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EDITORIAL

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Why does research performed in health care institutions matter and should be rewarded?

There are several lessons to take from COVID-19 pandemic and one of them is the unavoidable importance of scientific research.

In a way that has never been conceivable before, we watched a great effort in bringing the world's scientists and global health professionals together to accelerate the research process, and to develop new standards to contain the spread of the coronavirus pandemic and help care for those affected. This demanding task required not only full-time researchers and scientists working in pharmaceutical industries, but each heath care practitioner. COVID-19 pandemics made us physician-scientists: when addressing the best evidence-based practices in COVID care (for those in charge of infected patients) or when learning how to proceed adequately in the health care environment, limiting transmission during work, while taking care of every other non-COVID patient. We were asked to report how the situation was going in our hospitals, to confront several sources of information, to evaluate its quality and to adapt our practice using that information.

Research produced at health care institutions is the backbone of critical thinking. It is relevant to influence national health policies and to improve service delivery and health outcomes [1]. This states not only for the COVID-19 pandemics but to everyday care. Research from health care institutions will inform about institutional monitoring and evaluation and will allow leadership to respond to local as well as global health problems[1].

While being overflooded with many clinical tasks, physicians are under a huge pressure and often lack the time and capacity to take part in medical research[2]. Furthermore, research is always seen as an unnecessary or secondary task and there is no protected time for research considered in the Portuguese legislation, as opposed to countries such as Belgium, United Kingdom, Switzerland and Australia. Trainees are encouraged to perform research during their internships as part of their curricula. Very often, even institutions that receive interns lack structured research development programs to support the way they frame their research, the questions asked, and the biases brought [2]. Once the trainee becomes a specialist the stimulus to engage research activities is further shrank. While clinical responsibility raises, the time and capacity to start and maintain a project that is amenable to be supported by a grant is almost unachievable. This is even harder for surgical careers, knowing that the number of surgeries performed is an important determinant of funding for hospitals. On the other side, despite the benefits that research can bring to an institution, there is no reward for institutions that publish their results, not even when accepted in high-impact peer-reviewed journals. This lack of recognition and compensation for the academic progress is another serious pitfall that prevents medical research to develop and achieve its goals[2].

The expected post-pandemic recovery funding offers an unpreceded opportunity to overcome these limitations[3]. Overall, research in health care institutions could benefit from: a) protected time for research-related activities, allowing joint clinical/research working schedules; b) institutionally led structured career development pro-

grams, that could provide specific funding to training programs and address research fields considered of interest to the institution; c) opportunities for collaborative research, that do not require full-time research dedication.

It is important to emphasize that protected time does not need to be a lifelong commitment[4]. The attribution of protected time should be dependent on attaining certain research outcomes such as publications, grants submissions and/or obtaining access to external funding. Even when it requires one's institution to forgo clinical revenue or directly supporting research salary and supplies, the obtaining of external funding makes the personal and institutional rewards of protected time realized.

Marina Dias Neto | Editor-in-Chief

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EDITORIAL COMMENT

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Ross surgery - but why not?

It´s been 53 years since the first description of Ross surgery by Sir Donald Ross[1]. Different times, when cardiac surgery was still an heroic endeavor reserved to very hardy patients and very very VERY hardy surgeons. The autologous pulmonary graft surgery developed when mechanical valves were appearing, biological valves were in its infancy, and patients with aortic valve pathology (a class of cardiac patients for whom, contrary to mitral stenosis patients, effective surgery was really lacking and medical therapeutic except diuretics was basically non-existant), suffered from high mortality and morbidity whether or not they underwent surgery.

Enter Sir Donald Ross, who cleverly developed a risky but effective surgery for these patients, albeit with a very significant homograft failure in the long term. Initial result were steadily improved, and by the late 1970´s Ross surgery was considered a very significant counterpart in the aortic valve surgical realm, allowing at least results as good as the ones obtained with ball-in-cage, disc-in-cage, and single leaflet mechanical aortic valves, while avoiding anticoagulation, having less endocarditis, and allowing homograft growth in young patients, with no limitation in physical exertion. Biological valves were hardly an option in younger patients, since early generations had a prohibitively high structural valve deterioration (SVD) rate under 60 years old.

In the nineties, Ross surgery expanded, due to the continued divulgation of this surgery worldwide. Known intraoperatory pitfalls were the lesion of the first septal artery during pulmonary autograft harvesting, which severely compromised hospital outcomes, and later known caveats were graft dilation, with subsequent neoaortic or neopulmonary insuficciency, risking the function of two valves for one. The technical complexity, coupled with later need for re-operation, and an increasingly better performance of standard aortic valves (mechanical or biological), cooled down the enthusiasm for this surgery worldwide, after technical modifications apparently improved the results and a significant experience was already obtained.

Current guidelines reserve Ross surgery for young patients in whom a very active lifestyle is desired, in whom anticoagulation is contra-indicated, and in woman who desire pregnancy.[2]

Simultaneously, mechanical valves now allow lower regimens of oral anticoagulation, and biological valves are promising a much more extended freedom from SVD, coupled with the possibility (absolutely not a theoretical one) of later valve-in-valve TAVI if such SVD occurs. Add also the current performance in aortic valvuloplasty (normally offered in aortic insufficiency), which is better than 10 years ago, and the best solution for many young patients with aortic valve dysfunction may be a lot of possible solutions.

Due to the promises and problems of Ross surgery, patients receiving this procedure were followed extensively, and in the last 10 years we have seen several centers publishing their isolated experiences. Some have abandoned it despite good results, some have kept it as an alternative, and some perform it whenever it is possible. [3]

In this issue of Portuguese Journal of Cardiac Thoracic and Vascular Surgery, one of the larger Portuguese centers publishes their long-term results with Ross Surgery. Rodrigues et al [2] have obtained a sample of 23 patients operated from 1999 to 2016, which averages little over one patient per year, with a mean follow-up of 15 years. Their patients were young (mean age 10.7 years, with the oldest patient having 20 years), and aortic stenosis was the most common indication for surgery. The authors present a long-term survival of 91%, and a mean follow-up of 15 years, with no reoperations noted and 100% of survivors in NYHA Class I or II. These results, mostly in children, are very good, and reflect a known objective of Santa Marta Hospital´s Cardiac Surgery department in having this surgical resource for these complex growing patients, which previous publications have documented [4].

We have another recent Portuguese publication,

from the Hospital de Santa Cruz group[5], which also concerns long-term results of Ross surgery. In it, Guerreiro et al present their experience with 56 adults who received Ross surgery, mostly due to aortic stenosis; mean age at surgery was 44 years, and median follow-up was 20 years. The long-term results were very good, with very good survival and 80% freedom from reoperation, despite about 43% of patients developing moderate homo or autograft dysfunction. The authors concluded that this procedure, despite having long-term valve dysfunction in a significant portion of patients, is a good option for middle-aged patients with aortic stenosis, and offers survival similar to the general population[5].

So, Ross procedure works and is effective in the long term; it also allows children to grow (contrary to prosthetic valves). Why isn´t it used more above 18 years old?

We have seen from previously published experiences that Ross surgery offers to patients a survival similar to the general population; it has the same valve reinterventions as a mechanical prosthesis in young patients, and obviates most valve related bleeding or stroke.[6-9] On the other hand, STS registry analysis from 2014 shows that operative mortality from Ross surgery far exceeds the one associated with aortic valve replacement in young adults (2.3% vs. 0.9%). [10]

Contrary to interventional cardiologists, surgeons are normally conservative when adopting new procedures, especially if they are technically more complex, and a recent emphasis on cardiac surgery results monitoring and public reporting has exacerbated this characteristic.

So the outlook for Ross surgery, in which results seem very dependent on experience, (about 100 cases are deemed necessary to attain proficiency[9]), will probably be similar to other niche operations in cardiac surgery - reserved for some patients, some surgeons and some centers, like cardiac transplant or complex aortic arch and descending thoracoabdominal procedures. While we believe that it definitely is not the answer to every aortic valve disease in young patients, it also isn´t going to disappear, because despite its technical difficulty and early and late attrition rate, it still is the best option for selected patients.

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EDITORIAL COMMENT

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Can we keep our patients safe from COVID?

In early 2020 COVID pandemic became a reality in Portugal! The entire population, starting with the decision makers, took measures to stop the spreading, with the known repercussions in the economy, mental and social wellbeing.

With the focus on COVID, many other diseases were forgotten, or set on a waiting mode with a timetable that no one could predict.

Last year's publications and the one now present in this issue, is the proof that it is possible to safely address and treat non COVID patients without putting them at risk.

Clean separate pathways and infirmaries, for the high priority patients, with the fulfillments of strict protocols of respiratory confinement and social distancing, keeps hospital contaminations to a minimum, and gives a fighting chance to patients that cannot wait forever!

Along with pre-admission testing, symptomatic and social questionnaires of close contacts, reduces the chance of in adverted admission of a contaminated patient to a covid free ward!

In the peak of the third wave, in the beginning of 2021, many public and private hospitals lost all possibilities of keeping these clean pathways open, for the surge was such that all the hospital beds and human resources could not cope with the tidal wave of confirmed or suspected covid cases.

The administration and clinical personnel worked together, to reorganize and convert spaces and personnel to assist as many patients as possible, and for a time, some of these safe pathways had to shut down.

As soon as safety could be guaranteed, they were reinstated, and the wards recruited as covid areas, reassigned as non COVID!

This past year taught us many hard lessons, with the loss of over 15.000 COVID patients but also many non covid patients who are the unknown victims of this pandemic, but as doctors we must keep in mind our mission as clinicians and educators for the general population and advisors for the decision makers.

Referral pathways and diagnostic exams must be kept in motion, available for the high priority patients. Family doctors must be allowed to return to their daily practice of preventive medicine, to detect such cases, in the early phases of disease, when cure is a possibility, returning our country to the XXI century medicine.

The starting of the vaccination process brought a glimpse of light at the end of the tunnel, but until we acquire the so much desired group immunity, precaution dictates not to relieve social distancing, and separate pathways for non-COVID patients.

The storm won't last forever. We just have to endure it!

Cristina Rodrigues

Cristina Rodrigues | Associate Editor

EDITORIAL COMMENT

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Supervised exercise therapy versus endovascular revascularization in patients with intermittent claudication

The AHA/ACC 2016[1] and ESC/ESVS 2017[2] guidelines recommend Cardiovascular Rehabilitation programs (CRP) as a multimodal approach for Peripheral Artery Disease (PAD), in order to obtain symptomatic relief, prevent future cardiovascular ischemic events, and influence prognostic survival. CRP include supervised exercise therapy (SET), in addition to optimal medical therapy and lifestyle modification, representing the first-line treatment for patients with Intermittent Claudication (IC), to prevent functional decline and improve quality-of-life.[3,4] SET must be offered as a structured program, involving a multidisciplinary team with expertise in exercise for cardiovascular patients, under the coordination of a physiatrist, that must prescribe the appropriate exercise modalities, taking in to account not only cardiovascular diseases but also other medical conditions that influence exercise performance.[1,3] Exercise intervention in PAD patients is usually based on treadmill and track walking, considered the most effective exercise modalities, performed for 30-45 minutes, 3 times per week for a minimum of 12 weeks.[1,3] Each session involves periods of intermittent bouts of walking to moderate-to-maximum claudication alternated with periods of rest, and a warm-up and cool-down period of 5-10 minutes adjusted periodically as the pain-free and maximal walking distance improves.[1,3] The improvement in the walking time of IC patients parallels with progressive normalization of lipid profiles, emphasizing beneficial effects of exercise therapy in cardiovascular risk factors.[5] SET has demonstrated to increase ischemic threshold, to improve exercise tolerance and enhance patient functional capacity recognized as a strong and independent predictor of mortality after a cardiovascular event.[5,6] It also highlighted the excellent safety profile of different SET in patients with PAD, when screened for absolute contraindications to exercise and treated by a team with the appropriate skills to provide the adjusted monitoring level.[7]

Endovascular revascularization procedures are readily available techniques, remunerated, and independent of patient motivation. Given their low procedural morbidity and high procedural success they are becoming increasingly attractive and widespread.[4,8] In clinical practice, endovascular treatment alone is being performed more frequently than SET alone, as recommended, despite endovascular techniques do not improve exercise capacity or lower the risk of revascularization or amputation compared with SET.[4] The ERASE trial has demonstrated faster and greater improvements in walking performance and disease-related quality-of-life with the combined therapy (endovascular revascularization plus SET) in patients with aortoiliac and femoropopliteal peripheral artery disease.[8] A recent meta-analysis also demonstrated that combined therapy is associated with greater maximum walking distance compared to each treatment alone, and the 1-year reintervention rate reported also seemed lower compared to endovascular treatment alone.[8] Even though additional SET after endovascular treatment in PAD patients does not

prevent restenosis, they appear to be less symptomatic, highlighting the role of exercise in preventing clinical deterioration.[8] SET alone is associated with a reduction of overall cardiovascular mortality by 52%, therefore, combining endovascular revascularization with additional SET might provide the optimal treatment.[3,8]

Included in a Rehabilitation intervention model, SET is safe and cost-effective for what it should be offered as a first-line treatment alone, or to eligible patients that have undergone endovascular techniques, aiming to improve clinical cardiovascular outcomes and reduce potential re-intervention costs.[3,7]

Despite carrying a class I recommendation for the initial management of IC, major limitations of SET are poor access in most countries due to reimbursement issues, dependence on patient motivation, and compliance.[3] In Portugal, there is still a paucity of Cardiovascular Rehabilitation Units, compared to other European countries, hampering access for patients to this multimodal approach. The lack of knowledge from patients and physicians about these programs also contributes to low referral rates and compromises their widespread use.[9]

The multiple barriers to the implementation of these programs motivate the use of alternatives such as unstructured community- or home-based walking programs that consist of providing recommendations for patients with claudication to simply walk. [1,3] However, these programs without supervision were considered ineffective for patients with IC presenting worse results in maximal treadmill distance and pain-free walking distance compared with SET.[3,10] Whenever SET is not available, the AHA/ACC 2016 Guideline recommends structured Community-based Exercise therapy or Home-based Exercise therapy with the guidance of healthcare providers.[1,3]

Future studies are needed, focusing on multidimensional approaches and clinically relevant long-term outcomes, to determine the most effective management strategy for these patients. Consideration on reimbursement issues for SET and greater awareness of the medical community on the importance of referring patients to CRP might be critical to improving adherence to these programs.

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SUPERFICIAL FEMORAL ARTERY OPPORTUNISTIC STUMP

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The treatment of patients with critical ischaemia unfit for surgery, in which endovascular is unfeasible or associated with considerable complications, is very challenging.

Additionally, endovascular treatment of unfit patients with flush occlusion of the superficial femoral artery (SFA) can be particularly problematic, with poorer outcomes and higher complication rates. In the recent Global Limb Anatomic Staging System (GLASS), a SFA flush occlusion is categorized as a GLASS stage II or III, which are associated with higher technical failure rates and lower 1-year limb-based patency. [1,2]

In such patients, the idea is to minimize critical ischaemia and achieve limb salvage. For that, unusual solutions must be explored.

For patients scheduled for common femoral artery (CFA) endarterectomy with proximal long occlusion of the superficial femoral artery, we propose the routine creation of an opportunistic stump in the superficial femoral artery, thus facilitating future endovascular interventions, if ever needed.

This technique can also be used in other surgeries

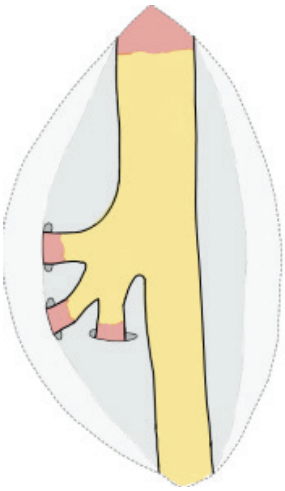

Figure 1 *CFA occlusion, profunda femoris artery (PFA) ostial occlusion and SFA proximal occlusion.*

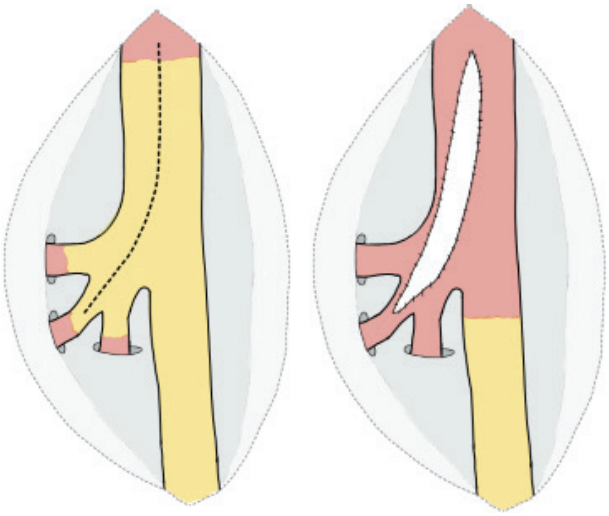

Figure 2 *CFA and proximal PFA endarterectomy with "SFA opportunistic stump creation" and patch angioplasty.*

with a femoral approach such as aorto-bi-femoral bypass, femoro-femoral bypass, femoro-popliteal or femoro-distal bypass (allowing a chance for a future endovascular intervention before bypass redo in case of bypass occlusion), with the same purpose which is to facilitate future endovascular interventions.

INTRODUCTION

After exposure and clamping of the common femoral, superficial femoral and profunda femoris arteries, a longitudinal arteriotomy and sequential femoral endarterectomy is performed.

Consecutively, a small stump is created at the origin of the superficial femoral artery using a curved Kelly forceps. The stump should be greater than 1 cm from the origin of the profunda femoris, and intimal flaps should be amended. Generous flushing with heparinized saline solution is recommended.

Femoral patch angioplasty or femoral anastomosis can be completed using the standard technique.

In this fashion, a small stump is created at the origin of the superficial femoral artery.

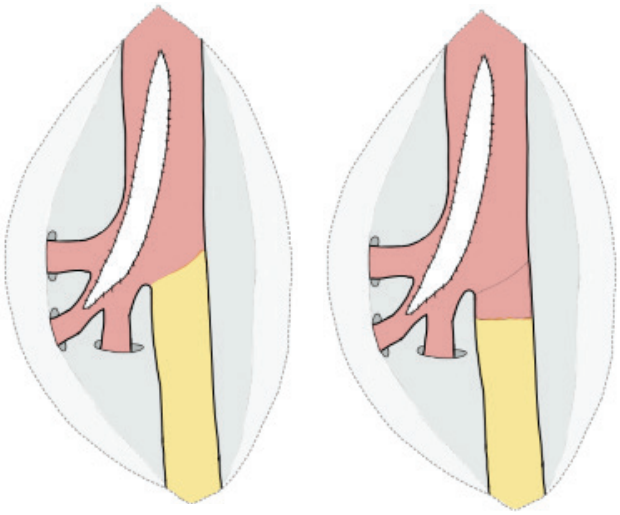

Figure 3 *Comparison between "normal endarterectomy" and endarterectomy with "SFA opportunistic stump".*

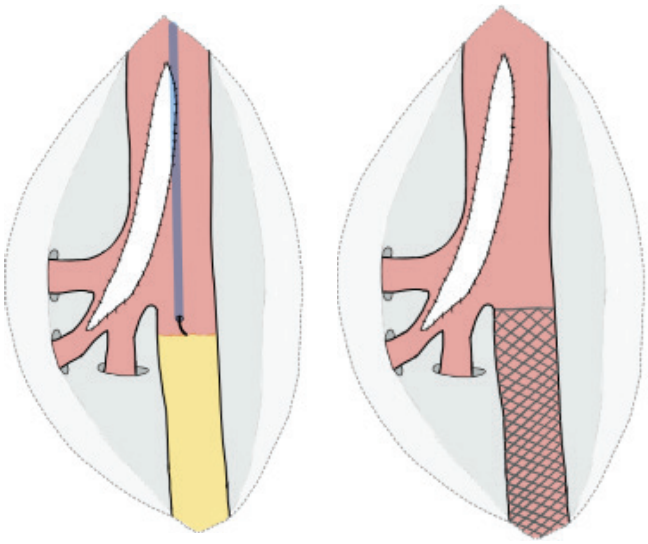

Figure 4 *SFA stump simplifies future endovascular interventions, enabling a safer angioplasty and/or stent deployment.*

CLINICAL CASE

One of the patients in which this technique was performed was an old patient unfit for bypass surgery with CFA occlusion, PFA proximal occlusion and long occlusion of the SFA in the right lower limb. Additionally, he had occlusion of the 2nd portion of the right popliteal artery.

Occasional paresthesias and rest pain with a small ulcer in the right first toe.

Common femoral artery endarterectomy and profundoplasty with PTFE patch under local anesthesia was performed, followed by careful wait-and-see clinical evolution.

Intraoperatively it was decided an SFA opportunistic stump creation with a small stump (more or less 2 cm) at the origin of the superficial femoral artery, favoring a safer future femoropopliteal endovascular intervention, if necessary.

Rest pain was resolved but the ulcer persisted. As a result, angioplasty and stenting of the superficial femoral artery and angioplasty of the popliteal artery was performed two months afterwards in an ambulatory setting, by contra-lateral femoral approach.

The ulcer healed approximately one month after the endovascular procedure.

