluções isovolumétricas de salina ou paclitaxel, intraperitonal. **Resultados:** A mortalidade foi 26,8%, maior no grupo de animais que recebeu paclitaxel ($p=0,003$). A força de ruptura completa foi maior no grupo nutrido-azeite-paclitaxel (NAP) em relação ao grupo desnutrido-azeite-paclitaxel (DAP). O índice de maturação de colágeno foi maior no grupo nutrido-azeite-salina (NAS) em relação ao grupo desnutrido-azeite-salina (DAS), menor no grupo desnutrido-azeite-salina (DAS) em relação ao grupo desnutrido-ômega3-salina (DOS) e menor no grupo nutrido-ômega3-salina (NOS) em relação ao desnutrido-ômega3-salina (DOS). A contagem do número de vasos sanguíneos foi maior no grupo desnutrido-azeite-salina (DAS) em relação ao grupo desnutrido-azeite-paclitaxel (DAP) e menor no grupo desnutrido-azeite-salina (DAS) em relação ao grupo desnutrido-ômega3-paclitaxel (DOP). **Conclusão:** a suplementação com ácidos graxos ômega-3 associou-se ao aumento significativo na produção de colágeno maduro nos animais desnutridos, à reversão do efeito deletério causado pela desnutrição em associação ao uso do paclitaxel, sobre a força de ruptura, e ao estímulo da neoangiogênese no grupo que recebeu paclitaxel.

Descritores: Anastomose Cirúrgica. Desnutrição. Ácido Graxo Ômega-3. Paclitaxel.

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Pulmonar recruitment in acute respiratory distress syndrome. What is the best strategy?

Recrutamento pulmonar na síndrome do desconforto respiratório agudo. Qual a melhor estratégia?

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A B S T R A C T

Supporting patients with acute respiratory distress syndrome (ARDS), using a protective mechanical ventilation strategy characterized by low tidal volume and limitation of positive end-expiratory pressure (PEEP) is a standard practice in the intensive care unit. However, these strategies can promote lung de-recruitment, leading to the cyclic closing and reopening of collapsed alveoli and small airways. Recruitment maneuvers (RM) can be used to augment other methods, like positive end-expiratory pressure and positioning, to improve aerated lung volume. Clinical practice varies widely, and the optimal method and patient selection for recruitment maneuvers have not been determined, considerable uncertainty remaining regarding the appropriateness of RM. This review aims to discuss recent findings about the available types of RM, and compare the effectiveness, indications and adverse effects among them, as well as their impact on morbidity and mortality in ARDS patients. Recent developments include experimental and clinical evidence that a stepwise extended recruitment maneuver may cause an improvement in aerated lung volume and decrease the biological impact seen with the traditionally used sustained inflation, with less adverse effects. Prone positioning can reduce mortality in severe ARDS patients and may be an useful adjunct to recruitment maneuvers and advanced ventilatory strategies, such as noisy ventilation and BIVENT, which have been useful in providing lung recruitment.

Key words: Valsava Maneuver. Positive-Pressure Respiration. Respiratory Distress Syndrome, Adult. Respiration, Artificial. Prone Position.

INTRODUCTION

The acute respiratory distress syndrome (ARDS) is a worldwide public health problem, occurring even today, with high rates of mortality. Despite the many strategies proposed so far, the only isolated therapy that effectively changed the prognosis of patients, with a significant reduction in morbidity and mortality rates, was the protective ventilatory strategy, characterized by the use of low tidal volume (4-8 ml / kg)^{1,2}. However, this strategy can facilitate alveolar de-recruitment and promote the cyclic opening and closing of alveoli, which is considered one of the mechanisms of promotion and exacerbation of lung injury³. In this context, various strategies, ranging from ventilation modes to specific maneuvers, have been proposed to minimize alveolar collapse and promote a more homogeneous ventilation distribution. The use of recruitment maneuvers (RM) aims to reopen collapsed alveolar units

based on a transient increase in transpulmonary pressure (P_{TP}) during mechanical ventilation^{4,5}.

