ARGENTINE JOURNAL OF



CARDIOVASCULAR SURGERY SCIENTIFIC JOURNAL OF THE ARGENTINE COLLEGE OF CARDIOVASCULAR SURGEONS



Alejandro Fogazzi is a surgeon, former resident and Chief Resident of Hospital Fernández. He was also Chief Resident of IMOS CABA and a surgeon at Hospital Fernández. At present, he is a surgeon at Hospital Municipal Gral. Villegas and Carlos Tejedor, a surgeon of the Dialysis Center, and a surgeon of Clínica Modelo de Gral. Villegas.

COVER ARTWORK Alejando Fogazzi Cirujano

Ex residente. Jefe de residentes. Hospital Fernández CABA. Ex Jefe de residentes IMOS CABA.

Ex cirujano Hospital Fernández. Cirujano Hospital Municipal de Gral. Villegas y Carlos

Cirujano de Centro de diálisis. Cirujano de clinica Modelo Gral. Villegas.

"Bosque de agua"



ISSN 1667-5738

FOURTH-MONTHLY JOURNAL, PROPERTY OF ARGENTINE COLLEGE OF CARDIOVASCULAR SURGEONS VOLUME XV - NUMBER 1 - JANUARY - FEBRUARY - MARCH - APRIL 2017

EDITORIAL COMMITTEE

Managing Director

PAOLINI, JUAN ESTEBAN City of Buenos Aires

Editor-in-Chief

BORRACCI, RAÚL ALFREDO

City of Buenos Aires

Editorial Assistant

FERRARI, AYARRAGARAY JAVIER City of Buenos Aires

Executive Board

CEREZO, MARCELO La Plata, Province of Buenos Aires

DOMENECH, ALBERTO City of Buenos Aires

_ _ _ _

DULBECCO, EDUARDO City of Buenos Aires

Ferreira, Mariano Luis

City of Buenos Aires

Editorial Board

ALLENDE, JOSÉ NORBERTO City of Córdoba, Province of Córdoba

Benetti, Federico

City of Santa Fe, Province of Santa Fe

CICHERO, FERNANDO City of Buenos Aires

DE PAZ, JORGE

Avellaneda, Province of Buenos Aires

ETCHEVERRY, RICARDO Pilar, Province of Buenos Aires

FARRANDO, MARTIN

City of Mendoza, Province of Mendoza

GOLDENSTEIN, CARLOS Haedo, Province of Buenos Aires

KOTOWICS VADIM City of Buenos Aires LAMELZA, VÍCTOR
City of Buenos Aires

LAMURA RICARDO
City of Buenos Aires

Lucas, Fernando City of Buenos Aires

Mancini, Blas Bernardino

City of Buenos Aires

NAVIA, JOSÉ City of Buenos Aires

Nigro Juan

Merlo, Province of Buenos Aires

NOJEK, CARLOS City of Buenos Aires

Parodi, Juan

San Isidro, Province of Buenos Aires

PATARO, EDUARDO City of Buenos Aires

PATARO MARCELO

Avellaneda, Province of Buenos Aires

PEIRANO, MIGUEL City of Buenos Aires

Presa, Carlos

La Plata, Province of Buenos Aires

RIVAS, ROBERTO City of Buenos Aires

SIMKIN ROBERTO
City of Buenos Aires

TURCO EMILIO
Pilar, Province of Buenos Aires

URIBE ECHEVARRIA, ADOLFO City of Córdoba, Province of Córdoba

WEINSCHELBAUM, ERNESTO City of Buenos Aires

Foreign Editorial Board

Bahamondes, Juan Carlos (Chile)

Juffe Stein, Alberto (Spain)

BAZÁN, MANUEL (CUBA) MESTRES, CARLOS (SPAIN)

Bernal, José Manuel (Spain)

Novitsky, Dimitri (US)

Braile, Domingo (Brazil) Pérez López, Horacio (Cuba)

Brofman, Paulo (Brazil) Picarelli, Dante (Uruguay)

CHACHQUES, JUAN CARLOS (FRANCE)

QUIROGA, ELINA (Seatlle, US)

CONNOLLY, JOHN E. (US)

SIORDIA, RODOLFO (MEXICO)

CRIADO, FRANK (US)

VERA, ANDRÉS (CHILE)

Deriú, Giovanni (Italy)

Zalaquet Sepúlveda, R. (Chile)

Gallo, Santiago (Paraguay) Zapolansky, Alejandro (US)

HERREROS, JESÚS (SPAIN)

Edition coordinator: María Laura Caruso Translation into English: TP Victoria Vincent

Style corrector: Marcelo Colombini

Design & layout: www.PixelStudio.com.ar

Editor: Argentine College of Cardiovascular Surgeons

Catamarca 536, City of Buenos Aires

Tel. (0054 11) 4931-5066 - Tel./Fax: (0054 11) 4931-2560

www.caccv.org.ar / raccv@caccv.org.ar

CACCV COMMITTEE BOARD

President: DR. FERNANDO CICHERO
Vicepresident: DR. JUAN ESTEBAN PAOLINI
Secretario General: DR. JUAN ANTONIO NIGRO
Tesorero: DR. JAVIER FERRARI AYARRAGARAY

Secretario de Actas: Dr. Marcelo Dándolo
Secretario Gremial: Dr. Hernán Delpersio
Vocales Titulares: Dres. Alberto Fregoni,

MIGUEL ÁNGEL AMORE, NÉSTOR GIRALDEZ, MARCELO PATARO

Argentine Journal of Cardiovascular Surgery - ISSN 1667-5738

Volume XV - Number 1 - January - February - March - April 2017

The Argentine Journal of Cardiovascular Surgery is the publication of the Argentine College of Cardiovascular Surgeons. It was first published in 2003 to provide updated information on research conducted by worldwide specialists; the introduction of surgical techniques; articles on the figures and milestones of the national and international history of our specialty, on other topics related to cardiovascular surgery, endovascular surgery, cardiac surgery, circulatory support, phlebology and lymphology, and on new trends incorporating technological innovation such as treatments with stem cells. It is a basically surgical journal published on a four-monthly basis.