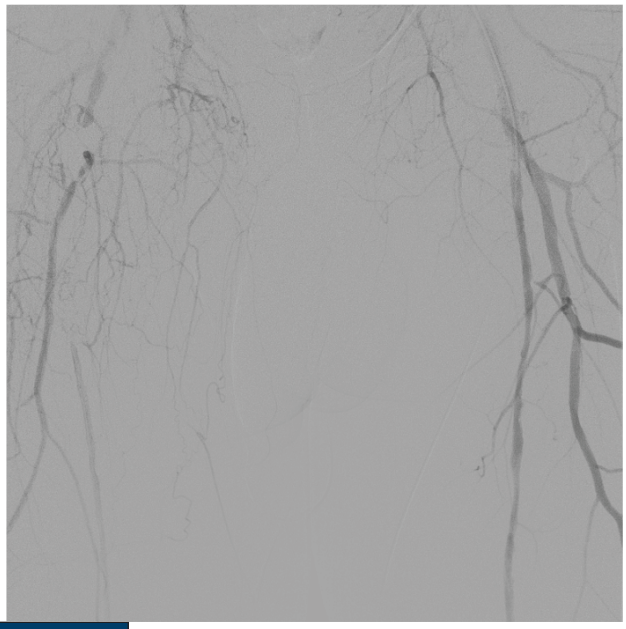

Figure 5 *Initial arteriography revealing CFA occlusion, PFA proximal occlusion and SFA long occlusion.*

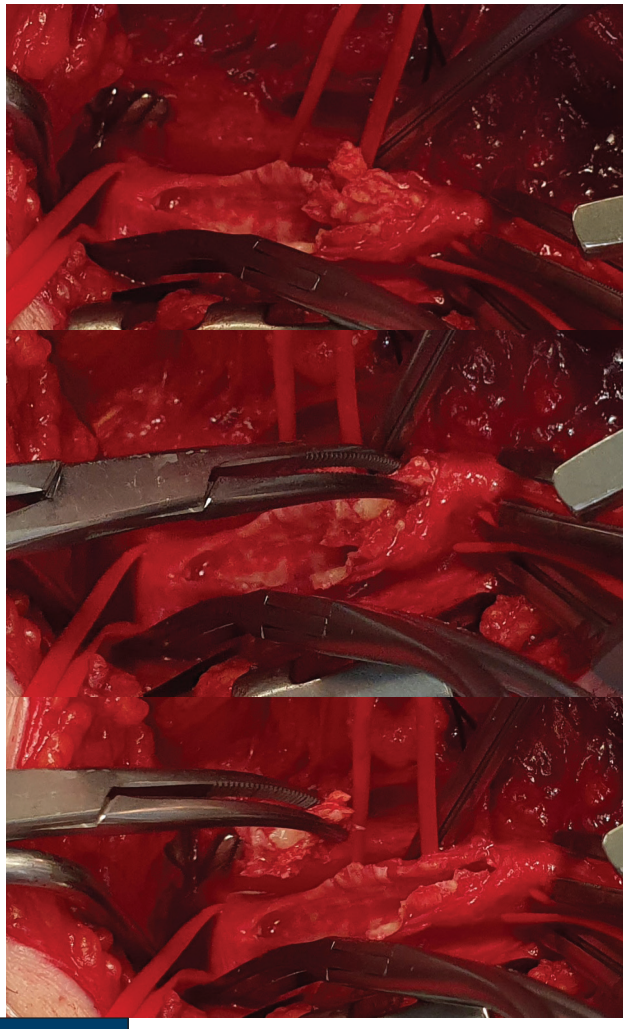

Figure 6 *SFA Opportunistic stump creation using a curved Kelly forceps.*

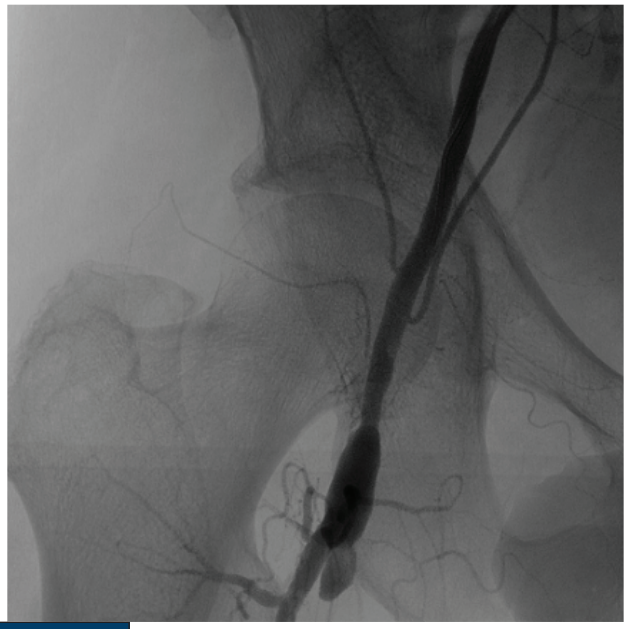

Figure 7 *Arteriography after common femoral artery endarterectomy and profundoplasty with creation of a SFA opportunistic stump.*

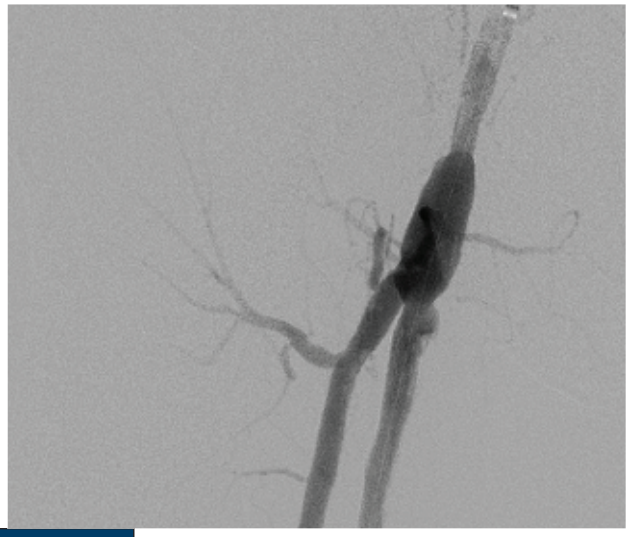

Figure 8 *End result after SFA angioplasty and stenting.*

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ORIGINAL ARTICLE

ROSS SURGERY: OUR EXPERIENCE

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Abstract

Objectives: *At Santa Marta Hospital, Ross Surgery was performed for the first time in 1999. Twenty years later, we feel it is desirable to evaluate the mid and long-term results of our experience, as well as estimate the future of this procedure.*

Methods: *Between March 1999 and June 2016, 23 Ross procedures were performed at our institution. We did a retrospective analysis of the patients´ data, results of the surgery, complications, freedom from reoperation and mortality.*

Results: *The majority (36,4%) of the patients had aortic stenosis, 22,7% had aortic regurgitation and 27,3% had aortic stenosis and regurgitation. Sub-valvular stenosis was present in 13,6% of patients. The mean follow-up is 15 years. The overall mortality was 9%, without early mortality. In our series, 83% of the patients are free from reoperation. Eighty percent (n=16) of the survivors are in NYHA class I, with the remaining 20% (n=4) in class II.*

Conclusion: *Ross surgery has strict indications and in this group of patients the advantages are undeniable and the outcomes, according to our results (with 83% of patients free from reoperation, at a mean follow-up of 15 years), are positive and encouraging.*

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INTRODUCTION

Performed for the first time in July 1967, by Donald Ross, Ross procedure is one of the surgical options for aortic valve replacement and correction of complex left ventricle outflow tract obstruction syndromes, using for that purpose the pulmonary autograft.

During the early years, Ross surgery faced skepticism motivated mainly by two reasons: the slow learning curve, especially in the sub-coronary implantation technique, and the fact that it involves the manipulation of two heart valves for correction of a single valve disease. Despite this, Ross surgery presents undeniable advantages, not achieved by any other surgical alternative, namely, growth potential, absence of need of anticoagulation, a theoretically lower incidence of infective endocarditis and a better hemodynamic profile.

Presently, more than 50 years later, the main concern about this procedure is the pulmonary autograft potential for dilatation, when submitted to systemic blood pressure, ultimately resulting in neo-aortic valve insufficiency.

Twenty years after the first Ross surgery performed at our institution, we feel it is desirable to review the mid and long-term results of our experience as well as estimate the future of this procedure.

MATERIAL AND METHODS

Retrospective study of all patients submitted to Ross surgery or Ross-Konno Surgery, in our Department, from January 1999 to December 2019. All procedures were performed by a single surgeon. Our electronic patient database was searched for patients´ identity, and outcomes were determined from clinical file consultation. All data was stored in Microsoft Excel, and descriptive statistics was utilized. Kaplan Meier analysis was performed for survival and event-free survival estimation. Operative mortality was defined as mortality in the first 30 days after surgery or during the same hospital admission.

Table 1 **Surgical indication for Ross procedure**

Surgical indication	Prevalence % (n)
Aortic stenosis	36,4% (n=8)
Aortic regurgitation	22,7% (n=5)
Aortic stenosis and regurgitation	27,3% (n=7)
Sub-valvular aortic stenosis	13,6% (n=3)

Population

Between 1999 and 2016, 23 Ross procedures were performed at our institution. 68% of patients (n=15) were male. The mean age at operation was 10,7 years (minimum 0,3 and maximum 20 years). All patients had congenital aortic diseases. The most prevalent surgical indication was aortic stenosis (36% (n=8)). Surgical indications are presented in Table 1.

Surgical Technique

In all patients, surgery was performed under cardiopulmonary bypass, with bicaval cannulation, aortic cross clamping, and anterograde blood cardioplegia. Broad mobilization of the great arteries was performed. Main pulmonary artery was transected almost at the level of its bifurcation and the pulmonary autograft was excised using the enucleation method described by Donald Ross, keeping the integrity of the first septal artery. Aorta was transected and the coronary ostia were removed with a broad button. When indicated, complementary procedures like sub-aortic membrane excision were performed. In all cases, the autograft was implanted using the total root technique. Autograft implantation was performed using interrupted polypropylene sutures, reinforced with bovine pericardium or Teflon® (Figures 1 and 2). The left coronary artery ostium was reimplanted. Then, the ascending aorta was reconstructed, followed by the reimplantation of right coronary artery ostium. Lastly, right ventricle to pulmonary artery continuity was reestablished with a conduit, most frequently a pulmonary homograft (Figures 3 and 4).

RESULTS

Mean cardiopulmonary bypass and aortic cross clamping times were 171 and 127 minutes, respectively. In 72,7% of cases, the right ventricle to pulmonary artery conduit used was a pulmonary homograft, while in 27,3% (n=6) was a xenograft (Contegra®, Medtronic plc, Dublin).

Mean homograft and xenograft sizes were 22 and 18, respectively. Nine patients were submitted to additional surgical procedures, namely sub-aortic membrane excision (n=3), Morrow myectomy (n=3) and Konno procedure (n=2).

Mean follow-up time is 15 years (minimum 4, maximum 21 years). There was no intra-operative or immediate post-operative mortality. Regarding post-operative complications, there were two cases of sepsis and one case of temporary atrioventricular conduction block.

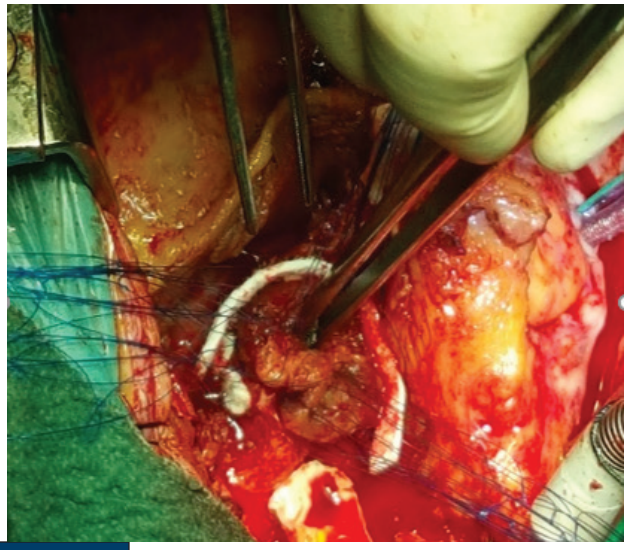


Figure 1 *Reinforcement of the sinotubular crest using a Teflon® band.*

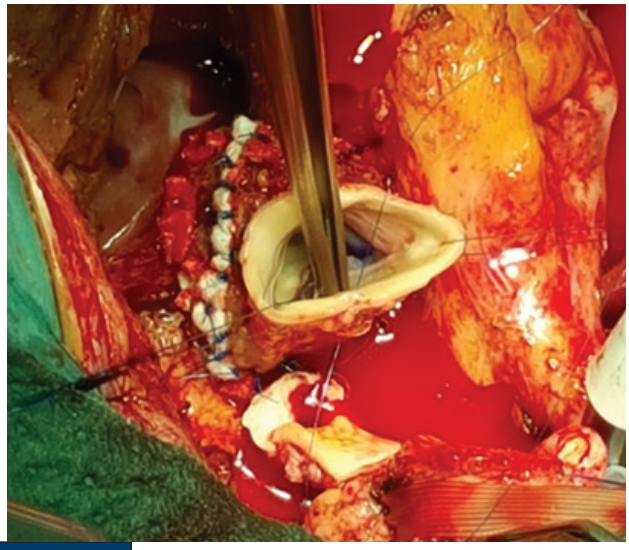


Figure 2 *Reinforcement of the sinotubular crest using a Teflon® band.*

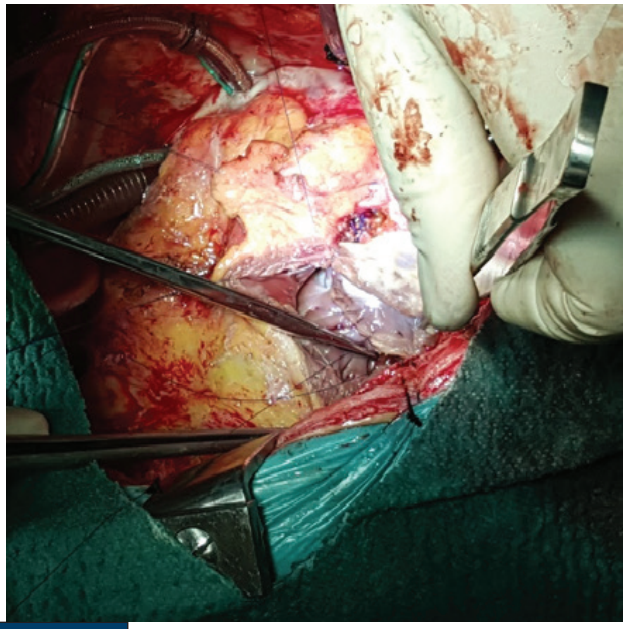


Figure 3 *Reconstruction of right ventricle to pulmonary artery continuity using a pulmonary homograft.*

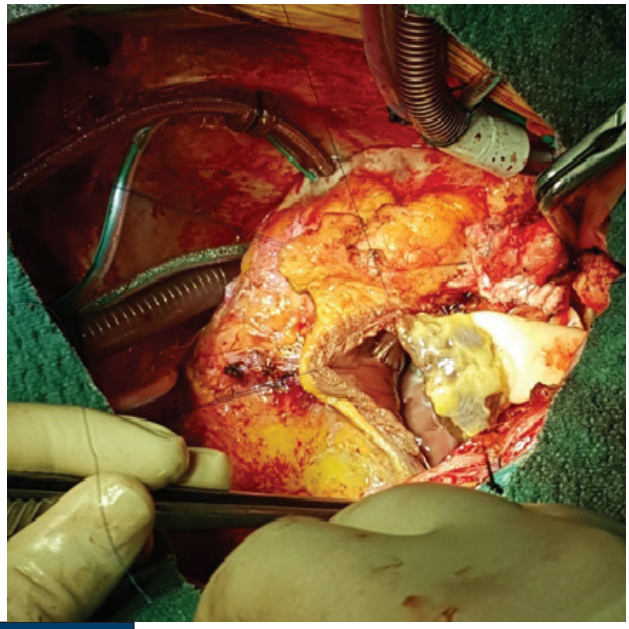


Figure 4 *Reconstruction of right ventricle to pulmonary artery continuity using a pulmonary homograft.*

In our series, 83%(n=19) were free from reoperation, while 4 patients were reoperated (Graphic 1). One patient underwent 2 reoperations. Mean time for reoperation was 9 years after Ross surgery. Reoperations were due to infectious endocarditis of the right ventricle to pulmonary artery conduit, namely a Contegra® (2 years later), mitral valve insufficiency and heart transplant (same patient, 5 and 6 years later, respectively), sub-aortic membrane (13 years later) and aortic insufficiency (16 years later). Accordingly with the last echocardiographic evaluation, four patients have moderate aortic insufficiency, four patients present moderate pulmonary insufficiency and one patient presents moderate pulmonary valve stenosis.

Cumulative mortality is 9% (n=2). One patient died suddenly at home, 7 months after the surgery. The cause of death was not determined. The other patient died 6 years after surgery, following heart transplantation.

Presently, 80% (n=16) of patients are in NYHA class I, while the remaining 20% (n=4) are in class II.

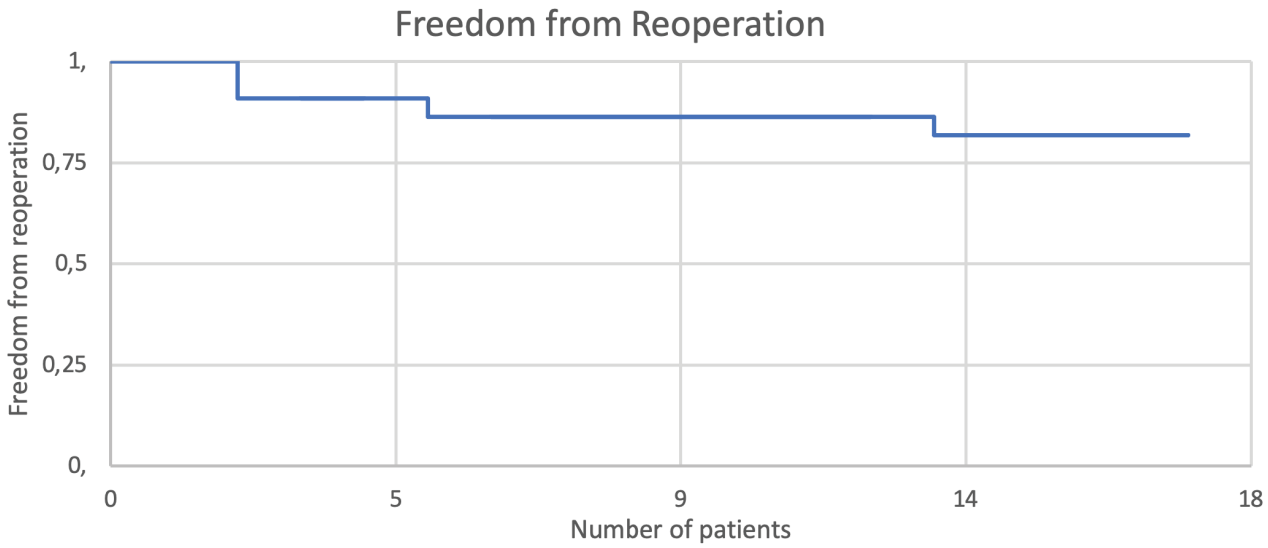
DISCUSSION

Literature reports an early mortality rate between 0.7-6,8% and a late mortality rate between 0.1-1,25%[1]. Currently, the main concern associated with Ross surgery is pulmonary autograft progressive dilatation, leading to aortic regurgitation. However, this is not apparent in our series. It is also consensual that this progressive dilatation does not happen homogeneously in all patients and does not affect the autograft uniformly. Progressive autograft dilatation occurs mainly in the presence of bicuspid aortic valve, male patients, younger ages at operation and aortic valve insufficiency [1,2]. Interestingly, in our series, with 70% of patients being male and 22,7% having aortic regurgitation, only one reoperation was due to pulmonary autograft dilatation and neo-aortic regurgitation. Although this is a small series, this is probably the result of an adequate selection of patients and of the reinforcement of the sinotubular crest performed in all patients. We also favor a short pulmonary autograft.

The survival and freedom from reoperation, in our series are actually very similar to the ones reported by Guerreiro et al.[3] In this retrospective portuguese single center study, a 80% freedom from reoperation, in a mean follow-up of 20 years, is reported[3]. Interestingly, this group used predominantly the subcoronary approach[3].

Ross surgery benefits predominantly children/adolescents given the growth potential, not achieved by any other surgical alternative. This procedure also exempts the patients from anti-coagulation required with mechanical heart prosthesis[4,5], which is especially relevant in this group given the associated active lifestyle, sports participation and, in female patients, possibility of future pregnancies. While bioprosthesis do not require anti-coagulation, they present an accelerated deterioration in younger ages[6].

Sinotubular crest reinforcement has been strongly recommended[7,8]. However, traditionally, this has been done using synthetic materials like Dacron or Teflon, re-



Graphic 1 *Freedom from reoperation after Ross procedure.*

ducing growth potential, stated as the main advantage of the procedure when performed in younger ages[9]. The solution may depend on the use of biocompatible materials providing structural support and inducing, at the same time, histological modifications in the autograft wall, therefore increasing tolerance to the higher systemic pressure conditions. Nappi and colleagues recently introduced the idea of the use of reabsorbable scaffolds as reinforcement of the pulmonary artery in an experimental model of Ross operation in the growing lamb[9]. A polydioxanone external mesh prevented pulmonary artery dilation and induced in vivo a favorable elastic remodeling of the autograft. A complex histoarchitectural rearrangement including medial thickening and increase in the elastic wall component was triggered leading to the creation of a "neovessel" similar to the native aorta[9]. They propose that a new impulse should be given to translational research to stimulate the development of bio-artificial vascular substitutes and provide a future for the Ross procedure, given its advantages in a very specific population.

CONCLUSION

Ross surgery has strict indications. However, in that group of patients, advantages are undeniable. Despite the reduced number of patients, we believe that our results, with 83% freedom from reoperation with a mean follow up of 15 years, are positive and encouraging. Fifty years after the first Ross surgery, the development of new materials may improve the performance of the pulmonary autograft.

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ORIGINAL ARTICLE

LONG TERM FOLLOW-UP IN SURGICAL STAGE I NON-SMALL CELL LUNG CANCER – A SINGLE CENTER EXPERIENCE

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Abstract

Introduction: *Lung cancer has a high mortality rate with an overall survival of 18% at 5 years. Surgical treatment is the gold standard for early stages and is associated with high rates of resolution with a 5-year survival of 80% reported in large studies.*

Purpose: *To determinethe survival of patients with non-small cell lung cancer (NSCLC) in stage IA (T1N0M0) undergoing surgical treatment with curative intent in our center.*

Methods: *: We performed a retrospective review of the clinical records of all patients with pathological stage T1a-c N0 (stage I) who underwent thoracic surgery with curative intent from 2010 and 2017 in our center. Overall survival and lung cancer-specific survival was estimated by the Kaplan-Meier method.*

Results:*87 patients (54 men and 33 women) with a median age of 66 years (range 36 to 83 years) were included. Lobectomy with systematic lymph node dissection was performed in 67 patients (77%). Adenocarcinoma was the predominant histological subtype (n=69; 79%). Overall survival at 5th years was 86,7%. Patients submitted to limited resection (segmentectomy or wedge resection) had lower overall survival compared to those submitted to lobectomy (66,4% vs 88,7%; p=0.008).*

Conclusions: *Our results show a high 5-year overall survival rate, in agreement with results from larger series studies. Lung cancer screening, although not yet widely implemented, has been shown to reduce mortality associated with lung cancer. These results reinforce the importance of screening programs for specific populations in order to identify patients in early stages and improve overall survival.*

INTRODUCTION

Worldwide, lung cancer ranks for the leading cause of cancer-related death among men and women, with non-small cell lung cancer (NSCLC) accounting for 84% of all types of lung cancer [1,2]. The most recent European projections show that, unlike most cancers, the trend in the incidence of lung cancer will rise especially in women[3]. Cigarette smoking is thought to be causal in 85 to 90% of all lung cancer, being crucial the promotion of smoking cessation[4]. It is essential to implement integrated primary and secondary prevention strategies. The clinical outcome for NSCLC is directly related to stage at the time of diagnosis. Based on the 8th edition of TNM classification for lung cancer 5-year survival using clinical staging ranges from 92% (stage IA1) to no survival (stage IVB)[5]. Despite advances in therapy, five-year survival rate is approximately 18% for all types of lung cancer, and for NSCLC is estimated to be 23% [6]. In the short term, awareness for smoking cessation and screening in high-risk individuals (smokers and former smokers) is the strategy that will have

the greatest impact in reducing tobacco-related mortalityADDIN BEC[3,6,7]. Results from screening clinical trials with low-dose computed tomography (LDCT) for selected patients are promising, with a remarkable 88% 10-year survival among patients with stage I lung cancer in the International Early Lung Cancer Action Program screening study[8].

Stage I NSCLC includes patients with tumors with 3cm or less in greatest dimension, surrounded by lung or visceral pleura without invading it, and no progression into the main bronchus[5]. For resectable disease in patients with low cardiopulmonary risk, complete surgical resection with lobectomy and systematic lymph node dissection remains the gold standard. The purpose of this study was to review our experience in patients who underwent surgical resection for stage I NSCLC.

MATERIAL AND METHODS

We retrospectively reviewed the clinical records of all patients who underwent surgical resection of NSCLC with tumors ≤ 3cm from January 2010 through December 2017 (7 years). Neuroendocrine tumors were excluded. We analyzed the medical records of each patient regarding age and sex, smoking habits, histology, tumor diameter, postsurgical stage, extent of pulmonary resection and overall survival.

Continuous variables are expressed as mean/median and standard deviation/ interquartile range (IQR), using T-student or Mann-Whitney-U-Test for its comparison. Categorical variables are described as percentages and compared using Fisher's exact test. All p-values are two-sided unless otherwise indicated. In all analysis p-values less than 0.05 were considered statistically significant. Survival analysis was performed using the Kaplan-Meier method.

RESULTS

In this study 87 patients were included (54 men and 33 women) with a mean age of 66 years (range 36 to 83 years). History of tobacco exposure was present in 88,5% of patients. Patients' characteristics are described in Table 1.

A curative lung resection (R0) was achieved in every patient. Lobectomy was performed in 67 patients (77%), segmentectomy in 10 patients (11,5%), wedge resection in 6 patients (6,9%) and bilobectomy in 4 patients (4,6%). Mediastinal lymph node dissection was completed in 85 patients (97,7%).

Tumor histologic characterization showed mostly adenocarcinomas (n=69; 79,3%), but also squamous cell carcinomas (n=16; 18,4%) and large cell carcinomas (n=2; 2,3%).

The tumor size was ≤1cm in 57,5% of cases; >1cm and ≤2cm in 40,2%; and >2cm and ≤3cm in 2,3%. There were no operative deaths.

At data capture for this study 10 (11,5%) of the 87 patients had died. In half of the patients, disease relapse was the cause of death (n=5; 50,0%). Other causes were stroke (n=2; 20,0%), pneumonia (n=1; 10,0%), cholangiocarcinoma (n=1; 10,0%) and hypovolemic shock (n=1; 10,0%). Mean follow-up time was 52 months (range 11-115 months). Disease specific mortality rate was 5,7%.

