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Oncologic surgery: a great challenge.

Cirurgia oncológica: um grande desafio.

Luiz Antonio Santini Rodrigues da Silva, ECBC-RJ[1].

A special issue of The Lancet Oncology[1], on September 2015, presented the report of a special committee, coordinated by Richard Sullivan, from the Institute of Cancer Policy, King's Health Partners Comprehensive Cancer Centre in London, England. Entitled "Global Cancer Surgery: delivering safe, affordable and timely cancer surgery," the report included 43 experts and managers from around the world and sought to build a picture of the state of the art surgical oncology globally. The document also brings suggestions and recommendations for countries and institutions interested in the subject. Accompanied by the Brazilian physician Audrey Tsunoda, I had the opportunity to participate in this group.

The forecasts for growth in the cancer incidence and mortality in the world, presented in another recent publication, the Atlas of Cancer[2], are catastrophic. The estimate is an increase in the number of new cases from about 14 million, in 2012, to 19.3 million in 2025. As for mortality, it is projected an increase from approximately eight million deaths that occurred in 2012, to 11.4 million in 2025. One should also consider the trend that cancer is to become the leading cause of death in all regions of the world in the coming decades, regardless of socioeconomic status.

To address the serious problem of the increased incidence of cancer, many actions have been developed in the prevention field, some with enough efficiency and visibility, as the reduction of smoking, in which Brazil is a world reference. Early detection campaigns and vaccines, such as hepatitis B and, more recently, HPV, are also featured. The World Health Organization estimates that effective preventive measures could reduce by 40% the incidence of new cases of cancer. Regarding these data, the committee's report draws attention to the fact that, of about 15.2 million new cancer cases occurred in 2015, 80% must have needed a surgical procedure at some point of the disease evolution . Rob Brierley and David Collingrige[3] stated that despite the advances in the field of radiotherapy and chemotherapy, surgery remains the cornerstone of cancer care, playing many roles in the prevention, diagnosis, curative treatment, supportive measures, palliation treatment and reconstructions. In this sense, the authors consider surgery a vital specialty for reducing premature mortality due to cancer.

The report concluded that the overall picture shows great disparity and inequity in access to surgery and to economic resources. Most patients do not have access to cancer surgery. Failures in forming and training of more surgeons and the weakening of health systems can result in a cumulative loss of about 6.2 trillion dollars of the global gross domestic product by the year 2030. Supply and quality problems of surgery essential support services, such as pathology, imaging and anesthesia were also mentioned in the document. The lack of investment in access to organized services, research, training and education is strongly demonstrated, especially in countries of low and medium development. The report recognizes that there are some innovations and solutions that need to be known and utilized as examples of efforts being carried out, including Brazil.

Among the pros, I highlight the existence of the Unified Health System (SUS) in Brazil. A national system with universal coverage, regulated by a specific legislation and ministerial decrees to establish the amplitude of services to be offered according to technical training and technological resources of providers. It is also worth noting that the incorporation of technologies or new procedures are regulated by the *Comissão Nacional de Incorporação de Tecnologias no SUS* (CONITEC – National

1 - Departamento de Cirurgia Geral e Especializada da Universidade Federal Fluminense (UFF), Niterói, RJ, Brasil.

Commission for Incorporation of Technologies into SUS). There is also a permanent council formed by scientific organizations, managers and other representative institutions and coordinated by the *Instituto Nacional do Câncer José Alencar Gomes da Silva* (INCA). The INCA Advisory Council (CONSINCA) prepares and submits technical studies and reports to the Ministry of Health.

A a negative note, there is the imbalance of funding between the different forms of cancer treatment. Only 9% of the total funds allocated to Oncology are assigned to oncologic surgery. In almost all countries there is a growing imbalance in the sources of funds for the public sector, with most of the resources flowing through and to the private sector, which increases inequality. Of the resources for research in the world, only 9% are intended for surgery, and a small fraction of this percentage is intended for clinical trials, which are effectively able to promote the best outcomes for patients. Although cancer control can not do without cooperation between surgery, radiotherapy and chemotherapy, I draw attention to the results obtained with surgery, which can be much more positive, strongly depending on high-quality training of surgeons.

Hence I believe that cooperation between the *Colégio Brasileiro de Cirurgiões* (CBC) and the *Sociedade Brasileira de Cirurgia Oncológica* (SBCO) could have a huge meaning to meet this challenge. The starting point? Cooperation for the development of an action plan based on data from the aforementioned report that is being deepened with Brazil's data by SBCO.

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Cultural adaptation and the Clavien-Dindo surgical complications classification translated to Brazilian Portuguese.

Adaptação cultural e teste da escala de complicações cirúrgicas de Clavien-Dindo traduzida para o Português do Brasil.

Luis Fernando Moreira, TCBC-RS[1]; Marcelo Castro Marçal Pessôa, TCBC-RJ[1]; Diego Sachet Mattana[2]; Fernando Fernandes Schmitz[2]; Bernardo Silveira Volkweis, ACBC-RS[2]; Jorge Luiz Antoniazzi, ACBC-RS[3]; Liacyr Ribeiro, ECBC-RJ[4].

ABSTRACT

Objective: to generate a translated and validated version of the Clavien-Dindo Classification of Surgical Complications (CDC) to Brazilian Portuguese (CDC-BR). ***Methods:*** the process of translation and adaptation followed the guideline of Beaton et al., 2000. We divided 76 participating surgeons, in different levels of experience, from the Department Surgery of the Hospital de Clínicas de Porto Alegre, into two groups: Group I applied the original version (CDC, n=36);r Group II used the modified version (CDC-BR, n=40). Each group classified 15 clinical cases of surgical complications. We compared performance between the groups (Mann-Whitney test) relating to the level of experience of the surgeon (Kruskal-Wallis test), considering p value <0.05 as significant. ***Results:*** the performance of the Group II (CDC-BR) was higher, with 85% accuracy, compared with 79% of Group I (CDC), p-value =0.012. The performance of the groups as for surgeons experience displayed p=0.171 for Group I, p=0.528 for Group II, and p=0.135 for overall performance. ***Conclusion:*** we produced a translated and validated version of the CDC for Brazilian Portuguese. The instrument will be a useful tool in the production of evidence on surgical outcomes.

Keywords: Surgery/Complications. Quality Improvement. Data Curation. Outcome Assessment (Health Carre). Morbidity.

INTRODUCTION

Programs for quality assessment were developed and implemented in Japan in the postwar period, and are already well established in the industry branch. However, in health care the application of quality concepts has happened more slowly and is still considered incomplete[1].

In recent decades, there has been an increased demand for care and services in health care. Due to the scarcity of resources, rising costs and a clear change of behavior in clinical practice, indices and quality references have been increasingly sought[2,3]. The interpretation of these data allows comparison of institutional performance across teams and treatment modalities, retrospectively or with follow-up over time. To obtain such parameters, one needs to apply a standardized and reproducible methodology[3].

For a long time, mortality was the only parameter of assessment of surgical outcomes[2,4,5]. However, with the significant decrease in mortality rates, there was a shift in the focus for morbidity and quality of life[4,6-8]. Morbidity has been recently reported as a key factor in the analysis of surgical outcomes, particularly among treatment modalities with similar efficacy[9]. Postoperative complications are commonly used factors among many authors who discuss quality in surgery, and their account favors analysis under different aspects and perspectives[2,4].

Although there has been an increased effort towards reports regarding surgical complications, on the other hand there is a huge contradiction in the literature, especially as for their definitions and an objective description of their severity levels[10-12].

Amid this scenario, Clavien *et al*. launched in 1992 a proposal for the classification of surgical complications with general principles and definitions for use in cholecystectomy. The treatment required for the surgical complications was the reference point for the differenti-

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ation of their severity levels. After 12 years, Dindo *et al*. showed an enhanced version for the classification of surgical complications, based on the first proposal by Clavien *et al*. Since then, Pierre Alain Clavien group has been conducting a series of studies, recommending new methods to classify surgical complications, testing the reliability of the method and subjecting it to testing in several centers around the world. The tests were applied with instruments produced in English and in German. New perspectives were assessed from the point of view of all parties involved in the decision-making processes of surgical treatments, doctors, nursing staff and patients[2,3,9,12,13]. From there, it was suggested the need for translation adjustments and cross-cultural adaptation of instruments produced for application in multi-center studies in different countries, with different languages and different cultures[9,13,14]. The concepts proposed by Clavien group have since been adopted by a growing number of authors of various specialties, seeking to discuss and create quality benchmarks in their fields through the report of surgical complications[15-23].

Although previously tested, accepted and published around the world, the Clavien-Dindo Classification of Surgical Complications (CDC) has not had a translated and tested version for Portuguese in Brazil. Therefore, this work aims to establish and test a version translated into Brazilian Portuguese CDC (CDC-BR), to be used as an instrument faithful to the content of the original classification, thus exceeding any language and cultural barriers.

METHODS

The process of translation and cross-cultural adaptation of the source instrument, the original CDC[3], followed the methodology disclosed by Beaton *et al*. in 2000. This is a methodology also applied by the American Association of Orthopedic Surgery (AAOS)[24,25], which comprises five stages (I - V) arranged to maintain and maximize the semantic, idiomatic, experiential and conceptual equivalence between the source instrument and the target one, the CDC-BR. After obtaining the translated version of the CDC, the CDC-BR was subjected to a validation test. We chose 15 cases of surgical complications, previously tested and published in Clavien's group publications[3,12], and appraised by 76 surgeons with different levels of experience, randomly divided into two groups, one using CDC and the other, CDC-BR, to classify the surgical complications. This study is part of a research line of the Southern Surgical Oncology Research Group (SSORG) and was approved by the Ethics in Research Committee, under the number 0587/12, *Hospital de Clínicas de Porto Alegre*, RS, Brazil (Figure 1).

- Stage I (Initial Translation)

The first step produced the initial translation of the source instrument, CDC, into Brazilian Portuguese. Three translators participated at this stage (T1, T2 and T3), one "Expert" (T1) proficient in English and two "Lay" translators, one a Native English speaker (T2) and other proficient in English (T3). Each translator produced an initial version that was used in the next stage.

- Stage II (Summary of Initial Translation)

The "Expert" translator (T1) gathered and synthesized the initially produced translations (T1, T2 and T3) in order to keep the contents of the source instrument. In this step was then produced the "Literal Translation" (LT).

- Stage III (Back-translation)

Three other translators that did not participate in the previous stages acted at this stage, one

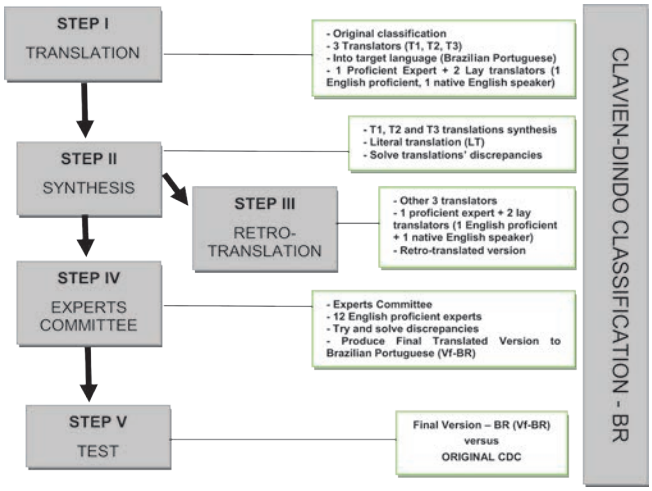

Figure 1. *Graphical representation of the methodology applied in the process of translation and Intercultural Adaptation of the Clavien-Dindo Classification of Surgical Complications, source instrument for obtaining the target instrument, CDC-BR. Adapted from Beaton et al., 2000.*

"Expert" translator (RT1) and two "Lay" translators, one with English as mother tongue (RT2) and the other proficient in English (RT3). Each translator produced a back-translated version of the LT. The RT1 gathered, compared and synthesized the produced versions, generating a back-translated version (BTV). At this stage, they generated the equivalent LT in relation to the source device, CDC.

- Stage IV (Expert Committee)

Twelve "Experts" of different surgical specialties of from the departments of General Surgery (3), Surgical Oncology (3), Vascular Surgery (1), Pediatric Surgery (1), Thoracic Surgery (2) and Coloproctology surgery (2) of the Hospital de Clínicas de Porto Alegre (HCPA), all familiar with the CDC and proficient in English, integrated this Committee. This stage was meant to adjust the differences identified in the previous ones, seeking to consolidate the semantic, idiomatic, experiential and conceptual equivalence of the target instrument, generating the translated Final Version (TFV), which we called CDC-US, then forwarded to the validation test (Table 1) .

- Stage V (TFV Test – CDC-BR)

The TFV (CDC-BR) test was conducted at the Department of General Surgery of the HCPA between October and December 2013. We created two groups, randomly distributed, with 76 participating surgeons. We segregated the surgeons in three different levels of experience (Residents, HCPA Staffs Surgeons with at least ten years as specialists, and Senior Surgeons, Medical School professors from the Universidade Federal do Rio Grande do Sul – UFRGS). Group I (n = 36) received the original CDC, and Group II (n = 40) received the CDC-BR, both to classify 15 hypothetical clinical cases of surgical complications originating from Dindo *et al*. and Clavien *et al*. publications, and translated into Portuguese by the Experts Committee coordinator, (LFM)[3,12] (Table 2). All participants were provided a list of examples of surgical complications as published by Dindo *et al*.[3], translated by

Table 1. *Classification of Surgical Complications of Clavien-Dindo – Brazilian Portuguese version (CDC-BR).*

Grau de Classificação	Definição	
Grau I	- Qualquer desvio do curso pós-operatório Ideal sem necessidade de tratamento farmacológico ou de intervenções cirúrgicas, endoscópicas, e radiológicas - Regimes terapêuticos permitidos são: drogas antieméticas, antipiréticos, analgésicos, diuréticos, eletrólitos, e fisioterapia. Esta categoria também inclui feridas operatórias drenadas à beira do leito	
Grau II	- Requer tratamento farmacológico com drogas diferentes daquelas permitidas para complicações grau I - Transfusão sanguínea e nutrição parenteral total também estão incluídas	
Grau III	Exige intervenção cirúrgica, endoscópica ou intervenção radiológica	III a. Intervenção sem anestesia geral
		III b. Intervenção sob anestesia geral
Grau IV	Complicação com Risco de vida (incluindo SNC) * Necessidade de UTI	IV a. Disfunção de um só órgão (incluindo diálise)
		IV b. Disfunção de múltiplos órgãos
Grau V	Morte do Paciente	
Sufixo "d"	Se o paciente persiste com uma complicação no momento da alta o sufixo "d" (para "Deficiência") é adicionado para o respectivo grau de complicação. Esta marca indica a necessidade de seguimento futuro para avaliar completamente a complicação	

**Hemorragia encefálica, AVC isquêmico, sangramento subaracnoideo, mas exclui acidentes isquêmicos transitórios.*

Traduzida e adaptada segundo metodologia divulgada por Beaton et al., em 2000. Instrumento fonte: Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240(2):205-13.

Table 2. *Distribution of the sample members according to groups and the level of experience of surgeons.*

Groups	Characteristics of the sample		
	Classification of surgical complications		
	CDC	CDC-BR	Total
Residents	17	22	39
Staff	16	14	30
Professors	3	4	7
Total	36	40	76

Distribution of participants between groups and subdivided according to their level of experience.

LFM under the endorsement of the Experts Committee, as a reference in the classification of clinical cases.

- Statistical analysis

Demographic data and the sample accuracy performance profile were analyzed by the Shapiro-Wilk test (median calculation) for accuracy, Mann-Whitney test (performance relationship between grades, the suffix "d" alone and overall performance) and the Kruskal-Wallis test (performance between groups of different surgeons experience levels). For all analyzes we considered a 95% confidence interval. The calculation tool was the SPSS software, version 17.0, Chicago, IL.

RESULTS

The members of Group II, n = 40 (translated version, CDC-BR), obtained a better performance, with 85% accuracy, compared to 79% of Group I, n = 36 (original CDC in English). When subjected to the Mann-Whitney test for the analysis of the total number of hits, we obtained a value of p = 0.012 (Figure 2). Considering the complication Grade, Group I presented a median 13 [11.75-14], maximum 14 versus median 13 [12-14] Maximum 15) in Group II (NS). When analyzing the suffix "d", Group 1 had median 14 [14-15], maximum 15, and Group II, median 15 [14-15], maximum 15, p = 0.05. In the full analysis, Group I presented median 12 [11.5-14], maximum 15, and Group II, median 13 [11-13], maximum 15, p = 0.012 (Figure 3). When we considered the surgeons experience level, the accuracy among Group II CDC-BR was higher among residents (87%) and HCPA Staff (83%). However, the hit rate among the UFRGS Professors was higher for Group I, who used the original CDC in English (Figure 2). We applied the Kruskal-Whallis test to assess whether there was difference when considering the level of experience of surgeons distributed between groups. The test showed that the performance between the groups was not changed by the level of experience among residents, Staff and Professors (Table 3).

DISCUSSION

Among the possible outcomes, surgical complications stand out as the indicator most commonly used to assess the quality of surgical treatments[22]. They have great influence on well-being and quality of life of patients, and great impact on the cost of hospitalizations[3]. For decades, many authors have pursued a systematic and standardized form of reporting surgical outcomes[23]. Such efforts date back to the first decade of the 1900s, when Ernest Amory Codman, one of the founders of the American College of Surgeons, started what was after defined as "End Result", or results medicine. He dedicated his life to the systematic account of his surgical results, prompting the comparison between surgeons, treatment modalities and institutions. For these reasons, Codman is considered a "Quality Martyr" and one of the

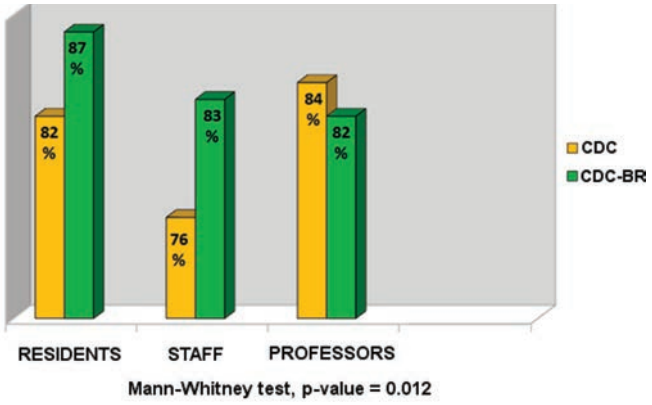

Figure 2. *Representation of the percentage of correct answers between groups according to surgeons level of experience. Mann-Whitney test p < 0.05 for significance.*

Table 3. *Comparison of performance between groups and the level of experience of surgeons. (NS).*

	Kruskal-Wallis test		
	Classification of surgical complications		
Groups	Group I – CDC (%)	Group II – CDC-BR (%)	Overall performance (%)
Residents	82	87	84
Staff	76	83	79
Professors	84	82	83
p-value	0.171	0.528	0.135

There was no difference between the groups as for the level of experience of surgeons.

forerunners of Evidence-Based Medicine (EBM)[26-28]. Despite the efforts of several authors to follow the concepts of EBM, there are, however, still great inconsistency in the reports of adverse events between researchers and hospital records. The absence of consensus on the best way to report and define surgical complications certainly hampers the proper comparison of performance between surgeons, teams, treatment modalities, institutions and possibly advances in the surgical field[3,12,23].

In 1992, Clavien *et al*. published a standardized classification for reporting surgical complications, with four levels of severity, based on the therapeutic intervention applied to treat the complications[2]. In 2004, Dindo *et al*. reviewed the classification proposed by Clavien, based on the same principles of applied therapy, modifying it to five levels of severity. Tests with a large cohort of patients involved ten surgical services around the world assessing its acceptance and reproducibility[3]. This was the first validation of the classification proposed by Dindo. In 2009, Clavien *et al*. held a new test on the classification modified by Dindo *et al*. through a systematic review to assess the number of citations in the literature and the degree of perception from the non-specialists, nurses and patients, point of view. Since then, it is referred to as Clavien-Dindo classification (CDC) for reporting surgical complications[12].

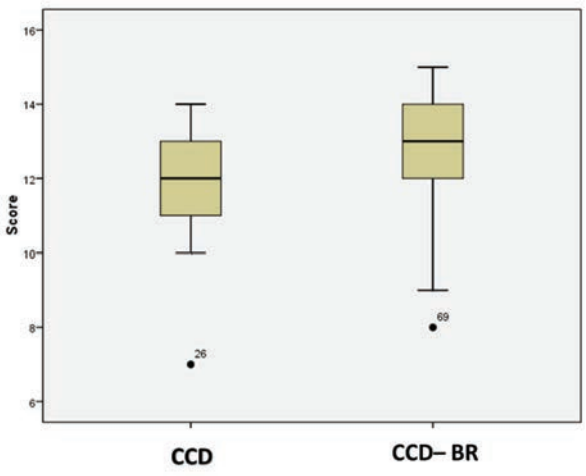

Figure 3. *Box plot with representation of the median of the correct answers in the full analysis between groups. There is better accuracy of the group using the translated version, CDC-BR.*

Since 2004, the CDC system has been cited by nearly three thousand publications, and validated in hundreds of studies in several surgical specialties[9,13,16,18 20,22,23,29,30], allowing the comparison of surgical outcomes of different institutions with greater accuracy, as well as a better communication between surgeons worldwide. The application of this methodology has facilitated the production of multi-center studies and the conduction of systematic reviews[23]. Despite the CDC wide acceptance, some authors have proposed changes in order to adapt it to the reality of their specialties[19,20,22,23] .

Slankamenac *et al*. and Marcondes *et al*. discussed the need for translation adjustment and intercultural adaptation of the CDC when applied from the perspective of patients, since literal translations can tarnish semantic, idiomatic and conceptual features of features originally made and tested in German and English[2,3,9,12,13,25]. In this context, we consider that there is a clear demand for translation and intercultural adaptation of the CDC into other languages. Thus, a standardized system for the classification of postoperative complications should be simple, reproducible, flexible and applicable in different cultures, without language and cultural barriers[20]. The definitions must be clear, taking into account the specific vocabulary in different languages and cultures[23].

With the growing trend in conducting multicenter studies, there is a clear need for appropriate methodology application for the translation and cultural adap-

tation of questionnaires and/or tools used in the research field. The validation test aims to maintain equivalence between the versions of origin and destination, maintaining the instrument's reliability[24,31,32].

Although considered a useful tool for generating evidence on the quality of surgical treatments, the CDC had not been translated into Brazilian Portuguese, nor tested. Therefore, our study used the methodology published by Beaton *et al.*, in 2000, for the process of translation and cultural adaptation of performance assessment tools in health care and quality of life[24] (Figure 1). All stages were followed so that the translation and cultural adaptation process reached the most of semantic, idiomatic, experimental and conceptual equivalence between the origin (CDC) instrument and the destination (CDC-BR) one.

During the translation stages I and II, all discrepancies were identified and corrected. In stage III, Back-translation, we could note that the produced versions were very close to the source instrument, CDC, which confirmed the good quality of the translation process. In stage IV, the Experts Committee noted that to translate the suffix "d" from the original instrument, there was a discrepancy between the literal translation and the meaning of the word. In English, the word "disability" has its literal translation as "incapacidade". The Experts Committee decided to keep the letter "d", as provided in the original CDC; the word with greater semantic equivalence with the instrument source is "deficiência". The function of the Experts Committee (Stage IV) is therefore crucial to maintaining linguistic and cultural equivalence.

The CDC-BR was tested in order to validate it as a faithful instrument for application. The test showed an index of correct answers of 85% for Group II, who used CDC-BR (translated version), versus 79% for Group I, who used CDC (original version), Mann-Whitney displaying p = 0.012, therefore significant. This result reflects that the methodology applied in the translation process was successful. We noted that the level of surgeons experience did not influence performance in assessing the clinical cases presented, in accordance with data shown in the literature[3,9,12,13]. We found in our sample, however, that the performance of professors was higher in Group I, which used the original CDC, which can be attributed to higher English proficiency by professors.

Dindo *et al*. found accuracies ranging from 86% to 93% when the test was applied to 144 surgeons with different levels of experience in ten centers around the world. Clavien *et al*. sent 11 difficult example cases to seven centers in different continents, in which CDC had routinely been used. Accuracy ranged from 89% to 100%. In both publications, the CDC has been described as a simple, objective and reproducible manner for assessment of surgical outcomes, likely to be used by surgeons in different levels of experience[3,9,12]. In our study, we observed that the CDC-BR, when tested, has similar performance to the one presented in publications that tested and validated the previously CDC [3,12] (Figure 4).

This study shows that there was proper translation and cultural adaptation of the Brazilian version of the CDC. The CDC-BR has proven to be reliable and now may be a useful tool for generating evidence about the surgical outcomes between teams, institutions and treatment modalities. Therefore, we recommend the wide dissemination of CDC-BR among surgeons from various specialties in our country. In the future, this could facilitate the achievement of better benchmarks, so that protocols that are more appropriate can be applied in research on morbidity and quality control for the surgical treatment and care.

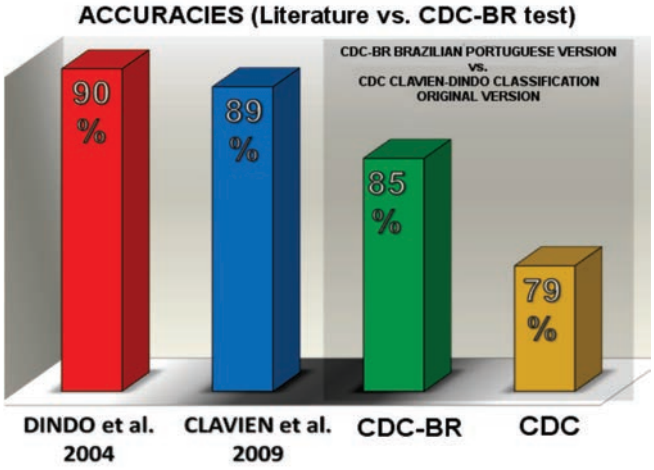

Figure 4. *Percentages of correct answers of CDC-BR test compared with the results reported in the literature.*

R E S U M O

Objetivo: *gerar uma versão traduzida e validada da Classificação de Complicações Cirúrgicas de Clavien-Dindo (CCD) para o Português-Brasileiro (CCD-BR).* **Métodos:** *o processo de tradução e adaptação seguiu a diretriz de Beaton et al., de 2000. Formaram-se dois grupos, Grupo I, que utilizou a versão original (CCD, n=36) testado em relação ao Grupo II, com a versão modificada (CCD-BR, n=40), com um total de 76 cirurgiões participantes em níveis de experiência distintos do Departamento de Cirurgia do Hospital de Clínicas de Porto Alegre. Quinze casos clínicos de complicações cirúrgicas foram classificados em cada grupo. Comparou-se o desempenho entre grupos (teste de Mann-Whitney) relacionando ao nível de experiência dos cirurgiões (teste de Kruskal-Wallis). Valor de p<0,05 como significativo.* **Resultados:** *o desempenho do Grupo II (CCD-BR) foi superior, com 85% de acertos, contra 79% do Grupo I (CCD), p-valor=0,012 do teste de Mann-Whitney. O desempenho dos grupos em relação à experiência dos cirurgiões foi p-valor=0,171 para o Grupo I, p-valor=0,528 para o Grupo II, e p-valor=0,135 para o desempenho geral, teste de Kruskal-Wallis.* **Conclusão:** *foi produzida uma versão traduzida e validada da CCD para o Português-Brasileiro. O instrumento produzido será ferramenta útil na produção de evidências sobre os resultados cirúrgicos.*

Descritores: *Cirurgia/Complicações. Melhoria de Qualidade. Validação de Dados. Avaliação de Resultados (Cuidados de Saúde). Morbidade.*

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Type 2 *Diabetes Mellitus* remission eighteen months after Roux-en-Y gastric bypass.

Remissão do Diabetes Mellitus Tipo 2 dezoito meses após gastroplastia com derivação em Y-de-Roux.

Marcelo Gomes Girundi, TCBC-MG[1].