Intellectual property pending. All rights reserved. Its total or partial reproduction is prohibited unless previously authorized in writing by its publisher.

The contents of these articles are the sole responsibility of their authors and do not necessarily reflect the opinion of the Editorial Committee.

Correct and up-to-date information is provided in the selected material published; however, the continuous evolution of medicine makes the doctor the person ultimately responsible for evaluating whether it is valid and appropriate for a patient. No scientific or legal liability for the products or services advertised is assumed, and no complaints by those responsible for them will be answered.

For online version (ISSN 1669-7723) and additional information: www.caccv.org.ar/raccv - E-mail: raccv@caccv.org.ar Argentine College of Cardiovascular Surgeons. Catamarca 536, City of Buenos Aires.

Tel +0054 11 4931 5066 - Tel/Fax +0054 11 4931 2560.



6 FIFTEEN, FIFTY AND SIXTY-FIVE

EDITORIAL

- 7 III END OF THE WORLD INTER SOCIETIES CONSENSUS (III EWIC) BARILOCHE 2015
- 9 ENDOVASCULAR MANAGEMENT OF THORACOABDOMINAL ANEURYSMS
- 19 ACUTE MANAGEMENT OF ISCHEMIC STROKE
- 31 SUBCRITICAL ARTERIAL LOWER LIMB ISCHEMIA
- 41 VARICOSE VEIN SURGERY BY RADIOFREQUENCY ABLATION: IMMEDIATE AND 6-MONTH POSTOPERATIVE EVALUATION OF THE TREATMENT FOR GREAT SAPHENOUS VEIN INSUFFICIENCY

ARTICLE

- 49 65TH ANNIVERSARY OF THE ARGENTINE ASSOCIATION OF ANGIOLOGY AND CARDIOVASCULAR SURGERY
- 53 DR. EDWARD B. DIETHRICH 1935-2017 OBITUARY AND PERSONAL TRIBUTE
- 57 TRIBUTE. FRIEDRICH WILHELM MOHR: HOW I KNEW HIM DR. ROBERTO BATTELLINI

SCIENTIFIC LETTER

62 IMPLEMENTATION OF A VASCULAR AND ENDOVASCULAR SURGERY SERVICE AT THE HOSPITAL NACIONAL DE CLÍNICAS IN CÓRDOBA

READERS LETTER

66 ABOUT THE EVIDENCE BASED MEDICINE

PERSPECTIVES

69 CACVS VASCULAR SYMPOSIUM 2017 – PARIS, FRANCE: PERSONAL INSIGHTS AND OPINIONS DR. FRANK CRIADO

OFFICIAL LECTURE (FIRST PART)

31 ENDOVASCULAR VENOUS PROCEDURES IN THE DEEP VENOUS SYSTEM MARCELO DÁNDOLO



FIFTEEN, FIFTY AND SIXTY-FIVE

This 2017 has a special meaning for cardiovascular surgery, and also for angiology. First, this is the 15th consecutive year of edition of our Argentine Journal of Cardiovascular Surgery, with major innovations and advances; we must also mention that it marks the first 50 years of the performance of the first aortocoronary bypass, by the founder and first president of the CACCV Dr. René Favaloro; and finally, it is the 65th anniversary of the Argentine Association of Angiology and Cardiovascular Surgery, the oldest association in Latin America. This first number includes the conclusions of the 3rd Consensus from the End of the World, which involved 14 scientific societies of various Latin American countries, referred to the management of thoracoabdominal aneurysms in acute stroke and defined the so-called subcritical limb ischemia. We consider that the publication of the Argentine Association of Angiology official lecture given by Dr. Marcelo Dándolo on "Endovascular venous procedures in the deep venous system" is relevant. Dr. Roberto Battellini sent us the tribute to Dr. Mohr, who is retiring from cardiovascular surgery, and Dr. Eduardo Pataro provides an insight on the history of the Argentine Association of Angiology and its development. Dr. Frank Criado wrote the obituary of Edward Dietrich, who unfortunately passed away in February this year, pioneer of endovascular surgery, master and mentor of endovascular surgeons from around the world. From Córdoba, Dr. José Norberto Allende tells us about the creation of the Service at Hospital de Clínicas. Also, Frank Criado provides his opinion in the Perspectives section and Dr. Tea Acuff, from Texas, writes the letter from our readers on the medical error. Topics are diverse and cover all aspects of our specialization. This number can be summarized particularly with the words of the poet Antonio Machado: "Everything passes and everything stays, but our fate is to pass", "Walker, there is no road but the one made as you walk". Dr. Juan Esteban Paolini, Director.

Dr. Juan Esteban Paolini
Director



EDITORIAL

III END OF THE WORLD INTER SOCIETIES CONSENSUS (III EWIC) BARILOCHE 2015

PARTICIPATING MEMBERS

Erica Bernich, Guadalupe Bruera, Luis Gerardo Cadavid (Colombia), Marta Calvagno, Julio Cigorraga, Rodrigo Cunha (Brazil), Marcelo Dándolo, Elvio Demicheli, Marcelo Diamant (Uruguay), Javier Ferrari Ayarragaray, Mariano Ferreira, Guillermo Garelli, Carmelo Gastambide (Uruguay), Guillermo Lacour, Víctor Lamelza, Cristobal Licudis, Alicia Ludueña, Sergio Massetti, Esteban Mendaro, Alberto Muñoz (Colombia), Marcelo Pataro, Gustavo Vitancurt (Uruguay), Arno Von Ristow (Brazil), María C. Zurru.

DRAFTING COMMITTEE

Érica Bernik, Marcelo Cerezo, Marcelo Dándolo, Elvio Demicheli, Javier Ferrari Ayarragaray, Guillermo Garelli, Sergio Massetti, Juan Esteban Paolini, Rubén Velletaz, María Zurru.