Nevertheless, the RM can also exacerbate the damage to pulmonary epithelial⁶ and endothelial⁷ cells, increasing the alveolar-capillary permeability, which can exacerbate the syndrome⁸.

The objective of this study is to discuss the main strategies used to promote alveolar recruitment in patients with ARDS, as well as its benefits, indications and limitations. Finally, it aims to apply the concepts to clinical practice, in patients with ARDS.

METHODS

We conducted a wide survey in the database of "National Library of Medicine" / Pubmed using the following key words and descriptors, alone or in combination:

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"Mechanical ventilation", "Acute respiratory Distress Syndrome", "Recruitment maneuvers" "Prone positioning," "Noisy ventilation", "positive end expiratory pressure." We selected the most relevant articles, as well as the classic works on mechanical ventilation in acute respiratory distress syndrome. We included in the selection clinical and experimental original articles, multicenter studies and meta-analyses. We tried to make a critical analysis of the current data available regarding the use of recruitment maneuvers in ARDS, as well as its benefits, indications and limitations.

Lung recruitment

The recruitment aims to promote reopening of collapsed alveoli. Therefore, there can be used several mechanical ventilation strategies, patient positioning and specific recruitment maneuvers or association of one or more of these mechanisms.

Prone positioning

The prone position is a relatively simple and safe method for improved oxygenation, which can be regarded as a recruitment maneuver itself, improving gas exchange, promoting alveolar recruitment, without providing areas of hyperinflation^{2,9}.

When patients are placed in the prone position, the chest wall compliance decreases, and the P_{TP} is redistributed from dorsal to ventral and, as a consequence, there is a recruitment of pulmonary dorsal regions, which directly reflects the improvement in patient's oxygenation¹⁰⁻¹². By promoting a more balanced ventilation associated with recruitment, the prone position also results in a better distribution of blood flow¹³, preventing its inappropriate redirection from hyperinflated areas to the collapsed ones in response to increased average airway pressure and positive end-expiratory pressure (PEEP)^{14,15}.

In addition to direct effects, studies show that the ventilation in prone protects from, or at least slows the development of, injuries associated with mechanical ventilation¹⁶. Therefore, to provide a more homogeneous distribution of the P_{TP} gradient, there is a redirection of ventilation, making it more uniform¹⁷, which helps to establish and maintain lung recruitment in response to PEEP¹⁸, as well as reducing alveolar hyperinflation¹⁹.

The benefits of the prone position to ARDS patients during mechanical ventilation have been proven by several studies. However, the reduction of the mortality rate was proven recently in the PROSEVA study, published in 2013²⁰. The multicenter data established that this position is strongly indicated in patients with severe ARDS²⁰, which, according to the latest definition of Berlin (2012), includes patients with a PaO_2 / FiO_2 ratio of less than 100mmHg²¹. Moreover, these data clearly show that there is no advantage of this positioning in relation to increased survival in mild ARDS (PaO_2 / FiO_2 from 200 to 300 mmHg)²⁰.

Regarding moderate ARDS, the data are still controversial. By making a more detailed analysis of recently

published large studies^{20,22,23}, it can be suggested that prone positioning should be considered for patients with PaO_2 / FiO_2 below 150mmHg, when they are under a PEEP than higher 5cmH₂O and FiO_2 the greater than 0.6.

Another point to be considered is at what ARDS stage should the patient be put in the prone position. Despite promoting effective improvement in oxygenation after many days of the onset of the syndrome, the data on survival suggest that the best response is related to the early positioning of the patient in prone²⁰. This fact can be explained by factors for which the prone position has its most evident benefit, such as edema, reversible alveolar collapse areas and absence of major structural lung changes. In addition, prone applied early is more effective at reducing the risk of ventilator-associated lung injury (VALI) when compared with more advanced stages, since in these the damage has already been established^{20,23}.

Importantly, due to prone positioning promoting significant improvement in oxygenation, it eventually reduces the need for other ventilatory interventions that may be iatrogenic. Moreover, it may allow reducing the fraction of inspired oxygen (FiO_2) and airway pressure, also reducing the need for fluid infusion and, thus, the risk of additional injury to the mechanically stressed membranes and of cardiac overload.