Patients were divided into two groups for comparison by the type of surgical procedure. The formal resection group (included lobectomy and bilobectomy) included 71 patients (81,6%). The sublobar resection group (underwent either wedge resection or segmentectomy) included the

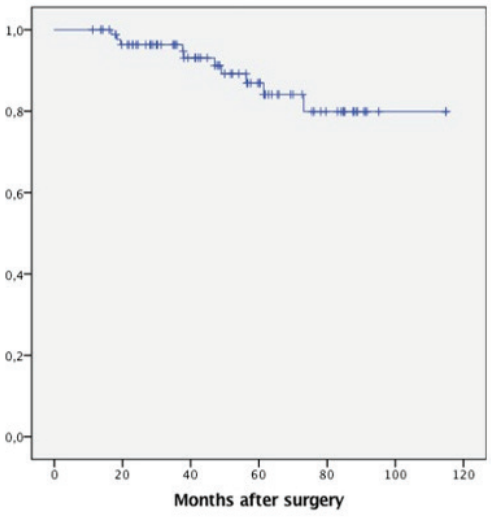

Figure 1 *Overall survival for patients who underwent thoracic surgery for stage I NSCLC.*

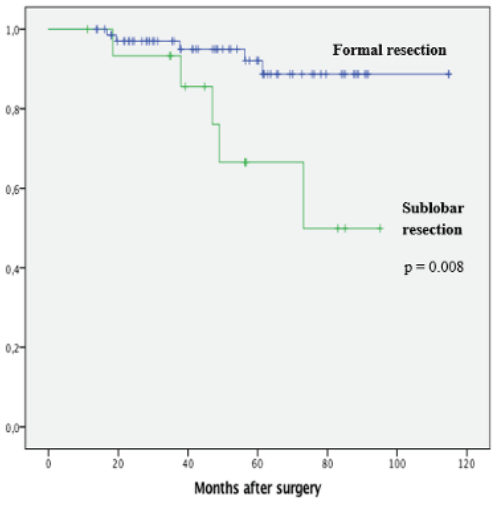

Figure 2 *Overall survival for patients who underwent formal resection (blue line) compared with patients who underwent sublobar resection (green line). Five-year survival for the formal group was 88,7% versus 66,4% for the lobar group (p=0,008).*

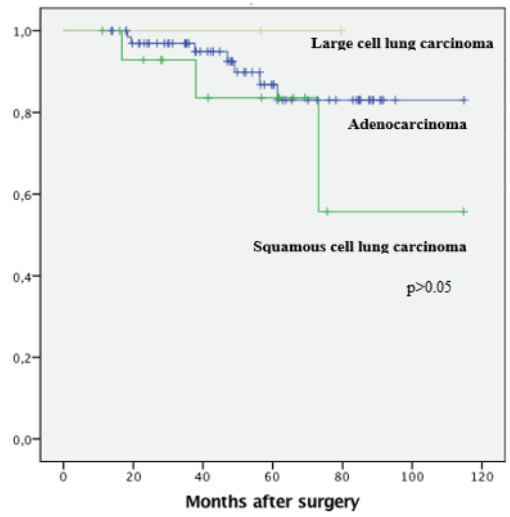

Figure 3 *Overall survival for patients according to the histological subtype (p>0.005; large cell carcinoma grey line; adenocarcinoma blue line; squamous cell lung carcinoma green line).*

remaining 16 patients (18,4%). Patients' characteristics are detailed in Table 2. There was a significantly lower number of deaths in the formal group resection (7,0% vs 31,3%; p= 0,016). Death caused by disease progression occurred in 2 patients in the formal resection group and in 3 patients from the sublobar resection cohort.

The overall 5-year survival was 86,9% (figure 1). Sub-analysis by group showed a significantly lower 5-year survival of the sublobar resection group when compared to the formal resection cohort (66,4% vs 88,7%, log rank testing Mantel-Cox p=0.008) (figure 2).

There were no differences in survival concerning to histological subtype (p>0,05; figure 3).

Regarding surgical technique, video-assisted thoracoscopic surgery (VATS) was performed in 42 patients (48,3%) and thoracotomy in 45 patients (51,7%). When comparing both techniquesaccording to 5-year survival rates, no significant differences were found (79,8% for VATS versus 80,5% for thoracotomy, log rank testing Mantel-Cox p=0.512).

DISCUSSION

Surgical intervention remains the gold standard for early-stage lung cancer. In a recent study conducted by Lu et al., the average of localized stage cancer was 18,8%, with an increasing trend from 16,6% in 1988 to 23,6% in 2015[9]. With the rising number of individuals diagnosed in early stages, it is important to define the most appropriate and effective treatment strategies.

In a retrospective analysis of our results, and according to the current recommendations, the majority of patients

Table 1 **Patients characteristics**

Patients characteristics (n=87)	n	%
Gender		
Male	54	62,1
Gender	33	37,9
Age (years) mean (SD)	66 (±10)	
Tobacco exposure		
Current smokers	56	64,4
Former smokers	21	24,1
Non smokers	10	11,5
Size of the tumor (T)		
T1a (≤1cm)	50	57,5
T1b (>1cm ≤2cm)	35	40,2
T1c (>2cm ≤3cm)	2	2,3
Surgical procedure		
Lobectomy	67	77
Bilobectomy	4	4,6
Wedge resection	6	6,9
Segmentectomy	10	11,5
VATS	45	51,7
Thoracotomy	42	48,3
Mediastinal lymph node dissection	85	97,7
Histological type		
Adenocarcinoma	69	79,3
Squamous cell carcinoma	16	18,4
Large Cells lung cancer	2	2,3

Table 2 **Group comparison by surgical procedure**

	Formal resection (n=71)	Sublobar resection (n=16)	p-value
Age (years) mean (SD)	64 (11) min 36; máx 82	69 (9) min 50; máx 83	p=0,16
Histological type			
Adenocarcinoma	58 (81,7%)	11 (68,8%)	
Squamous cell carcinoma	12 (16,9%)	4 (25,0%)	
Large cell carcinoma	1 (1,4%)	1 (6,3%)	
Deaths	5 (7,0%)	5 (31,3%)	p<0,05
Causes of death			
Disease relapse	2 (2,8%)	3 (18,8%)	
Stroke	1 (1,4%)	1 (6,3%)	
Pneumonia	0 (0,0%)	1 (6,3%)	
Cholangiocarcinoma	1 (1,4%)	0 (0,0%)	
Hemorrhagic shock	1 (1,4%)	0 (0,0%)	

was submitted to formal resection (lobectomy/bilobectomy in 81,6% of cases). Only a minority underwent sublobar resection (18,4%) due to significant comorbidities, lung function prohibited for lobectomy or previous surgically treated lung cancer.We observed an inferior 5-year overall survival for the sublobar resection group (66,4% versus 88,7%, p=0.008), which is in accordance with other series that show superiority of the lobectomy approach[10]. It is important to note that in this study we chose to include theanatomical segmentectomies and the non-anatomical wedge resections inthe sublobar resection group, due to the reduced number of patients in each procedure. Considering the smaller size of the sublobar resection cohort, these results may be explained by the fact that they were older and had more comorbidities when compared to the group submitted to formal resection. The higher disease-related mortality observed in the sublobar resection cohort (18,8% vs 2,8%) is attributable to 2 cases of wedge resection and 1 case of segmentectomy.

When comparing surgical techniques, we did not find differences in the 5-year survival rates between VATS and toracotomy. Our 5-year overall survival of 86,9% in the total cohort of patients was comparable with the results obtained in larger series reports [11-16]. These results are in accordance to the published data in literature, but also lead to several ongoing topics regarding surgical treatment in stage I lung cancer. Standard therapy for patients with stage I lung cancer is anatomic surgical resection with lobectomy and systematic sampling of mediastinal lymph nodes, mostly based on the Lung Cancer Study Group trial published in 1995. This trial compared lobectomy to sublobar resection (including both segmentectomies and wedge resections). Results showed that the limited resection group had an incidence of local recurrence three times higher(p=0.008), a 30% increase in overall death rate (p=0.08) and a 50% increase in cancer-related death (p=0.09) compared with patients undergoing lobectomy[10]. Sublobar resections, preferably anatomical segmentectomy, or wedge resection, may be appropriate in highly selected patients, as those with limited respiratory reserve or comorbidities that increase the perioperative risk, with peripheral nodules ≤ 2 cm and at least one of the following features: 1) pure adenocarcinoma in situ, 2) C/T ratio 50% or less, or 3) radiologically surveyed long tumor doubling time of 400 days or greater[6].

Despite several single center retrospective studies have been published with disagreeing conclusions about the comparison between sublobar and lobar resections, there has not been another published prospective trial on this topic[7]. Ongoing trials in the USA, France and Japan may prove similar overall survivals in the treatment of stage I lung cancer between lobectomy and segmentectomy[17,18].

The surgical technique approach has also been discussed for years. The safety of VATS was established by 2

phase II trials that were conducted over a decade ago[19]. In a phase III randomized controlled trial (RCT) conducted by Long et al, the safety and reliability of VATS for treatment NSCLC was demonstrated[20]. There has been controversy about the safety regarding the complete lymph node dissection with VATS, but the RCTs have showed that a standard lobectomy with lymph node dissection can be performed by VATS with no inferiority compared to toracotomy[21].

Globally, stage I NSCLC has excellent survival however most patients are diagnosed in advanced stages of disease. Aside from primary prevention by promoting smoking cessation, the aforementioned results reaffirm the role of lung cancer screening in identifying patients in early stages of disease. Largerandomized trials showed that screening with low dose computed tomography (LDCT) in high risk populations of current or former smokers was associated with a decrease in lung cancer and all-cause mortality[22,23]. In order to have cost-effective screenings it is essential to develop strict algorithms that define the diagnostic and procedure steps that should be ensured when abnormalities are found. Predictive risk models must also be ensured to identify the individuals who benefit most from screening[3].

In conclusion, our results are in line with what will be the trend and the need for health care systems to adapt to the implementation of screening programs for lung cancer and our results are in line with these premises.

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ORIGINAL ARTICLE

THORACIC SURGERY IN A COVID-19 FRONTLINE HOSPITAL. ARE THE PATIENTS SAFE?

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Abstract

Introduction and Objectives: *COVID-19 pandemic forced a change in health care resources and provision due to the emergence of a new group of patients, requiring extraordinary protective measures and the adoption of new organization for the treatment of urgent or priority COVID-19 negative patients.We reviewed our practice during the first pandemic period to evaluate our surgical outcomes and identify if patients COVID-19 negative submitted to thoracic surgery had an increased risk of being infected or die.*

Methods: *We retrospectively reviewed our surgical results between 11th March and 15th May 2020. Thirty patients underwent thoracic surgery at the Department of Cardiothoracic Surgery of Centro Hospitalar Universitário de São João.*

Results: *None of the patients was COVID-19 positive and cross-transmission of the disease was not recognized. The majority of patients were admitted from home, with a high priority indication, namely an oncological disease. There was only one case of in-hospital mortality.*

Conclusion: *During the first wave of the pandemic it was safe to be admitted and submitted to thoracic surgery at CHUSJ. Our patients, including oncological patients, received the adequate surgical treatment without an increase of risk of death or infection.*

Keywords: *COVID-19 Pandemic; Thoracic Surgery; Patient non-COVID-19 Safety; Priority Surgery*

INTRODUCTION

COVID-19 was declared a pandemic by the World Health Organization (WHO) on March 11th, however incoming patients with diseases other than COVID-19 related infection that required priority or urgent treatment continued to exist.

The fear of being infected in the hospital facilities pushed away or delayed patients from the adequate treatment[1] and our experience can be very useful to set orientations for an eventual second wave.

Without a vaccine or a specific medication, with the ending of strict confinement measures, the national health system will have to readjust in order to maintain an attempted response to other severe diseases while ensuring adequate protective measures to the staff and patients[2,3].

Centro Hospitalar Universitário de São João (CHUSJ), the major Hospital of the North of Portugal, with the largest Cardiothoracic Department of the Portuguese National Health Service, was the main hospital in the North of Portugal on the front line against COVID-19.

Our hospital had to adjust its activity and during the first wave of COVID-19 pandemic most of the surgical elective cases were postponed. The majority of patients submitted to thoracic surgery from March 11th to May 15th, 2020 were operated in a specific operating room (OR), from the three specific of the department. Our department reorganized its activity with the creation of "COVID-free circuits" and, with the reduction of the staff and number of surgeries, all patients submitted to surgery in this period of time were urgent, emergency or high priority out-patient cases, exclusively oncological patients.

We retrospectively reviewed our surgical results from March 11th to May 15th 2020 to understand if admissions on CHUSJ increased the risk of being infected or die when submitted to thoracic surgery and to evaluate the surgical outcomes during the COVID-19 pandemic.

METHODS

Between 11th March and 15th May 2020, thirty patients underwent thoracic surgery at the Department of Cardiothoracic Surgery of CHUSJ. Population was characterized by demography and clinical variables and surgical results were displayed. Study protocol was approved by the Ethics Committee of CHUSJ.

Statistical Analysis

Descriptive analysis was performed and data presented as counts and proportions for categorical variables. Measures of central tendency and dispersion were applied for continuous variables, according to their distribution. Specific group analyses awere conducted using Mann-Whitney and Spearman's correlation test. Results were considered statistically significant if $p < 0,05$.

RESULTS

Demography and Clinical Presentation (Table 1)

None of our patients tested COVID-19 positive before or during admission. Until March 26th only symptomatic (new onset or persistent symptoms like cough, shortness of breath or fever) patients were tested for COVID-19. From the 26th March, all patients (even asymptomatic) who underwent thoracic surgery were tested on admission and every five days during their hospital stay.

The majority of this group (60%) was admitted from home, with a high priority indication for surgery and only one case was performed as an emergency surgery (hemothorax).

Early outcome

The median waiting time for surgery was 16 days(range 0-50). The median post-operative length of drainage was 4 (range 1-28) days, and median post-operative length of stay was 4,5 (range 1-52) days.

One patient was re-operated for bleeding and another one had a new onset atrial fibrillation. Both recovered well and no other major complications occurred. We reported 6 minor complications (1 case of non-nosocomial respiratory infection and 5 cases of prolonged pulmonary air leak).

Among the thirty patients who underwent thoracic surgery at the Department of Cardiothoracic Surgery of CHUSJ, one patient was considered an outlier (initial operation prior March 11th) and was excluded when specific group analyses were performed. This patient was initially operated by Orthopedics and Thoracic Surgery with a thoracic spondylitis complicated with contiguous pneumonia and empyema. Despite the absence of pulmonary complications, this patient was submitted to a redo thoracotomy to drain an extrapleural hematoma. He eventually died of septic shock, due to uncontrolled nonthoracic infection.

There was no statistically significant differences in hospital length of stay according to patient´s gender ($p = 0.134$); presence of cardiovascular risk factors ($p= 0.779$); smoking history [active or former smokers ($p=0.33$)]; chronic obstructive pulmonary disease; [COPD ($p=0.801$)] and a forced expiratory volume in 1 second (FEV1) inferior to 80% prior to surgery ($p = 0.582$).

Patients with other neoplasms previously diagnosed were associated to shorter length of stay in the postoperative period ($p=0.039$). No association was found between surgical waiting time ($p =0.46$) [even in the subgroup of non-small-cell lung carcinoma (NSCLC); $p=0.472$] and the length of in-hospital stay.

Patients submitted to Video-assisted Thoracoscopic Surgery, VATS, (versus open technique) had statistically significant ($p= 0,025$) lower in-hospital length of stay.

The subgroup of patients operated for pleural-space disease, other than pneumothorax (one case of hemothorax and three cases of empyema) were associated to a higher length of drainage ($p= 0.013$) and a higher hospital length of stay ($p=0,025$) than the rest of the patients.

In our sample, a past medical history of ipsilateral surgery (reoperation) didn't increase the time of chest tube drainage ($p=0,896$) neither the length of in-hospital stay ($p =0.896$). As expected, there was a strong (Spearman's correlation = 0.847) and a significant ($p< 0,001$) correlation between the number of days with a chest tube and the length of in-hospital stay. There was a trend for the patients with complications in the post-operative period to have a higher in-hospital length of stay, although it was not statistically significant ($p=0.059$).

Table 1 **Patients characteristics**

Thoracic Surgery n=30		
Sex – n (%)	Male – 19 (63,3%); Female – 11 (36,7%)	
	Median (min-max)	
Age (years)	62 (23-77)	
Waiting Time for surgery (days)	16 (0-50)	
Tobacco	n (%)	
Active smoking	10 (33,3%)	
Former smoking	9 (30,0 %)	
Non-smoking	11 (36,7%)	
Comorbidities	n (%)	
Hypertension	11 (36,7%)	
Diabetes	5 (16,7 %)	
Dyslipidemia	10 (33,3%)	
CVD	4 (13,3%)	
CKD	0	
COPD	5 (16,7%)	
Asthma	1 (3,3%)	
FEV1 < 80%	8 (26,7%)	
Others Neoplasms	11(35,7%)	
Reoperation	6 (20,0%)	
Surgical indications	n(%)	
NSCLC	14 (46,7%)	
*Adenocarcinoma	*10	
*Squamous	*2	
*Neuroendocrine tumour	*2	
Solitary Pulmonary Nodule	2 (6,7%)	
Metastases	3 (10,0%)	
Pneumothorax	4 (13,3%)	
Hemothorax	1 (3,3%)	
Empyema	3 (10,0%)	
Anterior Mediastinal Mass	2 (6,7%)	
Extrapleural Hematoma	1 (3,3%)	
Surgical intervention	cases (%)	VATS (n)
Lobectomy	14 (46,7%)	14
Sublobar Resection	5 (16,6%)	5
Drainage of Hemothorax	1 (3,3%)	0
Pleural Decortication	3 (13,3%)	2
Blebs resection + Pleurodesis	4 (13,3%)	4
Mediastinal mass biopsy	2 (6,7)	1
Exploratory thoracotomy	1 (3,3%)	0

Table1 – Thoracic Surgery: Min-minimum; Max-Maximum;CVD-Cardiovascular disease; CKD-chronic kidney failure; COPD-Chronic Obstructive Pulmonary Disease; FEV1-Forced Expiratory Volume in 1 Second;NSCLC-non-small-cell lung carcinoma; VATS-Video-assisted Thoracoscopic Surgery.
** Histology subtypes ** One case converted to toracotomy*

DISCUSSION

All patients who underwent thoracic surgery at the Department of Cardiothoracic Surgery of CHUSJ were COVID-19 negative and there was no evidence of cross-infection, among staff or patients or between staff and patient. This fact is further emphasized as, during the same period, 118 cardiac patients, originated from different referral areas of CHUSJ, such as Emergency, Cardiology or Pediatric Intensive Care Unit shared the same facilities with these thirty patients[4]. Although there is an ongoing debate over the benefits of COVID-19 Free Hospital for the treatment of specific pathologies, our experience revealed that the creation of "COVID-free circuits" in hospitals treating COVID-19 patients and the implementation of adequate protective measures, like individual protection equipment, policies to reinforce social distancing in clinical and social areas, strict standards for environmental sanitation, allows safe thoracic surgical interventions, even in oncological patients. We should highlight summing to the universal infection control measures, contact and droplet precautions were universally used. All aerosol generating procedures were substituted by closed circuit procedures and when indispensable, airborne precautions, as specialized garb and high efficiency filters were used.

We reported only one case of in-hospital mortality due to refractory septic shock, initially operated before the first pandemic wave was declared.

Our results are similar to other studies[5] reporting that patients submitted to VATS had a shorter hospital length of stay than patients submitted to open technique. However, in our group, the surgical indication could have biased this result, as two of the patients that underwent thoracotomy were submitted to pleural decortication for empyema and hemothorax, which were the diagnostics associated in the univariated analysis with a higher length of drainage and a longer in-hospital stay. This is further highlighted as patients with other previously diagnosed neoplasms (none of them had a case of empyema or hemothorax) were associated to shorter length of stay in the postoperative period.

As expected, there was a strong and significant correlation between the in-hospital stay and the days of chest tube drainage explained by the fact that our patients are discharged home in the day of chest tube removal.

We should disclose that in this high-risk group of patients, operated under extraordinary conditions during the first wave of COVID 19 pandemic, we tended to be extremely cautious about chest tube removal to prevent subsequent pleural procedures. This fact might explain why some of the patients might have a somewhat longer period of pleural drainage.

One limitation of our study is the small number of included patients. It may be the reason why we found a trend instead of statistically significant difference between the complications in the postoperative period and a higher hospital length of stay.

Surgical waiting time remains an issue of utmost importance when we consider the access to efficient health care provision. More than half of the patients who underwent thoracic surgery in this period of time were cancer patients. The patient with the highest waiting time for surgery (50 days) was a case of neoadjuvant treatment in which timing of different treatments were perfectly accomplished.

CONCLUSION

It was safe to be admitted and operated in the Department of Cardiothoracic Surgery of CHUSJ during the first wave of the pandemic. The numbers of surgeries were reduced with the non-oncological cases postponed, maintaining prompt response to high priority or urgent cases.

The precautionary measures implemented avoided the patients-staff or staff-patients transmission of the disease, allowing the patients to receive the adequate surgical treatment in a COVID-19 reference Hospital without an increased risk of death or infection. The indication for surgery in more than half of the patients was lung cancer and most of them received treatment with a curative intent. Surgical results were not influenced by the COVID-19 pandemic.

Conflicts of interest: The authors have no conflicts of interest to declare.

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ORIGINAL ARTICLE

ENDOVASCULAR PROCEDURES FOR LOWER LIMB PERIPHERAL ARTERIAL DISEASE IN AN AMBULATORY UNIT

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Abstract

Objectives: *To analyse the safety and outcomes of endovascular procedures in an ambulatory practice.*

Methods: *Data were collected from a cohort of patients admitted in an ambulatory unit for an endovascular procedure for lower limb (LL) arterial occlusive disease during a one year period.*

Results: *A total of 168 procedures were carried out in 134 patients. Patients' mean age was 67 (39-91) years and 78% were male. Most patients presented with lower limb ulcer or gangrene (43%) or disabling claudication (40%). Most frequent comorbidities included hypertension (75.4%), dyslipidemia (72.4%) and diabetes mellitus (57.5%). The preferred vascular access for the procedures was the common femoral artery (52%), superficial femoral artery (24%) and humeral artery (21%). Global complication rate was 19% but only one major, non-fatal complication was identified. The most common complication was arterial dissection (8.3%), none compromising blood flow. One-year amputation rate was 6.7%, and one-year mortality was 3.0%. Factors significantly associated with procedure complications were female sex, hypertension and dyslipidemia.*

Conclusion: *Ambulatory endovascular procedures for PAD are safe and effective in selected patients. Both the low rate and low severity of complications make them an attractive option in the prospect of diminishing the burden of these patients on the health-care system while improving patient comfort.*

INTRODUCTION

Peripheral artery disease (PAD) is a major health problem affecting more than 200 million people globally[1]. PAD affecting the lower limbs leads to symptoms that significantly decrease patients' quality of life (QoL) and increase the risk of local complications and potential limb loss. Rest pain and skin ulceration are markers of limb threatening ischemia with a high risk of amputation unless vascular intervention is pursued. These patients may benefit from early intervention to attain limb salvage[2].

From the beginning of the century, endovascular procedures have overpassed open surgery for lower limb revascularization, even for the most complex anatomical cases[1]. This change in paradigm was boosted by technological and technical improvements and a faster recovery of patients with minimally invasive, low-morbidity procedures. The cost-saving for health systems cannot be overemphasized. Endovascular procedures have been shown to be feasible, even in non-hospital-based settings and that is a major trend in PAD treatment globally[3,4]. Nonetheless, articles that evaluate the safety and efficacy of ambulatory treatment of these patients are lacking[5].

The goal of this work was to analyse the safety and

outcomes of the ambulatory endovascular procedures in a vascular surgery department of a community hospital.

MATERIAL AND METHODS

Data collection

This was an observational study where we retrospectively collected demographic and clinical information of patients submitted to ambulatory endovascular procedures for lower limb PAD. We analysed the procedures done in the period of 01 January 2017 to 31 December 2017.

Statistical analysis

Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations. The Student's t-test was used to compare continuous variables. Categorical variables were compared with the Pearson's chi-square test. Variables found to be statistically significant by a univariate analysis were then entered into a multivariate logistic regression analysis to identify independent risk factors for procedural complications. The results were considered significant at the $P < 0.05$ level. Data analysis was performed using SPSS ®v25.0 (SPSS Inc, Chicago, Illinois, US).

RESULTS

Facilities

All interventions were carried out in a dedicated hybrid angiography suite under local anesthesia by a vascular surgeon. All the patients were admitted to an ambulatory unit. All procedures were performed under local anesthesia at the puncture site (1% lidocaine), with basal analgesia with acetaminophen or opioids in selected cases. An anesthetist was present and would supervise any further sedative or analgesic drugs required only for the non-cooperative patient (e.g. severe pain). Our ambulatory unit runs from Monday morning to Friday afternoon and allows overnight stay. The decision whether to discharge or to stay overnight was made by the operating surgeon on a case by case basis. Unfortunately no reliable data could be collected on this topic since the information on the patients' files was not explicit on the hour of discharge.

Patient Characteristics

Patients' demographic and clinical data are presented in table 1. Female and male populations are compared in table 5.