EDITING COMMITTEE

Álvaro Balcazar (Bolivia), Frank Criado (USA), Héctor Delvalle, Claudio Schönholz (USA), Marcelo Ferreira (Brasil), Luis Fernando Lucas, Fernando Ibañez (Chile), Alberto Muñoz (Colombia), Juan Barrera (Colombia), Jorge Valdecantos y Arno Von Ristow (Brazil).

CHAIRMAN:

PAOLINI, JUAN ESTEBAN

CO CHAIRMAN:

CEREZO, MARCELO

REGIONAL CHAIRMAN:

NASIF, MOISÉS

CORRESPONDENCE: marcelohectorcerezo@hotmail.com

INVITED ASSOCIATIONS

ARGENTINE ASSOCIATION OF ANGIOLOGY AND CARDIOVASCULAR SURGERY (AAACV)

COLOMBIAN ASSOCIATION OF ANGIOLOGY AND VASCULAR SURGERY (ASOVASCULAR)

PATAGONIA ASSOCIATION OF PHLEBOLOGY AND LYNPHOLOGY (AFLP)

LATIN AMERICAN ASSOCIATION OF VASCULAR SURGERY AND ANGIOLOGY (ALCVA)

ENDOVASCULAR SURGEONS OF LATIN AMERICA (CELA)

ARGENTINE COLLEGE OF CARDIOVASCULAR SURGEONS (CACCV)

ARGENTINE COLLEGE OF INTERVENTIONAL RADIOLOGISTS – ARGENTINE ASSOCIATION OF RADIOLOGY (CARI-SAR)

ARGENTINE COUNCIL OF VENOUS AND LYMPHATIC HEALTH (CASVEL)

PAIN FOUNDATION - ARGENTINE ASSOCIATION OF ANESTHESIOLOGY AND RECOVERY (AAAR)

ARGENTINE ASSOCIATION OF DIABETOLOGY (SAD)

ARGENTINE ASSOCIATION OF MEDICINE AND FOOT AND LEG SURGERY (SAMECIPP)

ARGENTINE ASSOCIATION OF NEUROLOGY (SAN)

BRAZILIAN ASSOCIATION OF ANGIOLOGY AND VASCULAR SURGERY (SBACV)

URUGUAYAN ASSOCIATION OF VASCULAR AND ENDOVASCULAR SURGERY (SUCIVE)

WORLD FEDERATION OF VASCULAR SOCIETIES (WFVS)



ARTICLE

ENDOVASCULAR MANAGEMENT OF THORACOABDOMINAL ANEURYSMS

ABSTRACT:

Introduction: The endovascular treatment of thoracoabdominal aortic aneurysms is limited to centers of excellence, considering that conventional treatment involves high mortality and endovascular treatment is of first choice.

Aim: To propose an endovascular classification of thoracoabdominal aortic aneurysms (TAAAs); to provide recommendations for their diagnosis and endovascular treatment options.

Materials and method: Under evidence-based medicine (EBM), agreement was reached on different aspects of TAAAs thus creating recommendations on the various aspects.

Conclusions: TAAA endovascular treatment constitutes an extremely complex procedure with high morbidity and mortality rates, even in highly experienced centers.

TAAA endovascular treatment should be performed by teams highly trained in endovascular and open techniques.

This therapeutics should be performed in qualified centers with high-resolution technological equipment and imaging storage according to the procedure complexity.

Palabras Clave: Thoracoabdominal aneurysms, endovascular treatments, fenestrated endoprosthesis, branched endoprosthesis, hybrid procedures

AUTHORS:
CEREZO, MARCELO;
CUNHA, RODRIGO;
FERREIRA, MARIANO;
GASTAMBIDE, CARMELO;
LAMELZA, VÍCTOR;
PATARO, MARCELO;
VON RISTOW. ARNO.

CORRESPONDENCE: marcelohectorcerezo@hotmail.com





INTRODUCTION

First, and since the topic relates to the endovascular management of thoracoabdominal aortic aneurysms (TAAAs), the following consensus items regarding open treatment were established:

- It is limited to a few centers of excellence (mortality @ 5%).
- Mortality in common centers of the United States is extremely high, with rates reaching 26%.
- Although there are no statistics on the subject in Latin America, this panel considers that morbidity and mortality rates are high and that open surgery should be reserved to the few renowned specialized centers.
- Recent endovascular techniques of TAAA repair show, at initial and mid-term stages, less incidence on the complication rate.
- Endovascular procedures in the thoracoabdominal area represent the most appropriate therapeutic alternative for the region.

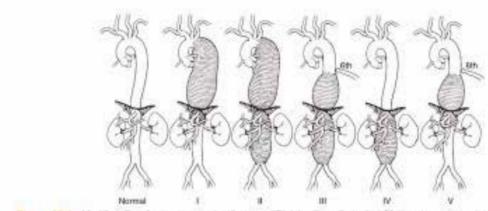


Figure 18-1. Modified Crawford anatomic classification of TAAAs, (From Rutherford R8: Vosculor surgery ed 6. Philodelphia, 2005, Sounders, p. (491, Fig. 103-2.)

CLASSIFICATION OF THORACOABDOMINAL ANEURYSMS

There is a 5-type classification:

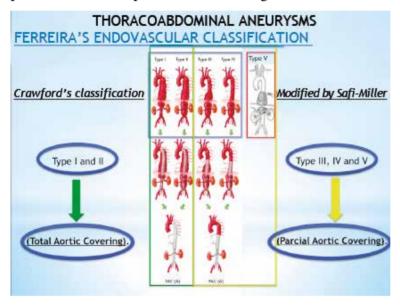
- Type 1: Extends from the left subclavian artery to the renal arteries.
- Type 2: Extends from the left subclavian artery to the aortic bifurcation.
- Type 3: Extends from the sixth intercostal space to the aortic bifurcation.
- Type 4: Extends from the diaphragmatic aortic hiatus to the aortic bifurcation.
- Type 5: Extends from the sixth intercostal space to the renal arteries.

This classification is common for Crawford and was modified by Safi-Miller (type 5).