ABSTRACT

Objective: to evaluate the effectiveness of **Roux-en-Y gastric bypass** in improving the glycemic profile of obese patients with type 2 Diabetes Mellitus (DM2) after 18 months of follow-up. **Methods:** four hundred sixty-eight pacients with DM2 and BMI ≥35 were submitted to Roux-en-Y gastric bypass, from 1998 to 2010. All patients were submitted to glycemic control analysis in the 3rd, 6th, 9th, 12th and 18th postoperative months. We considered: type 2 diabetic patients, the ones with fasting glucose ≥126mg/dl and HbA1C ≥6.5 in two dosages; high risk patients for diabetes, those who presented fasting glucose ≥ 100 to 125 mg/dl and HbA1C between 5.7%-6.4%; and normal patients, those presenting glucose <100mg/dl and HbA1C <5.7%. Such diagnostic criteria were based on the official position of *Sociedade Brasileira de Diabetes*, published in July, 2011. **Results:** The remission of DM2 was seen in 410 (87.6%) out of 468 patients 18 months after the surgery, that being a meaningful difference, with p<0.001. Fourty-eight (10.3%) patients sustained criteria for the disease and ten (2.1%) continued at high risk for DM2. **Conclusions:** Roux-en-Y gastric bypass was effective in the promotion and maintaince of long-term glycemic control. There are evidences showing that the remission of DM2 is not only related to weight loss and that other enteroinsular axis mechanisms must be involved.

Keywords: Bariatric Surgery. Diabetes Mellitus, Type 2. Gastric Bypass. Obesity. Gastroplasty.

INTRODUCTION

Obesity is a serious problem of public health worldwide, affecting developed and developing countries. People with a BM >30kg/m^2 represent 7% of the global population[1]. According to a survey organized by the *Sociedade Brasileira de Cirurgia Bariátrica e Metabólica*, 51% of Brazilians are overweight[2]. Obesity is an independent risk factor for the development of various associated diseases such as type-2 diabetes *mellitus* (DM2), hypertension (HT), dyslipidemia, metabolic syndrome (MS), hepatic steatosis, gastroesophageal reflux disease, cholelithiasis, among others[2].

Diabetes *mellitus* is the most common metabolic disease in Western countries, with an estimated 300 million people affected in 2025, of which 90% will be carriers of DM2. There is also a strong association between obesity and type-2 diabetes, and 80% of patients with type-2 diabetes have some degree of obesity[3]. Diabetes is a major cause of mortality and early disability. An increasing body of evidence suggests that most of the complications of diabetes can be prevented or delayed by prospective treatment of hyperglycemia. The timing and quality of therapy, consequences of early diagnosis and immediate continued control of hyperglycemia, are crucial to improving outcomes[4].

Surgical treatment of obesity has been documented as the most effective for obesity of large proportions, both in loss of excess weight and in its long-term maintenance, as well as to the improvement of comorbidities, among these DM2. Previous studies demonstrate the clinical resolution of DM2 in 48% of patients undergoing adjustable gastric banding, 84% after vertical Roux-en-Y gastroplasty and 98% after biliopancreatic diversion[5]. The remission of DM2 after adjustable gastric banding is proportional to the weight loss; however, the remission of DM2 after mixed and predominantly disabsorptive procedures occurs more effectively and more quickly, even before weight loss, suggesting a participation of the small intestine in the

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metabolic benefits, a fact also demonstrated in pioneering works from Rubino et al.[6].

The aim of this study is to evaluate the effectiveness of Roux-en-Y gastric bypass (RYGB) in improving glycemic control in obese patients with BMI ≥ 35 who meet the criteria for DM2.

METHODS

We obtained the study sample by convenience, patients being selected prospectively and consecutively, constituting a observational, descriptive and longitudinal study. The selection of patients was based on the recommendations of the *Sociedade Brasileira de Cirurgia Bariátrica e Metabólica*. An interdisciplinary team clinically evaluated the patients. The protocol was approved by the Ethics in Research Committee (chsf-005/98) and all patients signed an informed consent before entering the study.

RYGB was performed in 5211 patients with BMI ≥35 in the presence of comorbidities or BMI ≥40 regardless of the presence of comorbidities, either by laparotomy, comprising 4609 patients (88.4%), or by laparoscopy, 602 patients (11.6 %), by the same surgical team at São Francisco, Mater Dei and Lifecenter Hospitals between May 1998 and December 2010.

Of these 5211 cases, 492 patients were considered as having type-2 diabetes mellitus, ie patients with fasting glucose ≥126mg/dL and HbA1C ≥6,5% in two different dosages.

Clinical follow-up was performed in 468 patients during the 18-month period, through quarterly outpatient visits in the first year and twice in the second year. The fasting glucose and HbA1C were measured in the third, sixth, ninth, 12th and 18th months postoperatively. The evaluation was made by the same multidisciplinary team. According to the analysis of glycemic control in the postoperative period, the patients were divided into three groups and repositioned over the 18 months of follow-up: Group A- Patients with disease remission: fasting blood glucose <100mg/dL and HbA1C <5.7%; Group B- Patients with increased risk for diabetes: fasting glucose between 100 and 125 mg/dL and HbA1c between 5.7% and 6.4%; Group C- patients with DM2 unchanged: fasting glucose ≥126mg/dL and HbA1c ≥6,5%. These diagnostic criteria are in line with the position of the *Sociedade Brasileira de Diabetes*[7].

The gastric pouch was performed with the use of linear cutting staplers and endoscopic staplers molded by a Fouchet catheter, leaving a capacity of approximately 30ml, with or without silicone ring. The gastrojejunal anastomosis was performed with mechanical and manual sutures with a diameter between 1.5 and 2.0 cm; the biliopancreatic loop had 100cm and food loop, 150cm.

In order to verify whether there was a statistically significant and consecutive improvement in blood sugar levels over time, we used the McNamer test (Agresti, 2002). To evaluate the percentage of improvement between genders at each follow-up time, we used the chi-square test (Agresti, 2007). We set up a marginal regression (Liang and Zeger, 1986) for binary data to enable multiple inferences of patient improvement, without sample stratification, gaining statistical power. The Marginal model has been preferred as an extension of the Generalized Linear Models for longitudinal data (Fitzmaurice, 2011) due to its ease of interpretation and lack of distributional assumptions. The marginal regression was adjusted considering an unstructured working matrix. The software used in the analysis was the "R" version 2.15.0.

RESULTS

Of the 492 selected patients, 24 were lost to follow-up; one of them died in the early postoperative period due to pulmonary thromboembolism. Of the 468 remaining patients, there was a remission of type-2 diabetes after 18 months of surgery in 410 (87.6%), placed in Group A, this difference being significant, with $p<0.001$. Ten patients (2.1%) remained with increased risk for DM2, placed in Group B. Disease criteria remained in 48 patients (10.3%), allocated in group C.

When analyzing the evolution of the results in Table 1, we observed the progression of DM2 remission every quarter. Only in the period from 12 to 18 months, the remission of the disease was not significant by the McNamer test ($p=0.134$), with no evidence of improvement in the latter semester (Figure 1).

Table 1. *Contingency for the distribution of the times between groups after surgery.*

Times after surgery (months)	Groups							
	C		B		A		Total	
3	259	55.3%	17	3.6%	192	41.0%	468	100%
6	210	44.9%	13	2.8%	245	52.4%	468	100%
9	75	16.0%	3	0.6%	390	83.3%	468	100%
12	60	12.8%	2	0.4%	406	86.8%	468	100%
18	48	10.3%	10	2.1%	410	87.6%	468	100%

In the evaluated series, there were 330 (70.5%) female patients and 138 (29.5%) male ones. The mean age was 40.7 ± 10.6 years (range 18-69).

The analysis of groups distribution over time was stratified by gender (Figure 2).

Through regression analysis, we can infer that there is no significant difference in remission between genders over time (p=0.092). There was a significant difference between the periods for remission (p<0.001), and the chance of DM2 remission at six months was 1.58 times (1.41-1.78) the chance in the third month; between the ninth and the sixth months, 4.58 times (3.66-5.74); and between the 12th and the ninth month, 1.31 (1.15-1.49). There was also a significant difference between the 18th and 12th month (p = 0.044), and the chance of finding a patient with remission of DM2 in the 18th month was 1.09 (1.00-1.16) times the chance in the 12th month.

DISCUSSION

The main mechanisms for the remission of DM2 after RYGB are restricted caloric intake, reduction of ghrelin, which stimulates the reduction of appetite, intestinal malabsorption, weight loss, with reduction of visceral fat, reducing insulin resistance, increased metabolic rate, and especially modulation of gastrointestinal hormones, the incretins[8-15].

The incretins are intestinal peptides that stimulate insulin secretion after food ingestion. The two major gastrointestinal hormones identified as incretins are GIP (gastric inhibitory peptide) and GLP-1 (glucagon-like peptide-1). GIP is secreted by K-cells mainly located in the duodenum and proximal jejunum, while GLP-1 is secreted by the L-cells found primarily in the ileum. The incretins are rapidly secreted during a meal, circulate in the blood and have a relatively short half life (3-7 minutes), since they are rapidly inactivated by DPP-IV (dipeptidyl peptidase-IV). Certainly the participation of other hormones such as ghrelin, PYY (peptide YY), leptin and others, plays an important role in glucose homeostasis[15]. The results of this study corroborate previous ones[8,15,16] in that they associate RYGB with such hormone modulation, so as to provide an increase in insulin sensitivity and improved beta-cell function, with recovery of insulin secretion in response to the incretin stimulation[16].

We obtained 87.6% of remission of type-2 diabetes and many of these results were observed in the early

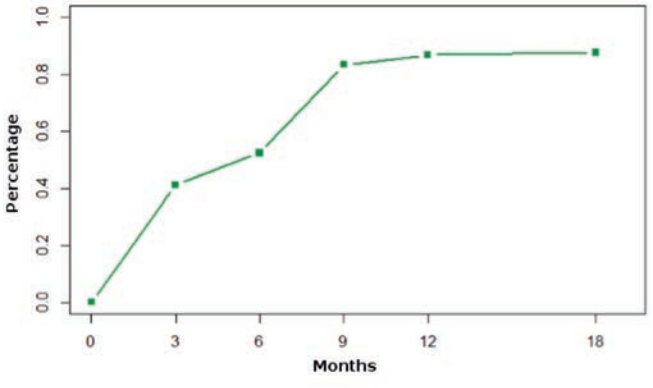

Figure 1. *Percentage of patients with DM2 remission over time.*

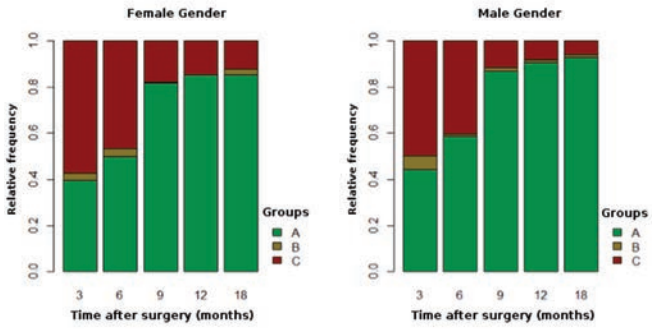

Figure 2. *Distribution of groups between times after surgery, stratified by gender.*

postoperative period, before significant weight loss, which corroborates the hypothesis mentioned above. On the other hand, patients that had not complete remission had a slower evolution as for results improvement. Patients with longer time of disease progression, associated with chronic use of insulin before surgery, may show greater functional impairment of beta cell capacity. Because of this, we suggest the dosage of C-peptide in subsequent studies.

The effects of surgery on diabetes control are overwhelming, but the validity of available data is questionable. Methodological flaws are dute to lack of adequate control groups and to the short duration of the evaluation period. Bariatric surgery may have adverse effects for life, such as nutritional deficiencies and osteoporosis, which can appear and worsen after years of follow-up[17]. In addition, diabetes is a chronic disease, and expressions such as healing, remission and improved disease should be used with prudence.

Multidisciplinary teams are essential in assisting surgery. Undoubtedly, clinical, endocrinological, nutritional, physiotherapeutical and psychological control, as well as regular, oriented physical activity can improve surgical outcome.

New surgical techniques should be considered, but we cannot resort to the past empiricism when bariatric surgery, "by chance", was effective to treat diabetes[18]. Any new proposal should present a physiological principle and first be studied in animal models, which can later show a safety and efficacy profile comparable to existing and well-studied techniques, such as the gastric bypass[19]. After fulfilling these steps, new surgeries can obtain official approvals and be considered as surgical procedures alternative to already established techniques.

Remission of type-2 diabetes has been observed as an additional result of morbid obesity surgical treatment. There is evidence that the DM2 remission is not simply related to weight loss and other mechanisms of the enteroinsular axis must be involved. Medicine is entering a new era in the treatment of the obese diabetic, and additional studies are certainly needed for a better understanding of interventional diabetology.

In conclusion, Roux-en-Y Gastric Bypass proved to be very effective in controlling glucose levels in obese diabetic, resulting in remission of the disease in most patients observed in this study.

R E S U M O

Objetivo*: avaliar a eficácia da gastroplastia com derivação em Y-de-Roux, em pacientes obesos e portadores de Diabetes Mellitus tipo 2 (DM2), na melhoria do perfil glicêmico após 18 meses de seguimento.* **Métodos***: foram submetidos à derivação gástrica em Y-de-Roux 468 pacientes com IMC ≥35 e portadores de DM2, no período de 1998 a 2010. Todos os pacientes tiveram a análise do controle glicêmico realizadas no terceiro, sexto, nono, 12ª e 18ª meses de pós-operatório. Os critérios diagnósticos de diabetes foram baseados no Posicionamento Oficial da Sociedade Brasileira de Diabetes, publicado em julho de 2011.* **Resultados***: observou-se a remissão do DM2 em 410 pacientes (87,6%) após 18 meses da cirurgia, sendo essa diferença significativa com p-valor <0,001. A doença se manteve inalterada em 48 pacientes (10,3%), e dez pacientes (2,1%) permaneceram com o risco aumentado para DM2.* **Conclusão***: a gastroplastia com derivação em Y-de-Roux foi efetiva na promoção e manutenção do controle glicêmico em longo prazo.*

Descritores*: Cirurgia Bariátrica. Diabetes Mellitus Tipo 2. Derivação Gástrica. Obesidade. Gastroplastia.*

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Alterations of blood flow pattern after triple stent endovascular treatment of saccular abdominal aortic aneurysm: a porcine model.

Alterações do padrão do fluxo sanguíneo após tratamento endovascular do aneurisma sacular da aorta abdominal com triplo stent: modelo em suínos.

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ABSTRACT

Objective: to determine the blood flow pattern changes after endovascular treatment of saccular abdominal aortic aneurysm with triple stent. **Methods**: we conducted a hemodynamic study of seven Landrace and Large White pigs with saccular aneurysms of the infrarenal abdominal aorta artificially produced according to the technique described. The animals were subjected to triple stenting for endovascular aneurysm. We evaluated the pattern of blood flow by duplex scan before and after stent implantation. We used the non-paired Mann-Whitney test for statistical analysis. **Results**: there was a significant decrease in the average systolic velocity, from 127.4cm/s in the pre-stent period to 69.81cm/s in the post-stent phase. There was also change in the flow pattern from turbulent in the aneurysmal sac to laminate intra-stent. **Conclusion**: there were changes in the blood flow pattern of saccular abdominal aortic aneurysm after endovascular treatment with triple stent.

Keywords: Regional Blood Flow. Sacular Aneurysm. Aortic Aneurysm, Abdominal. Stents. Swine.

INTRODUCTION

The endovascular treatment of abdominal aortic aneurysms has become an increasingly used surgical alternative instead of traditional surgery[1]. Treatment is successful when there is full suppression of blood flow and systemic pressure in the aneurysmal sac, which prevent rupture[2-4]. Although we have achieved significant technological advances since the first generation of aortic stents, recent information from late postoperative follow-up have shown a significant percentage of complications requiring surgical reintervention. The reason for treatment failure, in many cases, is still connected to the endoprosthesis used (type III leakage) [5-7].

Studies have focused on the deterioration of the currently marketed prosthetic material, which is made by the association of a metal structure with PTFE or polyester coating[8-10]. Thus arises a new therapeutic method, based on experimental haemodynamic studies, the multilayered stents: uncoated metal prostheses, capable of promoting redirection of blood flow within the aneurysm sac, preventing its expansion and rupture, even without total flow abolition in the aneurysmal sac[8-14].

The aim of this study is to experimentally analyze the effects of the implant, in pigs, of three stents with the same design (triple stent) on the redirection of blood flow of the aneurysmal sac, and to determine possible changes in the abdominal aorta blood flow pattern after treatment.

METHODS

The research project was approved by the Ethics in Research Committee of the Universidade Estadual de Ciências da Saúde de Alagoas (UNCISAL) Protocol 61-A, and strictly followed the ethical principles of animal experimentation of the *Colégio Brasileiro de Experimentação Animal* (COBEA), based on Resolution 714/02 of the *Conselho Federal de Medicina Veterinária*[15,16].

The sample consisted of seven female pigs from the crossing of Landrace and Large White, weighing 20 to 25 kg, supplied by the same producer, proper-

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ly vaccinated and dewormed according to the age. We submitted them to the artificial production of infrarenal abdominal aortic aneurysms according to the modified technique of Perini[17] as described: transabdominal exposure of the abdominal aorta, with xyphopubic median incision, followed by aortic exposure through circumferential dissection between the renal arteries and the distal trifurcation (common iliac arteries and internal iliac artery trunk); election of a 3cm segment for making of the aneurysm, the branches repaired with 3.0 linen thread, and administered intravenous heparin (100IU/kg); clamping of the aorta proximal and distal to the chosen segment and conduction of a longitudinal arteriotomy followed by the patch suture with bovine pericardium in the form of a previously prepared bag of 3x3 cm, 6.0 polypropylene continuous sutures (Figure 1); Fifteen days after surgery, we performed Duplex Scan evaluation to confirm the aneurysms patency, as well as analyze the pre-stenting blood flow parameters. Then they underwent triple stent implantation and reevaluation of blood flow to assess the variables. Anesthesia was performed following the CCEB/UNCISAL general anesthesia protocol for porcine.

Stents Implantation

Vascular access to aortography was obtained by surgical dissection of the right femoral artery, and the arterial puncture performed under direct vision with a 16 Jelco catheter. After the advance of a 0.035x260 cm angled tip hydrophilic guidewire, we introduced a 11 cm 5F sheath. We advanced the sheath under fluoroscopic control until the common iliac artery. Further, we performed the aortography with a 100 cm 5F MP angiographic catheter to identify the aneurysm, follow by the positioning of the catheter in the thoracic aorta, above the aneurysm site.

We later performed the vascular access for the implantation of stents through surgical dissection of the right carotid artery, the arterial puncture being performed under direct vision with a 16 Jelco. After the advance of 0.035x260 cm angled tip hydrophilic guidewire, we introduced a 11 cm 7F sheath. We advanced the sheath under fluoroscopic control until the aortic arch, and positioned the guidewire in the thoracic aorta with the aid of an IM catheter.

After positioning of the femoral catheter within the aneurysmal sac to angiographic control, we proceeded to the sequential insertion with deployment of the stents through the right carotid artery, in the following order of sizes: 8x40 mm, 9x40 mm and 10x40 mm, starting the deployment from the porcine aorta trifurcation. Then, we carreid out a control aortography with a 5F MP angiographic catheter via the right carotid artery (Figure 2).

The nitinol stents used in the experiment were manufactured by the company Braile Biomedica (Brazil), of self-expanding type, with an over-the-wire deployment system, compatible with a 7F introducer. The stent features a closed cell design, with monofilament braids in tubular form, in diamond shape, with proximal and distal radiopaque markers in gold.

We recorded the images through the Duplex

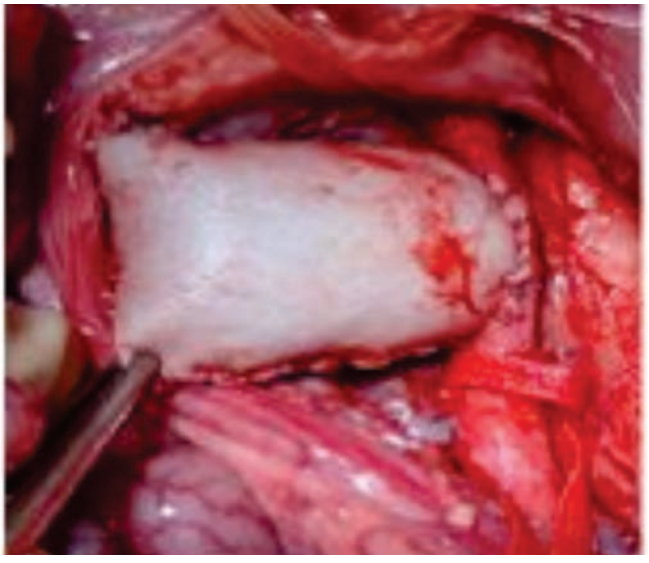

Figure 1. *Saccular aneurysm after blood flow release.*

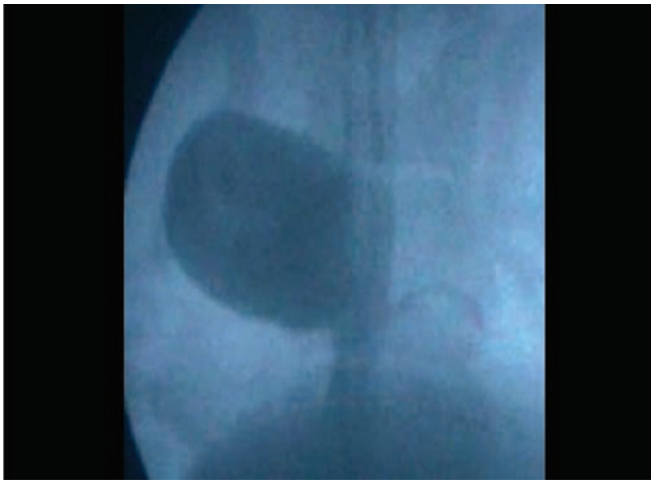

Figure 2. *Aortography post-stent implantation.*

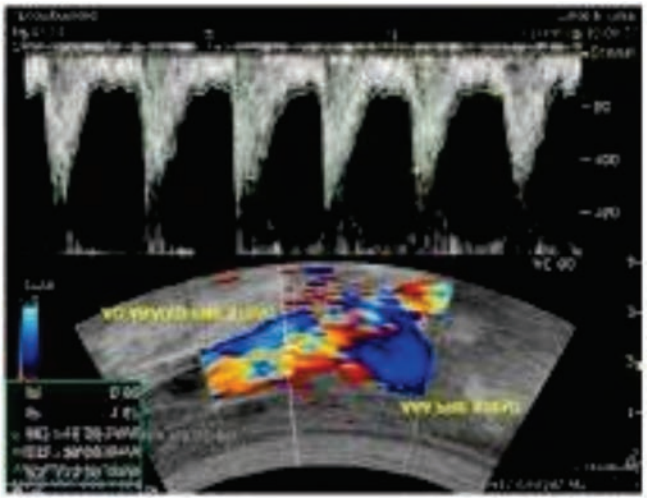

Figure 3. *Pre-stent aneurysm in animal 1.*

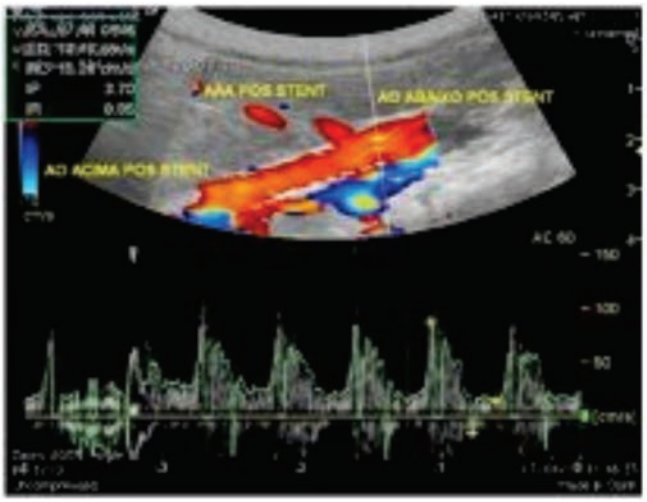

Figure 4. *Post-stent aneurysm.*

Scan 30 minutes before the stents implantation and 30 minutes after the procedure.

We evaluated the images as for the flow pattern change, turbulent and laminar, as well as for the peak systolic velocity obtained in the aneurysmal aorta. We also evidenced the change of flow pattern from turbulent to laminar after the stent release by aortography.

Study variables

Primary Variable

Change in the blood flow pattern after endovascular treatment of saccular aortic aneurysm. We quantified the flow by vascular ultrasound, using a portable device.

Secondary Variables

Average blood flow velocity in the aorta; frequency of thrombosis in the aneurysmal sac.

As additional information, we evaluated the averages of the animals ages, of their weights and of the procedure time.

We performed the statistical analysis using the unpaired Mann-Whitney test and calculating the confidence interval (CI) of 95% for each point estimate. We evaluated the statistical hypotheses H0 (pre-stent flow equals post-stent flow) and H1 (pre-stent flow is not equal post-stent flow) with the GraphPad Instat Prism 5 (2012) statistical program for Windows. The sample size was based on previous studies on the subject conducted in pigs[18-21].

RESULTS

All seven animals were successfully submitted to implantation of stents without technical difficulty. The surgical procedure time was 190 minutes, and we did not observe any complications such as malposition, migration or inadequate expansion of stents.

In table 1, we describe the quantitative variables that constitute Systolic Peak velocity (PSV) and resistance index (RI) before and after the triple stenting, which revealed significant changes, i.e., loss of systolic velocity after placement of stents, as well as the fall in resistance index in many animals. Regarding systolic velocity, we observed a significant decrease with an average pre-stent velocity 127.4cm/s (95% CI 79.93±0174.8) and a mean post-stent velocity 69,81 cm/s (95% CI 40.18±99.43), confirming the change in blood flow patterns.

The qualitative variables, which represent the change in the flow pattern from turbulent in the aneurysmal sac to laminar intrastent after treatment with triple stent, were demonstrated through the duplex scan (Figures 3 and 4).

DISCUSSION

The treatment of abdominal aortic aneurysms by endovascular technique has been performed with increasing frequency. This has lead to the increased observation of leaks related to the endoprosthesis[6], usually due to early defects of components or material fatigue. Recently, a new kind of stent

Table 1. *Distribution of aortic aneurysms blood flow measurements values.*

	Triple Stent Table			
	Peak Systolic Velocity cm/s (PSV)		Resistance index (RI)	
Animal	Pre-stent	Post-stent	Pre-stent	Post-stent
1	110.29	87.49	0.6/8	0.85
2	50.33	24.89	1.0	0.07
3	189.86	95.43	0.88	0.67
4	163.22	86.89	1.0	0.66
5	178.35	98.33	1.0	0.83
6	110.39	71.23	0.87	0.76
7	89.04	24.39	0.65	1.17

came up that brought a different concept for the treatment of aneurysms[12]. These stents with multiple layers allow the redirection of the flow in the aneurysmal sac, leading to loss of local pressure and preventing expansion.

Several models of assessment of aortic aneurysm flow have been described. Through the dynamics analysis of aortic flow one observes the flow behavior and compares stents and endoprosthesis in the treatment of aortic aneurysms. It is therefore apparent that the pressure and flow pattern changes occur due to change in the systolic velocity during stent use. Augsburger *et al*., through a silicone aneurysm model, also present findings of changes in the flow pattern, as well as the change in the volume flow after aneurysm stenting[13]. Jiang et al., on their turn, evaluated the default behavior of the flow through angiography and computer simulations of fluid dynamics in dogs with artificially produced aneurysms[22].

In this pioneering study, we used an experimental model in pigs to assess the changes in the flow pattern with duplex scan after triple stent implantation for the treatment of aortic aneurysm in animals previously submitted to the making of aneurysmal sac with bovine pericardium by the modified Perini technique[17].

Changes in blood flow pattern in this study were evaluated through duplex scan analysis. Two analyzes were carried out, one in the animal with the aneurysm before the stents implantation, the and other after implantation of stents. We obtained the blood flow pattern analysis and also the parameters systolic velocity and resistance index.

The systolic velocity showed a significant decrease, with an average pre-stent velocity of 127.4cm/s (95% CI 79.93±174.8) and a mean post-stent velocity of 69.81cm/s (95% CI 40.18±99.43), confirming the change in blood flow patterns.

Images by duplex scan showed change in the flow pattern, ie, from turbulent in the aneurysmal sac to laminar intrastent, the aneurysmal sac presenting with blood flow or excluded. Doppler ultrasonography in pigs showed the possibility to analyze not only the presence of flow within the aneurysmal sac, but also the hemodynamic features of such flow, with more information.