Endovascular Treatment

All vascular accesses were ultrasound guided. Table 2 summarizes the characteristics of the endovascular procedures. In one quarter of procedures a vascular closing device was used to close the artery entry site (Perclose ProGlide™ (Abbott), and Exoseal™ (Cordis)) (Table 2). For all other cases a standard 15 minutes manual compression was performed by the intervention surgeon at the end of the procedure extending the duration if necessary to obtain full hemostasis. A compressive dressing was left in place and the patient - as well as the attending nurse when the patient wasn't able to fully comply with this - were noticed as to not bend the knee (for femoral punctures) or flex the elbow (for braquial punctures) for 2 hours after the procedure. Patients were then allowed to walk (e.g. go to the toilet) under supervision.

Table 1 **Demographic and clinical characteristics of patients**

	n (%)
Sex	
Male	104 (77.6)
Female	30 (22.4)
Age (years) - Mean ± SD	67 ±10.6
30-39	1 (0.7)
40-49	3 (2.2)
50-59	32 (23.9)
60-69	40 (29.9)
70-79	39 (29.1)
80-89	18 (13.4)
90-99	1 (0.7)
Comorbidities and Risk Factors	
Dyslipidemia	97 (72.4)
Hypertension	101 (75.4)
Diabetes mellitus	77 (57.5)
Obesity	15 (11.2)
Chronic Kidney Disease	14 (10.4)
CPOD	12 (9.0)
Ischaemic Heart Disease	42 (32.3)
Stroke	11 (8.2)
Smoking History	78 (58.2)
Previous Vascular Interventions	59 (44.0)
PTA	46 (78.0)
Open surgery	21 (35.6)
Amputation	3 (5.1)

CPOD – Chronic Pulmonary Obstructive Disease; PTA – Percutaneous Translumi-nal Angioplasty; SD – standard deviation

Complications

Complications are described in table 3. Global complication rate was 19% including minor complications

like pain (n=2) or cutaneous allergic reaction (n=1). Arterial dissection accounted for 14 cases (8.3%), but none was flow limiting. The majority of complications was intraprocedural and all were minor, with none requiring surgical intervention except for one patient that presented 6 days after discharge with pain and a groin and thigh hematoma. A false aneurysm of the femoral artery was diagnosed by ultrasound. The patient required the transfusion of one unit of packed red blood cells and was treated successfully with ultrasound-guided thrombin injection. One patient presented to the emergency department with puncture site bleeding. In this case a compressive bandage was enough to stop the bleeding. We considered ProGlide™ application failure as a procedure complication, although in all cases hemostasis could be achieved by local compression.

Other minor complications included a popliteal arteriovenous fistula without flow implications, one artery perforation and one arterial rupture, all self-limited, and one early stent thrombosis. Two patients presented hypotension and hypertension respectively, and both could be controlled with medical treatment alone. Three patients had intolerance to pain on supine position leading to premature procedure interruption.

Table 2 **Endovascular procedure characteristics**

Characteristic	n (%)
Sheath size (Fr)	
4	86 (52.1)
5	26 (15.8)
6	47 (28.5)
7	1 (0.6)
8	4 (2.4)
Arterial Punctures	
1	143 (85.1)
2	23 (13.7)
3	2 (1.2)
Vascular Access	
Common femoral artery	90 (51.7)
Superficial femoral artery	41 (23.6)
Brachial/Humeral	41 (23.6)
Axillary	1 (0.6)
Common iliac artery	1 (0.6)
Access direction	
Antegrade	52 (32.3)
Retrograde	109 (67.7)
Contrast	
Iodine-based	146 (90.7)
CO2	15 (9.3)
Segment treated	
Aorto-iliac	63 (37.5)
Femoral-popliteal	113 (67.3)
Infra-popliteal	37 (22.0)
Multiple sites	55 (32.7)
Hemostasis of puncture site	
Manual compression only	124 (74.7)
Closure Device	42 (25.3)
ProGlide™	31 (18.7)
EXOSEAL™	11 (6.6)

Outcomes

Ankle-Brachial Index (ABI) was significantly improved in post-angioplasty patients. This difference was valid for in the male and female patient population (Figure 1). The one-year amputation rate was 6.7% (n=9/134). During this period 2 patients were submitted to transfemoral amputation, 3 patients to transmetatarsal amputation and 6 patients to toe amputations. The crude one-year, and two-year mortality rate was 3.0% (4/134) and 6.7% (9/134) respectively. No procedure related mortality was observed.

Univariate and multivariate analysis of risk factors and complications

The association between risk factors and complications of the endovascular procedures is presented in table 4. Independent predictors of complications were female sex (odds ratio [OR] 2.54; 95% CI:1.04-6.2; P=0.036), hypertension (OR 2.5; 95% CI: 1.05-6.0; P=0.034) and dyslipidemia (OR 2.02; 95% CI:1.00-5.52; P=0.047). Older age (>70 years old) did not reach statistical significance (OR 2.16; 95% CI:0.92-5.03; P=0.071). In the multivariate logistic regression analysis female sex was the only variable having statistical significant association with higher complication rates (OR 2.12; 95% CI:1.07-6.71; P=0.045) (Table 4).

DISCUSSION

This work results support our practice experience that endovascular treatment for PAD can be safely adopted as an ambulatory procedure. The first studies reporting the safety of endovascular angioplasty treatments were published in the 80's of last century[6]. Since then data has accumulated for the safety, clinical and financial advantages of these procedures. Clinical outcomes have steadily improved since then, not only because of the technical evolution but also because of the growing experience and training of the vascular teams (nurses, doctors and tech-

nicians) involved in periprocedural care of these patients[7].

In our cohort, patients that were submitted to angioplasty had a significant increase in the mean values of ABI from 0.52 to 0.71 ($p<0.001$) (Figure 1). A recent study identified increases in ABI>0.15 after endovascular procedure as an independent predictor for freedom from major amputation after 1 year[8]. We did not find this correlation in our cohort. Nonetheless, hypertension and previous stroke were significantly associated with failure to achieve increase of ABI>0.1 (data not published). The one-year amputation rate was 6.7% and the all-cause mortality rate was 3.0% (4/134). After two-years the all-cause mortality rate was 6.7% (9/134) in accordance with the severity of the arterial disease and its impact on survival.

Global complication rate was 19% with a very low incidence of major complications (1/168 interventions, 0.6%). In a systematic review that included 3883 procedures for PAD, Hauguel H. and colleagues found complication rates that varied from 1.5 to 33%, including minor complications such as mild pain and bruising[9]. Our rates were even lower than what has been reported by other authors although the definition of what constitutes a complication can be very heterogeneous. We have considered failure of percutaneous closure devices as a complication, although there was no consequence for the patients. Furthermore, non-compromising flow dissection may be considered as a "normal" consequence of most balloon angioplasties and not a complication by itself. We choose to consider them as long as they were considered important enough to be reported.

At the end of every procedure, hemostasis was achieved by a minimum of 15 minutes of manual compression by the attending surgeon. This was done if needed also after the application of a closure device. Some studies pointed to lower hematoma formation when vascular closure devices were used[10]. Nonetheless, more recent meta-analysis and systematic reviews seem to indicate comparable efficacy, safety and complication rates between vascular closure devices and manual compression. Moreover closure devices seem to be associated with increased rates of wound infection and thrombosis[10]. In our hospital, closure devices are usually applied for sheath diameter equal or greater than 5Fr, but the majority (64%) were used in 6Fr sheaths.

Ultrasound guided arterial puncture was routinely performed. The use of ultrasound allows real time evaluation of femoral artery atheromatosis increasing the accuracy of single puncture of the artery anterior wall and avoiding unnecessary failed punctures and hematomas[12,13]. Eighty-five percent of procedures were done with only one access site. Only one case of significant bleeding and/or hematoma was reported in our series with a very late presentation: an 89 years old female patient was brought to the emergency department 6 days after the index procedure because of leg pain and extensive bruising of the thigh. The patient was admitted and ultrasound confirmed the diagnosis of a pseudoaneurysm of the superficial femoral artery. The patient eventually needed a transfusion of packed red blood cells and the pseudoaneurysm was treated through ultrasound-guided thrombin injection.

A 65 years old male patient returned to the emergency department the day after the procedure with moderate bleeding from the puncture site. He was treated by manual compression and compression bandage. The low rate of patients that returned to the hospital (2/134 patients, 1.4%) does not support the idea that overnight stay might be a safer choice for all the patients. In fact, the majority of complications occurred during the procedure or in the next few hours afterwards.

Femoral artery is commonly the prefered access for

Table 3 **Endovascular procedures complications**

	n (%)
Global Complications	32 (19)
Arterial dissection	14 (8.3)
Arterial perforation/rupture	2 (1.8)
Patient intolerance to pain	2 (1.8)
Bleeding	1 (0.6)
Early stent thrombosis	1 (0.6)
Arteriovenous fistula	1 (0.6)
Other	8 (4.8)
ProGlide™ failure	5 (15.2)*
Hypertension	1 (0.6)
Hypotension	1 (0.6)
Allergy to contrast	1 (0.6)

** % of total ProGlide™ systems used.*

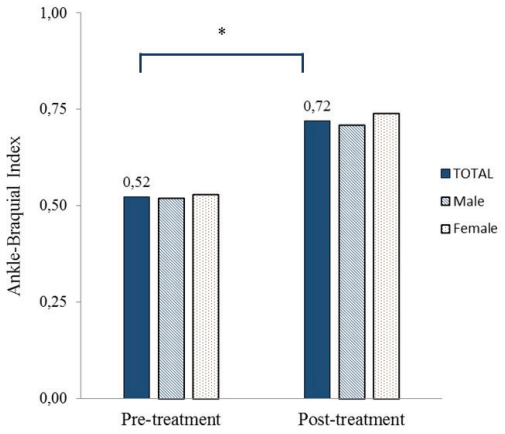

Figure 1 *Variation in Ankle-Brachial Index of patients submitted to angioplasty for the whole population, and for the subgrups of male and female patients. * p<0.001*

endovascular procedures, mainly because of technical ease and patient tolerance[13,14]. The use of alternative accesses is related to the need for multiple access points in complex procedures[15]. In our series the use of brachial accesses represented 23.6% of punctures. No complications were found related to this access point.

Risk factors associated with complication in the univariate analysis were sex (odds ratio [OR] 2.54; P= 0.036), hypertension (OR 2.5; P=0.034) and dislipidemia (OR 2.02; P=0.047). Being over 70 years old had no noticeable impact despite a trend towards statistical significance. No association was found between the severity of disease and complications. Other vascular risk factors like diabetes did not show correlation with procedural complications. Other studies showed similar dissociation between diabetes and complications and concluded that diabetes should not be a contraindication for same day endovascular procedures[16]. Nonetheless, it is well known that diabetes increases the odds of amputation and mortality by several fold[1]. One year amputation rates and all-cause mortality didn't differ between sex.

Female sex was the only variable that remained significantly associated with complications in the multivariate logistic regression analysis (OR 2.12; P=0.045). The significance of these results is not completly understood but sex disparities have been discribed in previous retrospective studies[17,18,19]. Factors pointed as responsible, have been older age at presentation, delayed diagnosis and atypical presentations of disease. In fact, in our study, the female population is on average 10 years older than the male population and has more advanced disease as evaluated by the Leriche-Fountaine classification, and has a higher burden of diabetes. On the other hand, women are less likely to be smokers or ex-smokers (Table 5). More studies are needed on this subject to better clarify the significance of these results.

We acknowledge there are several limitations of this study, such as its retrospective nature and potential patient selection bias. Patients were selected and proposed for endovascular intervention at the outpatient clinic appointment - meaning that the attending surgeon could consider predetermined characteristics known to minimize complications (e.g. avoiding uncooperating or extremely frail patients). Nevertheless our results seem to support individual criteria that were used. We cannot exclude that other minor complications like small hematomas or limited bleeding went unnoticed after the procedure. Same day discharge or overnight stay might be different in terms of approach leading to a more broad selection of patients that could in some cases need to be admitted on ward. In our group of patients none had to be admitted to the ward after intervention.

Many patients need close surveillance of their wounds with frequent surgical debridement. There is a close articulation with the diabetic foot clinic, so that the ward' beds are available for the more complex cases that may need additional IV antibiotics, large debridements or negative pressure therapy for instance.

CONCLUSION

Endovascular procedures for PAD carried out in ambulatory units are feasible and safe. Complications are

Table 4 **Demographic and clinical factors associated with endovascular procedures complications: univariate and multivariate regression analysis.**

	Complications	Complications (univariate regression analysis)		Complications (multivariate regression analysis)	
	n (%)	OR (95% CI)	p	OR (95% CI)	p
Sex: Female	10 (26.3)	2.54 (1.04-6.2)	0.036	2.12 (1.07-5.21)	0.045
Age >70	15 (21.4)	2.16 (0.92-5.03)	0.071		
Dyslipidemia	14 (11.9)	2.02 (1.00-5.52)	0.047	2.08 (0.84-0.52)	0.116
Hypertension	15 (12.0)	2.50 (1.05-6.0)	0.034	2.42 (0.96-6.13)	0.062
Diabetes mellitus	15 (14.7)	1.16 (0.5-2.78)	0.73	2.08 (0.82-5.26)	0.121
Obesity	1 (5.6)	3.40 (0.43-27.0)	0.11		
CKD	1 (6.7)	2.73 (0.34-21.7)	0.32		
CPOD	1 (5.9)	3.17 (0.40-7.14)	0.25		
IHD	7 (13.2)	1.30 (0.51-3.31)	0.58		
Stroke	2 (11.7)	1.43 (0.31-6.67)	0.65		
Smoking History	11 (11.6)	1.97 (0.85-4.6)	0.11		

CKD – Chronic Kidney Disease; CPOD – Chronic Pulmonary Obstructive Disease; IHD – Ischaemic Heart Disease; OR – Odds ratio;

usually mild and detected early after the procedure. In our cohort of patients, only female sex was associated with procedural complications. Further research is needed to establish quality benchmarks that should be implemented and followed in order to improve results and patient safety.

Table 5 **Demographic and clinical factors of male and female patients**

Factor	Male (n%)	Female (n%)	p
Age (years) Mean ± SD	65.3 ± 9.6	74.0 ± 10.8	<0.01
Severity of PAD (Leriche-Fontaine)			
Stage I	3 (2.4)	0 (0.0)	<0.01
Stage II	73 (58.4)	7 (20.6)	
Stage III	6 (4.8)	1 (3.0)	
Stage IV	43 (34.4)	26 (76.5)	
Dyslipidemia	76 (72.4)	21 (70.0)	0.798
Hypertension	79 (75.2)	22 (73.3)	0.832
Diabetes mellitus	54 (51.4)	23 (76.7)	0.014
Obesity	12 (11.4)	3 (10.0)	0.826
CKD	10 (9.52)	4 (13.3)	0.546
CPOD	13 (12.4)	0 (0)	0.043
IHD	32 (30.5)	10 (33.3)	0.766
Stroke	9 (8.57)	2 (6.67)	0.737
Smoking History	77 (73.3)	2 (6.67)	<0.01

PAD – Peripheral Artry Disease; CKD – Chronic Kidney Disease; CPOD – Chronic Pulmonary Obstructive Disease; IHD – Ischaemic Heart Disease; OR – Odds ratio.

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REVIEW ARTICLE

SCREENING OF THE ABDOMINAL AORTIC ANEURYSM: COST-EFFECTIVENESS AND HEALTH BENEFITS

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Abstract

Introduction: *The abdominal aortic aneurysm (AAA) is a nosological entity whose main complication is rupture, being associated with a high mortality rate. The early identification of this pathology in groups at risk through an ultrasound screening program can have benefits based on elective surgical repair before the rupture occurs, preventing death. In Portugal, no screening program for this aneurysm is implemented. Our goal is to review the impact of screening among risk groups on the global and aneurysm-related mortality rates, quality of life, cost-effectiveness and its applicability in Portugal.*

Materials and methods: *We performed a narrative review of the literature on screening for AAA.*

Results: *There is evidence that screening is effective in reducing aneurysm-related mortality in men aged 65 and over, but not in reducing overall mortality. In addition, the implementation of a screening program in several countries appears to be cost-effective in at-risk populations.*

Discusssion and conclusion: *Data from epidemiological studies on AAA suggests that the implementation of an AAA screening program, based on ultrasound, in men aged 65 and over, can bring health benefits and be cost-effective. Even so, taking into account that all the studies took place outside Portugal, the possibility of generalizing the results to the portuguese population is not clear.*

Keywords: *Aortic Aneurysm, Abdominal; Prevalence; Mass Screening*

INTRODUCTION

An aneurysm is defined as a localized dilatation of an artery greater than or equal to 50% of its normal diameter.[1] The abdominal aortic aneurysm (AAA) can be found in any area of the abdominal aorta, but it occurs most often in the infrarenal aorta, close to the bifurcation of the iliac arteries. As the diameter of the infrarenal aorta is usually about 2 cm, AAA is considered to be a dilatation corresponding to a diameter greater than or equal to 3.0 cm in the antero-posterior or transverse planes, which corresponds to more than two standard deviations above average.[2]

The main risk factors for the development of this aneurysm are male gender, age ≥ 65 years, smoking at least 100 cigarettes throughout life, family history in 1st degree of AAA, existence of other arterial aneurysms, arterial hypertension and dyslipidemia.[3-6] The main independent risk factor for the occurrence of its rupture is the size of the aneurysm.[7] Based on epidemiological studies carried out in developed countries, it is estimated that the prevalence of AAA is 4-9% in men and 1% in women.[8,11] In Portugal, there are only two studies on its prevalence. The first, provided by the screening program "Aorta não avisa", developed by the Portuguese Society of Angiology and Vascular Surgery, estimated a prevalence of 2.2% for men over 60 years of age and 3.94% for men over the age of 65 years. This study was conducted in every district capitals of Portugal.[12] The other study was conducted in 2016 in a primary care setting in a northern Portugal city and estimated a prevalence of 2.1% in men aged 65 years and over.[13]

This disease is, in most cases, asymptomatic before rupture, being detected as an incidental imaging finding in more than 80% of cases.[14] Its main complication is rupture, which constitutes a medical emergency, as it is associated with a high mortality rate (80%), requiring immediate surgical correction.[15] Most patients who suffer AAA rupture die before arriving at the hospital and of those who arrive there and undergo emergent surgical correction, only 50% survive.[16,17] The implementation of screening programs in risk groups for AAA - men aged ≥ 65 years - may contribute to the reduction of related deaths, through early detection, follow-up and elective surgical correction.[12] In addition, AAA has a natural history that favors its screening, such as its prevalence, the fact that it is almost always asymptomatic before rupture, has a prolonged latency period from its onset to rupture and an elective surgical treatment with low mortality rate and complications.[16,17] Besides that, the screening test is abdominal ultrasound, which is an economical and safe diagnostic and screening tool, with a sensitivity and specificity close to 100% for AAA detection.[18-21]

The ratio between the number of AAAs treated and the total population in Portugal is among the lowest described in the literature. Bearing in mind that the criteria for surgical intervention are similar in different countries, the paucity in the treatment of this pathology could be justified by the deficit of diagnosis or by the low prevalence of the disease in the Portuguese population.[13] However, the two prevalence studies of AAA in Portugal have shown that this is apparently superior to the prevalence of AAA in other European countries where the screening is already implemented, like the United Kingdom, with a reported prevalence of AAA of 1.18%,[22] and Sweden where the screening detected an AAA prevalence of 1.7%.[23]

Bearing this in mind, it is probable that the deficit in diagnosis becomes the most likely answer for the low ratio between the number of treated aneurysms and the total population in Portugal.[12,13]

Bearing these facts in mind, the purpose of this work is to review the impact of AAA screening in risk groups, in terms of mortality rate due to AAA and global mortality, quality of life, cost-effectiveness and applicability in Portugal.

MATERIAL AND METHODS

We conducted a classic review on screening for AAA, through research and consultation of randomized clinical trials, guidelines, meta-analyzes and review articles published to date in the main databases and sites of evidence-based medicine, such as MEDLINE / PubMed, Web of Science and Cochrane, using the Mesh Terms "Abdominal Aortic Aneurysm", "Prevalence" and "Mass Screening".

RESULTS

Impact of screening on AAA mortality and global mortality

In the early 1990s, the first large-scale randomized clinical trials (RCT) were conducted to determine the benefits of implementing AAA population-based screening programs. Two studies took place in the United Kingdom (Chichester[11] and MASS[24]), one in Denmark (Viborg[25]) and another in Australia (Western Australia[26]). Abdominal ultrasound was the test used to screen for AAA in all these RCTs. All of these studies included men aged 65 and over, with the exception of the Chichester study[11] which included men and women over 65 years. Participants were randomized into two groups: a group invited to perform abdominal ultrasound to screen for AAA and a control group that was not invited for screening. All these clinical trials were non-blind. The primary outcome of all trials was the AAA-related mortality rate. The all-cause mortality rate was a secondary outcome. The cost-effectiveness of screening was a secondary outcome in two of the four RCTs (MASS[24] and Viborg[25]). No significant loss from follow-up was reported in any of these studies. Table 1 summarizes the conditions for implementing each study and its main results.

In the Chichester RCT[11], the prevalence of AAA in the group undergoing screening was 7.6% in men, 1.3% in women and 4% in total. At 5 years of study, there was a 42% reduction in ruptured AAA-related mortality in males in the intervention group, compared to males in the control group.[27] However, in the long term, there was a decrease in the benefits of the screening program, with a 21% reduction in AAA-related mortality at 10-years of follow-up[28] and only 11% at 15 years.[11] Thus, this RCT detected a significant reduction in AAA mortality in the male screening group compared to the control group at 5 and 10 years of follow-up, but not at 15 years. The decline over time in the difference in the AAA mortality rate between the groups was expected, justified by the aging of the patients selected at the beginning of the study (the youngest patients after 15 years of this study were 80 years old). Because of this, the majority of patients with criteria for elective surgical correction had a high surgical risk at the end of the study, so they did not undergo surgical repair. Consequently, there was a significant increase in the AAA mortality rate in the group screened after 15 years of follow-up. There were no statistically significant differences in the AAA mortality rate in females. The overall mortality rate was similar between groups, in both genders, both at the beginning and at the end of the study.[11,27]

In the MASS RCT,[24] the prevalence of AAA in the intervention group at the end of the study was 4.9%. The reduction in the AAA-related deaths was 53% at 4 years of follow-up, [8] 47% at 7 years, [29] 48% at 10 years[29] , and 42% at 13 years (end of follow-up).[24] Therefore, the effectiveness of screening in reducing mortality from AAA has remained similar over time in this RCT. As for the impact of

AAA screening on global mortality, there was only a slight, though not significant reduction of 3%, either at the beginning of the study,[8] or at the end of it.[24] The number needed to screen (NNS) was 216, that is, the number of men needed to screen to prevent one death from AAA was 216.[24]

In the Viborg RCT,[25] the prevalence of AAA in the screened group was 4.2%. There was also a significant reduction in mortality from AAA, with a reduction of 66% over the 14 years of follow-up. As at the end of the MASS study, there was a slight, though not significant reduction in the overall mortality rate - 2%.[25]

In the Western Australia RCT,[26] the prevalence of AAA in the screened group was 7.2%. At the end of the 13 years of follow-up, there was a no significant reduction of only 8% in mortality from AAA.[26] This can be explained by the age of the participants, with individuals up to 83 years of age, low acceptance rate of AAA screening compared to other studies, the fact that there was a high percentage of incidental diagnoses and elective treatment with success of AAA in the control group and the fact that there was a large number of individuals in the intervention group who refused the invitation to be screened and who ended up dying due to complications associated with AAA. At the end of the follow-up, there was a statistically non-significant 2% reduction in global mortality in the intervention group. The NNS was 4784.[26]

Several meta-analyzes that included the four aforementioned RCTs were carried out with the aim of assessing the impact of AAA screening on the global and AAA-related mortality rate and its cost-effectiveness. The Cochrane Review meta-analysis by Cosford et al [30] estimated a significant reduction in AAA-related mortality in men (OR 0.60; 95% CI 0.47-0.78), but not in women (OR 1.99; 95% CI 0.36-10.88), although only one of the trials included females. There were no statistically significant differences in the overall mortality rate in men (OR 0.95; 95% CI 0.85-1.07) and in women (OR 1.06; 95% CI 0.93-1.21). The authors of this meta-analysis concluded that screening for AAA in men over 65 years of age has strong evidence for reducing AAA-related mortal-

Table 1 **Summary of the characteristics and results of large-scale randomized clinical trials related to screening for abdominal aortic aneurysm**

	Chichester[11]	MASS[24]	Viborg[25]	Western Austrália[26]
Number of participants	15 775	67 800	13 500	41 000
Gender	Men and women	Men	Men	Men
Age (years)	65-80	65-74	65-73	65-83
Date of study beginning (year)	1988-1990	1997-1999	1994-1998	1996-1998
Publication year	2007	2012	2010	2016
Number of years of follow-up	15	13	14	13
Acceptance rate in the screening group	68.4%	80.2%	76%	63.4%
Prevalence of AAA	4% (7.6% H; 1.3% M)	4.9%	4%	7.2%
Screening of AAA	Annual: 3-4.4 cm 3/3M: 4.5-6 cm	Annual: 3-4,4 cm 3/3 M: 4.5-5.5 cm	Annual: 3-5 cm	No indication for screeening
Elective AAA repair	≥ 6 cm	≥ 5,5 cm	≥ 5 cm	No indication for elective repair
Reduction of the relative risk of death related to AAA - Screened vs. Not Screened	11%	42%	66%	9%
Reduction of the relative risk of global death - Screened vs. Not Screened		3%	2%	2%

** AAA- Abdominal Aortic Aneurysm; M- Months.*

ity, but the same cannot be said for women. On the other hand, this screening has not been shown to cause a reduction in mortality from all causes, which may be an argument against its implementation.