MARCELO FERREIRA'S ENDOVASCULAR CLASSIFICATION

This classification is in line with the topic as it covers the endovascular treatments that should be performed in TAAAs, depending on the Crawford/Safi/Miller type.

Therefore, for patients with TAAA types 1 and 2, the endovascular procedure to be performed includes total aortic covering (TAC). For types 3, 4 and 5, the endovascular procedure to be performed includes partial aortic covering (PAC).

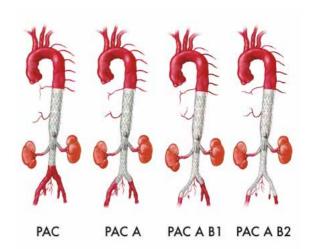


Marcelo Ferreira's classification covers those TAAAs associated with iliac aneurysms.

EWIC'S MODIFICATION 2015 adds those TAAAs that tactically require the covering of the left subclavian artery. We called this category TACs (total aortic covering including the subclavian artery).

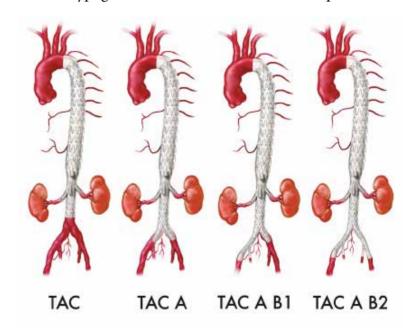
PAC SUBCLASS

- PAC: endovascular repair includes part of the descending aorta and the visceral aorta.
- PAC A: PAC that includes the aortic bifurcation and common iliac arteries.
- PAC A B1: PAC that includes branched endoprosthesis repair of one of the hypogastric arteries.
- PAC A B2: PAC that includes branched endoprosthesis repair of both hypogastric arteries.



TAC SUBCLASS

- TAC: endovascular repair of the complete descending aorta and the visceral aorta.
- TAC A: TAC that includes the aortic bifurcation and common iliac arteries.
- TAC A B1: TAC A that includes endovascular correction of one of the hypogastric arteries with branched endoprosthesis.
- TAC A B2: TAC A that includes endovascular correction of both hypogastric arteries with branched endoprosthesis.



EWIC 2015 adds to this classification the TACs subgroup for any of the above options in case the left subclavian artery should be covered, leaving the type of revascularization to the discretion of the operator.

EWIC 2015 RECOMMENDATIONS FOR DIAGNOSTIC EXAMINATION

The study par excellence in terms of diagnosis and planning for the examination of a patient with TAAA is the multi-slice angiotomography.

Its characteristics should include:

- Axial sections equal to or less than 1 mm.
- Scanning of supra-aortic vessels to femoral arteries.
- Dicom® imaging.
- Workstation to process digital images.

A previous neurological vascular study is advisable, if the revascularization of the left subclavian artery (TAAA TACs) is needed.

A detailed preoperative evaluation of physiological, hematological, cardiac, pulmonary and renal function reserves should be included.

If there is an associated coronary disease (16% - 30%), a detailed cardiac evaluation with transthoracic echocardiography and functional test is recommended. For patients requiring a previous coronary angioplasty, we do not recommend the use of drug therapy stents.

Regarding preoperative studies of spinal cord irrigation, we have not determined any benefit, whether by digital angiography, NMR or angio-tomography. It will not change the strategy of endovascular therapy.

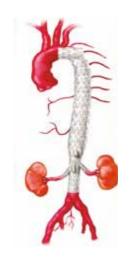
INDICATIONS FOR ENDOVASCULAR REPAIR

This panel has reached the following recommendations for TAAA endovascular repair:

- Asymptomatic TAAA greater than or equal to 60 mm in diameter in its entire length or in some parts.
 - Asymptomatic or complicated TAAA of any diameter.
 - Fast-growing TAAA, i.e., greater than 5 mm in 6 months.
- TAAA associated with connective tissue disease greater than 50 mm.

CONTRAINDICATIONS AND POSSIBLE TECHNICAL DIFFICULTIES RELATED TO ENDOVASCULAR REPAIR

- Anatomies with atheroembolism.
- Anatomic variations of aorta visceral branches.
- Excessive aortic tortuosity.
- Stenotic-occlusive aortoiliac arteriopathy.
- Comorbidity associated with life expectancy of less than 2 years.



TAAA ENDOVASCULAR THERAPEUTIC OPTIONS

- Branched or combined devices Branched/Fenestrated
- Use of parallel branches.
- Hybrid procedures.
- Bag sealing devices + Parallel branches.
- Flow diverter device.

It should be mentioned that:

- Results are directly related to the experience and volume of the treating center.
- It is a high-complexity procedure that requires multi adjuvant maneuvers.
 - Proper imaging technology should be available.
- Multidisciplinary work is necessary during pre, intra and postoperative therapy.
 - Costs of devices and other materials are expensive.

Branched or combined devices Branched/Fenestrated

This consensus panel considers that this is the endovascular option associated with the greatest technical success and the lowest complication rate.

- There are CUSTOM-MADE devices that are more anatomically accurate, whose design/construction/availability delay between 3 and 4 months.
- There are standard devices (T-BRANCH®) applicable approximately to 80% of the anatomies.
 - The procedure may be performed in stages

Use of parallel branches

- The options described include chimneys, snorkels, periscopes, sandwiches.
- The published series include a reduced number of cases and short-term follow-up, or are limited to "case reports".
- The main indication is in acute patients not eligible for surgery or custom-made devices, due to the latency time until material availability.
- They have higher incidence of endoleaks in relation to the number of parallel branches (type 1 endoleak).
 - Technically, they are easier to be performed.

Chuter TAM, Gordon RL, Reilly LM, et al: An endovascular system for thoracoabdominal aortic aneurysm repair, J Endovasc Ther 8:25-33, 2001.

Chuter TA, Schneider DB, Reilly LM, et al: Modular branched stent graft for endovascular repair of aortic arch aneurysm and dissection, J Vasc Surg 38:859-863, 2003.