Ventilation strategies

Some non-traditional ventilation modes have recently been suggested to promote lung recruitment. The biphasic positive airway pressure (BIVENT) mode allows ventilation with two levels of CPAP (Continuous Positive Airway Pressure) - high pressure (P_{high}) and low pressure (P_{low}) and, when associated with PSV (Pressure Support Ventilation), results in increase of the mean airway pressure and hence, increased P_{TP} ²⁴. Thus, it facilitates the opening of the previously collapsed airways by means of the installed pressure gradient. In addition, through the help of spontaneous breathing with diaphragmatic contraction, there is an increased ventilation of the lower posterior areas of the lungs, minimizing the airway pressure^{24,25}.

The "variable ventilation", characterized by changes in tidal volume and respiratory rate, cycle by cycle, simulates the breath of normal individuals. Experimental studies show that it leads to improved oxygenation and respiratory mechanics and the reduction of diffuse alveolar damage²⁶⁻²⁸. By generating different levels of volume within biological parameters, it reaches a critical opening pressure of the collapsed airways, followed by the opening the remaining airways with less opening pressure, leading to improvement in gas exchange and reduction of alveolar collapse^{29,30}.

Since these structures have different time constants in different regions of the lung, the mechanical ventilation with different pressure patterns and inspiratory times may be useful to recruit and stabilize the lungs when compared to regular respiratory patterns.

Recruitment maneuvers

The most used RM is sustained inflation, characterized by an abrupt increase in airway pressure (40 cm H₂O) over a specific time (within 60 seconds)³¹. The sustained inflation is effective in reducing pulmonary atelectasis³², improving oxygenation³³ and respiratory mechanics³³, preventing alveolar de-recruitment.

However, this maneuver requires high inspiratory flow and, when applied to an inhomogeneous lung parenchyma, may bring deleterious effects, predisposing to alveolar deformation during pulmonary distress, contributing to VALI, with bacterial³⁴ and cytokines translocation into the systemic circulation³⁵. Other studies have shown the benefit of this maneuver has limited duration, associated with high hemodynamic instability, increased risk of barotrauma / volutrauma³⁶, increased intracranial pressure³⁷, and reduced clearance of alveolar fluid⁸, resulting in poor oxygenation and³⁸ serious clinical consequences³⁶.

A recruitment maneuver considered "more physiological" is setting longer breath cycles during mechanical ventilation with a constant tidal volume, mimicking the sigh observed during normal breathing in healthy individuals. It can be obtained from a sequence of independent or consecutive breaths to reach a high plateau pressure in a volume- or pressure-controlled ventilation mode or by the periodic PEEP increase for a few cycles⁴. The sigh counterbalances the alveolar collapse tendency during ventilation with low tidal volumes, thus improving the respiratory function in patients with acute respiratory distress syndrome (ARDS), both in the controlled (PCV)⁴ and in the support (PSV)³⁹ ventilation modes. In the latter, experimental models suggest that the sigh reduces alveolar collapse and helps protect the lung from VALI⁴⁰.

Gradual recruitment (*step*) maneuvers have been quite effective when applied to heterogeneous lung parenchyma, with different time constants for small airways opening, thus promoting lower biological impact when compared with the abrupt pressure increase⁴¹. The *step* can be obtained through a slow and gradual increase of PEEP or also by increasing inspiratory driving pressure up to a threshold pressure, in general 40cm H₂O. Furthermore, in *step* there are smaller hemodynamic effects, since the average pressure achieved during this maneuver is lower⁴¹.

FINAL CONSIDERATIONS

Which patients have a better response to recruitment maneuvers?

Recruitment maneuvers (RM) are not without risks. To reduce the number of patients unnecessarily exposed can prevent potential complications. Importantly, to date no multicenter study demonstrated the superiority of RM, associated with protective strategy, in terms of survival. Thus, their use should always be cautious and some points should be observed. The earlier or exudative phase of acute respiratory distress syndrome (ARDS), the better the chance of RM success compared with a later or fibrotic phase⁴². Patients with extrapulmonary etiology of ARDS have better response to recruitment^{41,43}. Therefore, those with diffuse changes on imaging studies have better chance of RM success than those with focal changes³. Patients with severe ARDS respond better to RM¹⁹ and the high respiratory system elastance is associated with better response to recruitment in clinical trials¹⁹. On the other hand, when there is low thoracic wall elastance, the response to RM will be worse⁴².