The meta-analysis by Lindholt et al [31] analyzed the effects of AAA screening in the medium term (3.5-5 years) and long term (7-15 years). A significant decrease in the AAA-related mortality has been reported in the medium term (OR 0.56; 95% CI 0.44-0.72) and in the long term (OR 0.47; 95% CI 0.86-1, 02). A significant reduction in global mortality was demonstrated in the long term (OR 0.94; 95% CI 0.92-0.97), but not in the medium term (OR 0.94; 95% CI 0.86-1.02). The authors of this meta-analysis concluded that screening for AAA in men over the age of 65 years is effective in significantly reducing AAA-related mortality in the medium and long term, with the effects on global mortality being more tenuous and only significant in the long term.

Takagi et al 2010 and 2018 meta-analyzes analyzed the long-term impact of AAA screening (≥ 10 years).[32,33] The 2010 meta-analysis[32] demonstrated a significant reduction in AAA-related mortality in the screened group (HR 0.55 and OR 0.55; 95% CI 0.36-0.86), but failed to demonstrate a significant decrease in mortality from all causes. In this meta-analysis, the reduction in mortality from AAA was estimated at 4 per 1000 individuals, a value higher than that established in Cochrane's systematic reviews for screening programs already implemented, such as breast cancer (0.7 / 1000)[34] and colorectal cancer (1.5/1000).[35] In the 2010 meta-analysis, [32] the calculated NNS was 238, which is lower than that estimated in other screening programs already implemented, such as breast cancer (NNS= 1339)[34] and colorectal cancer (NNS= 671).[35] The 2018 meta-analysis assessed only the impact on all-cause mortality. Unlike 2010, the 2018 meta-analysis showed a significant, albeit slight, decrease in overall mortality (OR 0.973; 95% CI 0.95-0.997).[33]

Taking into account the promising results of RCTs and meta-analyzes, AAA population screening programs were implemented in Sweden, the United Kingdom and the United States of America (USA). Between 2006 and 2014, a AAA ultrasound screening program was gradually implemented in men aged ≥ 65 years in Sweden. The response rate to the call for screening was 84%, with the participation of more than 250 thousand people. The prevalence of AAA detected was 1.5%. The implementation of this program provided a significant reduction in the AAA-related mortality rate, more specifically a reduction of about 4% per year of screening. The NNS was 667, which for a population of 9.5 million corresponds to the prevention of 90 premature deaths from AAA per year and a gain of 557 years adjusted for quality of life (QALY).[36]

In the United Kingdom, in 2008, a national AAA screening program was implemented. This program was aimed at all men aged ≥ 65 years who were invited to perform AAA ultrasound screening. The response rate to the call in the first 5 years of screening was 78.1%, with the participation of more than 700 thousand individuals. The prevalence of AAA after 5 years of screening was 1.34%, well below the prevalence found in the MASS study, which was also carried out in the United Kingdom, but started in 1997. This decrease in prevalence may reflect important changes in lifestyle, such as changes in diet, regular physical exercise and decreased smoking habits, as well as better control of cardiovascular risk factors, such as hypertension and dyslipidemia. The number of screenings required to identify an aneurysm was 78 in caucasians, 154 in black people and 431 in asians.[22,37,28]

In 2007, Medicare® started an AAA screening program in the USA applied to beneficiaries of this insurer, offering a unique ultrasound screening to all 65-year-old men who have smoked at least 100 cigarettes throughout their lives and to all 65-year-old men and women with a family history of AAA. To assess the impact of this screening program, the intervention group was compared to three control groups that were not screened: a group of 70-year-old men, another group of 76-year-old men and, finally, a group of 65-year-old women. The variables under study were AAA surgical repair rates, AAA rupture rate, and all-cause mortality rate. The follow-up lasted one year. The program had a low performance, with only 1% of eligible users being screened. The impact of the program was modest, with no significant changes in the rate of repair of AAA, its rupture and overall mortality. This can be explained by the low adhesion of the eligible users to the screening program. [39,40]

Cost-effectiveness of the AAA screening program

The MASS[24] and Viborg[25] were the first to demonstrate the cost-effectiveness of implementing the AAA population-based screening program. The MASS trial proved that this screening was cost-effective and with potential for improving cost-effectiveness over time, with a cost per year of life gained estimated by £41,000 in the fourth year of study, £14,000 in the 7th year and £7,600 after 10 years of study. [29] By the 7th year of the study, it had already a lower cost than the amount referred to as acceptable for health interventions in the UK (£25,000 per year of life gained). [41] Viborg study was equally cost-effective, with an estimated cost of €157 per year of life gained and €179 per QALY at the end of the study, which is markedly lower than what is generally considered cost-effective. [25]

The metanalysis of Cosford et al from Cochrane[30] demonstrated that the cost-effectiveness of screening in men aged 65 years and over seems to be acceptable. The authors of the meta-analysis by Lindholt et al[31] concluded that the AAA screening seems to be cost-effective; however they admit the existence of differences between populations from different geographical areas (such as the prevalence of AAA) , influencing the cost-effectiveness of this screening.

The national screening program implemented in

the UK was effective in the first 5 years of implementation and is expected to remain effective unless the prevalence of AAA in subsequent years drops below 0.35%. [22,37] More recently, the cost-effective ratio of this program was assessed again, 10 years after its implementation, remaining cost-effective over a long term, with an estimated cost of £5,758 per year gained and £7,370 per QALY, well below the limit recommended by the National Institute for Health and Care Excellence (NICE), which is £20,000-30,000 per QALY. [42] In addition to the United Kingdom, the AAA national screening program implemented in Sweden demonstrated to be cost-effective, with a cost-effectiveness ratio of €7770 per QALY. [36]

Recent studies have demonstrated changes in the epidemiology of AAA over time, namely a decrease in the prevalence, which can be explained by the reduction of smoking habits and a better control of cardiovascular risk factors. However, the basis for the current implementation of a cost-effective AAA screening program can be questioned by this epidemiological change. The AAA screening program implemented in the UK in 2008 confirmed that screening remains cost-effective, even with a much lower prevalence of AAA compared to the MASS study that was applied several years earlier in the same country (1.34% vs. 4.9%).[24,37] The AAA screening program was also cost-effective in Sweden, where the prevalence of registered AAA was much lower than the announced by large-scale RCTs.[36] Another study conducted by Svensjö et al in 2014 aimed to determine the efficacy and cost-effectiveness ratio of single screening of men aged 65 years and over taking into account recent epidemiological changes in the prevalence of AAA. In this study, a comparative analysis was performed between a group of men aged ≥ 65 years invited to screening the AAA (intervention group) and a group not invited to screening (control group) using the Markov model. The data used on the natural course of AAA (rate of surgical repair and rupture) were based on data from large-scale randomized clinical trials. The prevalence of AAA in the follow-up group (1.7%), the rate of endovascular surgical treatment (50%), the outcome of the repair and the costs were based on contemporary population data. In this simulation study with the Markov model, and using the NICE cut-off to consider a health intervention cost-effective in the UK (£25,000 per year of life gained), the unique ultrasound screening of AAA in men aged 65 and over continued to be cost-effective given, regarding contemporary epidemiological context of this pathology (prevalence of 1.7%). In fact, Svensjö et al found that single screening in men ≥ 65 years of age remains cost-effective up to a prevalence of 0.5%. For Svensjö et al, in addition to being economically viable, AAA screening in this at-risk population continues to show important health benefits, with an absolute risk of death from AAA of 15.1 per 10,000 screened individuals, a 42% reduction in relative risk of death related to AAA and an NNS of 530. [23]

Impact on quality of life and disadvantages of screening

The two main disadvantages of AAA screening are psychological stress and complications of elective surgical correction.

Psychological stress is an important disadvantage in individuals undergoing screening without AAA or with a small AAA that does not require elective surgical repair. This idea is supported by an RCT conducted in Denmark[43] which demonstrated that individuals undergoing AAA screening had a lower QOL (quality of life) score than the control group not screened. However, as soon as the individuals undergo screening, and found that they had no AAA, the QOL score value increased significantly, becoming higher than the value presented by controls, suggesting that this screening causes transient anxiety even in people without AAA. For individuals who underwent screening and found to have a small AAA without indication for elective treatment, they maintained a high and significantly higher QOL score than the control group. [43]

Complications of elective surgical treatment of AAA are common and may be severe. In addition, elective surgery may result in the need for prolonged hospitalization and death. Several RCTs estimated a perioperative mortality rate (30 days after surgical correction) between 0. 5 and 2. 0% for endovascular surgical repair and between 2. 4 and 5. 8% for open surgical repair, still well below the mortality rate caused by rupture of AAA. [43,48]

***Guidelines* recommendations**

There are several guidelines for AAA screening. The recommendations of the most recent guidelines are summarily presented in Table 2. All guidelines contain recommendations about surveillance intervals for aneurysms without indication for elective surgery, emphasizing the need for elective surgical correction for AAAs with a diameter ≥ 5.5 cm.

With the exception of the Canadian Task Force on Preventive Health (CTFPHC),[49] all clinical guidance standards contain recommendations regarding surveillance intervals for aneurysms with diameters smaller than the threshold size for elective surgery. However, there is no consensus on the surveillance interval to be implemented in the follow-up of patients with AAA. These guidelines make different recommendations when compared to each other. Considering that aneurysms between 3 and 5.4 cm in diameter have a low risk of rupture, the indication for elective surgery defended by the European Society of Vascular Surgery (ESVS),[50] Society for Vascular Surgery (SVS) [7] and USA Preventive Services Task Force (USPSTF) [51] is for diameters equal to or greater than 5.5 cm, with the exception of the American College of Cardiology/American Heart Association (ACC/AHA), which considers a 5.0 cm of diameter the reference for surgical correction. [52] In addition, all these guidelines consider an annual growth rate greater than 1 cm as reference criteria for elective surgery. Despite this, the mean size of the aneurysm at the time of repair is not homogenous among

Table 2 **Summary of recommendations from the most recent guidelines on screening for abdominal aortic aneurysm and their strengths of recommendation and levels of evidence taking into account the respective taxonomy of each guideline**

Guideline	Country	Recommendations	Classes of recommendation	Evidence Level
ESVS 2019 [50]	Netherlands	Recommends single AAA screening through abdominal ultrasound to all men aged 65 and over	I	A
		Recommends against screening for AAA in women who do not have a family history in first-degree of AAA	III	B
		Men and women aged 50 years and over who have a family history in first-degree of AAA can be considered for screening at intervals of 10 years	IIb	C
		All men and women with a peripheral arterial aneurysm can be considered for screening every 5-10 years	IIb	C
SVS 2018 [7]	USA	Recommends single abdominal ultrasound screening for all men and women aged 65 to 75 who have smoked at least 100 cigarettes in their lifetime	1	A
		Suggests screening AAA for all men and women over 75 who have smoked at least 100 cigarettes in their lifetime, who are in good general health and who have never been previously screened	2	C
		Suggests screening AAA for all men and women with a family history in first-degree of AAA, and this screening should preferably be done between 65 and 75 years old or, if not possible, after 75 years old, as long as they have good general health state	2	C
CTFPHC 2017 [49]	Canada	Recommends single AAA screening by abdominal ultrasound in men aged 65 to 80	Weak	Moderate
		Recommends against screening in women of any age	Strong	Very Low
		Recommends against screening in men over the age of 80	Weak	Low
USPSTF 2014 [51]	USA	Recommends single AAA screening by abdominal ultrasound to all men aged 65 to 75 who have smoked at least 100 cigarettes in their lifetime	B	
		Recommends against screening in women, with no smoking history, family history of AAA and without other risk factors for AAA	C	
		Men and women between 65 and 75 years of age who have never smoked can be considered for screening, taking into account their medical and surgical history, family history of AAA and the presence of other risk factors for AAA	D	
ACC/AHA 2005 [52]	USA	Recommends single screening for AAA through physical examination and abdominal ultrasound in men aged 60 years and over who are brothers or children of patients with AAA	I	B
		All men aged between 65 and 75 years who have smoked at least 100 cigarettes in their lifetime should be considered for screening through physical examination and abdominal ultrasound.	IIa	B

** AAA- Abdominal Aortic Aneurysm; ACC/AHA- American College of Cardiology/American Heart Association; CTFPHC- Canadian Task Force on Preventive Health Care; ESVS- European Society of Vascular Surgery; USA- United States of America; SVS- Society for Vascular Surgey.*

all countries, in part due to their reimbursement systems, which are equally important for this decision in comparation with guidelines and clinical evidence in these countries.[53] The SSVS and ESVS agree on the surveillance intervals, recommending an ultrasound surveillance every three years for AAAs between 3.0 and 3.9 cm, annually for diameters between 4.0 and 4.9 cm and every three to six months for values between 5.0 and 5.4 cm. [7,50] The ACC/AHA recommends annual surveillance between 3.0 and 4.9 cm.[52] Finally, the USPSTF recommends ultrasound surveillance every three to twelve months for aneurysms between 3.0 and 5.4 cm in diameter. [51] None of the scientific societies recommend any kind of surveillance for diameters below 3 cm.

DISCUSSION AND CONCLUSION

The AAA is a potentially fatal disease if not diagnosed and treated early. Observing this, several studies have been developed in order to evaluate the health benefits and cost-effectiveness of a populational screening program for this pathology.

There seems to exist a robust evidence that AAA screening reduces aneurysm mortality in men ≥ 65 years of age, as demonstrated by three of the four RCTs and their respective meta-analyses. In addition, the analysis of the AAA screening program implemented in Sweden showed effectiveness in reducing AAA-related mortality by 4% per year of screening.

On the other hand, apparently, there is no evidence of this screening being effective in reducing overall mortality in this at-risk population. Thus, it is likely that the decrease in mortality from AAA observed with screening may not directly contribute to the reduction of overall mortality. The slight reduction in all-cause mortality found in some meta-analyses may be justified by a better control of cardiovascular risk factors associated with the lifestyle to which screening participants were subjected.

On the other hand, there also seems to exist evidence that this screening has greater health benefits than population screenings already implemented, such as breast cancer screening and colorectal cancer screening, taking into account the NNS and the reduction in the specific cause mortality rate estimated by multiple studies.

Regarding the cost-effectiveness of AAA screening in men ≥ 65 years of age, two of the RCTs demonstrated that screening programs implemented in the UK and Denmark were cost-effective. The meta-analyses by Cosford et al and Lindholt et al also demonstrated the cost-benefit of this screening. In the last decade, there has been a decrease in the prevalence of AAA, with a reduction to less than 2% in men aged ≥ 65 years, according to national screening programs in the United Kingdom and Sweden. Although the reduction in the prevalence of this disease may question the cost-effectiveness of the implementation of this screening program, several studies had shown that it has remained cost-effective in the UK and Sweden, even for lower prevalence values than those found in large-scale RCTs. [36,37] Thus, even considering this new epidemiological paradigm, AAA screening programs continue to be cost-effective and clinically relevant in men aged 65 years and more, up to a prevalence of 0.5%. [23]

There does not seem to be evidence to support AAA screening in women; however we must remember that only a large-scale RCT was performed on women and given the low prevalence of AAA in this sex, this trial may not achieved enough power to detect any benefit of screening in women. So, further studies are needed to assess the efficacy of screening in this gender.

Considering the effects on the overall mortality rate and cost-effectiveness, there seems to be robust evidence supporting the implementation of an AAA screening program in Portugal directed to men aged ≥ 65 years, since the prevalence of this nosological entity in men of this age group in this country is similar to the prevalence that was estimated in the studies that took place in other countries. [12,13] Thus, we consider that this screening program is likely to be viable, cost-effective and clinically relevant in Portugal. However, an important limitation of this conclusion is the fact that all data are obtained from studies that took place outside Portugal. In addition to the prevalence of the disease, many other factors may influence the health benefits and the cost-effectiveness ratio of the program, which also depends on the particularities of each health system. Thus, the possibility of generalizing the results for the Portuguese population is unclear, although the data seems to support its implementation in men aged ≥ 65 years. Considering the limitations identified, a cost-effectiveness analysis based in data from Portugal should be performed to confirm our assumptions and to substantiate the need of an AAA screening program implementation in Portugal, in men aged ≥ 65 years.

Conflicts of interest
We declare, as authors, that we do not have conflicts of interest.
Sources of funding
We do not request any source of funding.

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CASE REPORTS

PERCUTANEOUS TRANSAXILLARY TRANSCATHETER AORTIC VALVE IMPLANTATION

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Abstract

The transaxillary (TAX) approach for transcatheter aortic valve implantation (TAVI) results in comparable short and long-term clinical results compared to the transfemoral (TF) approach. However, adequate closure of the axillary artery is the most critical issue when performing the percutaneous approach. Compared to surgical transaxillary approach, the percutaneous approach was used only in selected cases due to this closure limitation.

In the present paper, we aim to demonstrate the feasibility of implanting the CoreValve Evolut Pro transcatheter heart valve via percutaneous transaxillary approach and make a literature review of procedure particularities and outcome.

We describe the case of a patient with severe aortic stenosis in the presence of small calibre and severely calcified femoral arteries. A CoreValve Evolut Pro 26 was successfully implanted percutaneously through the left axillary artery.

Percutaneous transaxillary transcatheter aortic valve implantation is a feasible and safe alternative in patients who have suboptimal iliofemoral vessels.

Keywords: *Percutaneous transaxillary approach; Percutaneous subclavian approach; Transcatheter aortic valve implantation*

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a well-established treatment option for patients with severe aortic stenosis (AS), specially in those who are at high or extreme surgical risk for conventional surgical aortic valve replacement (SAVR). Interestingly, in recent years its potential benefit has been proven even in lower risk patients. In 2011 and 2016, meta-analyses of randomized controlled trials (PARTNER and PARTNER 2) comparing TAVI to SAVR in high and intermediate-risk patients indicate a survival benefit of TAVI compared to surgical aortic valve replacement[1]. In accordance with this, in May 2019, two trials (PARTNER 3 and EVOLUT Low Risk) showed that TAVI was at least equivalent or even better (in rehospitalization) to SAVR in patients who were at low surgical risk[2,3].

The most commonly used access route for TAVI is the femoro-iliac access (transfemoral approach, TF), because it is minimally invasive and it is feasible under conscious sedation in a totally percutaneous fashion. Nevertheless, the TF approach is not possible in all patients warranting alternative access techniques for TAVI. In this regard, the transapical, direct aortic, transcarotid, transcaval, and transaxillary (TAX) implantation routes currently serve as alternative access options. However, the relative 'invasiveness' of one alternative approach compared with another is subject to

debate. Invasiveness relates to the need for a surgical cut-down, general anaesthesia (GA), vascular or heart lesion required for delivery system crossing, and potential impact on the other major systems such as the cerebral, respiratory and renal systems.

Since its introduction, the transaxillary approach results in comparable short and long-term clinical results compared to the TF approach. The short distance to the valve landing zone allows good control of the delivery system. Moreover, data suggests superiority of the TAX access compared to other non-TF access approaches[4].

The axillary artery can be reached either by surgical cut-down or by direct percutaneous puncture.

A truly percutaneous approach without the need for surgical cutdown is feasible and can be done under local anaesthesia with conscious sedation. Adequate closure of the axillary artery is the most critical issue when performing the percutaneous approach, because, due to the anatomical conditions, in most instances manual compression of the puncture site is not efficient. Thus, detailed planning of the vessel puncture and precise usage of closure devices (pre-closure) is of utmost importance[4].

In the present paper, we report a patient with severe aortic stenosis in the presence of small calibre and calcified femoral access. A CoreValve Evolut Pro 26 was successfully implanted percutaneously through the left axillary artery. We also make a literature review of procedure particularities and outcome. MEDLINE database was used to search for eligible studies published up to November 10, 2019.

CASE REPORT

The patient was an 80-year-old woman (height, 152 cm; weight, 54 kg) with symptomatic (NYHA class II) aortic disease, comprising moderate stenosis and severe regurgitation.

Her medical history included arterial hypertension, dyslipidemia, former smoking, alveolar hypoventilation syndrome, sleep apnea and cerebrovascular disease, with a history of stroke without sequelae in 1996.

The patient had concomitant coronary artery disease with stenting of the left anterior descending and the right coronary arteries 4 years prior to the latest presentation. The last one was occluded over 1 year ago.

The echocardiography showed mild dilatation of left cardiac chambers, mild and moderate mitral and tricuspid regurgitation, respectively; moderate aortic stenosis with severe aortic regurgitation conditioning a peak transvalvular pressure gradient of 50 mmHg and a mean transvalvular pressure gradient of 27 mmHg (Fig. 1). Left ventricular systolic function was preserved.

The chest computed tomography (CT) scan showed a calcified ascending aorta, which contraindicated SAVR (Fig. 2). Considering the patients' severe peripheral vasculopathy and the fact that CT scan of the great arteries demonstrated

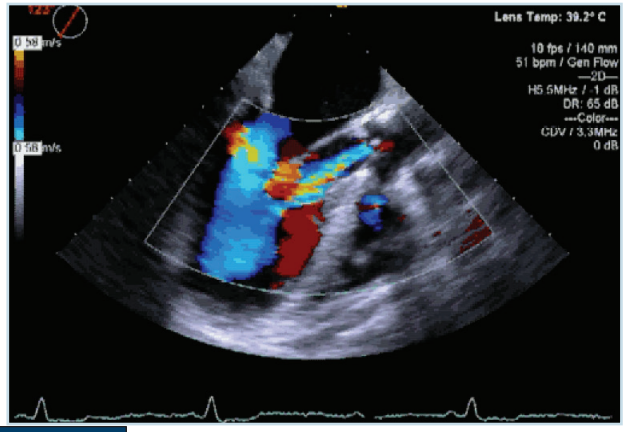

Figure 1 *Ecocardiography before TAVI.*

iliofemoral artery diameters smaller than 5 mm, the femoral approach was excluded (Fig. 2). Surgical accesses using minithoracotomy or sternotomy (for transaortic or transapical approach), although not contraindicated, did not appear to be good options due to the lung disease. Moreover, thinking about the patient's cerebrovascular disease, with a history of stroke and impairment of vertebral and carotid blood flow in imaging studies, the team did not favor the carotid approach. Moreover, it is a technique with which this team has no experience. On the other hand, the axillary arteries had a good caliber, were not calcified nor tortuous. For these reasons we opted for a completely percutaneous axillary access (Fig. 2). The patient provided detailed informed written consent.

In accordance with our institutional protocol, the patients were jointly evaluated by a Heart Team composed of a cardiac surgeon, an interventional cardiologist, the imaging cardiologist, and a cardiac anesthesiologist. In line with the statement of the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), transcatheter aortic valve implantation was preferred because of the high risk score, the patients' comorbidities and aortic calcification (logistic Euroscore of 13.7 % and Society of Thoracic Surgeons risk of mortality of 9.2 %).

The anesthetic goal was to be the least invasive possible, hence choosing to perform sedation while maintaining spontaneous ventilation. After admission to the procedure room, we monitored O2 saturation, conventional ECG tracing and noninvasive blood pressure. BIS® and INVOS® were used to monitor anesthetic depth and detect ischemic brain complications (aware of its limitation as it only allows regional monitoring).