In conclusion, this study showed changes in the blood flow pattern of saccular abdominal aortic aneurysms after endovascular treatment with the triple stent.

RESUMO

Objetivo: *determinar as alterações do padrão do fluxo sanguíneo após tratamento endovascular do aneurisma sacular de aorta abdominal com triplo stent.* **Métodos:** *estudo hemodinâmico de sete suínos das raças Landrace e Large White portadores de aneurismas saculares de aorta abdominal infrarrenal artificialmente produzidos segundo técnica descrita. Os animais foram submetidos a implante de triplo stent para correção endovascular do aneurisma e reavaliados por duplex scan quanto ao padrão do fluxo sanguíneo antes e após o implante dos stents. A análise estatística foi realizada com o teste Mann-Whitney não pareado.* **Resultados:** *verificou-se uma queda significativa da velocidade sistólica média de 127,4cm/s na fase pré-stent para 69,81cm/s na fase pós-stent. Houve ainda mudança no padrão do fluxo de turbilhonar no saco aneurismático para laminar intrastent.* **Conclusão:** *o estudo demonstrou alterações do padrão do fluxo sanguíneo do aneurisma sacular de aorta abdominal após tratamento endovascular com triplo stent.*

Descritores: *Fluxo Sanguíneo Regional. Aneurisma Sacular. Aneurisma da Aorta Abdominal. Stents. Suínos.*

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Augmentation mastopexy after bariatric surgery: evaluation of patient satisfaction and surgical results.

Mastopexia de aumento após cirurgia bariátrica: avaliação da satisfação das pacientes e resultados cirúrgicos.

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ABSTRACT

Objective: to evaluate patient satisfaction and surgical results obtained after mastopexy with breast implant inclusion. **Methods:** we conducted a prospective study of 20 consecutive female patients with a mean age of 39.9 years, submitted to augmentation mastopexy. We applied semi-directed psychological interviews pre and postoperatively. The answers to the evaluations were tabulated, categorized, and allowed patient satisfaction analysis. We evaluated surgical results through photographic analysis of three independent plastic surgeons, in the pre and postoperative periods, when scores were attributed to the following items: breasts shape, breasts volume, breasts symmetry, nipple-areolar complex position, and scar quality and extent. **Results:** nineteen patients (95%) referred satisfaction with the surgical results attained (p<0,001). The mean sum of the scores attributed by the three surgeons to each patient varied between 4.7 and 10, with an overall mean of 7.28. The results were considered good or great for 65% of the sample and poor for 8.4%. **Conclusion:** there was a 95% satisfaction rate among patients with the results obtained through augmentation mastopexy. The photographic analysis of the results obtained a mean score of 7.28, considered as a good result, albeit the weak correlation among evaluators.

Keywords: Mammoplasty. Breast Implants. Patient Satisfaction. Obesity, Morbid. Surgery, Plastic.

INTRODUCTION

Post-morbid obesity plastic surgery resects the dermo-lipomatous excesses and improves body contouring. Brachioplasty, abdominoplasty, cruroplasty, rhytidectomy, mammaplasty and mastopexy are procedures that enhance self-esteem and reduce health-related problems of these patients, which can again be productive members of society[1].

Breast ptosis and volumetric loss are common characteristics in women who had massive weight loss after bariatric procedures[2]. The mastopexy associated with breast implants insertion, also known as augmentation mastopexy, has proved to be an effective surgical solution in treating such dysmorphia[3].

We conducted this prospective study to evaluate the satisfaction of patients and the surgical results obtained.

METHODS

Patients (n=20, 100% women, mean age 39.9 years, range 21-63) underwent augmentation mastopexy in a single operative time. All had undergone malabsorptive-restrictive bariatric surgery by the technique of Fobi-Capella[4], between 19 and 96 months before plastic surgery, showed stable weight for a minimum of 12 months and had not had other plastic surgery before.

The average height of patients was 1.63m (1.56-1.70); the average pre-bariatric surgery body weight was 116.5kg (100-135); and the average pre-plastic surgery body weight was 68kg (57.5-78).

The mastopexies with inclusion of breast implants were not associated with other surgeries and were performed by the same surgical team, at the same institution, over a period of seven months.

Patient satisfaction assessment

We invited the twenty patients to participate in semi-structured psychological interviews in the preoperative period and six months postoperatively. The interviews were applied by a single psychologist in a suitable environment, when patients were assured that nothing

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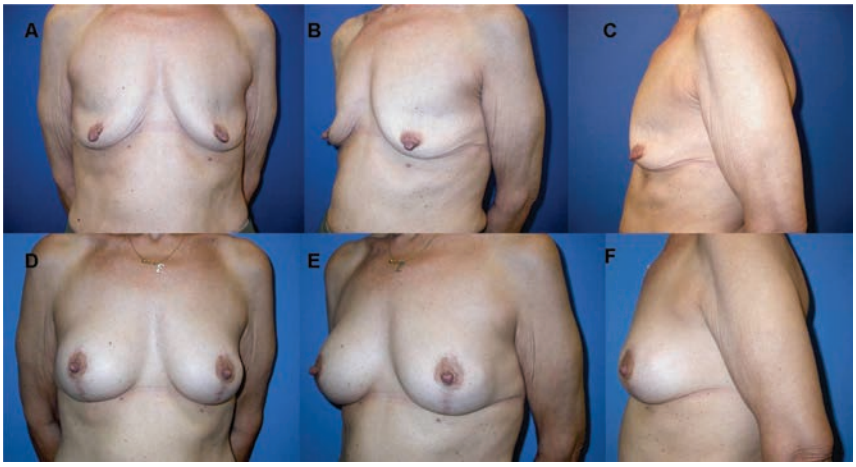

Figure 1. *Mastopexy with inclusion of breast implants (volume: 240ml). Preoperative: A) anterior view; B) obliquely right; C) right profile. Postoperative: D) right view; E) right oblique; F) right profile.*

would interfere in their treatment. After all interviews, open answers and spontaneous utterances were recorded and grouped by similarity, in categories, raised from the qualitative analysis. We then compared the answers obtained pre and postoperatively.

Assessment of surgical outcomes

Surgical results underwent critical and qualitative evaluation based on the pre and postoperative photographic documentation (Figure 1).

A standardized questionnaire formulated by the author was sent to three plastic surgeons with experience in the surgical treatment of breast deformities after massive weight loss, who were unaware of the clinical cases to be evaluated. This questionnaire was accompanied by pre and postoperative photographic images in five positions: frontal, right oblique, left oblique, right profile and left profile.

The evaluators assigned values zero, one or two for each following item: shape, volume, symmetry, position of the areola-papillary complex and quality and extent of scarring. Zero score corresponded to bad result; one, regular; and two, good result[5].

The sum of scores of the five items assessed varied between zero and ten. When the sum was between zero and four, the result was considered poor; five or six, regular or acceptable outcome. The sum of scores between seven and nine was considered a good result, and ten was considered optimal[5].

RESULTS

The interviews showed a positive interference of breasts plastic surgery in various sectors of the patients' life, as shown in Table 1.

Statistical analysis, by applying the McNemar test (Table 2), showed inferential results that proved a statistically larger percentage of patients satisfied after breast surgery (95%) when compared with the time prior to surgery (25% – $p < 0.001$).

The volume of the breast implants ranged between 200 and 280 ml, with a mean of 236ml. The volume of 240ml was the most used, for eight patients. The mean operative time was 229 minutes, ranging between 170 and 300. Surgical interventions were not carried out before the postoperative results evaluation.

Table 1. *Summary of the items evaluated in the pre and postoperative interviews.*

Item assessed	Patients (n=20)	
	Preoperative	Postoperative
Result close to expectations	-	100%
Improved professional life	-	20%
Improved social life	-	60%
Improved affective life	-	50%
Improved sexual life	-	50%
Improved body comfort	-	60%
Satisfaction with own body	50%	50%
Improved body care	-	85%
Satisfaction with breasts	25%	95%

Table 2. *Distribution of patients according to satisfaction with breasts before and after surgery.*

		Satisfaction with breasts after surgery		TOTAL
		satisfied	unsatisfied	
Satisfaction with breasts before surgery	Satisfied	5 25%	- -	5 25%
	Unsatisfied	14	1 5%	15 75%
TOTAL		19 95%	1 5%	20 100%

Two patients had postoperative complications. The first presented local hyperemia with serous secretion output through the surgical incision, was hospitalized and treated with intravenous antibiotics despite negative cultures for bacterial growth. The second patient presented dynamic asymmetry of the breasts at arms abduction, caused by a position of the left implant more cranial relative to the right one, which was addressed through surgical reintervention after postoperative evaluation.

The average of the sums of the grades given by the three surgeons for each patient varied between 4.7 and 10, and the overall average of the sums of the scores was 7.28.

The results were rated on average as good or excellent in 65% of patients, and bad in 8.4% (Table 3).

The intraclass correlation coefficient, estimated between the three surgeons for the final score, was 0.494, (95% CI 0.227-0.731), which confirmed a moderate reproducibility of the final grades among surgeons. The observed agreement between the three surgeons was 30% and the general Kappa coefficient was 23% (95% CI 6.6-39.4%), confirming a weak agreement among surgeons as to the final score.

DISCUSSION

Plastic surgery after massive weight loss aims at resecting skin excess, facilitating personal hygiene, increasing satisfaction with the body, improving sexual, social and interpersonal relationships, increasing self-esteem, and providing better quality of life[6].

Various augmentation mastopexy techniques have been described to improve breasts shape and increase their volume[7-9]. It is characterized as a surgical procedure of difficult planning and low predictability of results[10-12].

In the medical literature, there is conflict of views between performing the procudure in a single time or at different times, ie performing the mastopexy and later the inclusion of breast implants. Those who advocate the realization of mastopexy with the inclusion of implants in a single time cite as its advantages the lower physician and hospital costs, sole hospitalization and the low occurrence of additional surgeries. On the other hand, those who support the procedure at two different times cite as advantages the greater predictability of results and the possibility to associate procedures to refine results in the second surgical time[3,13].

The use of nonrigid demarcation technique[14] provided more freedom to the nipple-papillary complex repositioning and the resulting scars. Eighteen patients had a scar in the shape of inverted T; one patient had an only vertical scar; and one only periareolar.

The histological changes that occur in the skin of patients with massive weight lossmay be responsible for this discrepancy, being mainly characterized by the smaller

Table 3. *Percentage of patients and their results.*

Result	Surgeon 1 N (% patients)	Surgeon 2 N (% patients)	Surgeon 3 N (% patients)	Average
Poor	1 (5%)	1 (5%)	3 (15%)	1.7 (8,4%)
Regular	4 (20%)	5 (25%)	7 (35%)	5.3 (26,6%)
Good	12 (60%)	9 (40%)	9 (45%)	10.0 (50%)
Optimal	3 (15%)	5 (25%)	1 (5%)	3.0 (15%)

amount of elastin in the dermal matrix, which leads to lower retraction capacity and lower skin elasticity[15].

An important data found in the qualitative evaluation was the improvement in body care, which occurred for 17 patients (85%), demonstrating that they had become more vain, began to better observe their own body and to be concerned with it.

In the postoperative period, 95% of patients demonstrated to be satisfied with the breast surgery ($p<0.001$). The only patient considered dissatisfied with the surgical outcome, in fact, was partially satisfied, longing for greater breasts volume.

The objective assessment of surgical outcomes seem difficult to achieve. Even with the grading by assessors with the same qualification, ie, experienced plastic surgeons in the study subject, the assessment seems to be subjective and particular to each rater-observer. The weak correlation between the scores awarded by the evaluators does not invalidate the results, where only 8.4% of patients had poor results; and the overall average of the sums of the scores for all patients was 7.28, considered a good result.

In conclusion, the inferential results showed that there was a statistically higher percentage of satisfied patients after mastopexy with the inclusion of breast implants (95%) when compared with the preoperative period (25%). Surgical results, on average, were regarded as good, with the average of the sums of the scores assigned by the three assessors equal to 7.28, despite the poor agreement between them.

R E S U M O

Objetivo: *avaliar a satisfação das pacientes e os resultados cirúrgicos obtidos após a mastopexia com inclusão de implantes mamários.* **Métodos:** *estudo prospectivo com 20 pacientes consecutivas do sexo feminino, com média etária de 39,9 anos, que foram submetidas à mastopexia de aumento. Foram aplicadas entrevistas psicológicas semidirigidas nos períodos pré e pós-operatórios e cujas respostas foram tabuladas, divididas em categorias, e possibilitaram a avaliação da satisfação das pacientes. Foi realizada avaliação dos resultados cirúrgicos através da análise fotográfica por três cirurgiões plásticos independentes, nos períodos pré e pós-operatórios, que atribuíram notas aos seguintes itens: forma da mama, volume da mama, simetria entre as mamas, posicionamento do complexo aréolo-papilar e qualidade e extensão das cicatrizes.* **Resultados:** *dezenove pacientes (95%) referiram satisfação com o resultado cirúrgico obtido (p<0,001). A média das somatórias das notas atribuídas pelos três cirurgiões, referentes a cada paciente, variou entre 4,7 e 10, sendo a média geral de 7,28. Os resultados foram considerados bons ou ótimos para 65% da amostra e pobres para 8,4%.* **Conclusão:** *houve satisfação de 95% das pacientes com os resultados obtidos pela mastopexia de aumento. A análise fotográfica dos resultados obteve nota média de 7,28, caracterizado como bom resultado, apesar da fraca concordância entre os avaliadores.*

Descritores: *Mamoplastia. Implantes de Mama. Satisfação do Paciente. Obesidade Mórbida. Cirurgia Plástica.*

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Comparative evaluation of ventilatory function through pre and postoperative peak expiratory flow in patients submitted to elective upper abdominal surgery

Avaliação comparativa da função ventilatória através do pico de fluxo expiratório no pré e pós-operatório imediatos de pacientes submetidos a procedimentos cirúrgicos eletivos de andar superior de abdome

Caio Fernando Cavanus Scheeren[1]; José Júlio Saraiva Gonçalves[1].

ABSTRACT

Objective: to evaluate the ventilatory function by Peak Expiratory Flow (PEF) in the immediate pre and postoperative periods of patients undergoing elective surgical procedures in the upper abdomen. **Methods:** we conducted a prospective cohort study including 47 patients admitted to the Hospital Regional de Mato Grosso do Sul from July to December 2014, who underwent elective surgeries of the upper abdomen, and submiited to spirometric evaluation and measurement of PEF immediately before and after surgery. **Results:** of the 47 patients, 22 (46.8%) were male and 25 (53.20%) female. The mean preoperative PEF was 412.1±91.7, and postoperative, 331.0±87.8, indicating significant differences between the two variables. Men had higher PEF values than women, both in the pre and postoperative periods. There was a reasonable inverse correlation between age and decreased PEF. Both situations showed statistical significance (p<0.001). The group of smokers had lower PEF values both before and after surgery. The group of patients with comorbidities (hypertension and/or diabetes) showed lower PEF values both pre and postoperatively (p=0.005). In both groups, surgery resulted in a significant decrease in PEF (p<0.001). The type of surgery performed and the type of anesthesia did not show significant differences. **Conclusion:** the variables most involved in decreased lung function were: advanced age, smoking and presence of comorbidities. However, there is no consistent evidence to suggest conducting routine spirometry in such patients.

Keywords: Peak Expiratory Flow Rate. Surgery. Smoking. Thoracic Surgery. Elective Surgical Procedures.

INTRODUCTION

Pulmonary complications are frequent in any surgery postoperative period, but their incidence is higher in thoracic and abdominal surgeries performed above the umbilicus[1].

The occurrence of these complications closely relates to the existence of preoperative risk factors that are widely studied in the literature. Among them are: advanced age, presence of pulmonary disease or other medical illnesses, smoking and its intensity, obesity, malnutrition, type of anesthesia, duration of surgery and surgical technique, abnormal spirometric values, decreased ability to exercise and prolonged preoperative hospitalization time[1,2].

Lung function tests done prior to surgery have been used for decades to assist in estimating surgical risk[3]. Spirometry measures the volume of inhaled and exhaled air and respiratory flows, being especially useful in the analysis of data derived from forced expiratory maneuver and the peak expiratory flow (PEF). The latter is the clinically most useful measure of lung function[4].

This study aimed to compare the PEF measurements in the pre and immediate postoperative periods of patients undergoing elective surgeries of the upper abdomen, correlating them with some variables, such as smoking and comorbidities.

METHODS

After approval by the Ethics in Research Committee of the *Hospital Regional de Mato Grosso do Sul* (HRMS), Protocol 27/2014, according to Resolution 466

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Table 1. *Peak expiratory flow values before and after surgery, for both genders. Different letters indicate statistically distinct groups.*

	Gender	
	Male (n = 22)	Female (n = 25)
Preoperative PFE	464.1 ± 92.9 A	366.4 ± 62.6 B
Postoperative PFE	373.2 ± 92.1 B	293.84 ± 65.4 C

of 12/12/2012, the *Conselho Nacional de Saúde* (CNS), we held a prospective cohort study. We evaluated 47 patients from May to December 2014.

We measured the PEF with a portable device, the Mini-Wright® Peak Flow Meter 3103 (Airmed), ranging from 60 to 850 l/min, according to the Guidelines for Pulmonary Function Tests, 2002, with the patient sitting[4]. We instructed the patients to exert a maximal inspiration to total lung capacity followed by a maximal, short and explosive forced expiration through the measuring device, without extending the measure to residual volume. The expiratory effort needed last only a second or two. We repeated the test three times, considering the best result if the readings did not differ more than 20 l/min from each other.

We provided an informed consent form, and evaluated the patients within 24 hours preoperatively and within the first 24 postoperative hours. We selected the patients according to the following criteria: a) all patients over 13 years old, admitted electively in HRMS to undergo upper abdominal surgery, and accepted, or the legal guardian authorized, to participate in the study. The Exclusion criteria were: a) patients younger than 13 years; b) patient who refused to participate in the study; c) patients admitted on an emergency basis; d) patients who failed to properly perform the lung function test in pre or postoperative periods; e) patients whose surgical procedure was changed for some reason; f) patients with some type of postoperative complication, such as the need for hospitalization in Intensive Care Unit (ICU) or need for prolonged intubation.

We compared the data using descriptive and analytical parametric statistics, ANOVA package. The programs used were GraphPad Prism version 6.01 and SPSS version 22.0.

RESULTS

Pre and Post-operative Peak Expiratory Flow Analysis

The results of PEF analysis in the pre and postoperative periods of the 47 patients were mean ± standard deviation – PEF pre = 412.1 ± 91.7; PEF post = 331.0 ± 87.8.

The D'Agostino and Pearson Test (analysis of the distribution type) showed that the sample distribution was Gaussian, which authorized the use of a parametric test for statistical analysis.

The "t" test for paired data (analysis of differences between groups) showed significant differences between the pre and postoperative PEFs ($p<0.001$).

Correlation between groups

The result of the Pearson test showed a correlation coefficient $\rho=0.967$ ($p<0.001$), indicating a strong and direct relationship between the two variables.

Table 2. *Peak expiratory flow values before and after surgery, for the different age groups. Different letters indicate statistically distinct groups.*

	Faixa etária (anos)	
Age group	Preoperative PFE	Postoperative PFE
From 10 to 19 years (n=1)	460.0	391.0
From 20 to 29 years (n=11)	469.1 ± 94.6 A	389.1 ± 99.1 C
From 30 to 39 years (n=13)	440.8 91.1 ± AB	351.5 ± 77.6 CD
From 40 to 49 years (n=10)	366.0 ± 82.1 B	294.5 ± 79.0 D
From 50 to 59 years (n=10)	376.0 ± 56.2 B	294.0 ± 55.2 D
From 60 to 69 years (n=2)	300.0 ± 28.3 B	215.0 ± 21.2 D

Table 3. *Peak expiratory flow values before and after surgery, regarding smoking. Different letters indicate statistically distinct groups.*

	Smoking	
	No (n = 26)	Yes (n = 21)
Preoperative PFE	439.2 ± 93.3 A	378.6 ± 79.6 B
Postoperative PFE	364.7 ± 87.7 B	289.3 ± 69.4 C

Pre and Post-operative Peak Expiratory Flow Analysis and Other Variables

Gender

The two-way analysis of variance (two-way ANOVA) detected differences between the experimental groups. The post-hoc Bonferroni test showed that males has higher PEF values than females in both pre and postoperatively ($p<0.001$), as shown in Table 1.

Age Group

The two-way analysis of variance (two-way ANOVA) detected differences between the experimental groups. The post-hoc Bonferroni test showed that all age groups have higher PEF values preoperatively than postoperatively ($p<0.001$), as shown in Table 2.

Smoking

The two-way analysis of variance (two-way ANOVA) detected differences between the experimental groups. The post-hoc Bonferroni test showed that the group of smokers had lower PEF values both pre and postoperatively ($p=0.008$). In both groups, surgey determined a significant decrease in PEF ($p<0.001$), as brought by Table 3.

Comorbidities

The two-way analysis of variance (two-way ANOVA) detected differences between the experimental groups. The post-hoc Bonferroni test showed that the group of patients with comorbidities had lower PEF values both pre and postoperatively ($p=0.005$). In both groups, surgery determined a significant decrease in PEF ($p<0.001$), as shown in Table 4.

Postoperative PEF

Analysis of variance showed no significant differences between the types of surgery performed and PEF ($p=0.055$). Table 5 shows these values.

Anesthetic technique and PEF

The Mann-Whitney test showed no significant differences between the types of anesthesia used and postoperative PEF ($p=0.178$). Table 6 shows these values.

DISCUSSION

Postoperative Lung Complications (POLC) include atelectasis, pneumonia, bronchitis, bronchospasm, hypoxemia, respiratory failure and prolonged mechanical ventilation[5]. The incidence of POLC varies around 20% between studies[6], but they are at least as common as cardiac complications as regards the abdominal surgeries[7]. The most important predictor for the development of POLC is the surgical site. The complication rate when the surgical incision is in the upper abdomen or chest varies between 10% and 40% of all cases, while staying between 0.3% and 0.4% in laparoscopic cholecystectomy[8]. In the present study, we excluded from the analysis patients

Table 4. *Peak expiratory flow values before and after surgery according to comorbidities. Different letters indicate statistically distinct groups.*

	Time	
Comorbidity	Preoperative PFE	Postoperative PFE
Absent (n=18)	466.1 ± 98.9 A	389.5 ± 96.2 C
HT (n=17)	382.9 ± 71.0 B	295.0 ± 56.9 D
DM (n=4)	387.5 ± 78.9 AB	292.5 ± 70.9 CD
HT + DM (n=8)	365.0 ± 69.7 B	295.0 ± 66.1 D

HT: Hypertension; DM: Diabetes.

Table 5. *Peak expiratory flow values after surgery according to the different types of surgery. Different letters indicate statistically distinct groups.*

Type of surgery	Postoperative PFE
Videocholecystectomy (n=40)	345.2 ± 85.6 A
Conventional cholecystectomy (n=4)	275.0 ± 52.6 A
Incisional Herniorrhaphy (n=2)	225.0 ± 21.2 A
Gastrectomy (n=1)	200.0 A

who had some postoperative complications, not recording data about such conditions.

In addition to the surgical site, other factors also stand out, such as advanced age, presence of pulmonary disease or other medical illnesses, smoking and its intensity, obesity, malnutrition, type of anesthesia, duration of surgery and surgical technique, abnormal spirometry values, decreased ability to exercise and prolonged time of preoperative hospitalization[1,2].

Anesthesia, bed rest, phrenic nerve dysfunction, surgical trauma and pain affect respiratory muscle function after surgery, inducing a shallow, monotonous breathing pattern, without periodic physiological sighs. With the reduction of breathing efficiency, there is a decrease in vital capacity, functional residual capacity, tidal volume and forced expiratory volume in one second, factors that may facilitate the onset of pulmonary complications[9]. Thus, prior knowledge of these values in the preoperative period may allow the diagnosis and quantification of ongoing ventilatory disorders, preventing possible respiratory complications in the postoperative period[10].

The primary goal of preoperative pulmonary assessment is precisely to identify, quantify and reduce the risk of such complications[9].

The peak of postoperative diaphragm dysfunction occurs in the period between two to eight hours after surgery, returning to preoperative values in seven to ten days, interfering in most spirometric values, including PEF[10].

Silva *et al*. evaluated pre and postoperative PEF values in patients undergoing upper abdominal floor surgery and found a significant decrease of this variable, as well as smaller PEF values in females, data similar to those obtained in our study[11].

According to Filardo *et al*., in the patient preoperative evaluation, some important variables have been associated with increased risk for POLC: advanced age, presence of pulmonary disease or other comorbidities, smoking and its intensity, obesity and malnutrition[1].

Pereira *et al*. studied the incidence of pulmonary complications in the postoperative period of 408 patients undergoing upper abdominal surgery and identified several risk factors that associated with these complications. From there, they formulated a prognostic index, which included the presence of comorbidities (hypertension and/or diabetes) as one of the elements favorable to the emergence of POLC and decrease in spirometric values[12].

Both mentioned studies considered the presence of advanced age, smoking and comorbid conditions as some of the main factors related to changes in ventilatory function both pre and postoperatively, and such results agree with those obtained in this study.

In older studies (1984 and 1989), on the other hand, Warner *et al*. found that patients who still smoked or stopped smoking less than two months before surgery had complication rates about four times higher than patients who had stopped smoking more than two months before surgery, and all had greater impairment of ventilatory function regardless of which examination was held[13]. These data corroborate our study, which showed that smoking is inversely correlated to pre and postoperative PEF.

Table 6. *Peak expiratory flow values after surgery according to anesthetic technique. Different letters indicate statistically distinct groups.*

Type of anesthesia	Postoperative PFE
General (n=41)	335.1 ± 88.5 A
General + epidural (n=3)	270.0 ± 55.7 A

We conclude from our survey that the most involved variables in the decrease in ventilatory function were the same found in the literature, such as advanced age, smoking status and presence of comorbidities. However, there are still no significant evidence to suggest routinely conducting preoperative breath tests for such patients and each case should be individualized and evaluated by a specialist when necessary, a conduct adopted in the HRMS. The study reinforces the importance of greater attention to the ventilatory function in this patients group, which can determine interventions that reduce the morbidity and mortality rates related to POLC

R E S U M O

Objetivo*: avaliação comparativa da função ventilatória através do Pico de Fluxo Expiratório (PFE) no pré e pós-operatório imediatos de pacientes submetidos a procedimentos cirúrgicos eletivos do andar superior do abdome.* **Métodos***: estudo prospectivo de coorte incluindo 47 pacientes internados no Hospital Regional de Mato Grosso do Sul de Julho à Dezembro de 2014, e que realizaram cirurgias eletivas do andar superior do abdome, e submetidos à avaliação espirométrica e aferição do PFE no pré e pós operatório imediatos.* **Resultados***: dos 47 pacientes, 22 (46,8%) eram do sexo masculino, e 25 (53,20%) do sexo feminino. A média do PFE pré-operatório foi 412,1±91,7, e do pós-operatório de 331,0±87,8, indicando diferenças significantes entre as duas variáveis. O sexo masculino apresentou maiores valores de PFE do que o feminino, tanto no pré-cirúrgico quanto no pós-cirúrgico. Observou-se razoável correlação inversamente proporcional entre as variáveis idade e diminuição do PFE. Ambas as situações mostraram significância estatística (p<0,001). O grupo composto por fumantes apresentou menores valores de PFE tanto no pré como no pós-operatório. O grupo composto por portadores de co-morbidades (HAS e/ou DM) apresentou menores valores de PFE tanto no pré como no pós-operatório (p=0,005). Em ambos os grupos, o pós-operatório determinou uma diminuição significativa do PFE (p<0,001). O tipo de cirurgia realizada e o tipo de anestesia não mostraram diferenças significantes em relação ao PFE.* **Conclusão***: as variáveis mais implicadas na diminuição da função ventilatória, avaliadas através da PFE, foram: idade avançada, tabagismo e presença de comorbidades.*

Descritores*: Pico de Fluxo Expiratório. Cirurgia. Tabagismo. Cirúrgia Torácica. Procedimentos Cirúrgicos Eletivos.*

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Multiprofissional electronic protocol in ophtalmology with enfasis in strabismus

Protocolo eletrônico multiprofissional em oftalmologia com ênfase em estrabismo

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A B S T R A C T

Objective: to create and validate an electronic database in ophthalmology focused on strabismus, to computerize this database in the form of a systematic data collection software named Electronic Protocol, and to incorporate this protocol into the Integrated System of Electronic Protocols (SINPE©). **Methods:** this is a descriptive study, with the methodology divided into three phases: (1) development of a theoretical ophthalmologic database with emphasis on strabismus; (2) computerization of this theoretical ophthalmologic database using SINPE© and (3) interpretation of the information with demonstration of results to validate the protocol. We inputed data from the charts of fifty patients with known strabismus through the Electronic Protocol for testing and validation. **Results:** the new electronic protocol was able to store information regarding patient history, physical examination, laboratory exams, imaging results, diagnosis and treatment of patients with ophthalmologic diseases, with emphasis on strabismus. We included 2,141 items in this master protocol and created 20 new specific electronic protocols for strabismus, each with its own specifics. Validation was achieved through correlation and corroboration of the symptoms and confirmed diagnoses of the fifty included patients with the diagnostic criteria for the twenty new strabismus protocols. **Conclusion:** a new, validated electronic database focusing on ophthalmology, with emphasis on strabismus, was successfully created through the standardized collection of information, and computerization of the database using proprietary software. This protocol is ready for deployment to facilitate data collection, sorting and application for practitioners and researchers in numerous specialties.