Ohrlander T, et al: The chimney graft: a technique for preserving or rescuing aortic branch vessels in stent.graft scaling zones. J Endovasc Ther 15:427-432, 2008

Dr. Cerezo Marcelo and col. - Pages 9 to 18

Hybrid procedures

- These procedures imply debranching for visceral revascularization + endoprosthesis placement.
- They represent major abdominal surgery with great surgical approaches.
 - Some series report high morbidity and mortality rates.
- They are prescribed for very selected cases and for those patients with unfavorable anatomy for the other endovascular methods already mentioned.
- The complication rate is associated with the number of revascularized vessels.

Bag sealing device + parallel branches

- This procedure implies the use of Nellix® device + parallel branches.
- It is a recently known technique that seems to present better apposition and thus better sealing among endobags and chimneys.
 - Few reports.

Flow diverter or modulating device

- Limited use.
- Option for patients with contraindication to the other methods mentioned above.
- Recent publications describe a higher complication rate in those cases where the guidelines of use established by the device manufacturer were not followed.

ENDOVASCULAR TREATMENT **COMPLICATIONS**

These complications include:

- Renal failure.
- Spinal cord ischemia.
- Endoleaks.
- Visceral vessel complications.
- Lower limb ischemia.
- Stroke.

Black SA, Wolfe JH, Clark M, Hamady M, Cheshire NJ, Jenkins MP: Complex thoracoabdominal aortic aneurysms: endovascular exclusion with visceral revascularization, J Vasc Surg 43: 1081-1089, 2006.

Böckler D, Kotelis D, Geisbüsch P, Hyhlink-Dürr A, Klemm K, von Tengg-Kobligk H, Kauczor HU, Allenberg JR: Hybrid procedures for thoracoabdominal aortic aneurysms and chronic aortic dissections- a single center experience in 28 patients. J Vasc Sterg 47:724-732, 2008.

Verhoeven E, et al: Results of endovascular repair of TAAA in the first 50 patients. Zeneralbl Chir 136: 451-457, 2011.



RENAL FAILURE

- Multifactorial etiology.
- There is nephrotoxicity due to the use of higher doses of contrast material.
 - Renal branches occlusion.
- Iatrogenic lesion due to instrumentation within the vessels.
 - Embolization.

Recommendations

- 12-24 hour hospital stay before the procedure.
- Generous endovenous hydration.
- N-acetyl cysteine 1,200 mg every 12 hours during 48 hours before and after the procedure.
 - Bicarbonate 70 meq/kg before the procedure.

SPINAL CORD ISCHEMIA

- Multifactorial etiology.
- Arterial hypotension.
- Aortic covering above 20 cm.
- Occlusion of left subclavian artery and/or hypogastric artery(ies).
 - Previous abdominal aortic surgery.

Recommendations

- 48-hour PO monitoring of spinal cord pressure.
- Keep such pressure lower than 12 cm of h2o (10 mmHg).
- Avoid arterial hypotension and use of drugs with pressure lowering effects.
 - Perform procedures in sequential stages.
- Temporary perfusion of the bag by a spinal cord branch (closure two weeks later with plug).
 - Revascularization of subclavian/hypogastric artery.

VISCERAL ISCHEMIA

- Multifactorial etiology.
- By branch occlusion.
- Iatrogenic lesion by instrumentation.
- Atheroembolism.
- Renal ischemia is more frequent than mesenteric artery ischemia (due to collateral circulation and mesenteric arteries network).

Etz CD, et al: Staged repair significantly reduces paraplegia rate after extensive thoracoabdominal aortic aneurysm repair. J Thorac Cardiovasc Surg 139:1464-1472, 2010.

Griepp RB, et al: Spinal cord perfusion and protection during descending theracic and thoracoabdominal aortic surgery: the collateral network concept. Ann Thorac Surg 83:S865-S869, 2007

Recommendations

- Special attention in tortuous arteries.
- Use of non-covered stents for vessel alignment, in case it is bend.
 - Dual antiplatelet therapy.
 - First tomographic control after 30 days.
- Video-laparoscopy or colonoscopy in case of clinical and lab diagnostic suspicion.

LOWER LIMB ISCHEMIA

- -This ischemia is more common in cases that require hemostatic introducers of greater caliber (22-24 French) as in fenestrated endoprostheses.
 - It is associated with extended time of the procedure.

Recommendations

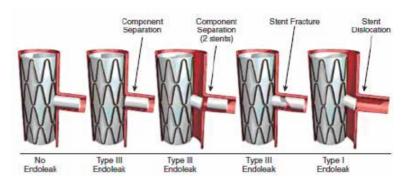
- Minimize surgery time.
- Monitor anticoagulation time (to keep ACT in more than 200 seconds).

ENDOLEAKS

- -Type 1 proximal and distal endoleak is less frequent in branched devices (there is a greater safety margin in anchorage areas).
- TYPE 1 D, corresponding to the insufficient sealing of the stent graft of a branch in the visceral artery, is added to the endoleak classification.
- TYPE 1C was added in the second EWIC, defining the retrograde leak due to the insufficient sealing of the contralateral occlusive plug in the corrections of abdominal aneurysms with con aorto-uniliac devices.
- Type 3 endoleak means the disconnection between the visceral branch of the endoprosthesis and the stent graft.
- Type 1 proximal and distal endoleak is more frequent when using parallel branches.

Recommendations

- Adequate planning.
- 1-mm oversizing for visceral branches.
- Overlapping of 2 cm within the visceral branch and 2 cm within the endoprosthesis branch.
 - Stent grafts flaring in the fenestrated entoprosthesis.
 - Generous overlapping in parallel prosthesis.



TYPE 1 C ENDOLEAK. THIRD EWIC 2015.

STROKE

- -Related to the instrumentation of the aortic arch.
- Related to the covering of the left subclavian artery.

Recommendations

- -Single preoperative antiplatelet therapy.
- Anticoagulation monitoring.
- Dual antiplatelet therapy.
- Revascularization of left subclavian artery (TACs).