R E S U M O

O suporte a pacientes com a Síndrome do Desconforto Respiratório Agudo (SDRA), realizado com baixos volumes correntes e limite da pressão positiva ao final da expiração (PEEP), é o padrão ouro no tratamento de pacientes internados em Unidades de Terapia Intensiva. No entanto, essas estratégias podem promover o desrecrutamento pulmonar levando ao fechamento e reabertura cíclicos de alvéolos colapsados e de pequenas vias aéreas. As manobras de recrutamento (MR) podem ser usadas em conjunto a outros métodos, como a PEEP e posicionamento dos pacientes, para promover melhora no volume pulmonar aerado. Diversos métodos são utilizados na prática clínica, mas o mais adequado e a seleção de qual paciente se beneficiaria de MR ainda não estão estabelecidos. Além disso, ainda permanecem consideráveis incertezas em relação a adequação da MR. Esta revisão objetiva discutir as últimas descobertas acerca das MR existentes e compará-las no que tange a suas eficácias, indicações e complicações. Descobertas recentes incluem evidências clínicas e experimentais que a manobra de recrutamento em "STEP" pode promover uma melhora do volume pulmonar aerado e reduzir o impacto biológico observado na insuflação sustentada tradicionalmente usada. O posicionamento em prona pode reduzir a mortalidade em pacientes com SDRA grave e ser um coadjuvante nas manobras de recrutamento e estratégias ventilatórias avançadas como a ventilação variável e o BIVENT tem se mostrado úteis em proporcionar recrutamento pulmonar.

Descritores: Manobras de Valsava. Respiração com Pressão Positiva, Síndrome do Desconforto Respiratório do Adulto. Respiração Artificial. Decúbito Ventral.

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Long-term professional performance of minimally invasive surgery post-graduates

Desempenho profissional, em longo prazo, dos egressos do programa de pós graduação em cirurgia minimamente invasiva

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A B S T R A C T

Objective: to evaluate the contribution of a post-graduation program in surgeons professional careers. **Methods:** participants were asked to answer a questionnaire with questions related to possible changes in their professional performance after the end of the course. **Results:** forty-three (76.7%) of the 56 participants eligible for the study responded to the questionnaires. Most participants, 32 (74.4%), had previous contact with laparoscopic surgery; however, only 14 (32.5%) reported the experience as primary surgeon. The expectations on the course were reached or exceeded for 36 (83.7%) participants. Thirty-seven (86%) incorporated minimally invasive procedures in their daily surgical practice, 37 (86%) reported improvements in their income above 10% and 12% reported income increase of over 100%, directly related to their increase of laparoscopic activity. **Conclusion:** the program in minimally invasive surgery provides a high level of satisfaction to its participants, enables them to perform more complex technical procedures, such as sutures, and improves their professional economic performance.

Key words: Laparoscopy. Education. Motor Skills. Teaching.

INTRODUCTION

The structured model of surgical education based in medical residency was proposed by Halsted over 100 years ago¹. In this, the operating room was the central environment of surgical skills acquisition over five to seven years of training. Although still present, it no longer responds to all surgeons' learning needs. The surgical education has undergone profound changes over the past two decades. Minimally invasive surgery (MIS) has created a growing demand for quality and high applicability medical information. Surgeons increasingly need to quickly learn new techniques and be able to use them with good results. In Brazil, about 200 residency programs in the area of surgery and their more than 1,000 offered vacancies are not able to offer, for the most part, sufficient MIS education for residents, as well as in other developing countries¹⁻⁵.

In addition to the deficiency in the formation of new residents, there is also the demand for surgical technical training for surgeons that ended their residency programs long ago and need to learn these new forms of treatment for the same disease for which they only learned "open surgeries". To meet this demand, many courses focused

on learning of specific skills have been created and, at the same pace, disappeared. The commitment to surgical education requires dedication from the teacher surgeon and student involvement. In the case of MIS, there is also the creation and maintenance of expensive and complex pedagogical structures.