Keywords: Protocols. Clinical Protocols. Data Collection. Ophthalmology. Strabismus.

INTRODUCTION

One of the biggest concerns and goals of medical educators for the next generation is to be able to demonstrate that knowing to better and faster perform the search for information is more important than trying to memorize and knowing the information itself. Discriminating what is good has become vital to finding the best routes and avoiding an "information shipwreck"[1].

The practice of medicine is changing due to the more efficient use of biomedical literature in decision-making. Factors that may explain the growing interest in evidence-based medicine are the effectiveness and efficiency of new technologies in health associated with the ease of search in the scientific literature through computers[2].

The use of computer resources, especially with regard to the capture, storage and retrieval of clinical data, has been of great importance in the production of relevant and reliable clinical studies[3]. These databases enable structured collection of clinical information for later analysis and production of prospective studies of large series of patients.

The integration of technological advances in information and health sciences enabled the emergence of a new science, Bioinformatics, which has been instrumental in developing a specific literature[4].

The Post-Graduate Program in Surgery of the Universidade Federal do Paraná (UFPR) articulates the practice, research and technology through a research line called "Computerized Protocols" and, since 1999, has improved the formatting and development of computerized protocols identified by the Acronym SINPE© - Inte-

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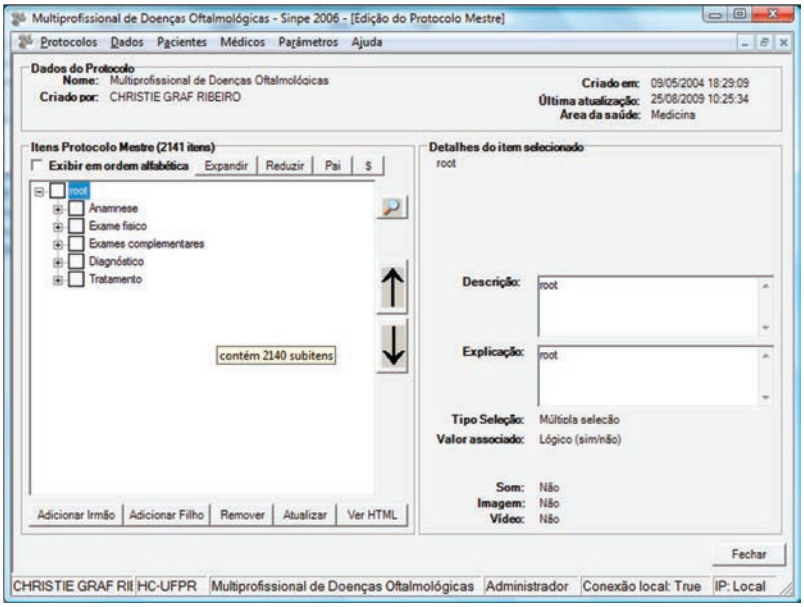

Figure 1. *Master protocol screen.*

grated Electronic Protocols, intellectual property of Professor Osvaldo Malafaia. The creation of a computerized clinical database, with the possibility of redemption and crossing of information, enables the production of scientific studies of high quality, credibility and less time spent on data research.

In the case of ophthalmology, the use of computers and, more particularly, the development of computer programs has been widely reported. However, few articles focus on electronic protocols. Ophthalmology needs constant research improvement. In this perspective, informatics is one of the ways that will enable new insights, questions and development in the knowledge of strabismus through research.

The objectives of this study are to create an electronic database in ophthalmology, with emphasis on strabismus, through standardized information gathering, and to computerize this basis in the form of software for the systematic collection of data called "Electronic Protocol" and incorporate this ophthalmology "Electronic Protocol" to the Integrated Electronic Protocols (SINPE©).

METHODS

The general aspects of the research were pre-established for strabismus diseases. We conducted the literature review in textbooks and by internet search in PubMed, Medline and LILACS. We opted for a direct and objective questionnaire, which was simple for the rapid and effective filling by the user.

There are 20 types of strabismus composing the database: alphabetical anisotropy, dissociated vertical deviation, accommodative esotropia, acquired comitant esotropia, congenital esotropia, restrictive strabismus, intermittent exotropia, constant exotropia, microtropia, other non-accommodative esotropias, other syndromes, other palsy type, paralysis of pair III paralysis of pair IV, paralysis of pair VI, supranuclear palsy, syndrome of the superior rectus muscle contracture, Brown syndrome, Duane syndrome and Mobius syndrome.

Figure 1 shows the main SINPE© screen, which presents the menu bar, named as: Protocols, Data, Patients and Help. In the bottom of the screen there is the user name, the institution, the name of the protocol, user type and connection information. With the selection of the "Protocols" button, two items will appear as an option: master protocol and specific protocol. The master protocol is a set of hierarchically arranged items called "folders", to represent data that can be collected on a particular subject.

Specific protocols are also hierarchical clustering of items, but their goal is to contemplate the specific data of the researched subject. Thus, the specific protocol is a subset of a master protocol. The first item named root, which appears with the opening of the master protocol, is required so that the analyzer can read all the data to be analyzed. The five items of second order are the main folders: history, physical examination, laboratory tests, diagnosis and treatment. The ramifications were created from these folders.

The "add brother" button is used when one wants to include some data in the same order, and the button "add child" when one wants to add any item related to the selected data. The program works as a tree system and automatically adds the plus sign (+) next to

the item that has sub-items (children). It cannot have items in the same order with the same name.

In the program, the one-choice items appear with a circle (O) on the left, and the multiple choice ones are displayed in the same orientation with a square (□) for marking. The item "Teller Cards", for example, is multiple choice and therefore can be marked with "Cardiff Cards". The item 20-21, which is one-choice, may not be signaled to item 20/41.

Each item may contain text, sound, image and video. Files can be entered in the program via CD-ROM and DVD-R, and can be attached through connections, such as Internet, Bluetooth and infrared.

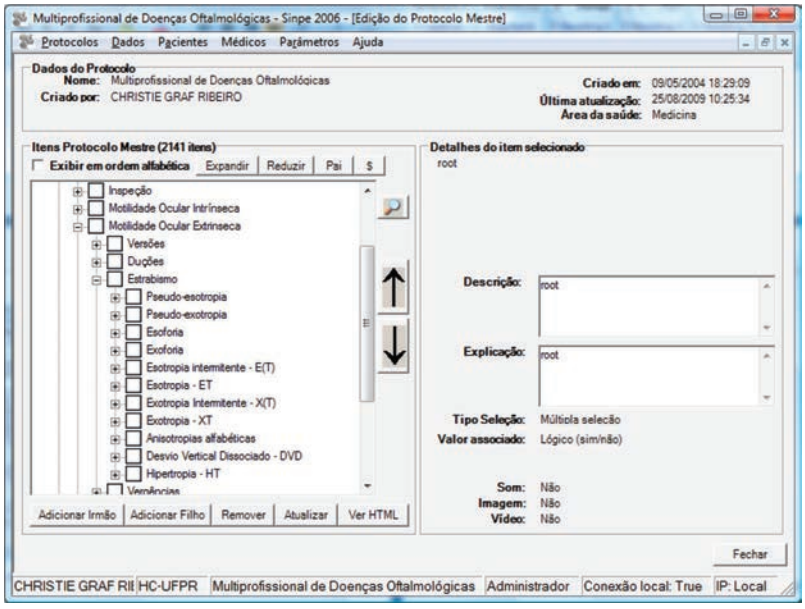

Figure 2. *Strabismus item expanded.*

To create Congenital Esotropia protocol, for example, one must first select it. Then, it captures, via transmission arrows, the data of the master protocol relevant for this disease. Thus, all the disease characteristics will necessarily be included.

The system allows to collect, simulate and search data. The item "New Collection" offers the options of different specific protocols in addition to showing all registered patients in alphabetical order.

The summary sheet displays the name of the specific protocol, its master protocol, data analysis and name of the disk file for reference. To generate statistics and graphs, one clicks on "Incidence" and selects what branched item will be analyzed, being able to choose which type of chart to be generated (sectors, bars and / or line graph). It is therefore possible to select the form of graphic representation, as well as the collection of statistics for each item. The final step of the research provides the basis for description of the work "results".

RESULTS

In the master protocol, we placed all the 2141 relevant pieces of information pertaining to ophthalmology, with greater emphasis on strabismus.

Medical history was divided into: current morbid history, clinical history, family morbid history, gestational history and perinatal history. Physical examination shows the complete eye examination: inspection, visual acuity, refraction, intrinsic ocular motility, extrinsic ocular motility, biomicroscopy, tonometry and ophthalmoscopy.

The inspection shows the signals that one must observe when examining the patient during an ophthalmologic consultation. In the folder "extrinsic ocular motility", the items describe the type of strabismus. Versions refer to binocular moves in the same direction and in the same sense. Ductions relate to the movements that one eye makes without taking into account what is happening with the other eye.

The "strabismus" item ranks strabismus in pseudoesotropia, pseudoexotropia, esophoria, exophoria, intermittent esotropia, esotropia, intermittent exotropia, exotropia, alphabetic anisotropy, dissociated vertical deviation, hipertropia (Figure 2).

The diagnosis includes medical, nursing and physiotherapy staff. Thus, since the same patient is assisted by several teams from different areas, we can have more comprehensive analysis of the patient's disease.

We also divided treatment in medical, nursing and physical therapy. Within medical, there is the "stra-

bismus" folder, along with other ophthalmology folders. Within "strabismus" treatment is divided into: clinical, surgical, post-surgical evolution, surgical complications and referral to other specialists.

At the opening of the "surgical" item, right eye, for example, will show the extraocular, medial rectus, lateral rectus, superior rectus, inferior rectus, inferior oblique and superior oblique muscles. Within each muscle, all major types of techniques used to treat strabismus thereof.

After listing and inserting all the data that the program could possibly generate, we carried out a pilot data collection study related to the specific ophthalmology protocol with emphasis on strabismus for confirmation and interpretation of results. This comprised 50 samples taken in the sector of Ophthalmology of the Hospital Universitário da Universidade Federal do Paraná. We interpreted and presented the data through graphs by the SINPE© Analyzer module. The program automatically analyzed the specific protocol selected, generating graphs, statistics and an analysis form.

Figure 3 shows an example of a collection of a patient who presented a visual acuity of 20/100 or 0.2 in the right eye measured with the uncorrected Snellen chart.

For a better explanation of the data generated by the SINPE© analyzer module, the graphics have been adjusted, using the X and Y axes. Figure 4 shows the result of past morbid history automatically generated by the program.

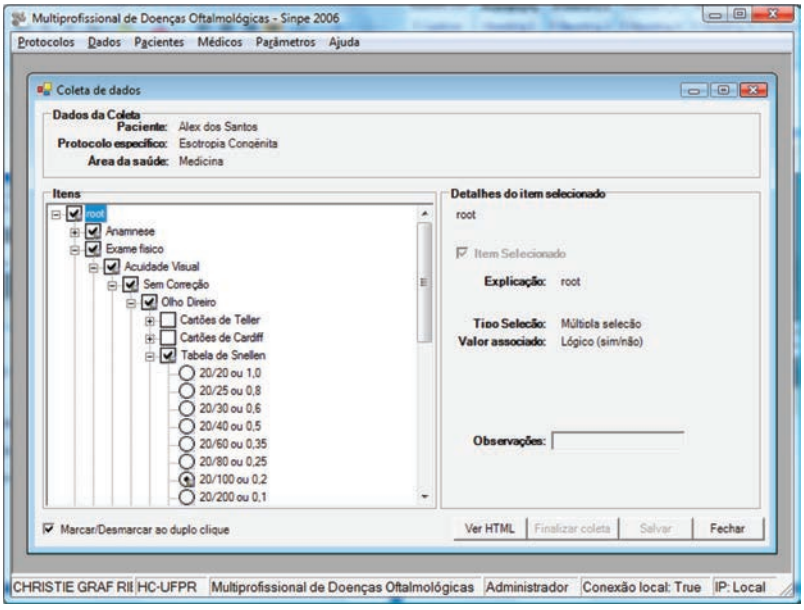

Figure 3. *Sample Screen; item 20/100 or 0.2 selected.*

DISCUSSION

We created an eye diseases multiprofessional protocol, in which we included strabismus. The selection of strabismus types used references considered as standard on the field study[5,6]. The use the data has obvious advantages in its compartmentalization between the general clinical practice and research. For example, examination of visual acuity has different goals in clinic and research. In the clinical setting, we want to get a good evaluation of how the patient is seeing and whether it is changing over time. The Snellen visual acuity chart is adequate for this task. But it does not provide data that are good for research. In research, the protocol requires the outcome of visual acuity obtained from the logarithm visual acuity card, usually after a refraction test. The data collected using the visual acuity from the EDTRS protocol (Early Treatment of Diabetics Retinopathy Study) is preferred in research[7]. In this study, beyond the Snellen chart and EDTRS, we included the Teller and Cardiff Cards for evaluation of visual acuity in the preverbal age.

The Ophthalmic Diseases Multidisciplinary Protocol with Emphasis on Strabismus followed the principles derived from the software created by Malafaia, following guidelines similar to the ones already developed[8]. These principles relate to the application of electronic protocols, able to generate a quality database in a prospective and multicentric way, characterized by simplicity in form filling, as shown in this work, similar to that found by Sigwalt. According to Ribeiro[9], the Integrated Electronic Protocols – SINPE© – is an important technological tool, since it facilitates the ordering of data and provides multiprofessionality and specificity to research. This is what we seek with the current work.

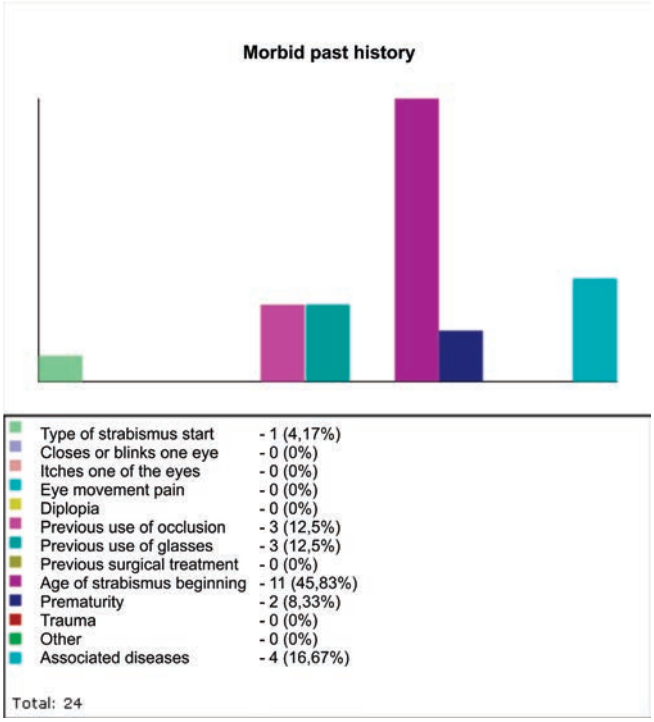

Figure 4. *Morbid past history of patients with congenital esotropia.*

The electronic protocol has numerous advantages over the conventional chart paper, among them is the ability to have full access to patient information at any time and anywhere, and save human and financial resources, as shown by Aylward and Parmar[10].

The security of stored data is one of the crucial points of electronic records. Currently, there is already in Brazil a detailed regulation on the subject, to safeguard the confidentiality of the reported clinical data. According to Borsato, the multicenter use of SINPE© through the Internet must be safe[11]. SINPE© has a special concern to this matter, with several tools that enable confidentiality and protection of entered data.

In this work, the ease of use of protocols for data collectors is justified by the simplicity of the software, which presents with closed items. These days, most people have enough digital knowledge required for handling computers. Therefore, there are no barriers or the need for intensive specific training to the device use.

In Extrinsic Ocular Motility sector of the Department of Ophthalmology, Faculdade de Ciências Médicas da Santa Casa de São Paulo, were registered 304 records of patients operated for esotropia. To register patients in the program, a questionnaire was elaborated with the relevant clinical variations in this type of deviation. In our study, we developed 20 specific strabismus protocols, with all possible clinical variations of deviations[12].

This work enables the insertion of images, videos and sounds. This facilitates understanding by the examiner, which will analyze the various diagnostic positions of the extraocular muscles, in addition to the values of the deviations noted in the protocols. In addition, the study through images by more than one examiner lowers the chances of erroneous conclusions, as well as serves as a basis for comparison with the future state of this patient.

SINPE© enables on-site and online collections, and searches can be determined to cover a specified subject, or one can specify certain characteristics to be observed. This gives great flexibility when it comes to clinical research, for it can be held in places of interest that have connections to internet data transmissions. Recently Internet II has been launched, linking Unifesp, Unicamp, USP, Incor, PUC and Papesp, enabling real time collaboration, with discussion of interactive tests. The same is seen in the work of Belfort Jr and Schor, where virtual doctors begin to be a reality and may carry out the activity anywhere, without leaving home[1]. The SINPE© electronic protocol in cervical cancer was created in the *Santa Casa de Misericórdia de Sao Paulo*, with insertion of 2,687 items[13].

The experimental use of specific protocols reinforced the need for use of computerized systems for credible work, which is consistent with Grimson, who says the control and standardization of data on protocols allow prospective and longitudinal studies. These, with records accessible on the internet along with clinical protocols and guidelines, could be connected to direct individuals' health care[14].

This database will critically 'provide relevant research in the field of ophthalmology, as the protocols presented are instruments that have quality, credibility and reliable information.

We can conclude that, with the making of an ophthalmic diseases multidisciplinary electronic protocol with emphasis on strabismus, we created an electronic database in ophthalmology with emphasis on strabismus through standardized information gathering. The computerization of this database was made in the form of software, so that future users will be able to use the ophthalmic diseases multidisciplinary electronic protocol with an emphasis on strabismus to collect data..

R E S U M O

Objetivo: *criar uma base eletrônica de dados em oftalmologia com ênfase em estrabismo através da coleta padronizada de informações. Informatizar esta base sob a forma de software para a coleta sistemática de dados chamado "Protocolo Eletrônico" e incorporar este "Protocolo Eletrônico" da Oftalmologia ao Sistema Integrado de Protocolos Eletrônicos (SINPE©).* **Métodos:** *este é um estudo descritivo e a metodologia aplicada em seu desenvolvimento está didaticamente dividida em três fases: 1) criação da base teórica de dados clínicos de oftalmologia com ênfase em estrabismo; 2) informatização da base teórica dos dados utilizando o SINPE©; e 3) interpretação das informações com demonstração dos resultados. A informatização da base de dados foi realizada pela utilização da concessão de uso do SINPE©. Foram incluídos neste protocolo 50 pacientes com estrabismo para validação do protocolo.* **Resultados:** *o protocolo eletrônico desenvolvido permitiu armazenar informações relacionadas à anamnese, exame físico, exames complementares, diagnóstico e tratamento de pacientes com doenças oftalmológicas, com ênfase em estrabismo. Foram incluídos neste trabalho 2141 itens no protocolo mestre e foram criados 20 protocolos específicos de estrabismo, cada um com suas particularidades. Os 50 pacientes que foram incluídos nos protocolos específicos demonstraram a eficácia do método empregado.* **Conclusão:** *foi criada uma base eletrônica de dados em oftalmologia com ênfase em estrabismo através da coleta padronizada de informações. Esta base de dados foi informatizada sob a forma de software onde os futuros usuários poderão utilizar o protocolo eletrônico multiprofissional de doenças oftalmológicas com ênfase em estrabismo para a coleta de seus dados.*

Descritores: *Protocolos. Protocolos Clínicos. Coleta de Dados. Oftalmologia. Estrabismo.*

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Comparative analysis of endoscopic and histopathological features of superficial elevated lesions resected by endoscopic mucosal resection in the distal and proximal colon

Análise comparativa dos aspectos endoscópicos e histopatológicos das lesões superficialmente elevadas ressecadas por mucosectomias no cólon distal e proximal

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ABSTRACT

Objective: to compare endoscopic and histopathologic features of superficial, elevated lesions with one or more centimeters in diameter, diagnosed by videocolonoscopy on the distal and proximal colon, and subjected to mucosal resection. **Methods:** we conducted a retrospective, cross-sectional, observational study involving 8,075 videocolonoscopies. From this total, we evaluated 166 mucosectomies in 145 patients with superficial, elevated lesions with a diameter equal to or greater than 1cm. **Results**: the lesion prevalence was lower in G1 than in G2 (34.9% vs. 65%). The mean age, gender distribution and size (1.9cm in G1 versus 2.0cm in G2, p=0.921) were similar. There was no difference of mucosal surfaces in relation to the location (p=0.575). Considering Intraepithelial neoplasias, both the low grade, high grade (including carcinomas) and hyperplasic ones showedd no difference (p=0.527), nor did the neoplastic lesions when divided into serrated and non-serrated (p=0.124). Excluding 13 hyperplastic lesions and two carcinomas, 124 (82.1%) were non-serrated and 27 (17.9%), serrated. **Conclusion**: were found no significant differences between endoscopic and histopathological aspects of superficial, elevated lesions of 1cm or more in diameter in distal colon compared with the proximal, when resected by mucosectomy. Although not significant, there was a tendency of association between the location of the lesion and the presence of serrated features.

Keywords: Colorectal Neoplasms. Endoscopy. Mucous Membrane. Colon. Colonoscopy.

INTRODUCTION

Colorectal cancer is one of the major medical problems throughout the world[1-3]. The proportion of proximal carcinomas has increased relative to the distal ones[4] and the protection afforded by colonoscopy in the proximal colon is lower than in the distal[5]. Many studies suggest that the interval carcinomas, which are diagnosed few years after colonoscopy, are more proximal, and whose diagnosis was missed, among various factors, due to the development from superficial lesions[5,6]. At the same time, endoscopists started to increasingly diagnose non-polypoid or superficial lesions, and Laterally Spreading Tumor (LST) lesions[7].

In recent years the serrated lesions, which are often superficially elevated lesions, have been subject of much discussion, but there are still some disagreements and difficulties in their diagnosis and characterization by endoscopists and pathologists. Even so, they are now considered important, representing 7.5% to 30% of all colorectal carcinomas according to several authors[8].

This work, emphasizing the histogenesis of colorectal cancer, aimed to study mucosectomy specimens of superficially elevated lesions of 1 cm or more in diameter, comparing their endoscopic and pathologic features in the distal and proximal colon.

METHODS

The study was retrospective, cross-sectional, observational, in which we evaluated the specimens from patients undergoing colonoscopies with endoscopic mucosectomies of superficially elevated lesions with

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more than 1 cm in diameter, in the period from 2011 to 2014 at the Hospital Nove de Julho, São Paulo, SP, Brazil. The examinations were performed with sedation controlled by an anesthesiologist and the lesions were resected by the mucosectomy technique. We considered both the 0-LST and 0-IIa lesions (classification of Paris) as superficially elevated lesions. We classified their surfaces as granular, nodular and smooth after chromoendoscopy with indigo carmine 0.4%. Lesions 2-2.5 cm in diameter were resected en bloc and with more than 2.5-3 cm by fragment (piecemeal) mucosectomy.

We stretched the specimens in cardboard with needles and fixed them in 10% formalin. Subsequently, we cut every 2mm, and microscopically examined them with hematoxylin and eosin. We divided the invasion of the submucosa into three levels: sm1, sm2 and sm3. We histologically classified lesions by the Vienna classification. Lesions with cellular atypia and cytoarchitecture were subdivided in serrated and not serrated, keeping hyperplastic polyps as a separate group.

Finally, evaluations of serrated lesions were reconsidered in accordance with the guidance of the World Health Organization (WHO), including hyperplastic polyps with 1cm or more in diameter as serrated lesions[8-10]. These, when with atypia (sessile serrated adenomas/polyps – SSA/Ps) were considered low-grade or high-grade intraepithelial neoplasias, serrated type (IN-LG-S or IN-HG-S). The adenomatous lesions were considered as low-grade or high-grade intraepithelial neoplasias, or as non-serrated low-grade or high-grade intraepithelial neoplasia.

The splenic flexure is considered proximal by some authors[11] and distal by others[12]. In this work, we considered the splenic flexure, descending and sigmoid colon as distal (G1), and the cecum, ascending and transverse colon as proximal (G2).

We described the results of the variables evaluated in the study as frequencies and percentages (qualitative variables). For the age of the patients, we present the mean values and standard deviation. For the comparison of lesions' locations (distal and proximal) with the qualitative variables, we used the Fisher exact test or chi-square test. W considered p values < 0.05 as statistically significant. Data were analyzed with the software IBM SPSS Statistics v.20.

RESULTS

We carried out 166 mucosectomies (2% of total colonoscopies) in 145 patients. Of these, 52 (35.9%) had 58 lesions in G1. The mean age was 64.2 years (+/- 12.3 years, 33-89); 25 (48.1%) were men and 27 (51.9%), women. In G2, 100 individuals (69%) had 108 lesions, with a mean age of 65.4 years (+/- 10.2 years, 38-89); 45 (45%) were men and 55 (55%), women.

Table 1 shows the frequencies and percentage of lesions according to ranges in size at each location.

When comparing the size of lesions in the distal colon with the proximal one, there was no significant difference (p=0.921). We also show the frequencies and percentage of lesions according to the surface's characteristics at each location. There was no significant difference between the locations of the injury and the surface's characteristics (p=0.575).

For the statistical test, we considered low grade, high-grade and hyperplastic intraepithelial neoplasia. The two cases of carcinoma were grouped with the high-grade intraepithelial neoplasias (Table 2).

When comparing G1 with G2 lesions, there was no significant difference (p=0.527). Table 3 shows the comparison between non-serrated intraepithelial neoplasias and serrated ones, excluding the hyperplastic polyps (n=13) and carcinomas (n=2).

In Table 3 we divided these 151 lesions in two groups, considering them as serrated and non-serrated and showed the results restricted to lesions with low-grade and high-grade intraepithelial neoplasia. In all analyzes, there were no significant differences between the types of lesions and their locations between G1 or G2.

Tables 4 and 5 present the frequencies and percentages according to the surface and size, with the histopathology, at each location.

When considering the 13 hyperplastic lesions and serrated lesions (would be sessile serrated adenomas without dysplasia), the serrated lesions would total 41 (Table 6).

The statistical analysis, although without significance, indicated a trend of association between the location and the presence of serrated lesions.