After initial preparation, fentanyl 0.05 mcg was administered and a target controlled infusion of propofol (Schneider model infusion for BIS value of 40-60) was started. During the procedure the patient maintained spontaneous breath and oxygenation was given by nasal cannula. The goals in terms of oxygenation / ventilation were: O2 Sat

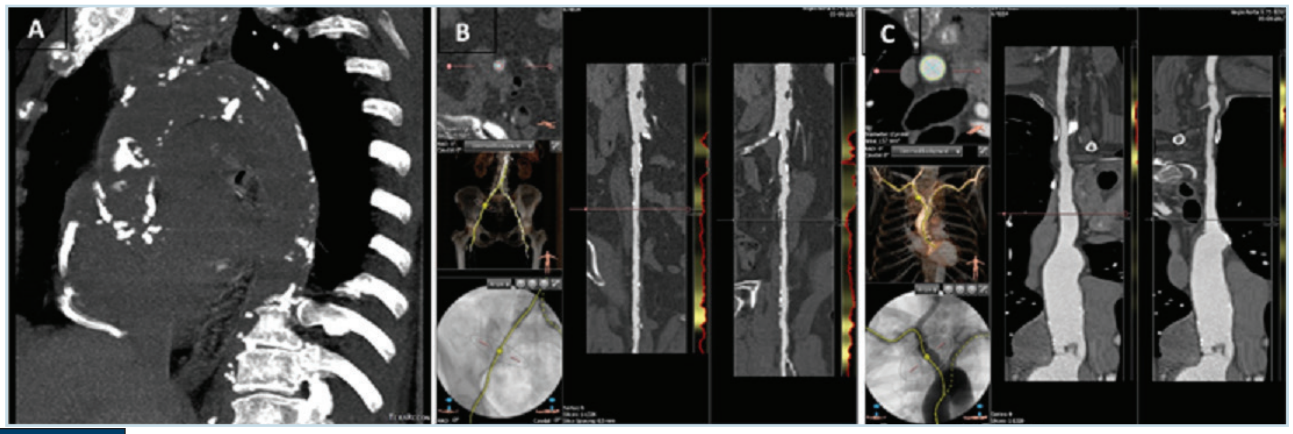

Figure 2 *A) Heavy calcification of the ascending aorta. B) Inadequate iliofemoral access. C) Subclavian artery bilateral (lateral view).*

> 95% and nasal capnography value between 35-40mmHg.

A 6-Fr pigtail catheter was inserted through the right femoral artery for hemodynamic monitoring and landmark aortic angiography.

From the left femoral artery a 6 Fr guiding catheter was placed through which a guidewire was passed to the left subclavian / axillary. For safety, through this guidewire a 6mm diameter peripheral balloon (matching the size of the subclavian artery proximal to the puncture site) was kept in place and inflated when changing the introducers for the valve delivery system and at the end of the procedure to obtain the so-called 'dry sealing'. This transitional area between the subclavian and axillary arteries is difficult to compress, so the second femoral access increases the safety of the procedure, minimizing blood loss and controlling with the balloon a possible hemorrhagic complication.

Some centers advocate exteriorization of the guidewire introduced by the femoral through the left radial artery, giving more support in case of vascular complication requiring the placement of a stent. However we considered that, in this case, exteriorization of the guide was not necessary.

A truly percutaneous approach was achieved without the need for vascular surgery. The approach of the left axillary artery was performed with the aid of ultrasound and fluoroscopy (Fig. 3).

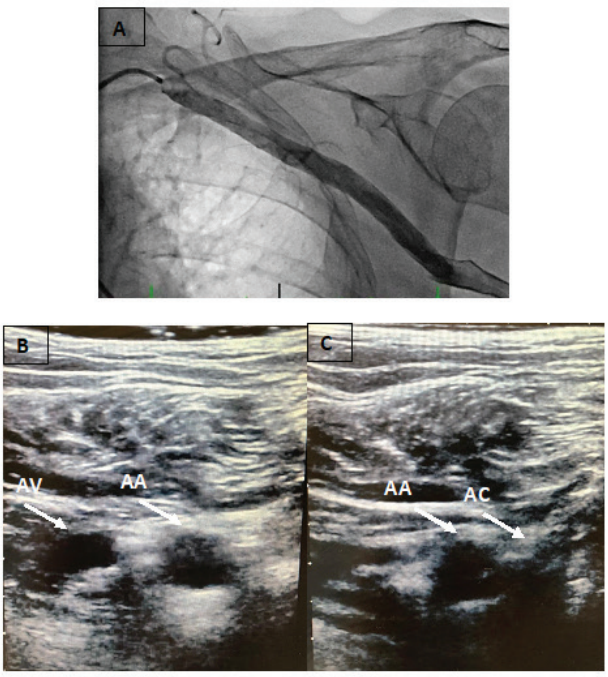

Figure 3 *A) Angiography of the axillary artery pre-procedure; B) and C) ultrassonography of axillary artery (AV Axillary vein; AA axillary artery; AC Axillary catheterization).*

Local infiltration with 20ml lidocaine 2% was performed and vascular puncture was obtained at the first attempt. Two Perclose ProGlide® vascular closure systems were placed. After initial placement of a 6 Fr introducer, progressive dilatations were performed until a 16 Fr sheath was introduced. The fact we were able to place a 16 Fr sheath in this artery allowed us to advance with the Evolut Pro system, the latest generation of this valve, designed to minimize the risk of paravalvular regurgitation - which was of interest in this particular patient who had mainly aortic insufficiency.

Aortic valvuloplasty was performed using a 22-mm balloon (NuMED) and rapid pacing was successfully made over the wire without complications. A 26-mm CoreValve Evolut Pro prosthesis was carefully inserted over a super-stiff guidewire and retrogradely implanted under angiographic and fluoroscopic guidance. Immediately after CoreValve Evolut Pro deployment, angiography of the ascending aorta was performed to assess the patency of the coronary arteries and the presence and location of any paravalvular leakage (Fig.4).

During the procedure heparin was administered for an activated coagulation time > 200sec, which was reversed at the end of the procedure with protamine sulfate.

Procedural success was obtained. After valve de-

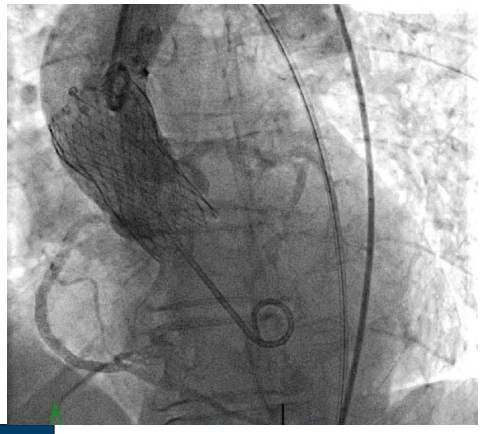

Figure 4 *Final angiographic result after obtaining the vascular access.*

ployment the mean transvalvular aortic gradient dropped to 2 mmHg with negligible aortic insufficiency (Fig. 5). The patient presented a transient prolongation of QRS compatible with complete left bundle branch block, which reversed to sinus rhythm with a QRS widening of 112 sec at the end of the procedure.

There were no problems in achieving hemostasis. Following satisfactory valve deployment, the delivery system was removed. The peripheral angioplasty balloon, previously placed through the left femoral artery, was advanced to the proximal subclavian during sheath removal to inflate and prevent bleeding, achieving a 'dry sealing'. To assess the effectiveness of vessel occlusion, the plethysmography wave was observed.

Angiographic control of the left axillary access showed good closure with 2 ProGlide® (Fig. 6).

The duration of the procedure was 180 minutes. During the procedure the patient remained hemodynamically stable (mean blood pressure > 65mmHg), however at the time of valve positioning the patient had an episode of hypotension with 58mmHg systolic blood pressure with repercussion on cerebral oximetry, reversed with 100mcg of phenylephrine. The fluid supplement was <1L, and paracetamol (1gr) was administered at the end of the procedure to complement postoperative analgesia. All vascular accesses were previously anesthetized with a mixture of 2% lidocaine with 0.375% Ropivacaine.

The patient's hemoglobin after the procedure was 9.6g/dL compared with 10.9 g/dL pre-procedure. The hemoglobin value reached a minimum of 8.4 g/dL on the 4th day of hospitalization.

The patient was mobilized during post-procedure day 1.

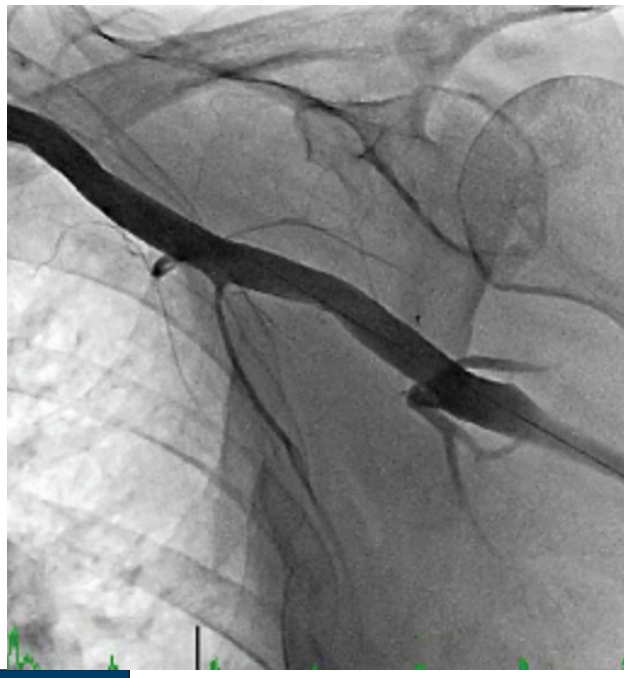

Figure 6 *Angiography of axillary artery after sheath removal.*

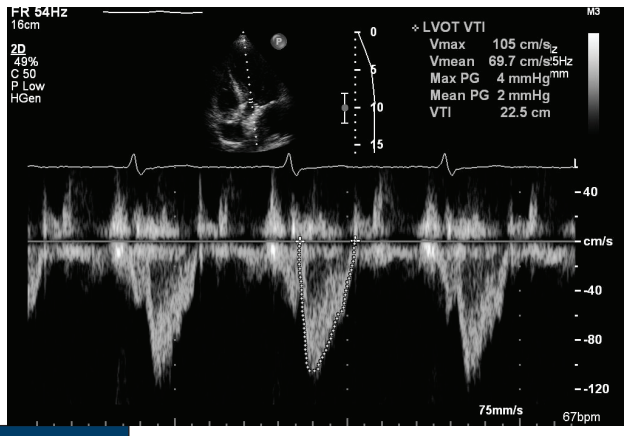

Figure 5 *Ecocardiography after TAVI.*

Concerning the patient medication, during hospitalization the patient maintained acetylsalicylic acid (100 mg) and discontinued clopidogrel (suspended prior to the procedure) because of postoperative anemia and a history of easy bruising. The patient was discharged with iron supplementation and folic acid.

No complications occurred and the patient was discharged from hospital 6 days after valve implantation.

The patient did not require permanent pacemaker implantation. A transthoracic echocardiography on the discharge day confirmed an excellent result with no intra or paravalvular regurgitation, and patient's reported symptoms improved. In follow-up consultation 3 months after the procedure the patient has no symptoms for daily activities and had no periprosthetic leak on transthoracic echocardiography.

DISCUSSION

The standard approach for TAVI is through the transfemoral retrograde route, because it is minimally invasive and it is feasible under conscious sedation in a totally percutaneous fashion. Although significant technical improvements in sheath diameter and delivery catheter design have been achieved, the transfemoral approach is contraindicated in case of vessel diameter less than 5.5 mm (plus 1mm if calcification). In addition, the transfemoral approach should be considered cautiously in case of severe tortuosity or calcification of the femoral or iliac arteries or of the distal aorta, previous iliofemoral surgery or stent implantation, or in patients with an aneurysm of the thoracic or abdominal aorta. Under these conditions, choosing the transfemoral access for TAVI increases the risk of periprocedural and postprocedural vascular complications, with a negative impact on clinical outcome[5].

Since alternative TAVI approaches have not been studied in a comparative fashion, the choice depends mainly on the experience and judgment of the heart team. Clearly, in selected cases the TAX access can serve as an alternative route.

The most obvious advantage of a direct TAX access for TAVI is: that it maintains the left ventricular integrity (in contrast to the transapical access), comes without opening the chest cavity (in contrast to a direct aortic and transapical access) and, when compared with the transfemoral approach, transaxillary access has the advantages of providing a less remote access to the aortic valve. The valve delivery catheter covers a shorter distance, and avoids bending in the tortuosities of the iliofemoral axis and of the thoracoabdominal aorta, with the potential to improve the control of the prosthesis during deployment. Therefore, the transaxillary approach may theoretically allow for a more accurate device positioning, reducing the incidence of paravalvular leak and the development of complete heart block requiring permanent pacemaker implantation[6].

Nevertheless, a possible limitation of the TAX approach is the assumed risk of vascular complications being frequently associated with significant bleeding, transfusion and renal failure. All these factors are proven to be independent predictors of short and long-term mortality in patients treated by TAVI. Hence, there is some reluctance to actively pursue the TAX approach. In addition, a lower threshold for stent graft implantation can be assumed (prevention of clinical significant bleeding), possibly explaining a higher vascular repair rate compared to other transvascular approaches[4].

Importantly, the transaxillary access did not require a significant learning curve in terms of procedural duration and complication rates, allowing for a quick shift from the initial use of general anaesthesia to the current standard of local anaesthesia with sedation. In fact, the possibility of performing TAVI under local anaesthesia is a major advantage of the transaxillary over the transapical and transaortic accesses considering the risks of general anaesthesia in elderly patients who suffer from multiple comorbidities[6].

Anatomical Specificities

The axillary arteries often show little calcification and tortuosity as well as larger lumina, even in the presence of diseased iliofemoral arteries. Particular care has to be taken as the axillary arteries are more delicate than the iliofemoral ones and effective manual compression is hampered by the anatomical conditions.

The left axillary artery is generally preferred over the right one due to a more favourable implantation angle providing better axial alignment of the device with the aortic root. An angle >30° between the annular plane and the horizontal axis is regarded as a significant limitation for right-sided TAx access.[1] For the EvolutPro valve (which has 16Fr delivery catheter) the artery should have a minimum diameter of 5.5mm and for the EvolutR valve (with 14Fr delivery catheter) it should have a minimum diameter of 5mm. These measurements are considered in noncalcified arteries. In the presence of circumferential calcium the minimum size plus 1mm margin should be given.

Specific conditions such as a patent left internal mammary artery (LIMA) graft or a pacemaker are not strict contraindications, but have to be considered when evaluating patients for a TAX approach.

In the former case, verification of a sufficiently large vessel diameter (at least 7-8 mm) is recommended to ensure perfusion of the graft during the intervention. In fact, positioning an almost occlusive sheath in front of the origin of the LIMA may cause myocardial ischaemia. To prevent such an occurrence, the axillary artery diameter should be at least 7 mm, free of atherosclerotic disease, especially proximal to or at the ostium of the LIMA, and with minimal tortuosity at the origin of the LIMA. An injection of dye can confirm a good antegrade flow in the LIMA. To minimise the potential limitation in LIMA flow during TAVI, the sheath can be withdrawn distal to the origin of the LIMA immediately after the advancement of the CoreValve prosthesis across the aortic valve. Experience reports in this subset of patients confirms the safety of CoreValve implantation through the left axillary artery, with no case of periprocedural myocardial ischaemia[6].

In the case of permanent pacemaker in the ipsilateral pectoral region, the left or right transaxillary access is feasible. The artery is usually medial enough to the pacemaker pocket not to interfere with the pacemaker generator and wires[6].

Importantly, although there was an association between iliofemoral and axillary artery diameters, axillary arteries were larger (>5.0mm) in the subset of patients with small (<5.0mm) and presumably diseased iliofemoral arteries suggesting that axillary access was feasible in these patients. In general, the upper extremity arteries were also comparatively free of calcification, stenosis and tortuosity

even when the iliofemoral arteries were diseased[7].

Technical Specificities

The transaxillary approach is currently approved as an alternative to the transfemoral approach for the CoreValve.

At the moment, the transaxillary route is also being tested for the Edwards SAPIEN[6].

Apart from procedural aspects, meticulous pre-procedural assessment of the access site by contrast-enhanced CT further supports patient safety. It enables adequate patient selection for the TAX approach by 3D-reconstruction of the supra-aortic branches and the subclavian/axillary artery and exact measurements of the vessel diameter and calcification pattern.

Ultrasound guidance has advantages over palpation and fluoroscopy, allowing the operator to directly visualize the artery and its anatomy, identify the needle puncture directly and to avoid posterior vessel wall puncture, inadvertent puncture of adjacent vein, and luminal atherosclerotic and calcified plaque. The use of ultrasound results in less number of attempts, and therefore contributes in reducing the potential risk of hematoma formation and neuronal lesion. It also contributes to diminish radiation exposure. While there is a learning curve for ultrasound use, we decided to use ultrasound in combination with fluoroscopy in the access' approach for a better outcome.

Risks and complications

Given the anatomic surroundings, manual compression of the axillary artery at the puncture site is usually not effective, potentially leading to severe bleeding or even hemorrhagic shock. Moreover, the axillary artery wall properties (a markedly thinner vessel wall) make severe vessel trauma after insertion of a large introducer sheath more likely (4). Thus, prevention of major vascular complications is crucial for this approach.

Schafer et al[6], in a population of 24 high-risk patients, observed closure device failure in 29.2% of patients, who subsequently received a stent graft implantation. In all cases with failed vessel closure, the ProStar® system had been used, whereas the use of the ProGlide® system resulted in a 100% vessel closure success rate. However, in the updated study cohort (additional 76 patients) [4] vessel closure was exclusively performed with two ProGlide® systems and resulted in 94.8% successful access site closures.

Such a difference in performance of the two closure device systems seems to be specific for the TAX approach, since it has not been reported for the transfemoral approach, where use of either system has been recommended. The superiority of the ProGlide® system for the percutaneous TAX approach may be explained by the different vessel wall properties of the axillary artery (elastic type) compared to the femoral artery (muscular type) and the less traumatic nature of the ProGlide® system compared to the ProStar® system[4]. In accordance with these findings, in our patient we chose to use 2 ProGlide® for vessel closure and there were no complications.

New arterial closure devices have been launched in the market with promising results, and their application in axillary artery closure post-TAVI has been studied. Examples of this devices are the MANTA™ (a collagen-based closure device); the InSeal (a membrane-based device consisting of a self-expanding nitinol frame, a biodegradable membrane and a bioresorbable polyglycolic acid tether); and PerQseal (a flexible intravascular patch supported by a scaffold). [9,10] Another aspect is that our team´s technical success improved over time, demonstrating a clear learning curve for this technique associated with ultrasound guidance. Ultrasound allows the differentiation of non-compressible and pulsatile arteries from compressible veins, specifically identifies and avoid surrounding nerves and pleura when performing the arterial puncture, and helps avoid a calcified arterial entry point.

Outcome

In 2010, Petronio and co-workers[11] published multicenter registry data of 54 high-risk patients, in whom the CoreValve was implanted by TAX access and surgical cut-down. Procedural and clinical outcome of TAX TAVI were excellent and mortality did not differ in comparison to a TF control group. In consideration of these results, the authors concluded that the TAX approach might be more liberally chosen in cases with a difficult TF access.

In 2018, Gleason et al[12] published data results that were completely in line with these findings, supported by low complication rates and a more than acceptable long-term mortality.

More recently, the results of the CoreValve ADVANCE study[13], a multicentre prospective fully monitored TAVI study (with 96 patients), showed a higher incidence of major adverse cardiovascular and cerebrovascular events (13.5% vs. 7.9%, p=0.05) compared to patients treated by TF TAVI, but they also had a higher mean logistic EuroSCORE (data presented at ESC 2012, Munich). However, for individual endpoints, differences in 30-day rates did not reach statistical significance.

A meta-analysis[14] encompassing 618 patients treated by TAX and 3,886 patients treated by TF TAVI reported no difference in 30-day mortality, stroke, major vascular complications or life-threatening bleeding despite a higher mean logistic EuroSCORE and a higher prevalence of coronary and peripheral artery disease in the TAX group.

With these results we can assume that the outcome between the transaxillary and transfemoral approach is at least similar. However in the vast majority of patients evaluated in these studies vascular access was surgically approached. In our case report and bibliographic review, we want to point out that the percutaneous approach does not interfere with the patient's outcome and does not add perioperative morbidity.

Percutaneous approach

Shafer [8] in 2012 described for the first time the true percutaneous TAX approach in a population of 24 high-risk patients (mean logistic EuroSCORE I 35.3±22.8%). Device success was 95.8% (23/24) and 30-day mortality rate was 8.4% with no major adverse cardiac and cerebrovascular events and no major vascular complications according to the Valve Academic Research Consortium (VARC2) criteria.

In 2017, Schäfer included more 76 patients[4] in whom access vessel closure was performed with two Perclose ProGlide® systems (Abbott Vascular) achieving successful closure in 94.8%; 11% required covered stent implantation, but no major access-site complications occurred. Thirty-day mortality was 6% and life-threatening bleeding 3%; no strokes were reported. There were no major vascular complications according to the VARC2 criteria. However, a lower threshold for stent graft implantation was chosen (prevention of clinically significant bleeding), possibly explaining a higher vascular repair rate compared to other transvascular approaches. No injury of the neuronal plexus or any other neuronal complications were experienced in this study.

With the surgical approach, we believe that surgical exposure of the vessel is more time consuming and could be associated a higher complication rate (hematoma, pseudoaneurysm, ipsilateral arm neurologic deficit, and stroke). Moreover, this exposure has an added risk of infectious complications. However, the worldwide experience for large bore percutaneous axillary artery access remains relatively small. More recently, the Axillary Registry to Monitor Safety was completed. Axillary Registry to Monitor Safety was a prospective multicenter registry of percutaneous upper extremity access for mechanical circulatory support devices. This registry, implemented across 10 institutions in the United States, was developed to evaluate the procedural and short-term safety of percutaneous axillary access for Impella devices (Abiomed, Davers, MA) and intra-aortic balloons pump and represent the largest prospective series to date. Formal publication of the completed dataset is expected soon, and an interim analysis of the first 80 patients has been presented, suggesting very favorable bleeding and complication rates and no cases of ischemic upper extremity or significant neurological injury. [15]

Anesthetic management

General anesthesia is associated with potential complications, particularly cardiovascular and respiratory-related. Patients referred to TAVI are elderly and many have comorbidities which place them at higher risk with general anesthesia [16]. Need of inotropic support seems to be higher in centers performing GA.

However, general anesthesia can be advantageous in patients who have hemodynamic compromise or other periprocedural complications when patient intubation is needed for more extensive rescue procedures[17].

As TAVI centers have gained experience, minimal approaches have been employed whereby the procedure is completed percutaneously on an awake patient, with only local anesthesia (LA) and monitored anesthesia care (MAC). The type of the anesthetic management has increasingly switched from GA to LA, especially in European centers. Sedation shortens procedural time, time to ambulation and hospital stay duration. In addition, the use of vaso-pressors in sedation is not as frequent as in GA procedures, which can be attributed to the vasodilating effects of the anesthetic agents. Furthermore, emergency intubation and switching to GA can be achieved in the procedure room to surgically handle cardiac or vascular complications should they arise during TAVI. LA has the unique benefit of real-time evaluation of the patient's mental status and cognitive function. This approach has been shown to be safe and effective and is potentially cost-saving: the cost for general anesthesia is eliminated, the patient is mobilized sooner, length of time in the intensive care unit (ICU) is decreased, and discharge is sooner[18,19,20].

Previous data showed that incidence of vascular complications is unrelated to the anesthetic technique. Transfusions, in the same way, present a similar percentage when GA or LA is used.[19]

In this case we used a moderate sedation with propofol, which translated into hemodynamic stability and maintenance of ventilatory dynamics throughout the procedur. Brain oxygenation also remained constant by INVOS® monitoring. This type of monitoring helps us determine the impact on the cerebrovascular system.

Although there were no complications to register, the anesthetic team was prepared to approach the airway at any time and convert to a general anesthesia.

CONCLUSION

The availability of alternative vascular accesses for TAVI should not modify the principle for which this procedure was conceived, that is the attempt to implant an aortic prosthesis in the least invasive fashion possible.

Percutaneous transaxillary transcatheter aortic valve implantation is a feasible and safe alternative access in patients who have suboptimal iliofemoral conduits. The ultrasound may become an indispensable tool for safe achievement of vascular access.

The ProGlide® system was effective in vascular closure, with no periprocedural and postprocedural vascular complications. Neuronal or respiratory complications were not experienced too.

A truly percutaneous approach is feasible and can be done under local anaesthesia with conscious sedation. This promotes hemodynamic stability, lower perioperative morbidity and increases patient safety and satisfaction.

Conflict of interest:

There is no affiliation, interpersonal relationship or financial interest from the authors that may constitute a source of bias or conflict of interest.