In 2004, the Jacques Perrissat Institute was founded in Curitiba, with the main objective to offer a thorough training opportunity in laparoscopic surgery for surgeons beginning their activity or for those who practice it.

The objective of this study was to evaluate the contribution of a post-graduation program in the professional careers of its graduates, one year after completing the course.

METHODS

The MIS post-graduation course was developed by the Jacques Perissat Institute (IJP), an independent center for surgical education in the city of Curitiba, in southern Brazil, in conjunction with the Positivo University

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(www.up.com.br), a private institution that offers medical school also located in Curitiba.

Description of the post-graduation program

The Post-Graduation Program in Surgery Minimally Invasive (MIS) consists of eight modules designed to meet the needs from basic to advanced laparoscopy, and is intended for general surgeons or other surgical specialties. Each of the eight modules consists of three full days of immersion in laparoscopic surgery.

The modules cover the following topics: 1) Laparoscopy Principles and new technologies; 2) Upper Digestive Tract; 3) Hepatobiliary Surgery; 4) Abdominal Wall Defects and Access to the Retroperitoneal Space; 5) Minimally Invasive Thoracic Surgery; 6) Colorectal Surgery and Emergency in Laparoscopy; 7) Urologic and Gynecologic Laparoscopy; and 8) Metabolic and Bariatric Surgery.

The courses are coordinated and taught by five teachers of the permanent core of the Jacques Perissat Institute (IJP) and by invited experts from other parts of Brazil and other countries.

On the first day participants have eight hours of lectures, divided into two blocks. Morning sessions will cover laparoscopic anatomy, physiology and other basic concepts. The afternoon sessions include strategies and step by step description of surgical techniques, indications, complications and results related to the module topic. At the end of the lectures, the participants perform a test with multiple choice questions.

The second day consists of live broadcast operations related to the module's theme and discussed in an interactive learning environment. There are two operating rooms equipped for high definition transmission of surgical procedures in the hospital auditorium that seats up to 100 participants. The faculty conducts an average of eight operations per day, and during the breaks between the live procedures, edited videos are presented by the moderators describing the details of each technique.

The third day includes practice in living tissue in the animal facility of the University (Figure 1). The practice

in animals, pigs, is tutored by one teaching assistant per table of up to three students, and is focused on the development of cognitive and manual skills to enable participants to simulate in the animals the procedures watched live the day before.

Moreover, anastomosis and suture techniques, dissection, holding and traction are taught and practiced in the exercise room in simulation models in synthetic fabrics, the so-called "dry lab". This is divided into six stations where activities are timed and supervised by faculty members (Figure 2).

Being a broad sense post-graduation program, it follows the rules established by the Ministry of Education. Participants must fulfill 420 hours of training; they are also required to follow the IJP Surgery Service for one week, when directly participating in the operations, and there is an end of course work, in accordance with the technical and scientific standards of the University. Only then participants are entitled to receive a certificate of specialization in Laparoscopic Surgery.



Figure 2 - Detail of students in practice with the laboratory simulators ("dry lab").



Figure 1 - Perspective of the Universidade Positivo vivarium for training in animals.

Study design

All participants in the MIS Post-Graduation Program of the Jacques Perissat Institute between 2005 and 2009 were invited to participate.

We collected basic demographic data at the time of enrollment in the course. Age, gender, level of surgical training, current practice profile, and previous experience in MIS were evaluated. After completing the program, all participants received a structured questionnaire.

To better assess the impact of such training in clinical practice, only those who had completed the course at least one year before were considered to participate. Questionnaires were sent by letter or email and focused on the assessment of the expertise acquired after the course, comparing with pre-course expectations. In addition, we assessed the professional and economic impact of the course in their lives. All data are presented as descriptive statistics.

RESULTS

Profile of MIS Post-Graduation participants and previous experience.