Table 1. *Frequencies and percentages of lesions according to ranges of sizes, surfaces, and histopathology in the distal and proximal colon.*

Size (cm)	Distal	Proximal	Total
1	13 (22.4%)	28 (25.9%)	41 (24.7%)
1.1 a 2	27 (46.6%)	45 (41.7%)	72 (43.4%)
2.1 a 3	12 (20.7%)	22 (20.4%)	34 (20.5%)
> 3	6 (10.3%)	13 (12%)	19 (11.4%)
Total	58	108	166
Surface	Distal	Proximal	Total
Granular-G	45 (77.6%)	88 (81.5%)	133 (80.1%)
Nodular-N	10 (17.2%)	19 (17.6%)	29 (17.5%)
Smooth-S	3 (5.2%)	1 (0.9%)	4 (2.4%)
Total	58	108	166
Histopathology	Distal colon	Proximal colon	Total
Hyperplasic	3 (5.1%)	10 (9.2%)	13 (7.8%)
Low-grade IN	38 (65.5%)	56 (51.8%)	94 (56.6%)
Low grade-serrated IN	6 (10.3%)	18 (16.6%)	24 (14.5%)
High degree IN	10 (17.2%)	20 (18.5%)	30 (18.1%)
High degree-serrated IN	0 (0%)	3 (2.8%)	3 (1.8%)
sm1 Carcinoma	1 (1.7%)	1 (0.9%)	2 (1.2%)
TOTAL	58 (100%)	108 (100%)	166

IN = intraepithelial neoplasia

DISCUSSION

The sessile serrated adenomas / polyps (SSA/Ps) predominate in the right colon[13]. They tend to be flat in the proximal colon (75%), 64% being bigger than 5mm, and 17% bigger than 10mm. The proximal hyperplastic polyps with more than 5mm could be classified as serrated[8], while most non-serrated or adenomatous lesions would occur in the left colon[14]. Authors state that the proximal hyperplastic polyps, greater than 10mm may be considered sessile serrated adenomas. With these criteria, we would have had 41 serrated lesions, nine (22%) in G1 and 32 (78%) in G2. In G1, they correspond to 15.5% of 58, and in G2, including the sm1 serrated carcinoma, 29.6% of 108. Of the 125 non-serrated lesions, 49 (39.2%) occurred in G1 and 76 (60.8 %), in G2. The statistical test (0.061) was not significant, but showed a tendency to the association between the location and the presence of serrated lesions.

In an American study of 100 serrated lesions, 88 were located in the colon proximal to the splenic flexure. The vast majority were superficially elevated lesions[15]. This paper presents similar data, ie, of the 41 serrated (including hyperplastic polyps), 32 (78%) were located in the G2 and nine (21.9%), in G1.

A Japanese multicenter study analyzed 154 hyperplastic polyps with 1cm or more in diameter. Most sessile serrated adenomas with atypia (SSA/Ps), 90 of 107 (84.1%), and those who were not sessile serrated adenomas (non-SSA/Ps, thus without atypia), 33 of 47 (70.2%) were in the proximal colon[16], as observed in this study, where 77.7% of serrated lesions with atypia (21 of 27 lesions) and 76.9% of serrated lesions without atypia (10 of 13 hyperplastic lesions) were located in the proximal colon (G2).

A very large series of a Korean group of 28,544 colonoscopies diagnosed 143 sessile serrated adenomas / polyps (SSA/Ps) (0.5%). Of these, 123 (86%) were proximal to the splenic flexure and nine (6.3%) had more than 1cm in diameter[17]. In the literature, the average size of sessile serrated adenomas was 8.1mm[16]. We diagnosed 27 sessile serrated adenomas with 1cm or more in diameter, six in G1 (22.2%) and 21 in G2 (77.7%).

In this series, with these criteria, four of 41 serrated lesions (9.7%) and 31 of 125 non-serrated (24.8%) had high-grade IN or sm1carcinomas. In G1, of the 49 non-serrated lesions, 11 had high-grade IN or sm1 carcinomas (22.4%) and

Table 2. *Histopathological aspects of the sample (n = 166).*

Histopathology	Distal	Proximal	Total
Low-grade IN	44 (75.9%)	74 (68.5%)	118 (71.1%)
High-grade IN and carcinoma*	11 (19%)	24 (22.2%)	35 (21.1%)
Hyperplastic polyp	3 (5.2%)	10 (9.3%)	13 (7.8%)
Total	58	108	166

** Two cases of adenocarcinoma (one distal non-serrated on and one proximal, serrated)*

none in the serrated lesions. In G2, 20 of the 76 non-serrated lesions (26.3%) and four serrated (4/32 = 16.7%) were high-grade intraepithelial neoplasia or sm1carcinomas.

In a Brazilian publication, it was shown that lesions larger than 1 cm tend to be pedunculated, with adenomatous component, and patients over 50 years of age are more likely to present sessile polyps in the proximal colon[18]. In an American study with 2400 patients, 10% of diagnosed polyps were serrated. The right colon lesions, when compared by size, were more likely to be dysplastic[19]. In this study we diagnosed 41 serrated lesions in 166 mucosectomies' specimens (24.7%), 55 being lesions with atypia in G1 (94.8%) and 98 in G2 (90.4%), with no statistical difference between the two groups.

In a Korean study of 47 proximal serrated lesions, 43 were slightly elevated lesions, and of these, nine were at high risk, two with dysplasia and seven with diameter greater than 10mm. The average size was 6mm[20]. In this study, 32 were slightly elevated lesions in G2, all with 1 cm or more in diameter, and four were high-grade IN or sm1 carcinomas.

Recent publications of few cases series (n=12)[21] demonstrated that even small serrated lesions may have invasive carcinoma, with sizes between 8.5 and 11.3 mm, suggesting malignant transformations are rare, but fast. This rapid progression aspect was not confirmed in another study, in which the average age of patients with sessile serrated adenomas was 61, of the sessile serrated adenomas with high-grade atypia, 72, and of the cancer related to sessile serrated adenomas, 76[22].

A Japanese research evaluated 141 serrated lesions, 107 being slightly elevated lesions, preferably in the right colon (81.8%), with an average size of 13 mm, with intramucosal carcinoma in 13.6% (3/22 SSA/Ps)[23]. In this study, considering the high degree IN as intramucosal carcinoma, we found three lesions of 27 sessile serrated adenomas (11.1%) and one sm1 carcinoma, which would total four carcinomas in 28 SSA/Ps (14 2%), with an average size of 14 mm, all in G2.

Table 3. *Serrated and non-serrated lesions and intraepithelial neoplasia.*

Serrated	Distal	Proximal	Total	
Low-grade IN. non-serrated	38 (70.4%)	56 (57.7%)	94 (62.3%)	
High-grade IN. non-serrated	10 (18.5%)	20 (20.6%)	30 (19.9%)	
Low-grade IN. serrated	6 (11.1%)	18 (18.6%)	24 (15.9%)	p=0.278
High-grade IN. serrated	0 (0%)	3 (3.1%)	3 (2%)	
Total	54	97	151	
Serrated	Distal	Proximal	Total	
No	48 (88.9%)	76 (78.4%)	124 (82.1%)	
Yes	6 (11.1%)	21 (21.6%)	27 (17.9%)	p=0.124
Total	54	97	151	
Low-grade serrated	Distal	Proximal	Total	
No	38 (86.4%)	56 (75.7%)	94 (79.7%)	
Yes	6 (13.6%)	18 (24.3%)	24 (20.3%)	p=0.237
Total	44	74	118	
High-grade serrated	Distal	Proximal	Total	
No	10 (100%)	20 (87%)	30 (90.9%)	
Yes	0 (0%)	3 (13%)	3 (9.1%)	p=0.536
Total	10	23	33	

IN= intraepithelial neoplasia

Table 4. *Histopathology and surface features of lesions in the distal and proximal colon*

Histopathology	(Distal. n = 58)			Surface (proximal. n = 108)		
	Granular	Nodular	Smooth	Granular	Nodular	Smooth
Hyperplastic polyp	2 (4.4%)	0	1 (33.3%)	9 (10.2%)	1 (5.2%)	0
Low-grade IN	29 (64.4%)	7 (70%)	2 (66.7%)	42 (47.7%)	13(76%)	1 (100%)
Low-grade IN. serrated	6 (13.3%)	0	0	18 (20.5%)	0	0
High degree IN	7 (15.6%)	3 (30%)	0 (0%)	16 (18.2%)	4(23.5%)	0
High-grade IN. serrated	0	0	0	2 (2.3%)	1 (5.2%)	0
Adenocarcinoma	1 (2.2%)	-	-	1 (1.1%)	0	0
Total	45	10	3	88	19	1

IN= intraepithelial neoplasia

The submucosal invasion index for lateral spreading lesions with homogeneous surfaces is very low (< 2%), even in large lesions, while in those with mixed surfaces, with larger nodules, this ratio is higher (up to 7%)[24]. The two cases of carcinoma in this series occurred lesions with granular surface (1.5% of 133), one being serrated with 1 cm in G2, and the other non-serrated, with a 2.5 cm diameter in G1.

Sessile serrated adenomas and traditional sessile adenomas (TSA) have been considered precancerous neoplastic lesions and the hyperplastic polyp, void of malignant potential. However, one author considers the hyperplastic polyp with more than 1 cm also with malignant potential[24]. Sessile serrated adenomas with obvious dysplasia present, according to some authors, with an estimated higher probability to evolve to cancer than conventional adenomas (5.3% versus 2.2%).

The progression of sessile serrated adenoma to cancer would be faster than that of conventional adenomas. Progress to invasive carcinoma has already been shown to take place in eight months. The data suggest that the serrated sessile adenomas may be present for many years with few changes; however, they may rapidly progress to invasive carcinomas, even without dysplasia and with less than 10mm in diameter[25.26].

New technologies can help to better distinguish hyperplastic lesions from the serrated and not serrated lesions and to determine the most adequate procedure to adopt in each case during colonoscopy[27.28].

In recent years, serrated lesions were also included in the colonoscopy follow-up recommendation. Nevertheless, it is not yet clear whether the size of 10mm – used to define conventional adenomas as advanced –

Table 5. *Histopathology and lesion size in the distal and proximal colon.*

Histopathology	Lesion size (cm) (Distal. n = 58)				Lesion size (cm) (Proximal. n = 108)			
	1	1.1 a 2	2.1 a 3	> 3	1	1.1 a 2	2.1 a 3	> 3
Hyperplastic polyp	2 (15.4%)	1 (3.7%)			1 (3.6%)	8 (17.8%)		1 (7.7%)
Low-grade IN	10 (76.9%)	19 (70.4%)	7 (58.3%)	2 (33.3%)	15 (53.6%)	21 (46.7%)	13 (59.1%)	7 (53.8%)
Low-grade IN. serrated	1 (7.7%)	2 (7.4%)	1 (8.3%)	2 (33.3%)	7 (25%)	9 (20%)	1 (4.5%)	1 (7.7%)
High-grade IN		5 (18.5%)	3 (25%)	2 (33.3%)	2 (7.1%)	7 (15.6%)	7 (31.8%)	4 (30.8%)
High-grade IN. serrated					2 (7.1%)		1 (4.5%)	
Adenocarcinoma			1 (8.3%)					
					1 (3.6%)			
Total	13	27	12	6	28	45	22	13

IN= intraepithelial neoplasia

Tabela 6. *Results according to the criteria of the World Health Organization (WHO).*

Serrated	Distal	Proximal	Total
No	49 (84.4%)	76 (70.3%)	125 (75.3%)
Yes	9 (15.5 %)	32 (29.6%)	41 (24.7%)
Total	58	108	166

p=0.061

should also be applied to serrated sessile adenomas[28].

In conclusion, there were no significant differences between the endoscopic and histopathological aspects of superficially elevated lesions with more than 1cm in diameter resected by mucosectomy from the distal colon compared with the proximal one. Although not significant, there is a tendency to the association between the location of the lesion and the presence of serrated features.

R E S U M O

Objetivo: *comparar aspectos endoscópicos e histopatológicos de lesões superficialmente elevadas, com um ou mais centímetros de diâmetro, diagnosticadas por videocolonoscopias e ressecadas por mucosectomias do cólon distal com as do cólon proximal.* **Métodos:** *estudo foi retrospectivo, transversal, observacional, envolvendo 8075 videocolonoscopias. Avaliou-se 166 mucosectomias em 145 pacientes com lesões superficialmente elevadas com diâmetro igual ou maior do que 1cm.* **Resultados:** *a prevalência de lesões foi menor no G1 do que no G2 (34,9% x 65%). A média de idade, a distribuição por sexo e o tamanho (1,9cm no G1 e 2cm no G2, p=0,921) foram semelhantes. Não houve diferenças das superfícies em relação à localização (p=0,575). Considerando neoplasia intraepitelial de baixo grau, neoplasia intraepitelial de alto grau (incluindo carcinomas) e hiperplásicas, não houve diferença (p=0,527), assim como quando foram divididas as lesões neoplásicas em serrilhadas e não serrilhadas (p=0,124). Excluindo-se 13 lesões hiperplásicas e duas com carcinomas, 124 (82,1%) foram não serrilhadas e 27 (17,9%) serrilhadas.* **Conclusão:** *não foram observadas diferenças significativas entre os aspectos endoscópicos e os histopatológicos das lesões superficialmente elevadas, com 1cm ou mais de diâmetro, ressecadas por mucosectomia do cólon distal em relação ao proximal. Embora não significante, há tendência à associação entre a localização da lesão e a presença de características serrilhadas.*

Descritores: *Neoplasias Colorretais. Endoscopia. Membrana Mucosa. Cólon. Colonoscopia.*

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Minimally invasive treatment of vesicourethral leak after laparoscopic radical prostatectomy

Tratamento minimamente invasivo para fístula vesicouretral após prostatectomia radical videolaparoscópica

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A B S T R A C T

Objective: to describe our experience with a minimally invasive approach for persistent vesicourethral anastomotic leak (PVAL) after Laparoscopic Radical Prostatectomy (LRP). **Methods**: from 2004 to 2011, two surgeons performed LRP in 620 patients. Ten patients had PVAL, with initially indicated conservative treatment, to no avail. These patients underwent a minimally invasive operation, consisting of an endoscopically insertion of two ureteral catheters to direct urine flow, fixed to a new urethral catheter. We maintained the ureteral catheters for seven days on average to complete resolution of urine leakage. The urethral catheter was removed after three weeks of surgery. **Results:** the correction of urine leakage occurred within a range of one to three days, in all ten patients, without complications**.** There were no stenosis of the bladder neck and urinary incontinence on long-term follow-up. **Conclusion:** the study showed that PVAL after laparoscopic radical prostatectomy can be treated endoscopically with safety and excellent results.

Keywords: Prostatectomy. Urinary Fistula. Anastomosis, Surgical. Minimally Invasive Surgical Procedures. Prostatic Neoplasms.

INTRODUCTION

Prostate cancer is the most common malignancy in men. A large portion of the male population is subjected to screening tests, which makes early diagnosis increasingly frequent. Many of these patients are currently treated with laparoscopic radical prostatectomy (LRP) as a primary surgical approach aimed at cure[1,2].

The vesicourethral anastomosis between the bladder neck and the membranous urethra for reconstruction of the lower urinary tract after removal of the prostate is a crucial point of LRP. Leakage of urine between the anastomosis stitches in the postoperative period is common, but is usually of low output and self-limited, during two or three days[3].

Persistent vesicourethral anastomotic leaks (PVAL) can be defined as significant urinary losses through the drain after the third postoperative day, usually above 100 or 200 ml. It is a rare event, about which there is little published literature. However, its occurrence is of difficult control for the medical staff and patients, prolonging hospital stay, and bringing risks of potentially serious complications.

The objective of this study is to analyze the results of a endoscopic, minimally invasive approach to control PVAL when conservative treatment fails, thus avoiding more invasive surgical procedures, such as repair by conventional open surgery or nephrostomy, options traditionally used as the last resort in such cases.

METHODS

A total of 620 patients with adenocarcinoma of the prostate, clinical stage T1c, and a mean age of 61 years, underwent transperitoneal laparoscopic radical prostatectomy (LRP). The vesicourethral anastomosis was made with wire 3-0 Monocryl, as described by Van Velthoven *et al*., without bladder neck plasty prior to the anastomosis[3,4]. Ten patients had persistent vesicourethral anastomotic leaks (PVAL), with urine output by the perivesical drain of 100-400 ml in 24 hours, reaching 400-1100 ml on the second day after surgery. The fluids collected from the

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tubes were consistent with urine after laboratory results. All patients underwent total abdomen computed tomography, which showed collection of fluid within the pelvis. The ureters were preserved and the bladder Folley catheters were correctly positioned in the bladder. A retrograde cystogram was also carried out by urinary catheters in all ten patients, clearly showing contrast leak through the vesicourethral anastomosis (Figure 1).

Initially, conservative techniques had been used, such as traction and attachment of the bladder catheter to the patient's thigh so that the catheter balloon occluded the urine leakage site, associated with a lower fluid intake. After the failure of these initial measures, these ten patients underwent endoscopic intervention for treatment of persistent urinary fistulas. The time interval between the LRP and the endoscopic reintervention ranged from three to nine days.

The procedure consisted of bilaterally placing ureteral catheters exteriorized alongside a new Folley catheter, to direct the urine out via the urethra and to reduce the leakage through the fistula, allowing its closure. Initially, we carried out a urethrocystoscopy with a rigid, 19Fr cystoscope, under sedation and local anesthetic gel, allowing the exact identification of the fistula opening and its location relative to the ureteral ostia (Figure 2). Then 6Fr ureteral catheters were inserted bilaterally over a hydrophilic guidewire under radioscopic control and externalized through the urethra, along with a new, 18 Folley bladder catheter, also placed in the bladder with the aid of a guidewire.

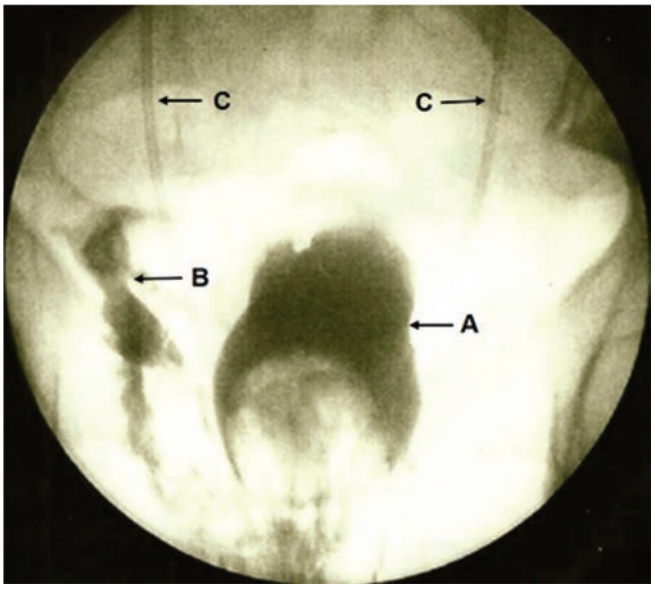

Figure 1. *Retrograde cystogram by the Folley catheter positioned in the bladder (A), where we can see the contrast leakage (B) from the posterior aspect of the anastomosis and the ureteral catheters (C) already positioned bilaterally*

All patients underwent a control retrograde cystogram to verify the complete resolution of the urine leakage before removal of the ureteral catheters, which took place after seven days. The bladder catheter was removed three weeks after prostatectomy.

RESULTS

The resolution of the persistent vesicourethral anastomosis leak (PVAL) occurred within a range of one to three days for all ten patients. There were no perioperative or immediate postoperative complications of the reintervention. The drains were removed after leakage become less than 50 ml per day (Table 1). There were no bladder neck stenosis or urinary incontinence after a mean follow up of 12 months (6-18 months).

DISCUSSION

Laparoscopic radical prostatectomy (LRP) is a procedure that requires great skill in making the vesicourethral anastomosis. Leakage of urine by the anastomosis is very common, but the persistent one is a rare event. The incidence of persistent vesicourethral anastomotic leaks (PVAL) after radical prostatectomy has been estimated at 0.9% to 2.5%. It is generally treated with ineffective conservative measures, and when it requires a therapeutic approach, procedures are very invasive for the patient, such as conventional open surgery or nephrostomy[5].

To confirm the PVAL diagnosis there are several available exams. Conventional cystogram remains a very useful tool to this day, and allows to record the contrast extravasation with simple radiographic images after injection through the bladder catheter. However, images obtained by computed tomography can provide more information, especially with three-dimensional volume estimate, which allows to better define the conduct in cases where the flow rate through the fistula is not very high. Lee *et al*. found a statistically significant difference between the urinary leak detection rate by cystography using tomography and con-

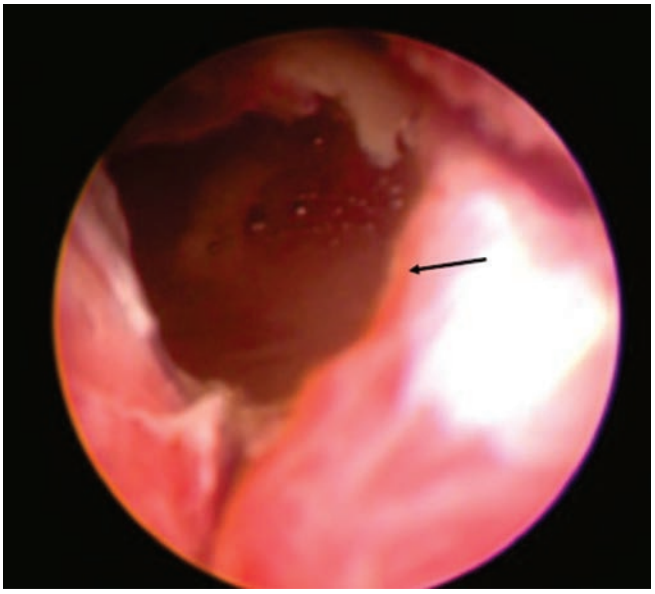

Figure 2. *Urethrocystoscopy showing the fistulous orifice (arrow) in the anastomosis.*

ventional cystography (80.4% *vs*. 54.3%). Therefore, even when conventional cystogram shows normal results, the leak can be detected by tomography[6,7].

After the PVAL diagnosis, it is in the form of treatment that lies the difficulty for urologists. This is a complication that can indefinitely prolong patients' hospitalization and presents risks of adverse developments, such as secondary infection by resistant germs.

Moinzadeh *et al*. previously presented a conservative technique of continuous suction by the Folley catheter to help in these cases. However, all conservative techniques, including continuous suction catheter, have failed to correct the intraperitoneal fistula[8].

In another study, the same group described the use of a percutaneous nefroureteral suction catheter having multiple fenestrae along its length and which allows the suction of urine, both from the bladder and from the renal pelvis. Thus, it forms a proximal urinary diversion, which allows the closure of the fistula. This minimally invasive technique avoids conducting bilateral nephrostomies or other reconstructive procedures, but also presents complexity compared to the endoscopic procedure[9].

Yossepowitch *et al*., from Urology Institute of the University of Tel Aviv, described their experience in treating PVAL after open radical prostatectomy, using the same endoscopic approach of our study. They treated 1,480 patients with open radical prostatectomy between 1996 and 2007. Seven patients had PVAL and underwent a rigid cystoscopy with a 19Fr cystoscope, followed by the bilateral placement of 5Fr ureteral catheters over a hydrophilic guidewire under fluoroscopic control. The average time between the intervention and removal of the pelvic drain (drain <50ml per day) was two days. The catheters were maintained for nine days on average. There was resolution of the urinary fistulas in all seven patients, which was confirmed by control cystography[10].

Our results were similar to the Yossepowitch group ones, with the same surgical technique. We believe, therefore, that the persistent vesicourethral anastomotic leaks (PVAL) can be treated by endoscopically draining the urinary system, with ease and security. The procedure is an alternative, less aggressive approach than any other surgical treatment, with excellent results.

Table 1. *Relationship between the high output of urine through the drain in patients with PVAL after LRP and the time of resolution of fistulas after endoscopic rapprochement.*

Patient	Interval between procedures (with PVAL)	Fistula output (mean 24h)	Resolution after rapprochement (output <50ml)
1	9 days	400ml	24 hours
2	6 days	720ml	24 hours
3	3 days	950ml	48 hours
4	5 days	650ml	48 hours
5	6 days	450ml	48 hours
6	4 days	800 ml	72 hours
7	4 days	850ml	72 hours
8	7 days	560ml	24 hours
9	3 days	1100ml	72 hours
10	6 days	480ml	48 hours

PVAL: Persistent vesicourethral anastomotic leak.

R E S U M O

Objetivo: *descrever nossa experiência com uma abordagem minimamente invasiva para fístula de anastomose vesicouretral persistente (FAVP) após prostatectomia radical laparoscópica (PRL).* **Métodos:** *de 2004 a 2011, 620 pacientes foram submetidos à prostatectomia radical laparoscópica realizada por dois cirurgiões. Dez pacientes apresentaram FAVP e o tratamento conservador foi inicialmente indicado sem sucesso. Esses pacientes foram submetidos a uma reoperação minimamente invasiva, por via endoscópica, com inserção de dois cateteres ureterais para direcionar o fluxo urinário, fixados a um novo cateter uretral. Os cateteres ureterais foram mantidos por sete dias, em média, até a completa resolução do vazamento de urina. O cateter uretral foi removido após três semanas da cirurgia.* **Resultados:** *a correção do vazamento de urina ocorreu dentro de um intervalo de um a três dias em todos os dez pacientes, sem complicações. Não foram observadas estenose de colo vesical ou incontinência urinária após acompanhamento em longo prazo.* **Conclusão:** *o estudo mostrou que a FAVP após a prostatectomia radical laparoscópica pode ser tratada por via endoscópica com segurança e excelentes resultados.*

Descritores: *Prostatectomia. Fístula Urinária. Anastomose Cirúrgica. Procedimentos Cirúrgicos minimamente Invasivsos. Neoplasias da Próstata.*

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Reliability of nutritional assessment in patients with gastrointestinal tumors

Confiabilidade da avaliação nutricional em pacientes com tumores gastrointestinais

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A B S T R A C T

Patients with gastrointestinal cancer and malnutrition are less likely to tolerate major surgical procedures, radiotherapy or chemotherapy. In general, they display a higher incidence of complications such as infection, dehiscence and sepsis, which increases the length of stay and risk of death, and reduces quality of life. The aim of this review is to discuss the pros and cons of different points of view to assess nutritional risk in patients with gastrointestinal tract (GIT) tumors and their viability, considering the current understanding and screening approaches in the field. A better combination of anthropometric, laboratory and subjective evaluations is needed in patients with GIT cancer, since malnutrition in these patients is usually much more severe than in those patients with tumors at sites other than the GIT.

Keywords: Nutrition Assessment. Gastrointestinal Tract. Malnutrition. Prognosis. Morbidity.

INTRODUCTION

Currently, cancer is a major public health problem worldwide[1]. In addition, malnutrition and subsequent weight loss have long been among the leading causes of morbidity and mortality, as well as increased costs with other organs dysfunction associated to cancer patients undergoing surgery[2]. Malnutrition is defined as the energy, protein and other specific nutrients deficient state, which significantly modifies organic functions[3].

Patients with gastrointestinal malignancy undergoing major elective procedures have a higher risk of postoperative complications and alterations resulting from their pre and post-admission nutritional status, particularly related to surgical stress, immune suppression induced by cancer or by blood transfusion. Among these factors, malnutrition is the most important due to its high prevalence and negative impact on clinical outcomes such as longer hospital stay[3] and mortality. The latter is much more related to malnutrition than cancer alone and can occur in 20% of cases[4]. Approximately half of the patients with malignancies has malnutrition, and in the case of gastrointestinal tract (GIT) tumors, the mortality rate varies from 30% to 50%, reaching 80% in cases of advanced pancreatic cancer[4,5].

Several nutritional assessment methods can be used[5], and must be sensitive enough to early identify changes according to specific nutritional imbalances. The method choice depends on the purpose of the assessment, prognosis or even on the response to nutritional interventions[2,4].

However, health professionals find it difficult to use most of the currently validated tools for nutritional assessment, due to limited time, method reproducibility, organization or cost[6-8]. Thus, all currently considered parameters show some sort of limitation to accurately assess the state nutritional[6]. In the absence of a gold standard, the option for the assessment tool and nutritional classification will depend on the institution and the target population in question, as well as on the resources available[8-10]. Although the use of indices and multivariate scores is often regarded as the solution to the lack of standardized and reliable evaluation, this is only a possibility[10].

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Therefore, in the daily practice of oncology, the definition of an appreciable and simple to apply nutritional assessment tool is necessary to identify nutritional risk patients and thus determine the best approach and appropriate nutritional support[8]. The objective of this review is to present an overview of the methods and tools used to determine nutritional risk, considering the pros and cons when applied to patients with GIT cancer.

METHODS

We systematically identified studies on nutritional status of patients with GIT cancer through the PubMed and MEDLINE databases. We researched articles published in the last ten years by combining the terms "nutritional assessment", "GI cancer", "gastrointestinal tract", "gastric cancer", "oesophageal cancer" and "pancreatic cancer". We considered for evaluation only complete articles with those terms in English or Portuguese. We identified additional articles from citations in the articles evaluated.