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CASE REPORTS

ASCENDING AORTA PSEUDOANEURYSM PRESENTING AS A PRESTERNAL PULSATILE MASS

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Abstract

Sixteen months after the replacement of the ascending aorta an 80-year-old lady was referred to our center for a presternal pulsatile mass. Computed tomography scan showed an ascending aorta pseudaneurysm extended through the sternum and filling the subcutaneous space. Surgical correction was successful. Specific surgical considerations of this case are discussed.

INTRODUCTION

Pseudoaneurysm formation after ascending aorta or aortic root replacement by a vascular prosthesis is a consequence of the dehiscence of the suture between the prosthesis and the aortic wall. The dehiscence causes the extravasation of blood that can be initially contained by remnants of the adventitia as well as by adhesions of the mediastinal structures avoiding a fatal haemorrhage. However, the formation of a pressurized chamber with blood flow in communication with the aortic lumen tends to expansive growth, which can cause numerous complications[1,2].

We present the case of a patient who underwent an ascending aortic aneurysm resection and aortic valve replacement who consulted for an asymptomatic, rapidly growing pre-sternal pulsatile mass.

CASE REPORT

An 80-year-old lady diagnosed with aortic regurgitation and ascending aortic aneurysm was referred for valve replacement and aneurysm resection. During the intervention, the femoral artery and the right atrium were cannulated. Immediately after initiation of cardiopulmonary bypass a retrograde aortic dissection progressed proximally into the aortic arch and ascending aorta. Deep hypothermic circulatory arrest was instituted. The suprasinusal ascending aorta was resected and a Dacron graft was sutured distally. The graft was cannulated, clamped, and antegrade perfusion was established. An aortic valve bioprosthesis was implanted, and the vascular graft was sutured to the proximal aorta.

The postoperative evolution was complex, requiring two reoperations for bleeding and prolonged mechanical ventilation. The patient also presented cerebellar ischemic stroke of possible cardioembolic origin secondary to episodes of paroxysmal atrial fibrillation. Persistence of residual dissection of the aortic arch and descending thoracic aorta was observed.

The patient was discharged and one year later consulted for retrosternal pain and sudden onset dyspnea. A computed tomography scan was performed and pulmonary embolism was ruled out. The clinical condition was diagnosed as hypertensive crisis.

Four months later she consulted for a pre-sternal tumour and her general practitioner performed a fine-needle puncture aspiration of the lesion, obtaining a bloody-looking fluid. The patient was referred to our centre. Upon admission, a 6x5 cm pulsatile pre-sternal mass was observed, with no signs of inflammation (Figure 1A). A computed tomography scan demonstrated an aortic pseudoaneurysm with leakage of contrast at the proximal graft anastomosis. The pseudoaneurysm extended through the sternum towards the subcutaneous plane (Figure 1B).

Due to the fragility of the patient, it was decided to treat only the pseudoaneurysm without correcting the persistent false

lumen at the level of the aortic arch. Before re-sternotomy, the subclavian artery and the femoral vein were cannulated. The patient was connected to the extracorporeal circulation circuit, cooled to 26 degrees (Figure 2) and afterwards a short circulatory arrest was instituted. The pre-sternal pseudaneurysm was incised and the sternum was opened. After removing some thrombotic material, adherences were dissected and cardiopulmonary bypass was re-stablished. A point of bleeding was identified between the graft and the proximal aorta which was corrected without aortic clamping. The postoperative course was uneventful.

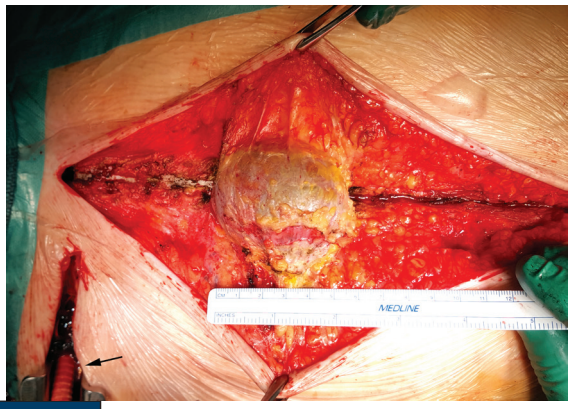

Figure 2 *Intraoperative image. The pre-sternal extension of the pseudoaneurysm is appreciated before the opening of the thorax (6 x 5 cm). The arrow indicates the cannulation of the right subclavian artery using a Dacron graft for connection to the cardiopulmonary bypass circuit.*

DISCUSSION

Risk factors for pseudoaneurysm formation after ascending aortic replacement include infection, some genetic aortopathies, the use of formaldehyde sealants, and acute dissection[1,2]. The time lapse between surgery and pseudoaneurysm formation is highly variable from one month up to two decades[2-4]. Due to their growth tendency, pseudoaneurysms can compress the surrounding structures and cause symptoms such as chest pain, dyspnea, heart failure and superior vena cava syndrome[1,2] In some cases, pseudoaneurysms may be asymptomatic and constitute incidental findings observed during a radiological examination. Exceptionally, they can erode the sternum or infiltrate through the sternotomy when bone healing is incomplete and appear as a pulsatile subcutaneous mass in the pre-sternal area[3-6]. The approach to ascending aortic pseudoaneurysms generally requires peripheral cannulation and deep hypothermia with a brief circulatory arrest before re-sternotomy to prevent bleeding[1,2]. Except in cases with an active infection, direct closure of the dehiscence between the aorta and the vascular graft may be enough to correct the problem[2]. The case described represents an unusual complication of ascending aortic surgery and highlights the need for close follow-up with imaging tests in these patients, especially when they have undergone surgery for acute dissection or a genetically based aortopathy.

Author Disclosure Statement: The authors declare that they have no conflict of interest

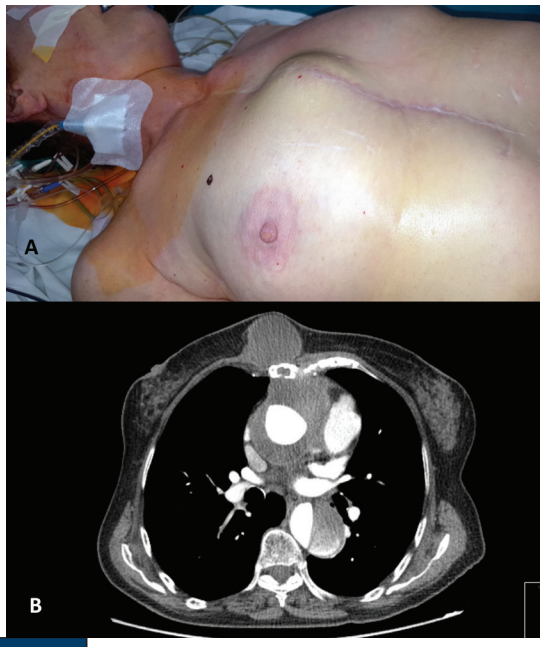

Figure 1 *A: Pre-sternal mass at the level of the middle third of the sternum. B: Computed tomography. Mediastinal pseudoaneurysm is direct contact with the sternum. Blood passes the sternum through the midline storing under the skin. Descending thoracic aorta dissection persists.*

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CASE REPORTS

BRONCHOPLASTY FOR A TYPICAL CARCINOID: AN UNUSUAL CHOICE FOR AN UNUSUAL PATIENT

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Abstract

Primary carcinoid tumours of the lung are rare tumours and when typical are associated with a benign behaviour and should be classified as low-grade neuroendocrine tumour/carcinoma.

A 67-year old HIV-positive female was admitted due to a typical carcinoid tumour on the distal third of the main left bronchus, occupying two thirds of the lumen.

Given she was HIV positive, had a moderately compromised lung function and in order to minimize surgical events, postoperative complications and to maximize postoperative lung function, the authors opted for a bronchoplasty using a patch.

The surgery was uneventful and as the resected area of the bronchus was small, patency was assured and the distortion was minimal.

During extubation, resistance was felt upon trying to the remove the bronchial blocker. After performing bronchoscopy it was seen that the loop at the end of the bronchial blocker was caught in the patch suture. Fortunately it was possible to cut the loop, freeing the blocker and avoiding a redo surgery.

There were several possible options, ranging from left pneumonectomy, superior left lobe sleeve lobectomy, resection of the left main bronchus with a Y bronchial reconstruction or a bronchoplasty using a patch.

The chosen technique has several advantages: From an oncological standpoint a typical carcinoid is indolent and needs only a clear resection margin. From a functional standpoint lung tissue resection was prevented. From a surgical standpoint it is less challenging, easy to perform and less prone to surgical events, essential considering the particular case of an AIDS patient.

INTRODUCTION

Primary carcinoid tumours of the lung are rare tumours which comprise approximately 0.5 to 5% of all lung malignancies in adults and roughly 20 to 30% of all carcinoid tumours.[1] Typical carcinoid tumours are associated with a fairly benign behaviour and should be classified as low-grade neuroendocrine tumour/carcinoma (G1)[2]. Treatment of choice for lung carcinoids is surgical resection, but there is still debate about the type of surgery, especially for peripheral tumours[3]. Surgery in HIV patients is associated with more postoperative complications, rapid progression, disease recurrence and poorer postoperative survival. Furthermore these patients have a higher risk of lung cancer and respiratory infections and therefore the rationale for lung sparing techniques is reinforced. Preoperative optimization and/or control of the infection improves surgical outcomes. [4]

CASE REPORT

A 67-year old HIV-positive female was admitted to a tertiary hospital with the diagnosis of pneumonia. A CT scan confirmed the diagnosis showing a "consolidation area in the right lower lung". Bronchoscopy revealed a spherical tumoral lesion in the distal third of the left main bronchus pedicled in the membranous part, occupying two thirds of the lumen (figure 1). Bronchoalveolar lavage showed an infection by Pneumocistis jiroveci and cytomegalovirus. As such patient had AIDS and started anti-infective agents. Histology of the tumour was suggestive of typical neuroendocrine carcinoid tumour (G1).

After resolution of the infection, the patient was referred to the authors' hospital.

PET DOTANOC revealed a single lesion in the left main bronchus (figure 2).

Patient was submitted to surgery with left lung exclusion by using a single lumen orotracheal tube and a bronchial blocker (ARNDT-COOK), as due to the patient's small size it wasn't possible to direct a double lumen orotracheal tube towards the main bronchus.

A muscle sparing left thoracotomy was performed. After isolation of the left main bronchus a patch of the membranous part of the left main bronchus with 14x10 mm was resected, which corresponded to the tumour. The resection was guided with bronchoscopy using its image and light as markers. Extemporaneous analysis of resection margins was performed, and as they were free of tumour,

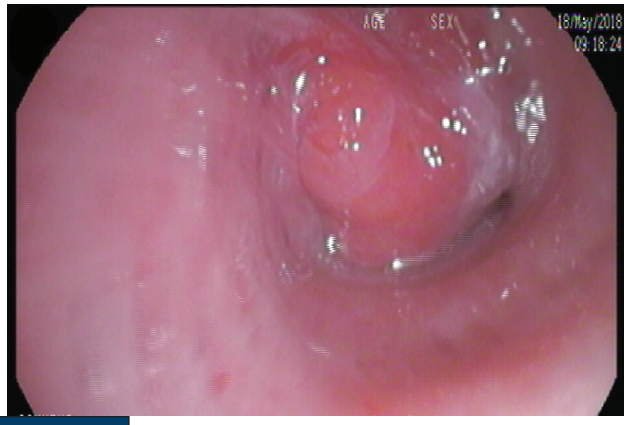

Figure 1 *Preoperative bronchoscopy showing a spherical tumoral lesion in the distal third of the main left bronchus pedicled in the membranous part, occupying two thirds of the lumen*

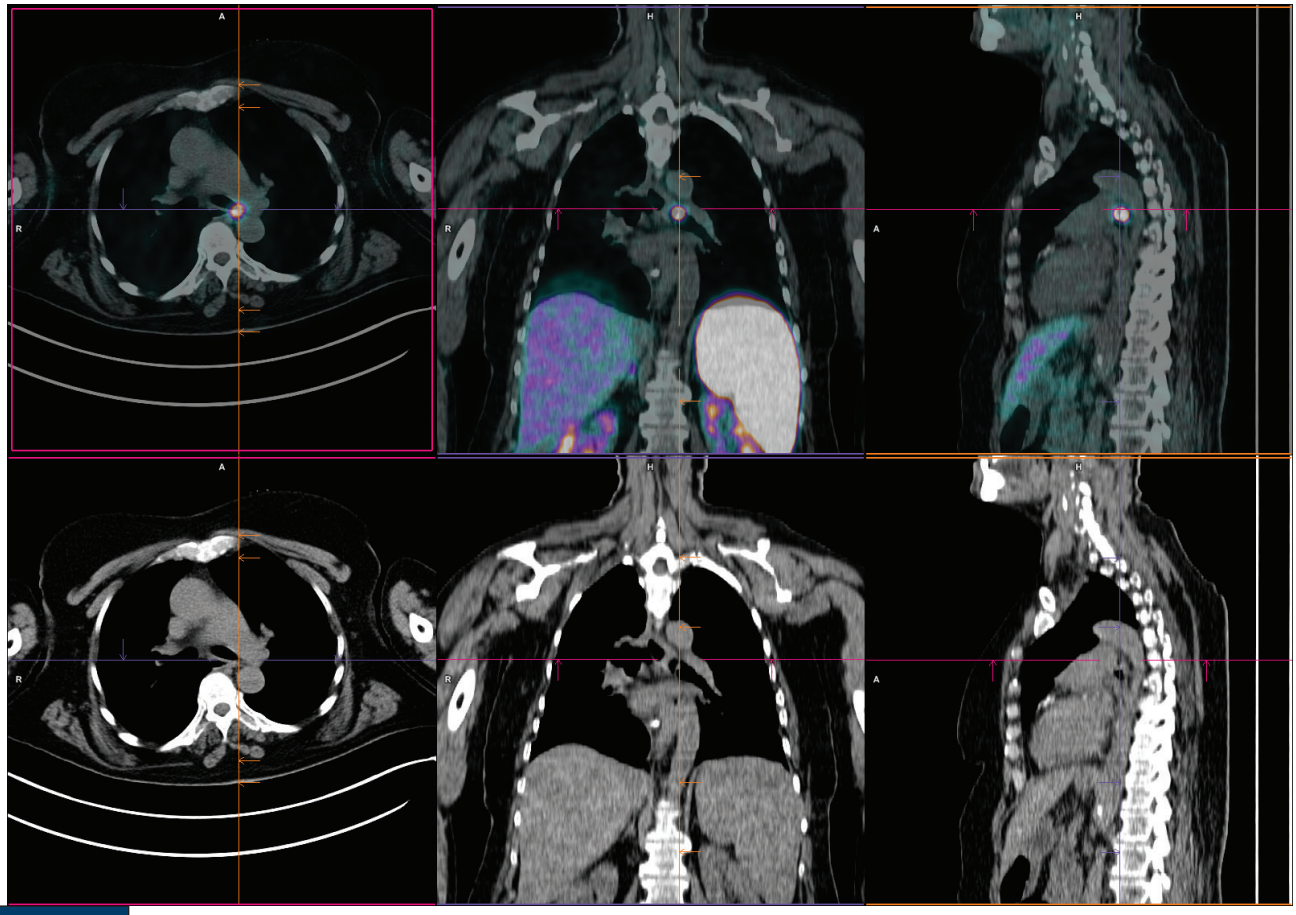

Figure 2 *PET-DOTANOC showing a single lesion in the left main bronchus.*

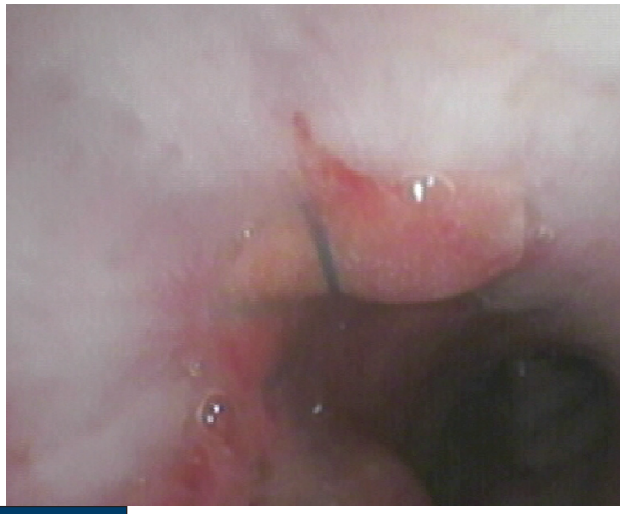

Figure 3 *Follow-up bronchoscopy three months after surgery showing left main bronchial patency.*

the bronchial blocker was pulled back and the left main bronchus was reconstructed with a duramater patch (DuraGen Plus®) using a parachute technique with a single continuous suture of Prolene™ 4/0. The surgery ended uneventfully.

During extubation, resistance was felt upon trying to the remove the bronchial blocker. After performing bronchoscopy it was seen that the loop at the end of the bronchial blocker was caught in the patch suture. With the help of a 2.8mm endoscopic scissors, the pneumologist cut the loop, freeing the blocker. The patient was extubated and awakened with no further incidents.

The postoperative period was uneventful and the patient was discharged on the 7th day.

Bronchoscopy before discharge showed the dura patch in the medial wall of the left main bronchus with no signs of dehiscence.

Follow-up at the first, third and every three months after that with bronchoscopy and CT scan, showed left main bronchial patency, no evidence of suture dehiscence and no signs of recurrence.

At this time the patient has 2 years of follow-up and is clinically well.

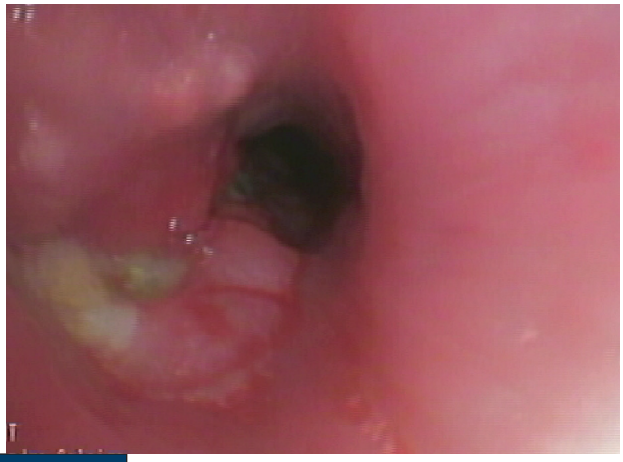

Figure 4 *Follow-up bronchoscopy one year after surgery showing left main bronchial patency, no evidence of suture dehiscence and no signs of recurrence.*

DISCUSSION

In the reported case, there were several possible options, ranging from left pneumonectomy, superior left lobe sleeve lobectomy, resection of the left main bronchus with a Y bronchial reconstruction (as the tumour was located on the opposite wall to the left superior bronchus) or a bronchoplasty using a patch.

The authors opted for this last technique for several reasons: from an oncological standpoint a typical carcinoid is an indolent, with a very good long term survival, and doesn't require an extensive resection, needing only a clear resection margin.[2,5] From a functional standpoint lung tissue resection was prevented. As there was a minimal left main bronchial area resected, patency was assured and there was minimal risk of distortion. On the other hand, from a surgical standpoint it is less challenging, easy to perform and less prone to surgical events. This is of greater importance in patients with AIDS, minimizing surgical complications and reducing postoperative morbidity.[4]

Despite this, an unforeseen and extremely rare complication occurred. Facing this event, an endoscopic resolution was the first option, as it was less harmful and less invasive. If it failed, removal of the patch with redo surgery was warranted with all the risks associated.

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CASE REPORTS

THORACIC KIDNEY THROUGH RIGHT BOCHDALEK FORAMEN

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Abstract

Ectopic thoracic kidney corresponds to less than 5% of all renal ectopia. An asymptomatic 81-year-old woman performed an x-ray which demonstrated a heterogeneous opacity in the right hemithorax. An ultrasonography showed a thoracic right kidney, and a computed tomography demonstrated the right kidney in her right hemithorax through Bochdalek foramen. Physicians must be aware that asymptomatic patients do not need any treatment or invasive procedures due to this malformation, although surgical interventions may be due in severe cases.

Keywords *Anatomy; Kidney; X-ray; Ultrasonography; Tomography, X-Ray Computed.*

INTRODUCTION

Urinary congenital anomalies are rather common in the general population, especially kidney ectopy; however, the most common presentation is in the pelvic position, followed by renal fusion.[1] Ectopic thoracic kidney usually presents itself on the left side, mainly due to liver positioning, and occurs more often in males.[1]

Thoracic kidney ectopy is characterized by the presence of the organ above the diaphragm and inside the posterior mediastinum. It´s usually asymptomatic and preserves renal function; the initial diagnosis is often misleading, through a plain chest x-ray, presenting as an opacity, simulating pleural effusion, or a mediastinal tumor. [2]

Our aim is to report this rare malformation diagnosed with three imaging tests, x-ray ultrasonography, and computed tomography (CT), in an elderly patient and familiarize health professionals about the avoidance of, often, unnecessary interventions.

CASE REPORT

Here, we present a case of an 81-year-old woman with a history of hypothyroidism and atrial flutter, under anticoagulation. The patient had a left side mastectomy

four years before, due to breast cancer. At consult, she referred a blunt trauma to the right thorax few weeks before, which became painful. The physical examination of the painful region was normal.

An ultrasound of the painful region was performed that identified the kidney above the diaphragm, in the right hemithorax (Figure 1). Moreover, on her chart, she had a plain chest x-ray that demonstrated heterogeneous opacity in the right hemithorax basis (Figure 1). A CT was performed, that displayed the right kidney in her right hemithorax through a right Bochdalek foramen (Figure 2). Routine laboratory analysis showed a preserved renal function.

The patient was discharged with symptomatic simple analgesic, and had remission of tenderness. Follow-up with imaging techniques, as well as estimated glomerular rate filtration evaluation, was the approach of choice.

DISCUSSION

In order for the kidney to surpass the diaphragm, this superior migration should happen in the first 8 weeks of intrauterine life, as the full diaphragm development ends after this period.[3]

Embryological basis of such malformation remains unknown. An excessive ascent of kidney during migration from the sacral region to the lumbar has been proposed; this process is completed 40 days after conception. It has been hypothesized that a rapid renal ascent, prior to complete closure of the diaphragm could drive to this anomaly.[3] Alternatively, a defective/delayed closure of the pleuro-peritoneal membrane could be the leading predisposing factor;[3,4] nevertheless, co-existence of intra-thoracic kidney and congenital diaphragmatic hernia is exceptional.

Newer mechanistic insights have implicated adrenal and liver development to distort renal position. Still, none of the described mechanisms are mutually exclusive, as they can coexist.[4]

Ectopic kidney is a moderately frequent abnormality (1 in 900 patients).[5] It may occur in various patterns, with the most usual being pelvic kidney, crossed fused/unfused renal ectopia; thoracic kidney is a rare presentation, and may be located supra,infra,or trans-diaphragmatic.[6]

The first report of thoracic kidney dates back to 1940, reaching over 200 reports in the modern literature,[5] and although renal ectopia is a common form of the disease (1: 900 living births), recent reports show that thoracic ectopia accounts for nearly 2% of all renal ectopias.[6]

The left-sided thoracic kidney is a more common abnormality than the right-sided thoracic kidney (62% x 36%); in 2% of the cases, it is bilateral).[7] This can be justified, because the spleen has a weaker barrier action than the liver.Associated anomalies are exceptionally rare[5], however, a case of right intrathoracic kidney with multiple skeleton defects has been published.[7]

Moreover, both environmental and genetic factors are thought to contribute to the etiology of congenital diaphragmatic hernia (CDH) that leads to herniation. Currently, about 30% of the cases have genetic causes identified;[8] two genes that encodes transcription factors, GATA4 and NR2F2, are the most cited by multiple studies to cause CDH. [9] Despite many genetic mutations implicated in congenital kidney and urinary tract anomalies, no precise finding have been related to isolated ectopic kidney.[10]

If not recognized in the antenatal stage, it may endure silently for several years until discovered incidentally, as it is usually oligo symptomatic, like our case.[6,7] However, obstruction or vesicoureteral reflux may be present, which could cause chest pain. Moreover, the presence of the long ureter and renal vessels can exit through the Bochdalek foramen, and so, in 0.25%, a Bochdalek hernia may coexist. Other renal complications, such as nephrolithiasis or infection do not have increased incidence, and in most cases, adrenal glands are normally situated.[5] The ipsilateral ureter is habitually elongated and not ectopic.[5]

There are many valuable tests in the recognition of thoracic ectopic kidney, which are:[5,6]

- Radiograph: presents soft-tissue opacity in the lower lung zones, but it is unspecific.
- Intravenous urography: demonstrates the position, function, rotational anomaly, and signs of obstruction.
- Ultrasonography: displays the ectopic kidney through the costo-phrenic angles and above the diaphragm.
- Color Doppler study: describes the course of the ectopic kidney vasculature.
- CT: show the position, function, ureteral passage with the aid of multiplan reconstructions.
- CT angiography: describes the path of ectopic kidney vasculature
- Magnetic resonance urography: indicated in cases of impaired kidney function.
- Magnetic resonance renal angiography: evaluates ectopic kidney's vasculature.