FOLLOW UP

Recommendations

- The study to be performed is the angio-tomography.
- The recommended frequency is after 30 days, 6 months, 1 year and once a year for life.
- Simple radiology and digital arteriography are methods that can be used to evaluate possible progressive complications.

LATIN AMERICAN REALITY

- -TAAA endovascular treatment constitutes an extremely complex procedure with high morbidity and mortality rates, even in highly experienced centers.
- TAAA endovascular treatment should be performed by teams highly trained in endovascular and open techniques.
- This therapeutics should be performed in qualified centers with high-resolution technological equipment and imaging storage according to the procedure complexity.



ARTICLE

ACUTE MANAGEMENT OF ISCHEMIC STROKE

ABSTRACT:

Introduction: Ischemic stroke is the fourth cause of death and the first cause of long-term disability. Due to the seriousness of this topic, we have decided to focus on recommendations and controversies related to specific clinical and surgical matters, such as the acute management of ischemic stroke, and the controversies derived from the "combined management of the carotid disease and cardiac surgery", and the "time of surgery in patients with symptomatic carotid atheromatous disease".

Aim: To define the characteristics of the ischemic stroke, its diagnosis and treatment in the so-called "golden hour"; to unify criteria regarding the combined management of the carotid disease and the coronary disease as well as of patients with symptomatic carotid disease.

Materials and method: Review of the literature, reaffirming evidence-based medicine recommendations.

Conclusions: The detection, diagnostic testing and treatment of acute ischemic stroke in the first hour brings considerable benefits; with respect to patients with combined carotid and coronary disease, the endarterectomy would be prioritized over stenting, since the latter would cause greater delay for acute coronary revascularization due to the antiplatelet therapy implemented and increased risk of bleeding after cardiac surgery. Patients with symptomatic carotid stenosis ≥ 70% benefited more if they were operated on within the first 2 weeks after the ischemic stroke.

Palabras Clave: ischemic stroke, symptomatic carotid disease, cerebrovascular and cardiac disease.

AUTHORS:

ZURRU, MARÍA C.;

FERRARI, AYARRAGARAY

JAVIER;

BRUERA, GUADALUPE;

CADAVID, LUIS GERARDO;

VITANCURT. GUSTAVO

CORRESPONDENCE: maria.zurru@hospitalitaliano.org.ar

INTRODUCTION

Ischemic stroke is the fourth cause of death and the first cause of long-term disability. Due to the seriousness of this topic, we have decided to focus on recommendations and controversies related to specific clinical and surgical matters, such as the management of acute care management of ischemic stroke, and the controversies derived from the "combined management of the carotid disease and cardiac surgery", and the "time of surgery in patients with symptomatic carotid atheromatous disease".

RECOMMENDATIONS ON THE ACUTE MANAGEMENT OF ISCHEMIC STROKE

The proper initial assistance of these patients allows to reduce morbidity and mortality associated with this pathology. Two stages are clearly distinguished:

- 1) Pre-hospital stage.
- 2) Hospital stage during the first hour.

PRE-HOSPITAL STAGE

Early recognition of symptoms:

The sudden onset of neurological symptoms is the most important recognizing sign. However, about 20% of patients who are suspected of suffering from an ischemic stroke presents another pathology. The most frequent ones include metabolic encephalopathies for hypoglycemia, hyperglycemia or hyponatremia, subdural hematoma, central nervous system tumors, complicated migraine, post-convulsive condition (Todd's paralysis), brain abscess, meningoencephalitis, exogenous intoxication and psychoactive drugs abuse. During the initial examination of these patients it is essential to ask for any history of vascular risk factors, seizures, trauma, chronic cephalea, usual medication and toxic substances exposure. (1,2) The most frequent clinical characteristics of stroke are generally related to the sudden appearance of any of the following symptoms:

- Weakness or clumsiness in one side of the body.
- Visual impairment of one eye or both.
- Patient unusual acute cephalea.
- Vertigo or instability.
- Dysarthria and language impairment.
- · Sensitivity alterations.
- 1) "While some observational studies show acceptable outcomes in combined surgery (6), *others do not succeed in doing so*".

• 2) "In his *review*, Naylor details risk of death, stroke (30 days) and prevalence of death/perioperative stroke in patients with carotid lesions, between 50%-99%, and without prophylactic treatment, *from* 3.8% - 3.8% and 3.8%, respectively. (10)

The appearance of these symptoms should be a sign to call an emergency service and make an urgent transfer of the patient to hospital. During the pre-hospital stage, some tracking scales such as FAST and Cincinnati Scale may be used. It is important to record the time the symptoms first appeared to choose the proper subsequent treatment. (1)

HOSPITAL STAGE

During the hospital stage, it is important to establish an adequate selection, allowing a quick detection of those patients who are in the therapeutic window for recanalization treatment.

Door-to-needle time should be less than 60 mins (golden hour), for which the implementation of guidelines or algorithms of treatment is advisable, as well as the establishment of priority codes for the performance of complementary studies. (3)

Since the hospital admission of the patient, several steps, shown in the attached algorithm, should be taken (Figures 1 and 2).

The measures to be taken are divided into two categories:

- 1) General management of ischemic stroke.
- 2) Specific acute management of ischemic stroke.

General management of ischemic stroke

- ABC: to examine the adequate airway protection, oxygenation and hemodynamic stability.
- Vital signs monitoring: heart rate, blood pressure, pulse oximetry and temperature.
- 30° headboard Neutral position. Nothing by mouth.
- Colocation of 2 high-flow peripheral venous catheters.
- PHP with normal saline. To keep the normal fluid balance.
- Oxygen by nasal cannula at 3 1 per minute to ensure peripheral saturation higher than 95% (except as otherwise indicated by the clinical examination or the pulse oximetry, or an airway protection with orotracheal intubation may be necessary).
- To treat hyperthermia with physical means and paracetamol.
- To put urinary catheter and stomach tube for discharging as necessary.
- To control blood sugar and correct any deviation.
- NIHSS scale.