RESULTS AND DISCUSSION

General review of nutritional assessment

It was in the 1950s that authors first published research related to nutritional assessment procedures. Between 1960 and 1980, malnutrition markers have emerged to evaluate surgical patients and new concepts and nutritional assessment methods have been developed[11]. In the following decades, the researchers analyzed the relevance of functional indices and combinations of clinical and laboratory parameters existing in an attempt to better predict nutritional risk. A new concept of body composition was defined from the use of new and more complex equipment and methods of assessment, but still considering subjective concepts[7]. From the beginning of this century, attempts have been made to demonstrate the nutritional assessment method that would be more accurate and reliable for certain types of patients or specific clinical conditions[3,8].

Subjective methods

In 1980, Detsky et al. described the Subjective Global Assessment (SGA) used to assess preoperative patients with GIT tumors (n = 202) undergoing major surgical procedures; They have shown that SGA could be easily applied and considered it a valid and reliable method to estimate the surgical patients' nutritional status[12].

Other authors have published several articles supporting the SGA in determining nutritional status, which differed from other methods in considering not only changes in body composition, but also functional changes. In addition, SGA is a simple, inexpensive, non-invasive method and can be performed at bedside. Correct guidance on the SGA application is essential, since its accuracy depends on the observer's ability to detect subjectively significant nutritional changes[8,13,14].

Subsequently, the SGA has undergone modifications and adaptations developed specifically to meet the oncological patient characteristics. Questions about symptoms of nutritional impact and resulting from the tumor itself or from the imposed treatment[8] were included and answered by the patient, becoming known as the Patient-generated SGA (PG-SGA). The main introduced difference was a numerical score that allows to better identify patients at nutritional risk and estimate the time required for re-evaluation.

In some multi-center studies on nutritional assessment of hospitalized patients using SGA, different results have been reported, particularly in patients with GIT cancer. Poziomyck et al. found 66% of malnourished patients in surgical cases of upper GIT tumors[8], while Bragagnolo et al. showed 77% of malnourished patients in a similar sample[15].

In another study involving 80 patients with GIT tumors, mainly colorectal, Cid Conde et al. found 50% of malnutrition by SGA[16], a result that were higher (70%) in another study with a similar sample[17].

Wu et al. had higher incidence of complications and longer hospital stay the worse the level of SGA in patients undergoing major procedures for GIT cancer (mainly gastric)[18]. These results were also supported by our series of patients with esophageal, stomach and pan-

Table 1. *Main objective and subjective methods used for nutritional assessment.*

Objective	
Anthropometrics	Body mass index, weight loss, skin-fold thickness and circumferences, adductor pollicis muscle thickness
Biochemical tests	Albumin, prealbumin, transferring, retinol-binding protein, nitrogen balance, creatinine-height index
Body composition	Bioelectrical impedance analysis
Functional tests	Hand grip strength, phase angle
Subjective	Subjective global assessment (SGA) and Patient-generated subjective global assessment (PG-SGA)

creas tumors[8]. Moreover, in patients with esophageal or stomach cancer, SGA appears to be associated with the Glasgow Prognostic score (GPS)[19]. A study comparing PG-SGA with the Mini Nutritional Assessment (MNA) revealed that these tools seem appropriate to define elderly patients as malnourished[10]. GPS and MNA concepts are described in Score Methods later in the text.

Anthropometric methods

The accuracy and reproducibility of anthropometric measurements may be affected by the equipment calibration, examiner and parameters used for the predictive equations[20]. Several essentially objective nutritional assessment tools have been used in clinical practice, each with its own characteristics[13].

Body weight is as simple and commonly used measure in clinical practice. However, it does not discriminate mass from fat, muscle, bone or extracellular fluids. Thus, it must be used with caution, since sharp alterations may reflect changes in hydration status, and not necessarily change in cell mass[21].

Renehan et al. demonstrated that increased body mass index (BMI) on the order of 5 kg/m^2 in both genders was strongly associated with esophageal adenocarcinoma[22]. Excess weight, visceral fat and abdominal obesity appears to be more disturbing than subcutaneous fat, and any further increase in BMI confers increased risk of developing colorectal cancer[19], which, however, has not been confirmed in other studies with this tool[8,15].

Functional markers are of particular importance, since they correlate well with clinical complications[20]. They may be more sensitive and relevant indicators of changes in nutritional state or response to additional support in the short term than conventional methods[8]. Loss of muscle function is indicative of malnutrition, particularly the loss of lean body mass. Usually expressed by the handgrip strength, it is important to determine the function and the ability of skeletal muscle. The authors consider this as evidence of compromised nutritional status as responsible for the loss of skeletal muscle function and, consequently, loss of

Table 2. *Advantages and disadvantages of subjective methods and nutritional assessment.*

Method	Advantage	Disadvantage
Subjective global assessment (SGA)	Simple Inexpensive Non-invasive Bedside use	Observer dependable Non-disease specific
Patient-generated subjective global assessment (PG-SGA)	Simple Inexpensive Non-invasive Bedside use Reproducible	Provides a good training for observers Unspecific to different types of cancer

Table 3. *Advantages and disadvantages of anthropometric methods.*

Method	Advantage	Disadvantage
Body Mass Index (BMI)	Simple Inexpensive Non-invasive Bedside use	Does not distinguish fat mass and lean mass Does not reflect body composition
Skinfold Thickness	Simple Inexpensive Non-invasive Bedside use	Database limited Insufficient correction factors (age, hydration status, physical activity, disease state) No standard for oncology
Bioimpedance	Simple Non-invasive Easy application / Shortly Accurate measurements	Requires several previous care (4h fasting, use of diuretics, exercise, alcohol intake)
Adductor Muscle Pollicis Thickness (APM) / Dinamometry	Simple Non-invasive Easy application/Shortly Accurate measurements	Does not evaluate the acute effects of cancer malnutrition Requires the evaluator training

handgrip strength[8,15,20]. Recently, the measurement of the thickness of the *adductor pollicis* muscle (APM) was standardized to anthropometric parameters relating to age, gender and physique[8]. APM has been used to indirectly determine the nutritional status[14,20,23], being considered as one of the best single predictors of mortality in a recent study with patients undergoing resection of upper GIT tumor[8].

The bioimpedance analysis (BIA) uses the measured phase angle, which is the result of the electric current stored in cell membranes. However, more accurate results depend on regression equations and lower values indicate reduction in cell integrity or cellular death[24].

Some authors also use weight loss as a nutritional screening marker. In a study of patients with esophageal cancer, Van der Schaaf et al. found that preoperative loss weight exceeding 10% was associated with a reduction of the overall five-year survival after resection, but not with increased risk of postoperative complications[25].

Laboratory Methods

Albumin and other proteins used as nutritional markers can be affected by many factors and clinical conditions such as inflammation, malnutrition, diabetes, liver disease or surgical trauma. But they also have been used to assess overall nutritional status, severity, progression and prognosis of the disease[26], assuming that plasma levels indeed reflect the rate of synthesis[27-29.] However, other factors such as liver function, inflammation markers and endocrine stress result in increased levels of cortisol, which also affects albumin regulation[27].

Serum albumin has also been described as an independent survival prognostic factor in many tumors, displaying an inverse relation to complications and length of postoperative hospitalization or intensive care, mortality, and resumption of oral intake[26,27]. Decreased serum albumin also proved to be an independent prognostic factor for cancer patients with unknown primary site[26], but further clinical trials are needed to better define the baseline risks in patients with cancer[26-29.]

Recently, a significant association between increased C-reactive protein (CRP) and poor clinical outcome has been demonstrated in patients with pancreatic cancer[30]. CRP has also been shown to be an independent prognostic indicator in colorectal carcinoma[31].

Score Methods

A number of studies have consistently shown that no method or tool alone is enough to predict nutritional status[3]. The mini nutritional assessment (MNA) classified as normal, borderline or malnutrition in the elderly involves anthropometric measurements, overall evaluation, dietary questionnaire and subjective evaluation[32]. A cross-sectional study with elderly patients (n = 109) observed that combined arm circumference (AC) and BMI allowed to predict the MNA classification[33]. In another study evaluating elderly patients with hepatocellular carcinoma, the results suggested that MNA was adequate to identify the risk of deterioration in the quality of life and functional status, and to determine the risk of malnutrition[23].

The Nutritional Risk Index (NRI) is calculated by the equation of serum albumin and weight ratio[3,34]; the levels of serum protein and albumin significantly correlated with malnutrition, but not with subgroups of SGA or Nutritional Risk Screening 2002 (NRS-2002)[34].

The Glasgow Prognostic Score (GPS) has been used to determine long-term outcome (survival) in cases of curable gastric cancer[34], according to the degree of inflammation inferred by the CRP and albumin levels,with scores ranging from from 0 to 2[35]. It may be useful in determining the nutritional status, since inflammation is a relevant factor in the development of cachexia, though not yet evaluated in the short term[34].

In a study with 74 patients, 54 (72%) with GIT tumors, the Nutrition Inflammatory Index (NII) was an alternative method for biochemical nutritional assessment and monitoring of patients with cancer and systemic inflammation[36,37].

The NRS-2002 is a nutritional and disease severity score, being the preferred method for evaluating patients at risk or malnourished and for selecting those that could benefit from nutritional support[3]. This nutritional screening was directly related to tumor stage in 100 newly diagnosed patients with stomach cancer, and inversely correlated with quality of life, making it a useful tool to identify patients in need of nutritional support throughout treatment[38].

Table 4. *Advantages and disadvantages of laboratory methods.*

Method	Advantage	Disadvantage
Albumin	Simple Inexpensive Independent indicator of survival in many cancers	Unreliable Affected by many factors and conditions Need better definition of baseline risk in cancer patients Reflects more on the severity of the disease than the nutritional status per se
C-Reactive Protein (CRP)	Independent prognostic indicator for some types of carcinoma Good correlation with other methods of nutritional assessment	Higher costs Alone is not cancer-specific
Pre-albumin	Sensitive stress level Good marker for visceral protein	Higher costs Non-disease specific Can be affected by non-nutritional factors (reduction in inflammation)
Retinol Binding Protein (RBP)	High sensitivity to protein and caloric restriction	Higher costs Few studies in cancer patients Potential confounder in vitamin A deficiency
Total Lymphocyte Count (TLC)	Associated with weight loss and visceral protein loss	May be affected by tumor type and use of chemotherapeutic drug

In 2011, Argiles et al. presented a new tool called "The Cachexia Score" (CASCO), which considers weight and loss of lean body mass, anorexia, inflammatory, immunologic and metabolic disorders, physical performance and quality of life. The score (up to 100) appears to be adequate, although further prospective studies are needed to better define its sensitivity and specificity in different types of cancers, including GIT tumors[39].

FINAL CONSIDERATIONS

Various methods have allowed measurements of body composition, protein and lipid reserves by traditional anthropometry with the use of more sophisticated equipment. Currently, the most accurate techniques for assessment of nutritional status are more expensive, less available and inappropriate for repetitive measures[2].

Many studies have also revealed the inadequacy of any tool or method used alone in safely predicting the nutritional status of patients with cancer, which clearly demonstrates the lack of a specific measure as the gold standard[3,8], although the real need for a specific pattern is questionable. Still, this led to the attempt to combine evaluation measures, such as anthropometric and laboratory data, in order to increase sensitivity and specificity[30], and thus to more adequately evaluate oncology and surgical patients. Overall, the assessment instruments routinely used do not consider the risk and complications of ongoing cancer treatment, such as chemotherapy and radiation, their side effects in the gastrointestinal tract or post-operative implications of the inflammatory response in cancer patients in general.

This is even more relevant when considering patients with GIT tumors, for whom there is no consensus on the best tool or method to assess nutritional status, especially those with upper GIT tumors, most severely affected by nutritional and immune deficiency, and by the effect of major surgical procedures and complications in the immediate postoperative period when compared with lower GIT tumors cases. Probably the course of nutritional depletion between the two tumor locations is very different, as are quite distinct the nutritional support requirements. Thus, attempts to develop new protocols, trials, scores or new combinations of more specific approaches are necessary to better assess the nutritional status in patients with GIT tumors, especially considering those patients with upper GIT tumors, who are more malnourished, more immunocompromised and at increased risk of morbidity and mortality, as recently demonstrated in our series[8]. To date, as far as we know, there is insufficient data to establish a consensus for this group of patients. Therefore, it would be interesting to simulate, add or combine features already validated with objective variables to test a single questionnaire specifically designed

Table 5. *Advantages and disadvantages of nutritional scores.*

Method	Advantage	Disadvantage
Glasgow Prognostic Score (GPS)	Powerful method for diagnosis of nutritional status Long-term survival in some cancer surgery	Not assessed for short-term outcomes
Reilly Nutrition Risk Score	Mix of different approaches in nutritional methods	Adults and children in the same group Different types of cancer altogether
Prognostic nutritional index (PNI)	Good and accurate	Difficult to obtain the hypersensitivity skin tests
NUTRA*	Anthropometric, Subjective and Laboratory data targeting GIT cancer patients	Ongoing trial

**Developed by SSORG (Southern Surgical Oncology Research Group)*

to better predict postoperative morbidity and mortality in patients with gastrointestinal cancer.

In summary, the GPS score, the PG-SGA and some anthropometric parameters are considered suitable for chronic and cancer patients in general. However, a better combination of laboratory, anthropometric and subjective evaluations is required, considering an instrument more focused in GIT cancer patients, since malnutrition in these patients is much more severe compared with the one in patients with tumors in other locations.

R E S U M O

Pacientes com neoplasia gastrointestinal e desnutridos são menos propensos a tolerar procedimentos cirúrgicos de grande porte, radioterapia ou quimioterapia. Em geral, apresentam maior incidência de complicações, como infecção, deiscência e sepse, o que aumenta o tempo de internação e o risco de morte, e reduz a qualidade de vida. O objetivo desta revisão é abordar os prós e contras de diferentes pontos de vista que avaliam risco nutricional em pacientes com tumores do Trato Gastrointestinal (TGI) e sua viabilidade, considerando o atual entendimento e abordagens de triagem neste campo. Melhor combinação de avaliações antropométricas, laboratoriais e subjetivas se faz necessária em pacientes com câncer do TGI, uma vez que a desnutrição nestes pacientes costuma ser muito mais grave do que naqueles indivíduos com tumores em outros sítios que não o TGI.

Descritores: *Avaliação Nutricional. Trato Gastrointestinal. Desnutrição. Prognóstico. Morbidade.*

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Ultrasound-guided biliary drainage: a new era of endoscopic surgery

Drenagem biliar ecoguiada: uma nova era da cirurgia endoscópica

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ABSTRACT

Despite the success rate of endoscopic retrograde cholangiopancreatography (ERCP), in about 10% of the cases, there is failure to access the biliary tree. In this context, the endoscopic ultrasound (EUS), which was originally only used for diagnosis and staging, today has a therapeutic importance. The purpose of this update is to demonstrate the various forms of ultrasound-guided biliary drainage, as well as to compare it with percutaneous transhepatic biliary drainage (PTBD).

Keywords: Endoscopy, Gastrointestinal. Bile Ducts. Ultrasonography, Interventional. Jaundice, Obstructive. Endosonography.

INTRODUCTION

The important technological evolution led the endoscopic ultrasound (EUS), which was previously only a diagnostic mode, to a therapeutic level[1], now being a well-established technique for obtaining tissue samples, injection with fine needle and drainage of collections and abscesses adjacent to the gastrointestinal tract (GIT). Widespread adoption of minimally invasive surgical and radiological procedures naturally led to increased EUS use in the treatment and/or alleviation of gastrointestinal diseases, including ultrasound-guided biliary drainage (UGBD).

In patients with preserved GIT, selective catheterization of the bile duct by endoscopic retrograde cholangiopancreatography (ERCP) achieves success in more than 90% of cases. When access to the bile duct is not viable, percutaneous transhepatic biliary drainage (PTBD), or even surgical drainage, have been used as alternatives[2-5]. However, the long recovery time, delays in the initiation of chemotherapy and percutaneous discomfort of PTBD impair the use of such therapies. In this context, UGBD is an alternative, less invasive method in case of ERCP failure[6].

Wiersema *et al*. were the first to publish on the ultrasound-guided biliary access in 1996, reporting seven patients successfully submitted to ultrasound-guided cholangiography after failed ERCP[7]. However, they did not perform ultrasound-guided biliary drainage in their series. In 2001, Giovannini *et al*.[8] published the first case of successful creation of a fistula guided by the EUS between the duodenal bulb and the common bile duct, using a plastic prosthesis in a patient with malignant biliary obstruction caused by an unresectable pancreatic head tumor. This was the first report of an ultrasound-guided choledochoduodenostomy. Mallery *et al*.[9], in 2004, introduced a new relevant concept, the *rendezvous* ultrasound-guided biliary drainage technique, where a guidewire is inserted through the needle after the puncture of the biliary tract. This wire is advanced into the duodenum and then endoscopically retrieved with a duodenoscope, followed by ERCP. Several studies have been published since then on various UGBD techniques and results[10-21].

UGBD can be performed by three methods. The *rendezvous* is the technique in which a guidewire is inserted through the papilla in the intrahepatic or extrahepatic bile duct and recovered by a duodenoscope for subsequent biliary intervention. Another option is the implantation of a direct transluminal stent using a transgastric or transduodenal approach (without access to the papilla)[22,23]. The third approach, less common, is an anterograde passage of a transpapillary biliary stent (or transanastomotic)[24,25].

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Rendezvouz

A sectoral EUS is used to achieve initial biliary access in a dilated segment, proximal to the site of obstruction. The tip of the EUS will be positioned in the gastric fundus or duodenal bulb to access the intrahepatic or extrahepatic biliary tract, respectively. The fine-needle aspiration (FNA) with a 19 or 22 gauge needle is used to access the bile duct, and confirmed by contrast injection under fluoroscopy. The guidewire is then advanced into the biliary tree, the UE and the needle is angulated to facilitate the anterograde passage of the guidewire through the site of the obstruction and then to the papilla. The EUS is removed, leaving the guidewire. A duodenoscope is passed to the papilla and a handle or biopsy forceps, and the guidewire is grasped and pulled through the apparatus with subsequent implantation of a stent. To perform this technique it is essential that the duodenal anatomy is preserved, which often becomes the main limitation of this technique[26].

Direct Transluminal Drainage

In this technique, the entire procedure is performed using the UE. After the biliary tract is accessed as described above, the puncture site is dilated with a dilatation catheter or a balloon dilator and the stent is passed through some devices for placement. These devices are selected based on characteristics of the patient's anatomy and obstruction. The stent insertion is then performed in an anterograde fashion[27,28]. This technique is chosen when the wire may be positioned through the papilla or due to any anatomy change (biliary obstruction by a tumor) or technical complication (awkward position)[26].

As for the stents, there is a tendency to use an entirely covered, self-expandable, metallic stent (SEMS), instead of a plastic stent (PS). The use of the SEMS could potentially prolong the stent patency period compared with PS. Moreover, the radial expansion of a SEMS may hypothetically minimize the possibility of complications such as bile peritonitis, pneumoperitoneum, because the leak is immediately sealed by the SEMS itself. However, stent migration is a serious complication that may still occur even with the use of a SEMS, especially shortly after the procedure[29].

Choledochoduodenostomy (CDS)

The CDS technique involves the creation of a fistula between the duodenum and the extrahepatic biliary tree, thus requiring an extra-hepatic puncture approach. The extrahepatic bile duct can easily be seen and punctured from the duodenal bulb, even if only minimally dilated. This procedure can also be performed in patients with ascites due to the duodenum retroperitoneal position[30]. The CDS cannot be used in cases of proximal biliary stricture. Another technical aspect is the impossibility to perform CDS in patients with altered anatomy of the upper gastrointestinal tract.

The process begins by placing the EUS in the duodenal bulb in the long handle position and locating the extrahepatic bile duct. The EUS in the bulb normally stays in a relatively stable position. The bile duct is then accessed and a cholangiography performed, followed by dilation and stent placement. The puncture angle is a very important aspect of the process and should be observed carefully. The puncture angle should aim at the wire to advance towards the hepatic confluence. This should be guided by radiography, since the bile duct presents almost parallel to the spine. With respect to dilatation of the biliary tree, it should be calibrated for the passage of the dilatation system. This can be accomplished by a needle knife, a cystotome or a dilator (Figures 1, 2 and 3).

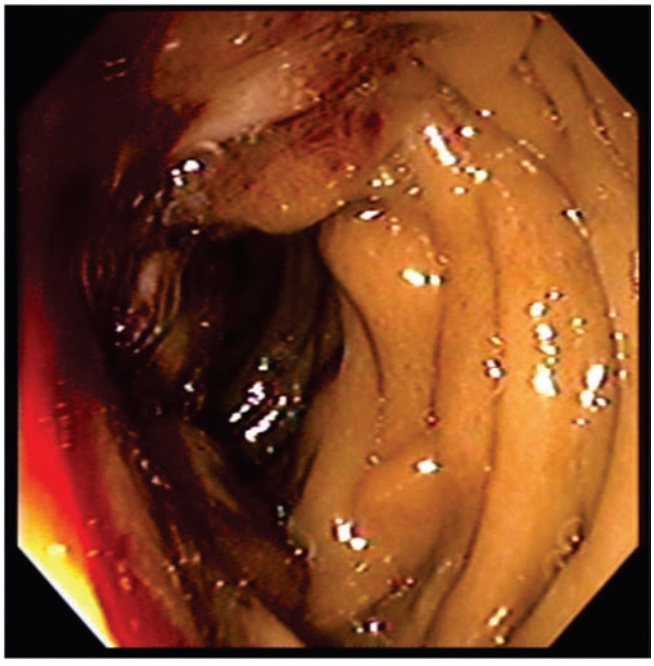

Figure 1. *Tumor infiltration in the duodenum.*

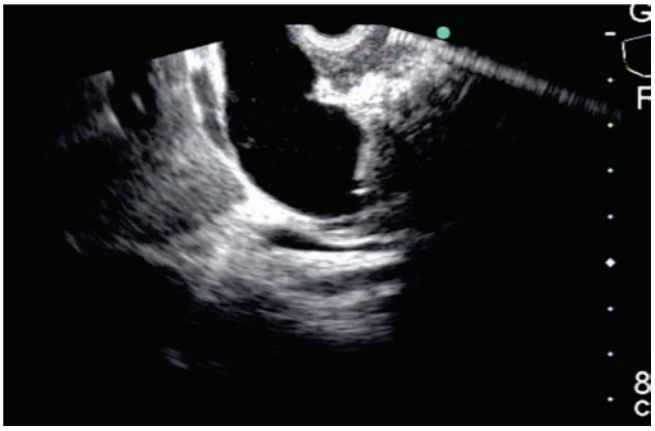

Figure 2. *Needle puncture in a dilated bile duct.*

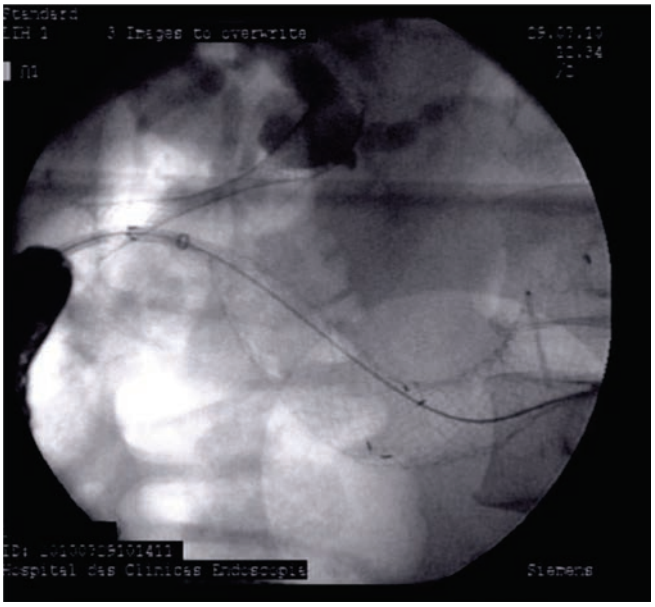

Figure 3. *Cholangiography appearance after passage of bile duct and duodenal stent.*

Hepatogastrostomy (HGS)

The intrahepatic biliary system can be reached either by a transesophageal, a transgastric or a transjejunal way (altered anatomy), the hepatic segment III being the most often accessed due to its best view, especially when the stent should be inserted through the cardia or lesser curvature[26,31,32].

The technique commonly begins with the sonographic observation of a dilated left hepatic duct. The EUS is positioned close to the cardia. In patients with large hiatal hernias, the puncture should be performed in a more distal gastric segment. Biliary puncture, dilatation and stent placement are then performed similarly to the CDS. An important concept during HGS is to leave about 3cm of stent in the gastric lumen to compensate for the stomach distancing from the liver during breathing.

The HGS technique is useful in patients with proximal biliary strictures and distal gastrectomy. In such cases, there is no sonographic window to access the extrahepatic bile duct due to the absence of antrum[11] (Figures 4, 5 and 6).

Anterograde Drainage

In cases where the transpapillary wire access is obtained by UE, but not by the *rendezvouz* due to a luminal obstruction, then placing an anterograde biliary stent through the obstruction point is a viable conduct[31].

This technique involves the following steps. The dilated biliary segment is accessed with a FNA needle followed by cholangiography. A hydrophilic guidewire is inserted through the needle in order to overcome the stenosis. The needle is then removed and the stenotic area is dilated to 7Fr or 8.5Fr using an ERCP catheter (eg: Soehendra bile Dilation Catheter, Wilson-Cook Medical, Winston-Salem, North Carolina). With the tip of the dilatation catheter into the bile duct, the hydrophilic guide wire is then replaced by a stiffer guidewire (e.g., 0.035 inch Jagwire, Boston Scientific, Natick, MA). Placement of the stent is carried by anterograde advancing the stent through the EUS therapeutic channel over the guide wire; the stent is then released at the level of stenosis in a transpapillary or transanastomotic way[33,34].

Results of ultrasound-guided biliary drainage

Despite the growing international experience and increase in the number of publications in recent years, concern remains about the safety and effectiveness of these techniques in comparison with the standard ones. Most data, despite involving small series of specialized centers, suggests that UGBD can be performed with great therapeutic success (87%), but is associated with 10-20% of morbidity (mild to moderate majority) and rare significant adverse events[6]. Recently, Artifon *et al*.[35] published the first prospective, randomized study comparing UGBD with transhepatic percutaneous biliary drainage (TPBD) in 25 patients (13 CDS- EUS and 12

TPBD) with malignant biliary obstruction and ERCP failure. Both groups were similar in terms of quality of life, total bilirubin (16.4 *vs*. 17.2, p=0.7), alkaline phosphatase (539 *vs*. 518, p=0.7) and gamma-glutamyl transferase (554.3 *vs*. 743.5, p=0.56). All procedures were technically and medically successful in both groups. On the seventh day of follow-up, there was a significant reduction of total bilirubin levels in both groups (CDS-EUS, from 16.4 to 3.3, p=0.002, and TPBD, from 17.2 to 3.8, p=0.01), although there was no difference between the two groups (3.3 *vs*. 3.8, p=0.2). There was also no difference regarding the complication rates between the groups (p=0.44): CDS-EUS 2/13 (15.3%) and TPBD 3/12 (25%). The cost was similar between the two groups (US$ 5,673 for CDS-EUS *vs*. US$ 7,570 for TPBD, p=0.39). Therefore, this randomized study showed that EUS conducted through a transluminal route (choledochoduodenostomy) had a similar success rate, complication rate, and costs compared with TPBD. Although this small prospective, single-center study offers hope that UGBD may be an acceptable alternative to TPBD, large prospective studies conducted by experts could also provide valuable information about the complications related to the procedure, efficiency and changes used to improve patient outcomes.