Forty-three (76.7%) of the 56 participants in the program eligible for the study responded to questionnaires and had their answers matched and compared with the ones provided at the beginning of the course. There were 38 men and five women. They had completed the post-graduation program in an average of 2.18 years (1-5 years). Twenty-four (56%) were between 25 and 40 years of age. Nineteen (44%) started the program less than five years after completion of residency training, while 10 (23.2%) had completed residency more than 20 years before. Fourteen participants (32.5%) were from cities with less than 200,000 inhabitants, while the majority (67.5%) was from larger cities.

Thirty-two participants (74.4%) had previous contact with laparoscopic surgery and 14 (32.5%) reported experience in the performed procedures as the primary surgeon. Prior to the course, seven of these participants operated only less complex laparoscopic procedures, such as cholecystectomies, while the other seven performed intermediate or advanced complex procedures, such as fundoplication or colectomy (Figures 3 and 4).

Motivations and expectations regarding the Post-Graduation

The main motivation of students to start the course were learning and the development of new techniques for 16 of them (37.2%) and the interest in the long-term course format. Eight students (18.6%) participated in the program to keep their knowledge up to date.

Thirty-two (74.4%) were defined as "active participants" throughout the program. Three (7%) confessed

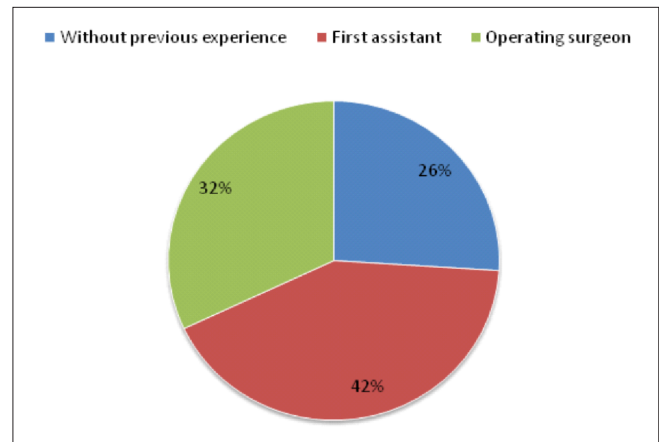


Figure 3 - Previous experience in laparoscopy before starting the MIS course.

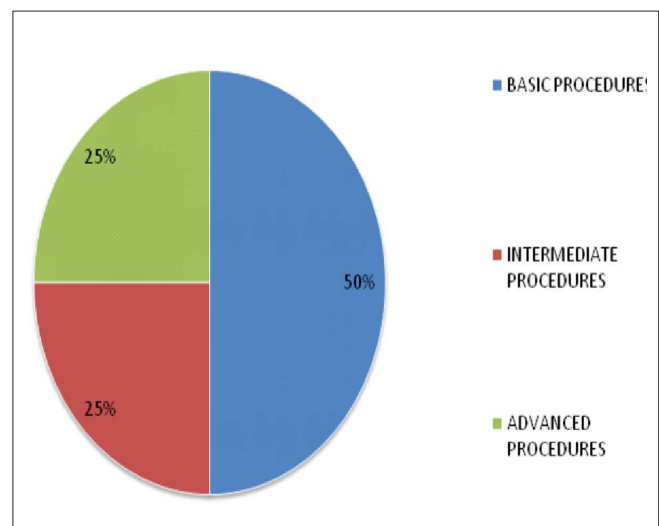


Figure 4 - Laparoscopic procedures performed before starting the MIS course.

little involvement. The expectations regarding the purpose of the course were fully achieved for 36 (83.7%) of them. Seven (16.2%) had partially met expectations. Of these, five (71.4%) were older than 40 years.

Professional and Economic Impact

Thirty-seven participants (86%) incorporated minimally invasive procedures in their daily surgical practice. Only six (13.9%) of the evaluated students mentioned not incorporating minimally invasive procedures to their routines. The main barrier to the adoption of MIS, both basic and advanced, was the lack of investment in infrastructure / equipment by hospital where they worked.