Physician must beware of such condition in patients that perform routine x-rays, as the opacity present in the chest radiograph may be misdiagnosed as a soft tissue opacity, loculated pleural effusion, or lung/mediastinum tumor.[6]

Asymptomatic patients do not require any treatment. In cases of reversible injury, intervention is needed to release the obstruction or repair of vesicoureteral reflux; also, repositioning of the kidney may be performed, along with closure of diaphragmatic defect.[5,6]. When the injury is irreversible, and the kidney is nonfunctional, nephrectomy is the elected procedure.[6]

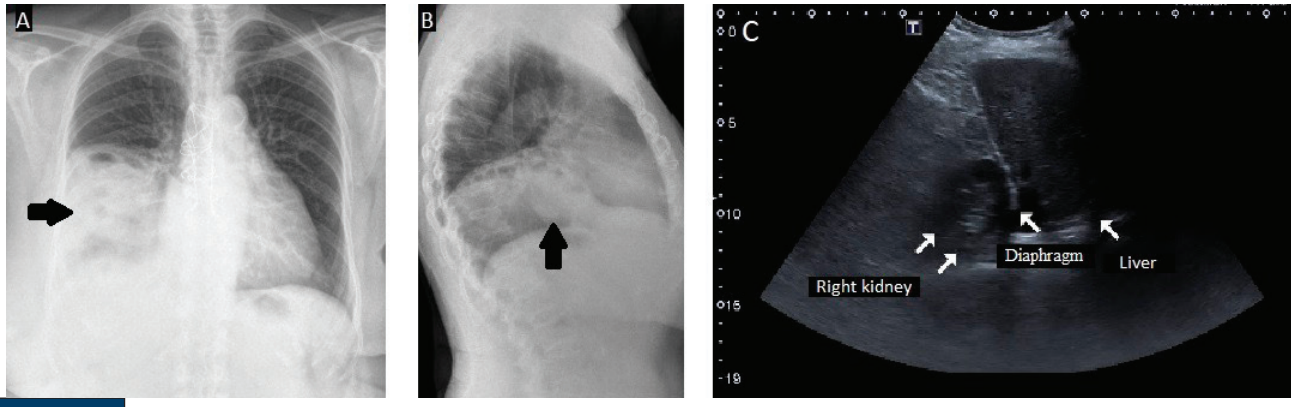

Figure 1 *X-ray in AP view in A and profile view in B demonstrating heterogeneous opacity in the right hemithorax (black arrow). In C, ultrasound displaying the right kidney above the diaphragm and the liver.*

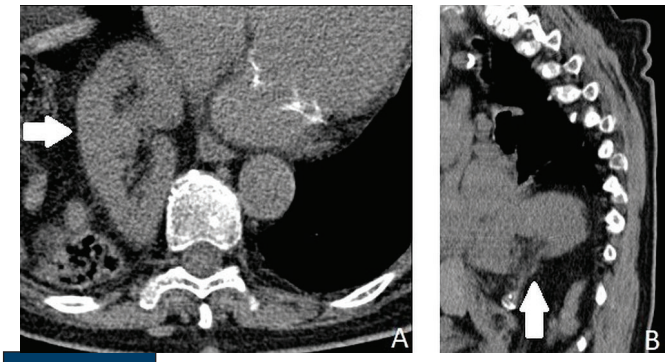

Figure 2 *CT scan in axial section in A and sagittal section in B demonstrating the intrathoracic right kidney (white arrow).*

CONCLUSION

Thoracic ectopic kidney is an, usually, asymptomatic condition, and the correct diagnosis should prevent patients from unnecessary diagnostic techniques or invasive procedures, as it can be easily diagnosed through imaging techniques such as ultrasound or CT scan, and seldom requires intervention.

Compliance with ethical standards
Funding: No funding was received for this study.
Conflict of interest: The authors declare that they have no conflict of interest.
Ethical approval: All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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CASE REPORTS

THORACIC ORIGIN OF THE RIGHT RENAL ARTERY: AN INCIDENTAL FINDING

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Abstract

Thoracic origin of a single renal artery with a normal position of the kidney is a very rare anatomical variant with just a dozen cases depicted in the medical literature. In this case report we describe an incidental finding of a main renal artery arising from the thoracic aorta at the 11th thoracic vertebral level in an asymptomatic 57 year-old man in a routine computed tomography (CT) on follow-up for chronic pancreatitis.

INTRODUCTION

The renal arteries are the most variable branches of the abdominal aorta regarding the site of origin and number, in such that anatomic variants of renal arterial supply are a common abdominal CT finding and frequently not reported by abdominal radiologists.[1,2] Knowledge of variations of the origin and course of the renal arteries is important for the management of renal trauma, surgery or transplantation and aortic surgery.

In a series of 855 consecutive patients studied by angiography, Özkan U et al found that in 98% of the times the origin of the main renal arteries of the aorta was between the upper margin of L1 and lower margin of L2 vertebra,[1] but renal arteries originating from the thoracic aorta are exceedingly rare. In this case report we describe and discuss an incidental detection of a thoracic renal aorta via contrast enhanced computed tomography (CT).

CASE REPORT

Mr. MC, a 57 year-old man, underwent an abdominopelvic CT exam at our institution to follow-up complications related to a recent exacerbation of a known chronic pancreatitis. Biphasic contrast-enhanced CT examination revealed a thoracic origin of the right main renal artery at the level of T11 vertebral body (Figure 1). The artery originated along the lateroposterior aspect of the aorta at 7 o'clock position and showed a linear course caudally through a hiatus in the right crus of the diaphragm to reach the renal hilum (Figure 2). Contralateral renal artery had a common origin at the level of L1 and there were no accessory arteries on both kidneys. There was a single vein for each kidney and a symmetrical renal enhancement was observed.

DISCUSSION/CONCLUSION

Renal arteries can be categorized as main renal arteries, accessory branches and accessory arteries, according to their origin and point of renal entry.[2,3] The main renal artery usually originates from the abdominal aorta below the superior mesenteric artery. Accessory renal branches, as their name implies, originate from the main renal artery

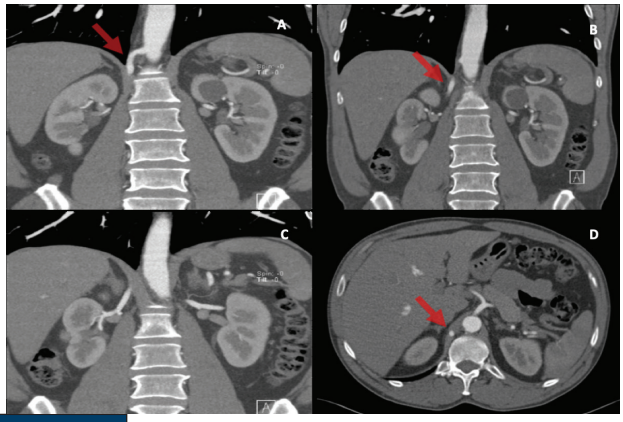

Figure 1 *Contrast enhanced abdominal CT (arterial phase) depicting a thoracic right renal artery on the coronal plane (A-C) and in the axial plane (D).*

before the hilum, while accessory renal arteries have a separate aorta origin and can enter the kidney at any point, most commonly at the poles. Renal arterial variations are common and the most common variation is the presence of an accessory artery, seen in about one-third of the population. [2]

All of these variations in renal vasculature are due to the existence of several mesonephric arteries during fetal life. [2,3] These arteries develop in the embryologic phase laterally to the aorta between the level of C6 and L3 vertebrae and are divided into cranial, middle and caudal group. Over time, they progressively degenerate leaving only one mesonephric artery, usually in the caudal group, which becomes the main renal artery. [2] Persistence of cranial mesonephric vessels results in a high anomalous renal arterial supply with the renal artery originating above the celiac axis. [2-4]

Renal arteries arising from the thoracic aorta are very uncommon, with our literature search revealing less than 15 reports of such variation, most of the times between T11 or T12. The first case was reported by Doppman in 1967, describing a case originated at the level of the T11 vertebra and arising beneath the right crus of the diaphragm.[5] The majority of these case reports describe a single ectopic renal artery located on the right side, though similar anomaly can also occur on the left side.[3,6,7] Renal artery vascular variants increase the risk surgical of complications, being more technically challenging, but other than these surgical considerations there are no indications that an thoracic origin of the renal artery have any major clinical implication for the patients.[2]

On reviewing patient's previous CT examinations, including an abdominal CT angiography, no consideration was made to the presence of any renal vascularity variant on the radiologist' report, highlighting a need for radiologists recognition of renal vasculature variantions, frequently not valued nor reported.

In conclusion, we incidentally identified a very rare right renal artery originating from the thoracic aorta with penetration though the diaphragm on a CT examination. It is very important for surgeons and radiologists to be aware of rare renal arterial anomalies and ectopically originating renal arteries must be considered when evaluating the suitability of renal donors for renal transplantation.

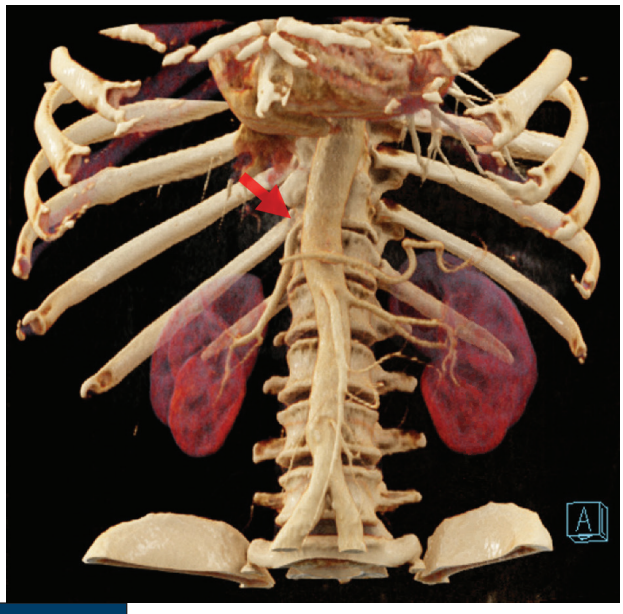

Figure 2 *Cinematic Rendering CT highlighting the right renal artery (red arrow). Left renal artery with a usual abdominal origin.*

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CARDIOGENIC SHOCK DUE TO VENTRICULAR SEPTAL DEFECT (VSD) AFTER MYOCARDIAL INFARCTION

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62 year-old man admitted in ICU post myocardial infarction with ventricular septal defect (VSD) and cardiogenic shock due to anterior descending artery stenosis. VSD corrected percutaneously after intra-aortic balloon pump insertion, resulting in iatrogenic tricuspid regurgitation. Tricuspid valvuloplasty, VSD correction and CABG performed after patient stabilization. Discharge after 26 days.

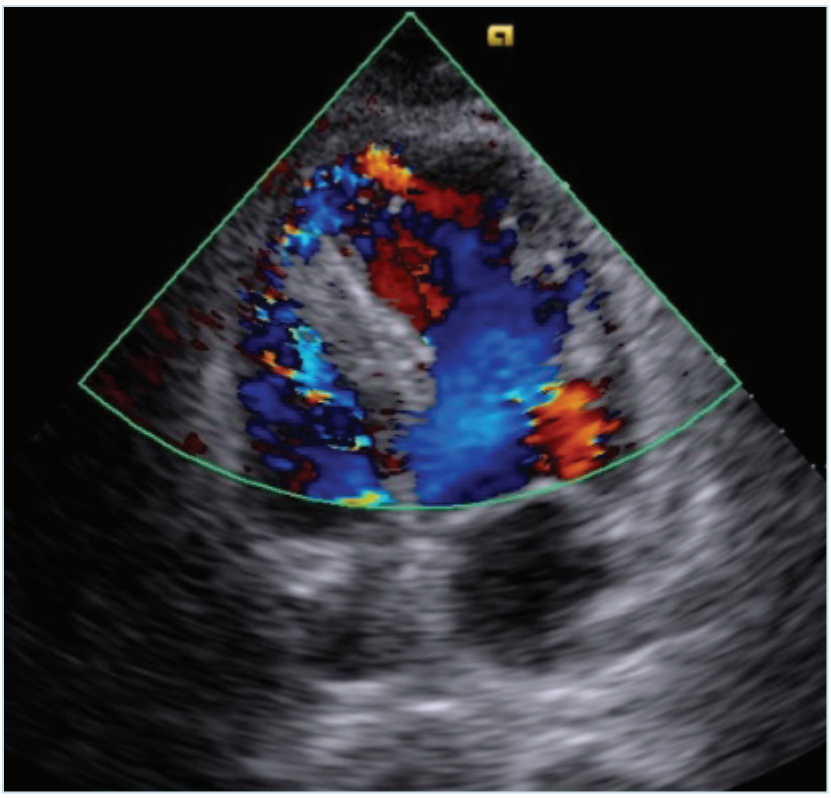

Figure 1 *Transthoracic echocardiography with Doppler showing VSD after myocardial infarction due to anterior descendent stenosis.*

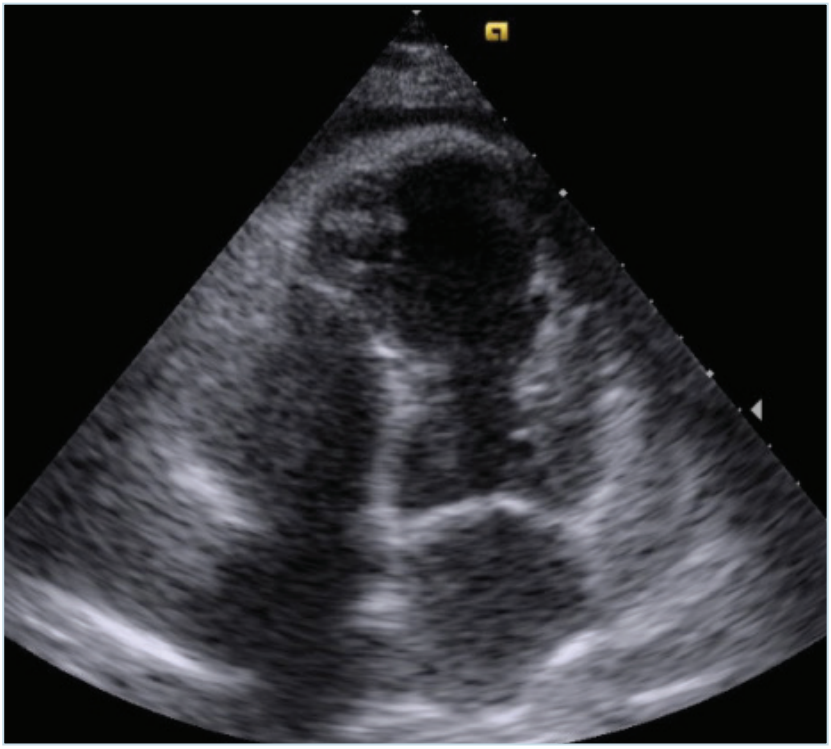

Figure 2 *Transthoracic echocardiography before discharge.*

IMAGES IN SURGERY

THE DEVELOPMENT OF BRONCHOPLEURAL FISTULA

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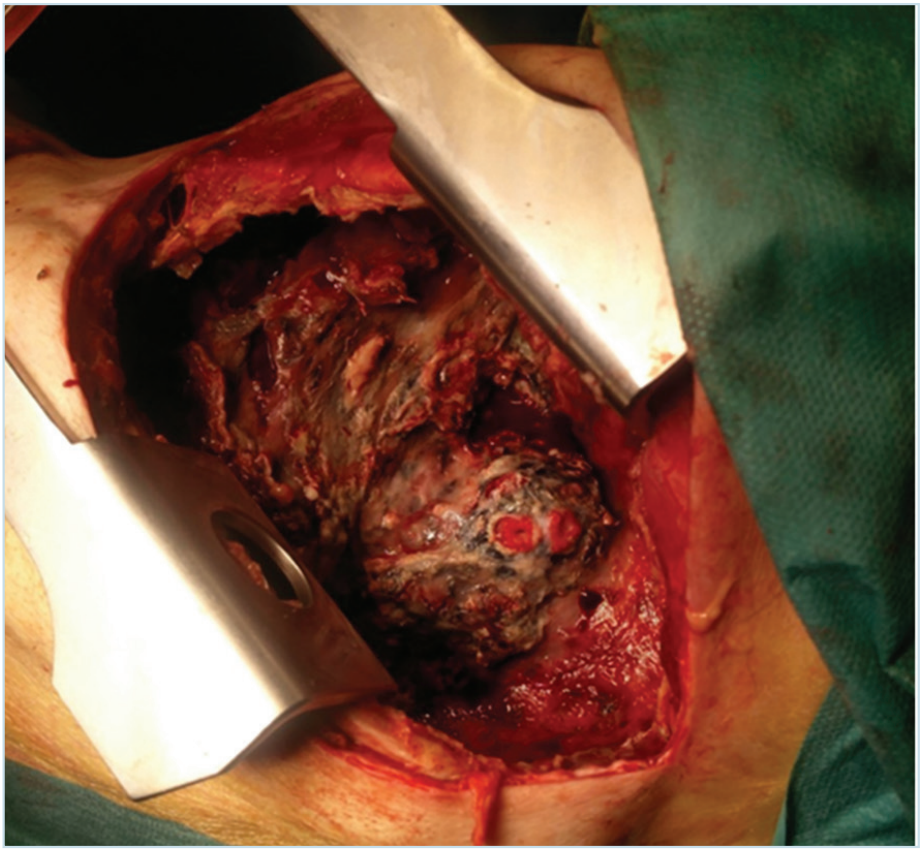
A 66-year-old male with an aspergiloma in the upper left lobe was submitted to a wedge resection in December 2019. Pneumostasis was performed using biological glue and afterward the test of submersion in water showed no significant alveolopleural leak. In the immediate postoperative period, the patient presented an expanded lung parenchyma and moderate alveolopleural leakage that gradually decreased.

A month later the patient was readmitted in intensive care unit with an acute respiratory distress after a sudden episode of coughing with abundant and purulent sputum and significant increase in alveolopleural leakage.

Intraoperatively it was found that the pulmonary parenchyma covering the segmental bronchi was necrotic.



RECURRENT INGUINAL LYMPHOCELE – A THERAPEUTIC CHALLENGE

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Recurrent lymphocele after repair of crural hernia without resolution after several aspirations and injections of sclerosing agents. Reintervention with lymphatic marking (injection of patent blue dye at the interdigital level, Figure 1), followed by en bloc removal of the ganglia of the saphenofemoral junction and the lymphocele capsule (Figure 2). No evidence of recurrence at 24 months of follow-up.

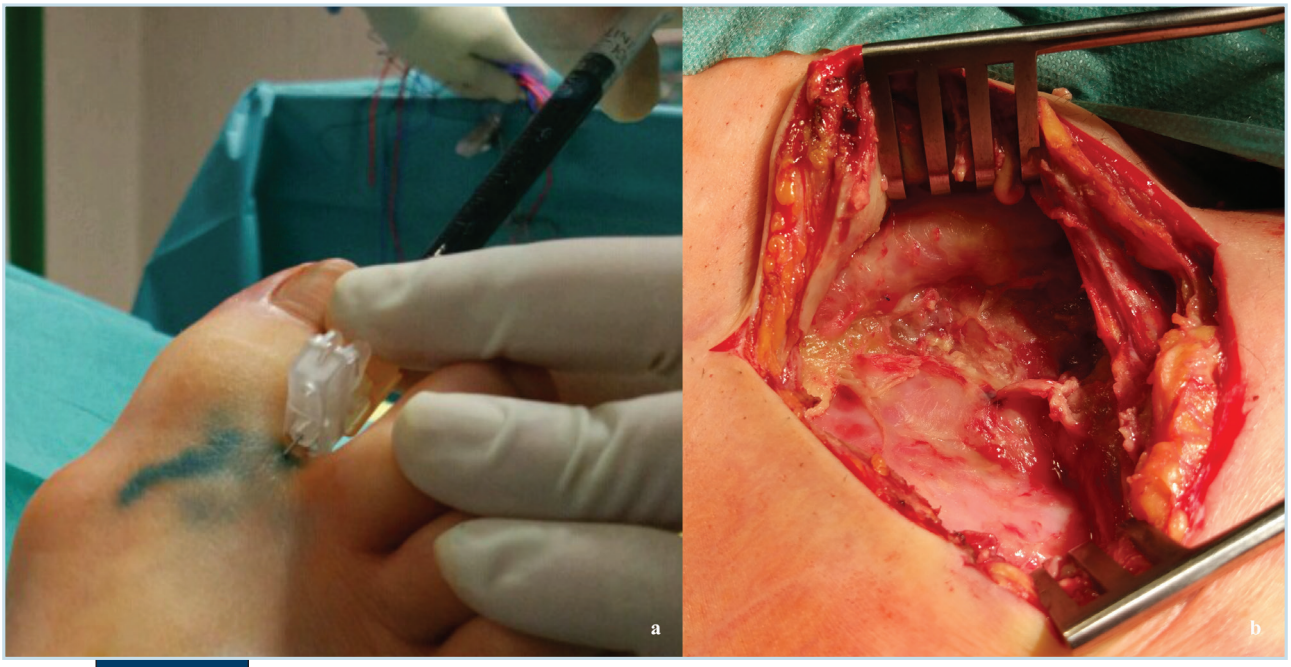

Figure 1 *a) Lymphatic marking through injection of patent blue dye at the interdigital level. b) Surgical approach of the inguinal region.*

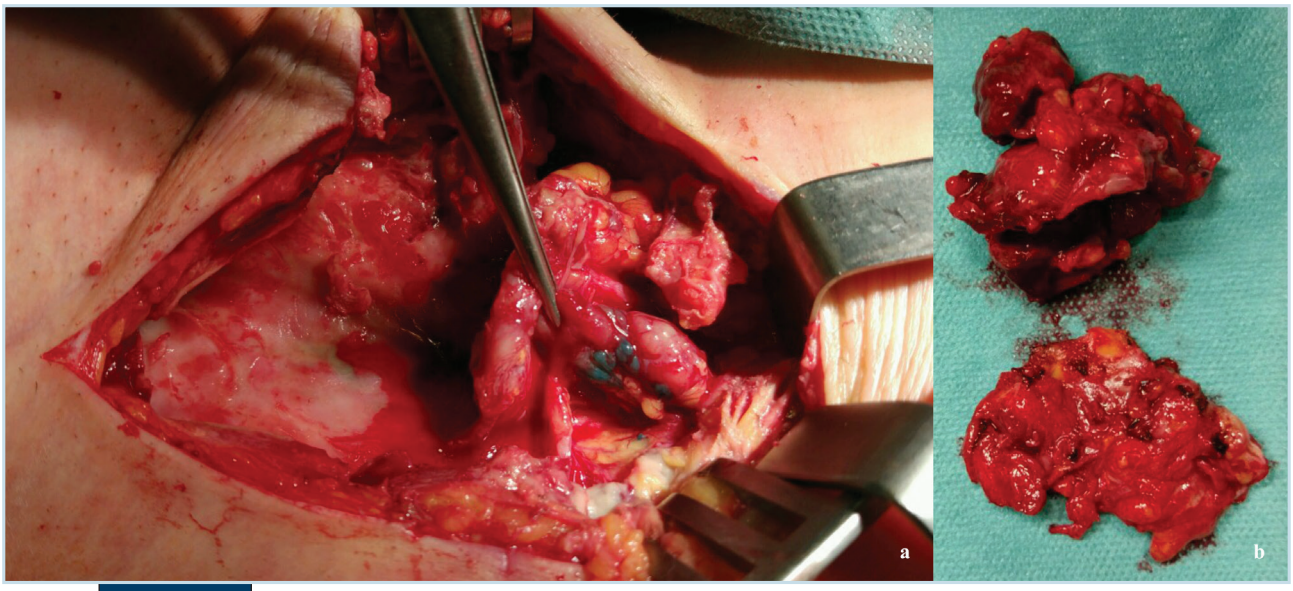

Figure 1

a) Block dissection of the ganglion structures of the saphenofemoral junction and the lymphocele capsule; b) Surgical specimen.