Shah *et al*. reported their experience with UGBD in patients with surgically altered anatomy and failed ERCP[21]. They attempted cholangiography guided by EUS in 70 patients, with a success rate of 97% (68); 66 patients had cholangiographic results that required intervention. UGBD using the *rendezvouz* technique was attempted in 50 patients and was successful in 74% (37),

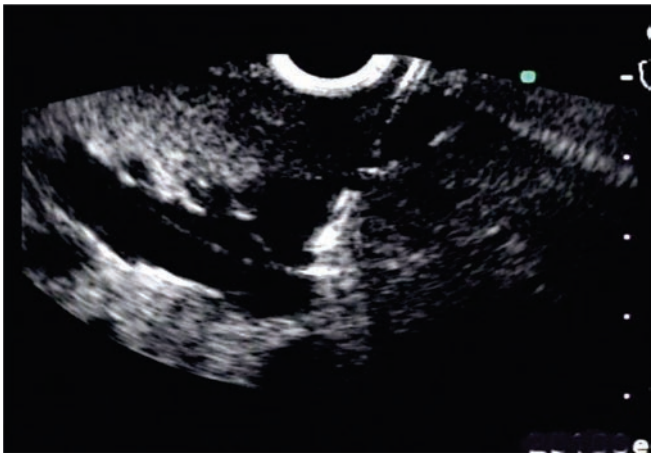

Figure 4. *Bile duct needle puncture.*

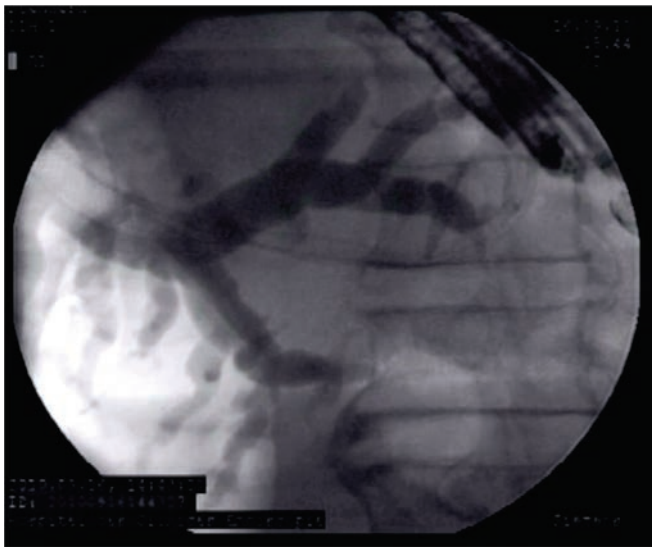

Figure 5. *Cholangiography appearance of the stent release.*

failing in 13. Direct transluminal interventions (hepatogastrostomy, choledochoduodenostomy, anterograde stent placement) were attempted in the remaining 16 patients and were successful 13 (81%). There were six complications, most treated conservatively. One perforation that required surgical intervention occurred in a sphincterotomy after a successfully performed *rendezvous*.

Recently, Park *et al*. reported their experience with UGBD in a large prospective cohort treated by a single experienced operator in a large volume center in Korea[36]. These authors previously reported a relatively high rate of adverse effects of 20%[10] for UGBD and the most recent study aimed to assess whether the modified technique of "enhanced guidewire manipulation" could improve the safety and efficacy of UGBD. The approach modified by Park *et al*. includes: 1) bile duct puncture angle optimization with the EUS needle; 2) use of smaller diameter guidewires to prevent failures; 3) introduction of a 4Fr catheter to guide the direction of the guidewire through the distal stenosis / papilla; and 4) a preference to catheterize the segment II intrahepatic bile duct to allow the wire to progress towards the hilum[36]. In this study, 45 patients with benign or malignant biliary obstruction were submitted to the same UGBD session after failed ERCP. They obtained technical success in 41 (91%) patients, defined as a well-located stent or balloon dilation along with the contrast medium flow through the biliary stent. Functional success, defined as the reduction

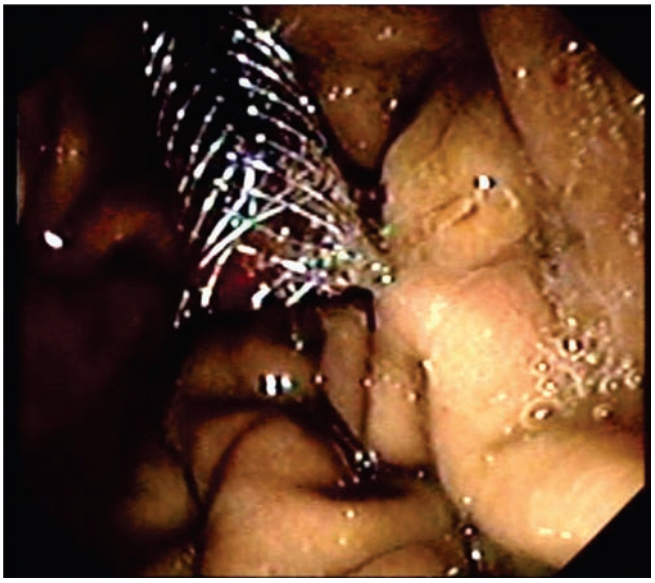

Figura 6. *Final endoscopic appearance.*

of cholestatic indexes below 75% of pretreatment value within one month after the procedure, was obtained in 39 (95%) of these patients. Five (11%) adverse events occurred in four patients: pancreatitis, focal biliary peritonitis, limited pneumoperitoneum, intraperitoneal stent migration and bilioma. The last complication occurred in an approach guided by the EUS with a "stent-in-stent" placement. Overall, three patients had mild complications and one patient had one moderate complication, according to the ASGE Lexicon classification system[37]. In this study, technical success and complications were similar to other studies.

As stated above, the primary intention of Park's study[36] was to evaluate if the "enhanced guidewire manipulation" may decrease by 20% (n=11) the adverse events rate that other authors have reported in a previous study of 55 patients who underwent UGBD[15]. To assess whether the authors successfully fulfilled this purpose, it is important to evaluate the potential reasons of complications in these 11 patients (classified as mild in seven and moderate in four). Interestingly, nine of the 11 patients underwent fistula dilation using a needle knife, its use being independently associated with adverse events (OR 12.4, p=0.01). In a more recent study, needle knife fistula dilation was used in only five patients. Therefore, we recommend avoiding the use of needle knife when possible.

Gupta *et al*. conducted a multicenter study on the long-term outcomes of 246 UGBD patients[38]. They used the intrahepatic approach in 60% of cases. They achieved success of biliary drainage in 87% of cases, with a success rate similar in extrahepatic and intrahepatic approaches (84.3% *vs*. 90.4%, p=0.15). The higher rate of clinical success was observed in malignancies when compared with benign disease (90.2% *vs*. 77.3%, p=0.02). Complications for all techniques included: pneumoperitoneum (5%), bleeding (11%), bile leakage / peritonitis (10%) and cholangitis (5%), with no statistically significant difference between the intrahepatic and extrahepatic approaches and between benign and malignant diseases.

It is important to note that the results of the studies discussed above come from tertiary centers, with large volumes of procedures and highly qualified interventional endoscopists. We believe that these procedures should ideally be carried out by one or more experienced endoscopists trained in ERCP and EUS, and in institutions where surgery and interventional radiology are available if ones encounters adversity.

Rendezvouz (REN) *vs.* Direct Transluminal (TL) Technique

Most endoscopists prefer the REN approach, since it avoids the need for a permanent bilioenteric fistula and the need to dilate the fistula path, which can lead to complications such as bleeding, pneumoperitoneum and pneumomediastinum. However, this approach may not be possible if the guidewire does not cross the papilla due to a difficult angulation or the presence of an insurmountable distal biliary stricture. The results comparing REN and TL in terms of efficacy and adverse events are not well known. Khashab *et al*. compared REN with TL in a study with 35 patients undergoing UGBD (REN 13, TL 20) for malignant distal biliary obstruction and ERCP failure[27]. Technical success was achieved in 33 (94%) patients and clinical success in 32/33 (97%) patients. The average post-procedure bilirubin was 1.38mg/dL in the REN group and 1.33mg/dl in the TL group (p=0.88). Similarly, the length of stay was not different between the two groups (p=0.23). There was no significant difference in the rate of ad-

verse events between REN and TL groups (15.4% *vs*. 10%, p=0.64). Long-term outcomes were comparable between the two groups, with one stent migration in the REN group in 62 days, and one stent occlusion in the TL group at 42 days post-UGBD. The authors concluded that UGBD is safe and effective when performed by experienced operators. Occlusion of the stent is not common in long-term follow. Both REN and TL techniques appeared to be equally effective and safe.

There are at least three potential noteworthy REN disadvantages. Firstly, even by experienced specialists REN is successful in only 75% of cases and requires an accessible papilla, which cannot be possible in patients with altered upper gastrointestinal anatomy[21]. In the study by Park *et al*.[36], the REN approach (or transpapillary anterograde stenting) was not possible in 11 (24%) patients and failed in nine (20%). The second difficulty with biliary drainage by REN is the prolonged procedure time, which is due to several factors, including: 1) the need for manipulation of the guidewire through the distal stenosis and the papilla; 2) exchange of the EUS for a duodenoscope; and 3) the need for retrograde biliary cannulation. Another potential REN disadvantage is the risk of acute pancreatitis due to the manipulation of the papilla[12,17,21].

Given that REN fails or is not technically possible in at least 25% of patients, is associated with prolonged procedure time and may lead to pancreatitis and other complications, it is essential that the endoscopist strives to improve and minimizing the risks associated with the TL technique to provide a full arsenal for patients with stenosis or malignant and benign biliary obstruction. However, the adoption by some endoscopists of the stent in the bilioenteric fistula has been slow due to concerns about the potential risks, especially bilioma and pneumoperitoneum. Nevertheless, our experience suggests that the insertion of a transluminal stent is safe when biliary drainage is achieved with success[18,19]. It is important to point out the risk of biliary fistula formation if the obstruction is not relieved. Some measures can ensure the successful and safe placement of the transluminal stent. Firstly, one should not dilate the transluminal tract until the guidewire has reached a good position for the stent placement. Secondly, one should dilate the tract only to a diameter to allow the stent insertion, avoiding aggressive expansion, which may predispose to the formation of a biliary fistula[18]. Thirdly, dilation using cautery should be avoided, due to the potential risk of complications, especially bleeding and bile leakage. Fourthly, fully coated metallic stents and carbon dioxide insufflation should be used to minimize the risk of bile fistula and pneumoperitoneum, respectively.

One benefit of the TL technique is the possibility of distal drainage of the tumor, while avoiding the obstructions and compressions[39]. We agree with the statement from many experts that the REN technique should be preferably attempted first, but we believe that a transluminal approach is an acceptable, effective and safe alternative, if the above measures are followed.

Choledochoduodenostomy (CDS) *vs*. Hepatogastrostomy (HGS)

Artifon *et al*. conducted a randomized study comparing the results of CDS and HGS[40] in 49 patients with unresectable malignant distal biliary obstruction and failed ERCP. The technical success rate was 91% for CDS and 96% for HGS (p=0.61). Likewise, clinical success was similar in both groups (77% *vs*. 91%, p=0.23). The average procedure time (48.4min *vs*. 47.8min, p=0.84) and the mean quality of life scores during follow-up were similar. The overall rate of adverse events was 16.3% (12.5% in the CDS group and 20% in the HGS one). The authors concluded that the CDS and HGS techniques are similar in terms of efficacy and safety and that the two techniques are valid alternatives for biliary drainage in patients with malignant distal biliary obstruction and failed ERCP.

Poincloux *et al*. [41] recently compared the results obtained over a period of seven years with patients with failed ERCP and submitted to CDS or HGS performed by the same endoscopist. Sixty-six patients underwent HGS, with a 94% effectiveness, and 33 patients were subjected to CDS, with a 90% effectiveness. Statistically, there was no difference in success between the two procedures (p=0.69) or in the rate of major complications (10.6% for the HGS group and 6.7% for the CDS group, p=1).

Intra-hepatic *vs*. Extra-hepatic access routes to UGBD

UGBD using the REN or TL techniques requires a needle puncture of an intrahepatic or extrahepatic duct in a patient with preserved upper gastrointestinal anatomy. However, the best access route it is not yet established for either technique. In cases of UGBD by REN, Dhir *et al*. recently found that an extrahepatic REN (via transduodenal puncture) was associated with significantly shorter procedure time, less post-procedure pain, lower bile leakage and pneumoperitoneum[42]. In addition, they found that success is probably greater with extrahepatic REN, as confirmed by Park *et al*. (93% vs. 50%)[36]. Similarly, in the case of UGBD by TL, the extrahepatic route (choledochoduodenostomy) is probably safer than an intrahepatic one (hepatogastrostomy)[15]. Therefore, it appears that the extrahepatic access during UGBD is better and safer than an intrahepatic one, performed either via REN or via TL.

Dhir *et al*. compared the success and complications rates in 68 patients undergoing UGBD by different techniques[43]. UGBD was successful in 65 patients (95.6%). There was no significant difference in success rates for the different techniques. Complications have been observed in 14 patients (20.6%) and mortality in three (4.4%). Complications were significantly higher for the intrahepatic route compared with the extra-hepatic (transduodenal) (30.5% *vs*. 9.3%, p=0.03). There was no significant difference in complication rates between placements of transpapillary and transluminal stents, or REN. The logistic regression analysis showed that the transhepatic access is the only independent risk factor for complications (p=0.03). The authors concluded that UGBD could be performed with high success rates, regardless of the choice of the access route, the stent direction or drainage pathway. However, complications are significantly higher with the intrahepatic access. They recommended that the extrahepatic (transduodenal) access be chosen for UGBD, and stent placement by the REN technique when both pathways are available.

Why does the intrahepatic pathway lead to increased risk of complications? First, an intra-hepatic route involves a needle puncturing into the peritoneal cavity, pneumoperitoneum and danger of bile leakage into the peritoneal cavity. Secondly, the movement of the liver during breathing can lead to both stent migration, with consequent biliomas, and to trauma to the biliary tree (which increases the risk of post-procedural pain and bile leakage). Another factor is that the smaller caliber of the intrahepatic ducts may not allow the placement of larger diameter, 8-10 mm metallic stents, which theoretically can predispose to pneumoperitoneum and bile leakage due to incomplete sealing of the bilioenteric fistula. The extrahepatic access, moreover, has many advantages, including the duodenum proximity with the dilated bile duct, the retroperitoneal location of the bile duct, which benefits patients with ascites[31], and a relatively fixed biliary tree, with minimal respiratory influence, better visualization of the biliary tract. Nonetheless, more prospective studies comparing the safety of different techniques are still needed.

UGBD vs. PTBD

Data from various centers confirm the efficacy and safety of DBEG[6]. However, comparative data with other techniques, for example, PTBD, are limited. These data are essential to decide whether patients with failed ERCP are best conducted with UGBD or PTBD. There is only one small, randomized controlled trial comparing UGBD and PTBD in 25 patients with malignant biliary obstruction and ERCP failure[35]. This study found that both procedures have efficacy, safety and equivalent cost. The main limitation of the study was that it evaluated only the direct procedure costs. This probably overestimated the cost-effectiveness of PTBD, which is associated with increased long-term costs due to the need for frequent interventions.

More recently, Khashab *et al*.[44] retrospectively compared UGBD and PTBD in 73 patients (22 UGBD, 51 PTBD). Although the technical success was greater in the PTBD group (100% *vs*. 86.4%, p = 0.007), clinical success was similar (92.2% *vs*. 86.4%, p=0.40). PTBD was associated with a higher rate of adverse events (index procedure: 39.2% *vs*. 18.2%; all procedures, including reintervention: 80.4% *vs*. 15.7%). Stent patency and survival were similar between the two groups. The total costs were more than twice as high in the PTBD group

(p=0.004), primarily due to a significantly higher reintervention rate (80.4 *vs*. 15.7%, p=0.001). The authors concluded that UGBD and PTBD are comparatively effective in the treatment of malignant distal biliary obstruction after failed ERCP. However, UGBD is associated with decreased adverse event rates and is significantly cheaper due to less need for reoperation.

Access through UGBD has several advantages with respect to PTBD[10]. The proximity of the transducer along the bile duct[10], possibility of elucidating the cholestasis etiology[7,10], using doppler to prevent accidental puncture of the vascular structures and the possibility of access the bile ducts from multiple pathways. Dilated intrahepatic bile ducts can be accessed in the liver through the distal esophagus or stomach, or the common bile duct can be accessed by the proximal duodenum, and occasionally the gastric antrum[43]. This choice of bile ducts access routes allows the success of endoscopic drainage even in patients with duodenal obstruction, or subjected to bypass surgery. Other advantages include UGBD viability, even in patients with ascites and hepatic metastases, as well as migration of percutaneous catheters, their associated complications (e.g., skin irritation, leakage) and negative impact on quality of life. Furthermore, UGBD can be performed during the same endoscopy session after ERCP failure, which avoids the necessity of repeated interventions and allow timely biliary drainage, with more rapid bilirubin decrease, allowing more rapid onset of chemotherapy and radiotherapy, if necessary[21,36]. UGBD is also more physiological and anatomical, keeping the bile into the gastrointestinal tract and ensuring proper digestion and absorption of nutrients.

UGBD Guidelines

We recommend obtaining informed consent for possible UGBD with the term for ERCP in patients at high risk for failure in biliary cannulation, with, for example: altered anatomy; prior ERCP failure; periampular cancer with duodenal invasion; and duodenal stent at the papilla level. This approach requires a long talk with the patient about other potential approaches should the cannulation fail, such as surgery or percutaneous drainage. Thus, obtaining the term for UGBD before ERCP avoids the need for repeated endoscopic interventions and allow timely bile duct drainage and the start of early chemo/radiation therapy, if necessary.

A final consideration about UGBD is when to perform the procedure on a patient with a benign or malignant biliary obstruction. Dhir *et al*. proposed that a single UGBD procedure could be a viable alternative to ERCP in patients with malignant distal biliary obstruction[45]. They conducted a multicenter, retrospective study to compare the results of stenting for malignant distal biliary obstruction by ERCP and EUS. UGBD patients underwent a choledochoduodenostomy (CDS) or anterograde drainage (AG) after one or more unsuccessful ERCP attempts, while patients in the ERCP group underwent SEMS retrograde placement. The study included 208 patients, 104 in the ERCP arm and 104 in the UGBD (68 EUS-CDS and 36 EUS-AG). The SEMS placement was successful in 98 patients of the ERCP group and 97 in the UGBD group (94.23% *vs*. 93.26%, p=1.00). The frequency of adverse events was similar (8.65% and 8.65%, respectively). The post-procedure pancreatitis rate was higher in the ERCP group (4.8% *vs*. 0%, p=0.059). The authors concluded that in patients with malignant distal biliary obstruction that require SEMS placement, the short-term results of UGBD and ERCP are comparable.

Hara *et al*. recently conducted a prospective study on UGBD for primary therapy of malignant biliary obstruction, ie no ERCP attempt, in 17 patients[46]. They achieved both technical and clinical successes in 94% of patients, without serious complications. While this approach may prevent post-ERCP pancreatitis, we believe that the current role of UGBD should be for salvage therapy in patients with failed ERCP.

FINAL CONSIDERATIONS

UGBD is a safe and effective procedure after failed ERCP when performed by *rendezvouz* or direct transluminal techniques. The extrahepatic access route is preferred for distal malignant obstructions and is associated with lower incidence of adverse events. UGBD

is less invasive than the transparieto-hepatic drainage and the limited data available suggest equivalent efficacy and safety. However, its use is still limited to tertiary centers with high technology available. Indications and methods for UGBD are still being standardized and therefore the approach should be individualized for each patient, based on the endoscopist's experience and the patient's anatomy. In addition, controlled, randomized, multicenter clinical trials are needed for defining the optimal technique.

R E S U M O

Apesar da taxa de sucesso da colangiopancreatografia endoscópica retrógrada (CPRE), em cerca de 10% dos casos há falha no acesso à via biliar. Nesse contexto o ultrassom endoscópico (UE), que inicialmente só era utilizado para o diagnóstico e estadiamento de doenças, hoje, tem importância terapêutica. O objetivo dessa atualização é demonstrar as diversas formas de drenagem biliar ecoguiada, bem como, compará-la com a drenagem transparieto-hepática (DTPH).

Descritores: *Endoscopia Gastrointestinal. Ductos Biliares. Ultrassonografia de Intervenção. Icterícia Obstrutiva. Endossonografia.*

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Minilaparoscopy-assisted transumbilical laparoscopic cholecystectomy

Colecistectomia laparoscópica umbilical assistida por minilaparoscopia

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ABSTRACT

The role of laparoscopy in the modern surgery era is well established. With the prospect of being able to improve the already privileged current situation, new alternatives have been proposed, such as natural orifice endoscopic surgery (NOTES), the method for single transumbilical access (LESS – Laparo-endoscopic single-site surgery) and minilaparoscopy (MINI). The technique proposed by the authors uses a laparoscope with an operative channel like the flexible endoscope used in NOTES. All operative times are carried out through the umbilical trocar as in LESS, and assisted by a minilaparoscopy grasper. This new technic combines, and results from, the rationalization of technical particularities and synergy of these three approaches, seeking to join their advantages and minimize their disadvantages.

Keywords: Surgical Procedures, Operative. Minimally Invasive Surgical. Cholecystectomy. Cholecystectomy, Laparoscopic. Vídeo-assisted Surgery.

INTRODUCTION

The role of laparoscopic surgery in the modern age is well established. With the prospect of improving the already privileged current situation, new alternatives have been proposed, such as surgery through natural orifices (NOTES) and the Laparo-endoscopic single-site surgery (LESS). At the same time, minilaparoscopy (MINI) returned to the agenda with the advent of greater resistance miniaturized grippers.

Among the main indications for minimally invasive techniques, there is cholecystectomy, the most commonly performed surgical procedure in the West[1]. The available literature shows no consensus on the best technical alternative to classic laparoscopic cholecystectomy (LC). In the literature review conducted by Gaillard et al., comparing the single-access approaches NOTES with minilaparoscopy, they found that none of these procedures showed benefits superior to LC[1]. Sulu et al. compared the cholecystectomies performed by the four-trocar classic laparoscopic access with those carried out by LESS and found no significant advantages of the latter technique[2]. Sinha et al. compared LC with LESS cholecystectomy using multiple transumbilical portals and conventional instruments[3]. LESS showed results comparable to LC, but with longer operative time[3]. In a randomized study, Dabbagh et al. compared cholecystectomies performed by LESS and MINI techniques. Despite displaying the same postoperative complications rates, the minilaparoscopy approach had lower operative time and hospital stay[4].

In this context, and taking into account the experience of our group in single-access surgery with an endoscope with an operative channel, we set up a fertile environment to the introduction of Laparoscopic Umbilical Monomini Assisted Surgery (LUMAS). In general, this proposed surgical therapy rests on the argument of combining technical features and the synergism of NOTES, LESS and MINI.

TECHNICAL ASPECTS

Patient, surgical team and equipment positions

We place the patient in supine with the legs separated. The surgeon stands between the legs of the patient and his assistant is on his left (patient's right), facing the laparoscopy equipment, positioned to the patient's right at the level of shoulder.

Laparoscopy instruments and accessories

The equipment used were: 1) Endoscope with 11mm diameter and 37.5cm length, with a Palmer-

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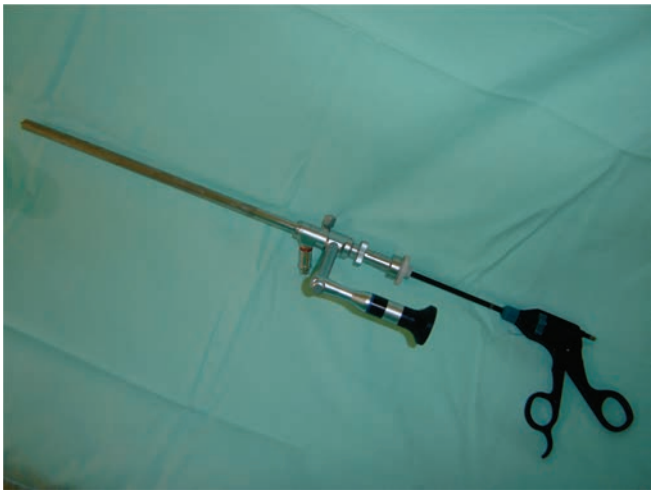

Figura 1. *Óptica laparoscópica com canal operatório.*

-type 5mm operative channel (Ref: S26034AA, Richard Wolf GmbH, Knitt Knittlingen, Germany) (Figure 1); 2) a 12mm reusable trocar; 3) a 5mm diameter and 43cm in length, curved, rotational, isolated, unipolar Maryland forceps for dissection and grasping; 4) a 5mm in diameter and 43cm in length, curved, rotational, isolated; 5) a 5mm in diameter and 43cm in length, reusable, rotational Hem-o-lok applicator; 6) a 5mm in diameter and 43cm in length, isolated, unipolar Hook clamp; 7) a 5mm in diameter and 43cm in length endoscopic cannula to suction and irrigation; 8) a 3mm in diameter and 36cm long, rotational, isolated grasping forceps (minilaparoscopy).

Operative technique

We conducted a single curvilinear incision of 12mm in the lower umbilical fold. We instilled the pneumoperitoneum through a Veress needle and introduced a 12mm trocar, maintaining the insufflation pressure at 15mmHg. Next, was inserted the Palmer endoscope into the cavity through the umbilical trocar with the Maryland forceps within its working channel. The minilaparoscopy forceps was introduced directly through a 3mm incision at the mid-axillary line level in the right flank under vision and without the need of a trocar (Figure 2). We then percutaneously introduced a 0 multifilament suture with straight needle in the right costal margin, lateral to the midclavicular line. Once inside the cavity, the needle transfixed the gallbladder fundus guided by the Maryland forceps inside the Palmer endoscope, and then exteriorized near the point of its introduction, exerting the required traction to approach the gallbladder to the abdominal wall and facilitate the exposure of the gallbladder pedicle.

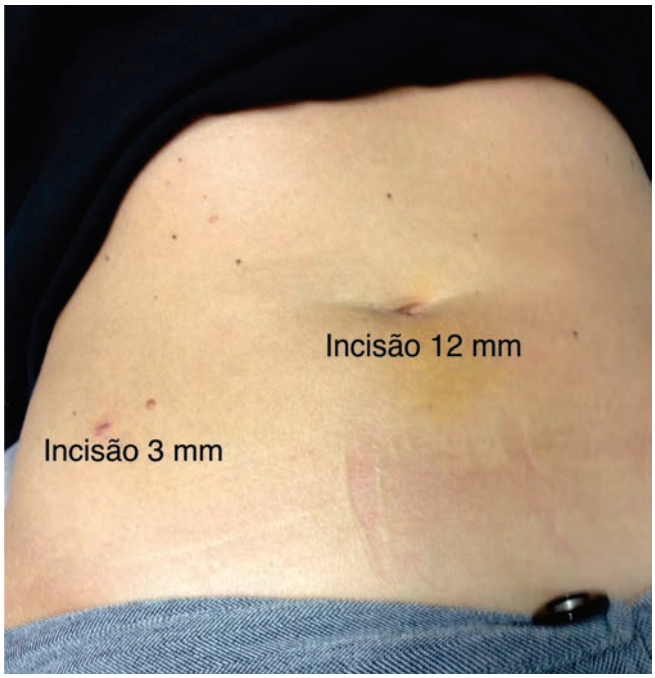

Figura 2. *Localização das incisões cirúrgicas.*

We performed the dissection of the cystic duct and cystic artery in the usual way with the Maryland forceps, associated with counter-traction of the gallbladder infundibulum exerted by the minilaparoscopy clamp. We ligated the cystic structures with the hem-lok-type clip deployed by a clip applier entered through the operative channel of the Palmer endoscope. Once ligated, the pedicle elements were cut by curved scissors and we proceeded to release the gallbladder from the liver bed with cautery through the hook (both instruments introduced by the endoscope's working channel) with sustained traction by the minilaparoscopy clamp. Before completing the separation of the gallbladder and liver, we took the advantage of the exhibition to double-check the clips and hemostasis of the bloody area. We extracted the gallbladder through the umbilical trocar, by grasping its neck with the Maryland forceps, after releasing the extracorporeal suture from the gallbladder fundus. We proceeded to the aponeurotic suture of the umbilical trocar orifice with a 0 Vicryl® "X" stich or continuous suture, depending on the

need to expand the incision. Modern endoscopes provide adequate visibility and their angulation favors the secure identification of the biliary pedicle elements.

DISCUSSION

Minimally invasive surgery has been introducing alternatives to LC, aiming to reduce surgical trauma and achieve better cosmetic results. These alternatives are minilaparoscopy cholecystectomy (C-MINI), Laparo--endoscopic single-site (C-LESS) and removal of the gallbladder through natural orifices (C-NOTES).

C-MINI uses 2mm and 3mm instruments and retains the classic arrangement of four trocars with an 11mm incision in the umbilical level. This approach minimizes the parietal trauma and promotes better aesthetic results compared with LC[5]. However, mini- instruments and the miniaturized endoscope are more fragile and less durable, less effective in grasping and more expensive[6]. However, C-MINI has not been completely abandoned and continued to be improved, becoming less labor intensive and less expensive by dispensing the clamping of pedicle elements and using a 10mm endoscope[5].

Takur *et al*., by means of a meta-analysis, compared the C-MINI with LC[7]. Minilaparoscopy tended to lower incidence of adverse events, earlier return to normal activities and better aesthetic results.