Considering the participant's self-perception of their technical skills, 28 (65.1%) felt fully able to perform laparoscopic suturing; 10 (23.2%) felt suitable, but slow; and five (11.6%) still felt unsafe to perform laparoscopic suturing. Three of these five (60%) were over 40 years of

age. Prior to the course, seven (16.2%) felt able to perform laparoscopic suturing.

Twenty-six (60.4%) participants reported that the course improved their basic knowledge and increased their professional self-confidence. Thirty-four (79.06%) began to use or increased their use of endoscopic stapler. Seventeen (39.53%) now hold more than 100 minimally invasive procedures per year (Figure 5). One student reported that completion of the course did not provide any impact on his professional practice (Figure 6).

As for the professional economic impact, six (13.9%) reported that the completion of the program did not affect their performance. Thirty-seven (86.04%) reported improvement in their yields higher than 10%, and 12% of these reported increase of over 100% with the introduction of laparoscopic.

DISCUSSION

The training in minimally invasive surgery (MIS) during surgical residencies in general is insufficient for the newly formed surgeons safely start their laparoscopic practice²⁻⁶. Several reasons justify this reality. On the one hand, there is lack of access to minimally invasive technology in public hospitals, where a substantial proportion of patients in Brazil receive their health care services and where much of the surgical residency training takes place. On the other, there is high cost of laparoscopic devices and their maintenance, which causes cumulative deterioration of the supplies, which when purchased, typically are already outdated. Furthermore, there is still the lack of understanding that, for the resident to acquire expertise in minimally invasive surgery, residency programs should undergo a profound restructuring, without which clinical outcomes may be worse than expected in conventional surgery. Finally, the surgical training is still dominated by conservative attitudes toward advances in surgical technologies, which then delay the practical adoption of new concepts.

Thus, several generations of Brazilian surgeons currently in practice are still unable to incorporate laparoscopy into their routines. In addition, there is increasing requirement for the use of new minimally invasive techniques by a demanding and every day better informed public. In an era of internet for all and evidence-based medicine, MIS has become a right of the patient and almost a duty for the surgeon.

There are many MIS courses of different modalities. Most of them, however, will disappear as rapidly as they are created. The lack of structure, clear educational objectives and follow-up of former students to better evaluate their results are some of the causes for the failure of such courses. Although they serve the immersion objective, the swift exposure, often without appropriate methodology, does not allow to apply the didactic principles

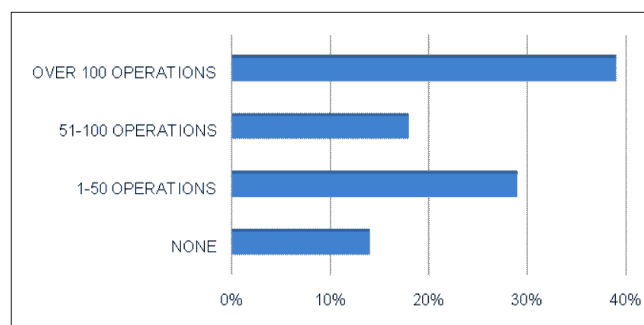


Figure 5 - Laparoscopic procedures performed one year after finishing the Minimally invasive surgery (MIS) course.

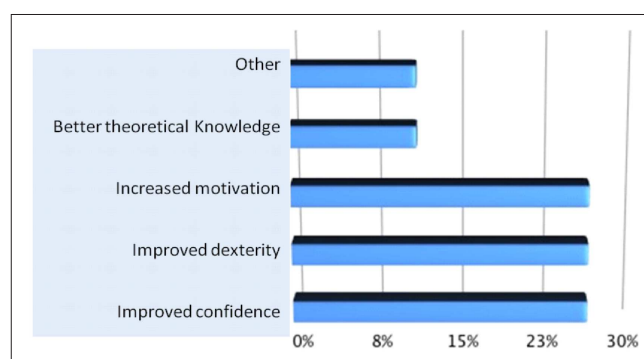


Figure 6 - Behavioral change after completion of the MIS course.

of repetition and gradual accumulation of knowledge. For this reason, they are usually not sufficient to promote the full domain of techniques and skills in MIS^{7 12}.

One third of our students feel frustrated with the results of previously completed short courses. Indeed, this has been the motivation to seek a longer course with postgraduate structure.