Complementary diagnostic studies

 Lab tests: complete blood count, blood sugar, uremia, serum electrolytes, creatinine and baseline values of coagulation including INR. Cardiac enzymes in patients with changes in the electrocardiogram.

- · Electrocardiogram.
- Chest x-ray.
- Imaging tests: brain CT, with angio-CT, whenever possible.
 A brain NMR may be performed as initial study, provided it does not delay treatment.

SPECIFIC TREATMENT MEASURES

Blood pressure treatment

In patients with ischemic stroke, blood pressure control should be conservative since blood hypotension could reduce brain blood flow and increase the ischemic area. It is considered adequate to reduce no more than 15% blood pressure values during the first 24 hours. The only clinical conditions that require more intensive management of blood pressure are: ischemic stroke in the context of aortic dissection, pregnancy, quickly progressive kidney failure, heart failure and signs of hypertensive encephalopathy. Patients undergoing rt-PA treatment should have a blood pressure lower than 185/110 mmHg during infusion and for 24 hours thereafter. The selected drug is labetalol by 10 and 20-mg intravenous bolus. If hypertension remains, continuous dripping may be initiated, controlling the heart rate. Patients with bradycardia requiring a more intensive blood pressure could begin with sodium Nitroprusside by continuous dripping. (4)

Antiplatelet drugs

Patients who are not undergoing a thrombolytic treatment should begin the antiplatelet therapy within the first 24 hours. The only antiplatelet drug evaluated in two studies with almost 40,000 patients is aspirin. When given early, aspirin proved to reduce recurrence and mortality. The recommended initial dose ranges from 100 to 325 mg/day. (5)

Anticoagulants

Anticoagulation was not effective as acute treatment of ischemic stroke. Bedridden patients after the vascular event or with moderate to severe motor deficit that prevents initial ambulation should receive heparin sodium or low molecular weight heparin for prophylaxis of deep venous thrombosis. (1)

Fibrinolytics

Measures aimed at recanalization are based on the ischemic penumbra concept, which states that, by reducing the brain blood flow to critical levels, a few minutes later a main area is produced with irreversible ischemic changes. Such area is surrounded by a zone with electrocerebral silence but with undamaged cellular membranes. This zone, called ischemic penumbra, can restore its function if the flow is quickly restored. (1)

Intravenous rt-PA proved to be effective in doses of 0.9 mg/kg, with a maximum dose of 90 mg, when administered in a three-hour window based on the outcomes of the NINDS study. The meta-analyses of the intravenous rt-PA study showed that this benefit, although less significant, could be kept up to 4.5 hours, and this was confirmed by the ECASS III. In case of fibrinolysis, the symptomatic bleeding rate is 6.4 %, which seems to be associated with the severity of the neurological focus, the existence of extensive ischemic changes in the CT performed upon the patient's admission and hyperglycemia. (6,7,8)

The administration of rt-PA in a 3-hour normal window or 4.5-hour extended window should be preceded by the evaluation of strict exclusion criteria (see Tables 1 and 2). Systemic fibrinolysis is a *class 1 indication, Evidence A*.

Mechanical thrombectomy

In the last two years, several studies have shown the benefit of mechanical thrombectomy in patients with arterial obstruction of M1 and persistent intracranial carotid artery after having received the systemic thrombolysis in a window of up to 4.5 hours; class I indication, Evidence A. (9,10)

For the mechanical thrombectomy, the following criteria should be met:

- 0-1 pre-stroke Rankin scale.
- Stroke of less than 4.5 hours of evolution that has received rt-PA pursuant to the guidelines.
- Occlusion of M1 or intracranial internal carotid artery.
- Patient older than 18 years old.
- NIHSS > 6 points.
- ASPECTS score > 6 points.
- Beginning of treatment within six hours after symptoms onset.

In these studies, *stent retriever*-type devices were used, which showed a higher recanalization level and a lower complication rate *class I Evidence A.* (11)

ISCHEMIC STROKE: "THE GOLDEN HOUR"

Sequence and time recommended to improve outcomes:

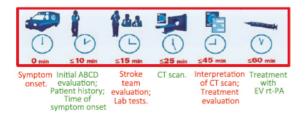


Figure 1. Initial management.

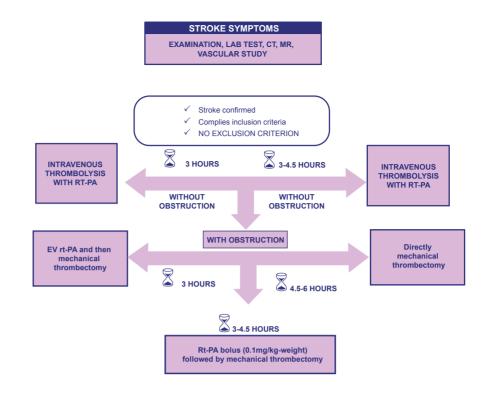


TABLE 1 Inclusion and exclusion criteria for thrombolysis with 3-hour window.

ELIGIBLE PATIENTS	ABSOLUTE EXCLUSION	RELATIVE EXCLUSION
 ✓ Symptoms onset 3 hours prior to treatment. ✓ Age ≥ 18 years old. 	 Severe TBI or stroke within previous 3 months. Suggestive SAH symptoms, even with normal CT. Non-compressible artery puncture in situ within previous 7 days. Intracranial bleeding history. Intracranial neoplasia, AVM or aneurysm. Recent intracranial or intraspinal surgery (previous 3 months). High blood pressure (SBP > 185 mmHg or DBP > 110 mmHg). Active internal bleeding. Hemorrhagic diathesis: platelets <100,000/mm3, prior treatment with heparin with long-term KPTT, prior treatment with oral anticoagulants with INR > 1.7 and TP > 15 seconds, current use of new anticoagulants (dabigatran, rivaroxaban o apixaban) Blood sugar > 400 mg/dl or < 50 mg/dl. CT showing multilobar infarction (hypodensity > 1/3 of the MCA area) 	 Minor stroke symptoms or of quick improvement. Pregnancy. Seizure at the onset with postictal residual neurological deficits. Major surgery or severe trauma within previous 14 days. Recent gastrointestinal or urinary tract bleeding (within previous 21 days). Recent AMI (within previous 3 months).