LESS requires the expansion of the umbilical incision for the introduction of multiple trocars or devices with three or four ports. The technique enables the use of widely available and regularly used instruments, and potentially minimizes parietal trauma in the case of removal of larger surgical specimens, since it dispenses performing minilaparotomies for the removal of organs. In operations for the extraction of the gallbladder, appendix and uterine attachments, its use becomes therefore controversial, since it would only entail better aesthetic result. Additional disadvantages of this method are the intraabdominal extra collisions of instruments and reduced triangulation.

Bucher et al., when comparing C-LESS with LC in a randomized study, concluded that the single-access route promotes better cosmetic results, less pain and earlier return to normal activities[8]. However, other studies reported higher incidence of parietal and biliary complications related to C-LESS[9,10].

NOTES proposes new accesses and ways to perform minimally invasive operations, in an attempt to reduce surgical trauma and eliminate the complications and parietal scarring. However, it requires knowledge and experience in advanced endoscopy and the use of flexible endoscopic equipment and instruments, which hinders their incorporation by most surgeons. Moreover, these procedures generate some degree of contamination of the peritoneal cavity and closing of the viscera still lacks effective known techniques[11,12].

These alternative procedures to LC provide better cosmetic results, but do not cause significant advantages over the reduction of postoperative pain, shorter hospital stay, earlier return to normal activities and lower immune response[13,14].

In this context, it seems logical to search for less invasive alternatives to achieve objectives other than the aesthetic ones. Our group proposed this tactical option when using the endoscope with an operative channel (Palmer), with minimization of C-MINI, to perform the procedure only with an 11mm umbilical access and another 3mm incision on the right flank.

In the proposed laparoscopic technique (micro-mini cholecystectomy), the forceps introduced through the endoscope operative channel replaces the subxiphoid trocar, the transmural suture replaces the gallbladder fundus tweezers, and minilaparoscopy forceps replaces the gallbladder infundibulum grasper. The Palmer endoscope is manipulated by the surgeon, who performs the main operative times and handles the camera.

The control of gallbladder pedicle elements is made by means of the hem-o-lok clip applier. The advantages of this clips type compared with the metal ones are: a) they are radiolucent; b) they provide greater security in ligation, since they have a closing system by lock, which is only triggered if the structure is smaller than the clip range; c) they allow to undo a ligation without damaging the structure; d) they withstand higher pressures; e) and one may safely use monopolar cautery near them. The disadvantage of the higher cost of this device is overcome

by the replacement of the disposable trocar, reimbursed by health insurance plans, by the reusable one.

Micromini cholecystectomy, as the C-MINI, is attractive when compared with C-LESS and C-NOTES, since it: a) keeps triangulation and proper trine of the Callot's triangle; b) allows the non-static lateral traction of the gallbladder infundibulum; c) Traction is more accessible from the training point of view; avoids intra and extra-abdominal instruments collisions and reversed hands motion.

The initial investment in the acquisition of an endoscope with an operative channel is offset by the significant number, in our service, of single-access transumbilical video-assisted appendectomies, laparoscopies for diagnosis and lysis of adhesions in gynecological interventions, and for performing classical laparoscopic cholecystectomies and appendectomies, subtracting one of the trocars. In our experience in LESS cholecystectomy, this endoscope minimizes the collision of instruments, since only two trocars are necessary in the umbilical incision, helping to overcome this limiting factor inherent to this method.

Carvalho *et al*. demonstrated, by means of a mathematical model, that the miniaturization of the grasspers results in considerable reduction of parietal trauma, compared with the usual 10mm and 5mm trocars[15]. Thus, the micromini cholecystectomy justifies its designation, for it dispenses the subxiphoid 3mm and the midclavicular line 2mm portals of the classic C-MINI.

By consulting the literature using the Pubmed platform, we found the description of cholecystectomy performed with an endoscope with an operative channel and single umbilical access, aided by extracorporeal suture manipulated by crochet needles. We believe that when we use the minilaparoscopy forceps we achieved a more effective traction and exposure of the gallbladder, with greater dynamism and comfort[6,16].

We believe that the future of minimally invasive surgery is the combination of NOTES, LESS and minilaparoscopy. The micromini uses an endoscope with a working channel, such as the NOTES flexible endoscope, carries out all operative times through the umbilical trocar, as in LESS, and is assisted by a minilaparoscopy clamp. We can therefore say that the technique herein proposed combines, and results from, the rationalization of technical features and the synergism of these three approaches, seeking to aggregate their advantages and minimize their disadvantages, hoping to achieve less invasiveness.

R E S U M O

O papel da videolaparoscopia na era moderna da cirurgia encontra-se bem estabelecido. Com a perspectiva de ser possível melhorar a já privilegiada situação atual, novas alternativas têm sido propostas, como a cirurgia por orifícios naturais (NOTES), o método por acesso único transumbilical (LESS - Laparo-endoscopic single-site surgery) e a minilaparoscopia (MINI). A técnica proposta pelos autores utiliza-se de óptica com canal de trabalho como o endoscópio flexível do NOTES, executa-se todos os tempos operatórios pelo trocarte umbilical, como no LESS, e é assistido por pinça de minilaparoscopia. Esta nova técnica combina e resulta da racionalização de particularidades técnicas e do sinergismo destas três abordagens, buscando agregar suas vantagens e minimizar as suas desvantagens.

Descritores: *Procedimentos Cirúrgicos Operatórios. Procedimentos Cirúrgicos Minimamente Invasivos. Colecistectomia. Colecistectomia Laparoscópica. Cirurgia Videoassistida.*

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The history of the parathyroid surgery

A história da cirurgia das paratireoides

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ABSTRACT

The authors conducted a review of the major aspects of progression of knowledge about the surgical treatment of hyperparathyroidism. Through literature review, we analyzed articles on the history of the evolution of anatomical, physiological, pathological and surgical knowledge of the parathyroid glands. Because of their unique anatomical features, the parathyroid glands were the last of the endocrine glands to be discovered, which greatly hindered proper treatment until the first decades of the twentieth century. Technological developments in the last 30 years greatly facilitated the location of the glands and hyperparathyroidism surgery. However, an experienced and dedicated surgeon is still essential to the excellence of treatment.

Keywords: Parathyroid Hormone. Hyperparathyroidism. Surgery. Parathyroidectomy. History of Medicine.

INTRODUCTION

Hyperparathyroidism is a condition in which there is an abnormal increase in the levels of parathyroid hormone (PTH), responsible for regulating the level of blood calcium and phosphate. The most common cause of hyperparathyroidism, seen in about 80% of cases, is the primary gland dysfunction due to an adenoma. Multiple adenomas or hyperplasia of the parathyroid glands are diagnosed in the remaining patients. Rarely the cause of hyperparathyroidism is a result of a parathyroid carcinoma. It is a disease for which therapy may be surgical, which involves the removal of the affected gland. When surgery is indicated in patients without prior treatment, the cure rate approaches 95%[1]. In cases where the initial operation is not successful, new surgical explorations become necessary, greatly increasing the number of complications and decreasing success rates to about 80%[2]. Therefore, regardless of the hyperparathyroidism origin, the surgeon who will treat these patients must indisputably have skill, experience and technical knowledge to obtain satisfactory results. Currently, advances in the identification of the glands through preoperatively performed diagnostic tests greatly facilitated parathyroid glands surgery. Frozen section biopsies[3], intraoperative measurement of PTH levels[4] and less invasive procedures[5] allow great improvement in patients' quality of life[6]. However, the identification of the parathyroid glands, the recognition of their important role and the understanding of diseases that affect them traveled a long journey to the present state of knowledge. Since inception, the history of the parathyroid glands is full of incidental findings, often the case in medical history.

The aim of this study is to provide the reader with a historical review of the discoveries fundamental to the understanding of the parathyroid glands and to discuss the current role and future prospects of surgery for the treatment of hyperparathyroidism.

ANATOMY OF THE PARATHYROIDS

The parathyroid glands originate from the third and fourth pharyngeal pouches and are usually located next to the thyroid gland. They more commonly lie adjacent to the capsule at the posterior face of the thyroid, two on the upper pole and two on the lower, although sometimes they may be located within the gland. A small number of patients can have three, five or, occasionally, a greater amount of glands. Anatomical variations in location are frequent, and they can be found even in the mediastinum near the thymus[7]. Each gland measures between three and six millimeters, weighing approximately 30 to 40 milligrams. During surgery, they can be diffi-

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cult to distinguish from the thyroid and the adjacent fat. However, their mustard-yellow color is quite characteristic. Probably because of these anatomical peculiarities, they remained ignored in the treaties of medicine, being described only in 1850 by the curator of the Museum of Natural History of London, Sir Richard Owen. The discovery came with an autopsy of a rhinoceros. Owen described it as "a small compact yellow glandular body attached to the thyroid at the point where the veins emerged" [8]. The famous German pathologist Rudolph Virchow may have identified one parathyroid gland in 1863, when he described a structure in the cervical region, emphasizing that it was not an accessory thyroid gland or lymph node, or any other structure that was familiar to him, though showing no interest in the finding [8]. Despite these initial descriptions, it was several years until, in 1880, a 25-year-old Swedish medical student, Ivar Sandström, definitively elucidated the existence of the parathyroid glands. In his paper entitled "On a New Gland in Man and Fellow Animals", he described the presence of a gland hitherto unknown in dogs, cats, rabbits and other animals. Then he initiated dissections in about 50 corpses and confirmed the presence of these glands in humans, naming them parathyroids due to their location[9]. In a detailed way, he described coloration, shape, variations in the location of glands and held a detailed microscopic analysis. As his report was a long one, about 50 pages, the editors of the time rejected it, and he managed to publish their findings long after, and only in his mother tongue[10]. The description in a little widespread language, associated with lack of understanding about the function these small glands, caused Sandström not to receive the proper recognition for his findings. Sandström, who received the physician title in 1887, was so disturbed by the lack of recognition of his discovery that fell into a deep depression. Perhaps this fact may have contributed to his suicide at the age of 37.

THE DISCOVERY OF THE RELATIONSHIP BETWEEN CALCIUM AND THE PARATHYROID GLANDS

Hypercalcemia occurs when serum calcium levels are high. It is a frequent diagnosis in clinical practice, which occurs when the calcium entry into the circulation exceeds its excretion in the urine or their deposition in bones. Among the most common etiologies, there is the exacerbated function of the parathyroid glands. Hyperparathyroidism results from increased production of PTH, a hormone that regulates the metabolism of calcium and phosphorus. When the excess in PTH production comes from a parathyroid dysfunction in itself, it is called primary. When it comes in response to low plasma levels of calcium, as in vitamin D deficiency situations or chronic kidney disease, it is called secondary. About 90% of hemodialysis patients have secondary hyperparathyroidism[11]. Hyperparathyroidism is tertiary when occurring in chronic renal failure patients undergoing kidney transplantation who persist with high levels of PTH. Regardless of its origin, the excess production of parathyroid hormone is harmful to the metabolism and should be treated[12]. The resection of the parathyroid glands plays a key role in the management of such patients, its indications being currently well-defined[13].

The term tetany describes a set of neuromuscular symptoms caused by nervous system hyperexcitability, which can vary from perioral paresthesias to cramps and muscle stiffness[10]. The contracture of the extremities, with or without peculiar seizures, has been described about 100 years ago when Corvisard introduced the term tetany for the first time in 1852[14]. Trousseau, in 1862, and Chvostek, in 1876, have defined the clinical signs that characterize it, without, however, defining its origin. The Trosseau signal is present when, by occluding the brachial artery, there is carpal spasm, manifested as flexion of the wrist and metacarpophalangeal joints, extension of the distal phalanges and proximal interphalangeal joints and adduction of the thumb and fingers. To perform this maneuver a blood pressure measurement cuff is placed around the arm and inflated to a level higher than the systolic blood pressure. The Chvostek sign is the presence of spasms of the facial muscles in response to facial nerve percussion in the zygomatic region[15]. The combination of symptoms of tetany after thyroidectomy was first recognized by Anton Wolfer, in 1879, in a patient undergoing total thyroidectomy by Billroth. His explanation for the seizures was that they stemmed from a "brain hyper-

emia" ensuing in these patients due to the thyroid removal[16]. This explanation led to the development of the theory of detoxification, which assumed that the tremors and convulsions were caused by toxins not removed from circulation by the thyroid and parathyroid glands[10]. The advances in general anesthesia (1840s), understanding the importance of antisepsis (1860s) and hemostasis (1870s) allowed the beginning of the first successful operations on the thyroid in the following decades. The high mortality rate faced by surgeons of the time (over 40%) began to reduce, mainly by the work of two remarkable surgeons in this area: Theodor Kocher and Theodor Billroth. The growing success shown through many surgical patients surviving thyroidectomy began to face the emergence of complications hitherto unprecedented for the time. Patients operated by Kocher presented, as complications, signs today clearly associated with hypothyroidism. Interestingly, the Billroth patients rarely developed such symptoms; however, many patients developed severe tetany with fatal outcome. William Halsted, after watching operations of the great masters, found that the difference was probably in the technique. Kocher was extremely meticulous and precise, operating carefully with strict hemostasis. He removed the entire gland and his patients rarely suffered voice changes or tetany due to preservation of the recurrent laryngeal nerve and parathyroids. Billroth, in contrast, worked quickly, with less rigorous hemostasis. Probably the lack of identification increased the risk of parathyroid removal and the remaining thyroid tissue prevented severe hypothyroidism to occur. For his contributions to thyroid gland physiology, pathology and surgery, Kocher received the Nobel Prize in 1909[17].

In 1891, the French physiologist Eugene Gley, when testing in rats, rabbits and dogs, described that tetany occurred after thyroidectomy only if the glands described by Sandström were also removed. Subsequently he confirmed that removal of the parathyroids alone caused the same effect. Based on these findings, he recommended extreme caution to surgeons to avoid damaging the parathyroid glands in thyroidectomy and was probably the first to define the essential character of these glands, although not clearly identifying their functions[9]. That same year, Friedrich von Recklinghausen, a famous German pathologist, first described a condition characterized by widespread decalcification of the skeleton, associated with the formation of cysts in the bones, which he called fibrocystic bone disease, without identifying the source of dysfunction. When evaluating that patient, he described the increase of a parathyroid gland, but he did not establish a causal relationship between the findings[9]. Max Askanazy, in 1903[18], described a tumor in the parathyroid in autopsies on patients who had died with the condition described by von Recklinghausen, though also failing to establish the relationship between the two findings. In the early twentieth century, it became clear that parathyroid removal or ischemia caused tetany. Nevertheles, the main hypothesis was that the glands were responsible for the removal of unknown human body toxins. The first evidence of the relationship between the parathyroid and calcium metabolism arose in 1907, when Jakob Erdheim, an Austrian pathologist who studied the parathyroid glands in patients with bone disease, noted that many patients with bone diseases such as osteomalacia and osteitis fibrosa had increased parathyroids. Unfortunately, he erroneously believed that the glands increase was a compensatory response caused by bone disease. That same year, Erdheim reported the diagnosis of a patient with two simultaneous tumors, one in the parathyroid gland and the other in the pituitary, an omen of the multiple endocrine neoplasia that would be described more than 50 years later. The determination of serum calcium levels, from 1909, finally allowed the association between this ion and the parathyroid glands. William MacCallum[19] was the first to describe the improvement of tetany in animals with the instillation of a parathyroid extract. As a complement to these studies, he also pioneered the evidence that post-parathyroidectomy tetany could be corrected with calcium injection. Despite the inconsistency of his results, he was one of the first to suggest that the cause of tetany was related to low levels of serum calcium. These data led William Halsted to initiate the use of calcium and parathyroid

extract in his patients with tetany[20]. Only in 1923, Adolf Hanson, a student at the University of Minnesota, was able to develop a stable and reproducible parathyroid extract from bovine parathyroid[21]. James Collip, a Canadian biochemist, recognized for collaborating in studies to identify insulin, independently developed studies to improve the parathyroid extract and define the best form of administration. In 1925, he proved that tetany and symptoms of hypocalcemia could be appropriately corrected, and obtained the first patent for PTH extract [22]. The review of all those data compiled by Boothby, condensing the knowledge of the time, definitely concluded that the parathyroid function was related to the calcium metabolism[23].

EARLY SURGERY AND INITIAL MISTAKES

Interestingly, the history of transplants probably began with the parathyroid gland. Anton von Eiselsberg, a Billroth disciple, held the first parathyroids autotransplantation in 1892. He transplanted thyroid and parathyroid tissue to the pre-peritoneal space of cats and demonstrated the absence of tetany and the formation of new vessels after the procedure. In contrast, several surgeons reported return of tetany when the transplants were removed[16]. Felix Mandl[24], a surgeon in Vienna, confirmed the misunderstanding of parathyroid physiology in the early twentieth century. When treating patients with cystic bone lesions in radiological imaging, which evolved with hip fracture and elevated urinary calcium, he initially tried to transplant parathyroid tissue taken from corpses to improve the clinical condition. With the failure of this form of treatment, on July 30, 1925, he indicated a pioneer neck exploration under local anesthesia for removal of a parathyroid tumor, with resolution of symptoms. Radiologic studies conducted four months after the operation showed significant improvement in bone density. Six months after surgery, the patient was free of bone pain. Despite the operation success, the symptoms returned six years later. After two years of new reviews, and diagnosed with recurrent hyperparathyroidism, the patient was again operated on, with resection of two more parathyroid glands, considered normal on histological examination. There was no remission of symptoms and the patient died three years after. The autopsy found no signs of parathyroid tissue. Even with the failure in this case, Mandl was responsible for a number of findings that were useful in the following years: he determined that the disease was not bone primary, but originated in the parathyroid glands; he demonstrated that tumor resection could be successful in controlling hypercalcemia; he found the possibility of recurrence and also suggested the possibility of a family illness[16]. Mandl also had the merit of helping Gold and Eiselsberg during an operation to remove a parathyroid adenoma in a patient with von Recklinghausen's disease two years after his pioneering surgery. The documentation of clinical and biochemistry improvement after the surgery was performed through rigorous monitoring of serum and urinary calcium levels. After that operation, the term hyperparathyroidism was first used in the literature[24]. David Barr and Harold Bulger[25] attended a case with similar clinical presentation in 1926, and indicated cervical exploration with removal of an adenoma in a 56-year-old patient. In a troubled postoperative period, which required high doses of parathyroid hormone and calcium by mouth to treat tetany, symptoms improved and the patient returned to normal life. They were probably the forerunners to define the clinical presentation of hyperparathyroidism with five clinical features: bone thinning, multiple cystic bone tumors, hypotonia and muscle weakness, abnormal calcium excretion in the urine with calcium calculi formation and high serum calcium levels.

One of the most picturesque cases that contributed to the understanding of the anatomy and function of the parathyroid glands occurred in the famous Massachusetts General Hospital [26]. The patient, the US Navy officer Charles Martell, was hospitalized due to severe decalcification of his bone structure. Tests indicated elevated calcium levels consistent with hyperparathyroidism. His neck was surgically explored six times between 1926 and 1932. Surgeons could not the parathyroid glands in the first surgery. Subsequent explorations identified only one gland, considered normal on histologic examination. The patient himself, intrigued by his clinical conditions,

conducted an extensive literature review in the library of the Harvard University, focusing on locations of ectopic parathyroid glands. After finding an account of mediastinal location of the parathyroid glands in the December 1931 volume of the Acta Medica Scandinavica journal, he realized the possible similarity with his own illness. He then insisted that surgeons carried out another surgical exploration, this time in his mediastinum through a sternotomy, which was then located a large encapsulated adenoma. About 90% of the lesion was removed, the remaining tissue being subjected to transplantation, which was not effective. Symptoms of hypocalcemia were serious and six weeks after the operation, the patient presented with a ureteral obstruction due a calculus. Then again, he was operated and died because of a laryngospasm after surgery[27].

HYPERPARATHYROIDISM AS A DISEASE

The first decades of the twentieth century witnessed the improvement in the diagnosis and treatment of hypoparathyroidism through MacCallum's, Halsted's, Hanson's and Collip's studies. However, the disease originated from the excessive hormone production was still unknown. Apparently, physicians at the Barnes Hospital in St. Louis were the first to define hyperparathyroidism in an article published in 1929: characteristic bone findings, muscle weakness, kidney stones and high levels of serum calcium[25]. The initial operation of Mandl and few other successful cases showed that surgery could be a good treatment option for cases of hyperparathyroidism. Nonetheless, little was known about the pathophysiology of this condition. The finding that many patients undergoing resection of adenomas did not have their symptoms improved worried the surgeons of the time. Patients with bone disease often had renal calculi. Fuller Albright [28], a North American physician formed by Harvard, after spending a year in Vienna following the work of Erdheim, began to show great interest on calcium metabolism. He undertook studies in patients with kidney stones without bone disease and, for the first time, he could relate the renal condition with the parathyroid diseases. Albright was the first researcher who managed to understand that the genesis of hyperparathyroidism could stem from different etiologies. In 1934, he was one of the pioneers in the distinction between the different types of hyperparathyroidism[28,29]. Understanding the different hyperparathyroidism etiologies led to a change in the paradigm of operations for treatment of hypercalcemia. In patients diagnosed with symptomatic primary hyperparathyroidism, surgery is the only treatment that offers the possibility of permanent cure. In asymptomatic patients, there is some controversy about the indication of surgical removal. Calcium serum 1 mg/dl over the limit, urinary calcium excretion > 400 mg, 30% reduction in creatinine clearance, osteoporosis, bone densitometry and age lower than 50 years are the accepted criteria to indicate surgery[30]. Secondary hyperparathyroidism is treated clinically. However, severe pain or bone fractures, significant itching and calcifications of non-vascular organs in patients refractory to appropriate clinical treatment prompt surgery for this condition. Patients with tertiary hyperparathyroidism are usually treated with total parathyroidectomy with preservation of a small fraction of one of the glands.

THE IMPORTANCE OF PTH MEASUREMENT

After the first findings of Hanson and Collip, laboratory tests for PTH detection were very inaccurate, hampering its applicability. It took about 40 years before the discovery of a more effective method for the measurement of PTH and other peptides by Berson and Yalow[31], causing a revolution in the evaluation of such patients. The improvement in the determination of serum calcium and PTH yielded an improvement in the understanding of metabolic disorders related to this important ion. The number of patients diagnosed with hyperparathyroidism, even asymptomatic, increased considerably[32], making it possible to uncover the various clinical and metabolic aspects related to diseases of the parathyroid glands. Nevertheless, detection methods were not yet sufficiently accurate, causing confusion in some patients, for whom the differentiation between the distinct causes of hypercalcemia was still inadequate. The search for greater diagnostic accuracy originated

the development of an analytical test carried out by radioimmunoassay by Rosalyn Yalow. From this improvement, obtaining a definitive diagnosis was more readily determined. Due to the relevance of this discovery, the researcher received the Nobel Prize in 1977[33]. This facility for the laboratory diagnosis of hyperparathyroidism led to an exponential increase in operations during the late 1980s. Due to improved diagnosis, patients no longer presented with advanced stages disease, and many were still asymptomatic. The responsibility of surgeons in indicating the proper procedure increased considerably. However, there were further discussions about the histologic diagnosis of lesions. Conflicting data in the diagnosis provided by pathologists showed the diagnostic difficulties between adenomas and gland hyperplasia. Obviously, this confusion opened the possibility of inadequate or too aggressive surgical procedures[16]. To try to resolve the therapeutic questions in the treatment of primary hyperparathyroidism Purnell et al. conducted a great analysis of 143 patients followed for ten years[34]. The main findings of this well-conducted study were: 1) there was a great loss to follow-up, both by patients and physicians; 2) lack of consensus on specific monitoring tests; 3) absence of predictive factors for disease activation; and 4) recommendation of surgery by an experienced surgeon (minimum of nine to ten operations per year).

THE TECHNOLOGY ADVANCES FACILITATING PARATHYROID SURGERY

The success of the aforementioned isolated cases encouraged surgeons to recommend parathyroidectomy as a routine procedure to treat hypercalcemia, soon appearing the first series of cases operated with good results[35]. There was also the realization that hyperparathyroidism was not only associated with the solitary parathyroid adenoma, but also with multiple adenomas and with glandular hyperplasia, which could affect all glands. Founded on this knowledge, bilateral cervical exploration became the recommended routine procedure. Parathyroid surgeries were often prolonged, tedious and unsuccessful operations. Advances in perioperative management, proper positioning of the patient on the operating table, endotracheal intubation and the proper use of drains contributed to the growing success of surgery[36]. However, the biggest challenge was still the precise location of the parathyroid glands. The search for a method for preoperative localization of patients' glands appeared as a need to avoid fruitless or inaccurately indicated explorations that could worsen patients' quality of life. Arteriography was one of the initial methods tried, but failed to demonstrate benefits [37]. Selective blood collection of cervical veins was superior to arteriography, though with difficult conduction and considerable morbidity. Surgical anecdotes of the time, faced with the difficulties of location of the parathyroid glands, originated the quote: "The only localization that a patient needs who has primary hyperparathyroidism is the localization of an experienced surgeon!"[38]. The use of nuclear medicine was another important advance, as well as the neck ultrasonography, allowing the neck exploration to be unilateral in selected cases[39].

A new revolution in the treatment of these patients occurred in 1987, when Samuel Nussbaum described a method for rapid detection of PTH[40]. In the past, the measurement of PTH levels took about 20 hours and it was common to inform the patient, still recovering from surgery, of the need for a new cervical exploration[27]. Due to the few minutes half-life of the active PTH, its rapid measurement during operation, before and after resection of the lesion, renders a higher degree of certainty to the complete withdrawal of abnormal glands. PTH levels falling more than 50% virtually assures the removal of all affected glands[41]. The introduction of this new detection method allowed greater procedure safety, more conservative operations, lower hypercalcemia recurrence rate, surgery without the need for hospitalization and a reduction of about 40% of hospital costs[42]. Devices for intraoperative identification through a mapping by marking the parathyroid glands also contribute to achieving a more efficient surgery[43]. The adaptation of minimally invasive techniques now allows performing surgeries with very short hospital stay, less pain, lower cost and minimal scarring, improving the cosmetic aspect[44].

FINAL COMMENTS

The parathyroid glands were the last of the endocrine glands to be discovered, this perhaps being one of the reasons that justify the difficulties in the evaluation of patients with hyperparathyroidism in the last century. The history of parathyroid surgery prospered in a way particularly similar to the history of surgery. Knowledge developed slowly from incidental findings, case reports, chance contributions from patients and medical students, laboratory research and, just recently, more well-designed scientific studies. Patients with hyperparathyroidism may present with a wide spectrum of symptoms, but often are asymptomatic and diagnosis is obtained in a routine examination. Current well-structured guidelines allow treatment to be well oriented, allowing highly satisfactory success rates. That responsibility lies with the surgeons of today, ensuring a surgical procedure of excellence, in appropriate hospitals.

R E S U M O

Os autores fizeram uma revisão dos principais aspectos históricos da progressão do conhecimento sobre o tratamento cirúrgico do hiperparatireoidismo. Por meio de revisão bibliográfica, foram analisados artigos selecionados sobre a história da evolução do conhecimento anatômico, fisiológico, patológico e cirúrgico das glândulas paratireoides. Devido às suas características anatômicas peculiares, as paratireoides foram as últimas das glândulas endócrinas a serem descobertas, o que dificultou sobremaneira seu tratamento adequado até as primeiras décadas do Século XX. A evolução tecnológica ocorrida nos últimos 30 anos facilitou sobremaneira a localização das glândulas e a cirurgia do hiperparatireoidismo. Contudo, um cirurgião experiente e dedicado ao tratamento dessa enfermidade ainda é fundamental para a excelência do tratamento.

Descritores: *Hormônio Paratireoideo. Hiperparatireoidismo. Cirurgia. Paratireoidectomia. História da Medicina.*

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INSTRUÇÕES AOS AUTORES

A Revista do Colégio Brasileiro de Cirurgiões, órgão oficial do CBC, é publicada bimestralmente em um único volume anual, e se propõe à divulgação de artigos de todas as especialidades cirúrgicas, que contribuam para o seu ensino, desenvolvimento e integração nacional.

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O resumo deve ter no máximo 250 palavras e estruturado da seguinte maneira: objetivo, método, resultados, conclusões e descritores na forma referida pelo DeCS (http://decs.bvs.br). Podem ser citados até cinco descritores. O abstract também deve conter até 250 palavras e ser estruturado da seguinte maneira: objective, methods, results, conclusion e keywords (http://decs.bvs.br).

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