The impact of training courses in MIS can be remarkable. Gröne *et al.* reported that the capability of performing laparoscopic sutures after a week of a basic course increased from 56 to 93% and the ability of making an anastomosis, from 21 to 60%. They also noted that 89% of participants reported that these courses should be integrated as part of the residency training¹³.

The IJP has developed an education program in MIS using a model designed to solve some of the problems common to short courses. Formatted into a 12-month program, it consists of eight different modules designed to expose participants to different techniques. The modules are short enough and sequential to facilitate the implementation and use of minimally invasive techniques for both already formed and still resident surgeons. In fact, 44% of our students started the program directly after finishing residency. Moreover, 23.2% had completed residency more than 20 years before. These figures show that there is a huge demand for continuing education in surgical new procedures and technologies.

The practical focus of the course is the repetitive skills training, allowing its gradual acquisition. Thus, given the individual development of each student, one can increase the degree of difficulty of the taught procedures. The principles of these teaching methods are based on well-established doctrines: 1- Identify the skill to be learned; 2- Provide the theoretical basis of the skill understanding and contextualize it for everyday use; 3- Develop exercises to practice it; 4- demonstrate the standard of such practice; 5- Supervise its training; and 6- objectively evaluate its execution¹⁴.

The 43 participants who completed the course over a year later returned to their work environment. The questionnaires showed that 83.7% of them had their prior expectations fully met by the course. Equally remarkable is that 86% of students reported an increase in their income with the addition of new minimally invasive surgery practices.

In addition to the practical focus on MIS courses, one should also look to counteract some other disabilities. The skills of a good surgeon go far beyond simple technical capacity¹⁵⁻¹⁷. As important as the techniques are the basic knowledge of medical, clinical judgment and the objective decision-making. Other elements, such as professionalism and clear communication skills are also critical components of the formation of a surgeon and are learned only with time and guidance.

Particularly encouraging to the program was the objective identification of its changing impact in

participants' daily practice. Eighty-six percent of them began to perform laparoscopic procedures in their routines. The importance of such a change in the surgeon's community is huge. Without a local competent professional, patients seeking a less invasive alternative to conventional surgery are required to look for them in other cities. Thirty-eight (88.3%) participants reported that they were able to perform endoscopic suturing with comfort and safety, a significant result that suggests training for advanced laparoscopic procedures by the end of the program.

The overall results show the improvement of the quality of operations, and also for the professional and economic development of the surgeon. The commitment to surgical education requires deep engagement of educators, as well as deep involvement of participants.

In conclusion, the Minimally Invasive Surgery Course of the Jacques Perissat Institute provided a high level of satisfaction to its participants, enabled them to perform more complex technical procedures, such as sutures, and improved their professional economic performance.

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R E S U M O

Objetivo: avaliar a contribuição de um programa de pós-graduação na carreira profissional de seus egressos. **Métodos:** os participantes foram convidados a responder questionário com perguntas relacionadas a eventuais mudanças em seu desempenho profissional após o término do curso. **Resultados:** quarenta e três (76,7%) dos 56 participantes elegíveis para o estudo responderam aos questionários. A maioria dos participantes, 32 (74,4%) já tinha contato prévio com a cirurgia laparoscópica, porém, apenas 14 (32,5%) relataram a experiência como cirurgião principal. As expectativas sobre o curso foram alcançadas ou superadas para 36 (83,7%) participantes. Trinta e sete (86%) incorporaram procedimentos minimamente invasivos em sua prática cirúrgica diária. E também 37 (86%) relataram melhorias em seus rendimentos superiores a 10%, e ainda 12% relataram aumento superior a 100% em seus rendimentos, diretamente relacionado com o incremento da atividade laparoscópica. **Conclusão:** o programa em cirurgia minimamente invasiva proporciona um elevado grau de satisfação aos seus participantes, e os capacita a realizar procedimentos técnicos mais complexos, como as suturas, além de melhorar seu desempenho econômico profissional.

Descritores: Laparoscopia. Programas de Treinamento. Habilidade Motora. Ensino.

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