Figure 2.

Treatment flowchart

TABLE 2 Inclusion and exclusion criteria with 4.5-hour window.

ELIGIBLE PATIENTS	RELATIVE EXCLUSION CRITERIA
 ✓ Symptoms onset 4.5 hours prior to treatment. ✓ Age < 80 years old. 	 The same criteria for the 3-hour window with the following changes to be excluded: Age > 80 years old. Stroke severity: NIHSS > 25 points or hypodensity > 1/3 MCA. History of OCP use, regardless of INR value. Combination of diabetes + stroke history.

REFERENCES

- 1) Jauch E. C., Saver J. L., Adams H. P. Jr., Bruno A., Connors J. J., Demaerschalk B. M., Khatri P., McMullan P. W. Jr., Qureshi A. I., Rosenfield K., Scott P. A., Summers D. R., Wang D. Z., Wintermark M., Yonas H.; American Heart Association Stroke Council; Council onCardiovascular Nursing; Council on Peripheral Vascular Disease; Council onClinical Cardiology. Guidelines for the early management of patients with acuteischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013 Mar; 44(3): 870-947.
- 2) Mosley I., Nicol M., Donnan G., Patrick I., Dewey H. Stroke symptoms and the decision to call for an ambulance. Stroke. 2007; 38: 361–366.
- 3) Saver J. L., Fonarow G. C., Smith E. E., Reeves M. J., Grau-Sepúlveda M. V., Pan W., Olson D. M., Hernández AF, Peterson E. D., Schwamm L. H. Time to treatment with intravenous tissue plasminogen activator and outcome from acute ischemic stroke. JAMA. 2013 Jun 19; 309 (23): 2.480-8.
- 4) Goodfellow J. A., Dawson J., Quinn T. J. Management of blood pressure in acute stroke. Expert Rev Neurother. 2013 Aug; 13 (8): 911-23.
- 5) Chen Z. M., Sandercock P., Pan H. C., Counsell C., Collins R., Liu L. S., Xie J. X., Warlow C., Peto R. Indications for early aspirin use in acute ischemic stroke: Acombined analysis of 40.000 randomized patients from the chinese acute stroketrial and the international stroke trial. On behalf of the CAST and IST collaborative groups. Stroke. 2000 Jun; 31 (6):1.240-9.
- 6) Hacke W., Donnan G., Fieschi C., Kaste M., von Kummer R., Broderick J. P., Brott T., Frankel M., Grotta J. C., Haley E. C. Jr., Kwiatkowski T., Levine S. R., Lewandowski C., Lu M., Lyden P., Marler J. R., Patel S., Tilley B. C., Albers G., Bluhmki E., Wilhelm M., Hamilton S.; ATLANTIS Trials Investigators; ECASS Trials Investigators; NINDS rt-PA StudyGroup Investigators. Association of outcome with early stroke treatment: pool edanalysis of ATLANTIS, ECASS, and NINDS rt-PA stroke trials. Lancet. 2004 Mar 6; 363 (9411): 768-74.
- 7) Hacke W., Kaste M., Bluhmki E., Brozman M., Dávalos A., Guidetti D., Larrue V., Lees K. R., Medeghri Z., Machnig T., Schneider D., von Kummer R., Wahlgren N., Toni D.; ECASS Investigators. Thrombolysis with alteplase 3 to 4.5 hours after acute ischemic stroke. N Engl J Med. 2008 Sep 25; 359 (13): 1.317-29.
- 8) Tissue plasminogen activator for acute ischemic stroke. The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. N Engl J Med. 1995 Dec 14; 333 (24): 1.581-7.
- 9) Berkhemer O. A., Fransen P. S., Beumer D., van den Berg L. A., Lingsma H. F., Yoo A. J., Schonewille W. J., Vos J. A., Nederkoorn P. J., Wermer M. J., van Walderveen M. A., Staals J., Hofmeijer J., van Oostayen J. A., Lycklama à Nijeholt G. J., Boiten J., Brouwer P. A., Emmer B. J., de Bruijn S. F., van Dijk L. C., Kappelle L. J., Lo R. H., van Dijk E. J., de Vries J., de Kort P. L., van Rooij W. J., van den Berg J. S., van Hasselt B. A., Aerden L. A., Dallinga R. J., Visser M. C., Bot J. C., Vroomen P. C., Eshghi O., Schreuder T. H., Heijboer R. J., Keizer K., Tielbeek A. V., den Hertog H. M., Gerrits D. G., van den Berg-Vos R. M., Karas G. B., Steyerberg E. W., Flach H. Z., Marquering H. A., Sprengers M. E., Jenniskens S. F., Beenen L. F., van den Berg R., Koudstaal P. J., van Zwam W. H., Roos Y. B., van der Lugt A., van Oostenbrugge R. J., Majoie C. B., Dippel D. W.; MR. CLEAN Investigators. A randomized trial of intraarterialtreatment for acute ischemic stroke. N Engl J Med. 2015 Jan 1; 372 (1): 11-20.
- 10) Campbell B. C., Mitchell P. J., Kleinig T. J., Dewey H. M., Churilov L., Yassi N., Yan



B., Dowling R. J., Parsons M. W., Oxley T. J., Wu T. Y., Brooks M., Simpson M. A., Miteff F., Levi C. R., Krause M., Harrington T. J., Faulder K. C., Steinfort B. S., Priglinger M., Ang T., Scroop R., Barber P. A., McGuinness B., Wijeratne T., Phan T. G., Chong W., Chandra R. V., Bladin C. F., Badve M., Rice H., de Villiers L., Ma H., Desmond P. M., Donnan G. A., Davis S. M.; EXTEND-IA Investigators. Endovascular therapy for ischemic stroke with perfusion-imaging selection. N Engl. J Med. 2015 Mar 12; 372 (11): 1009-18.

11) Saver J. L., Goyal M., Bonafe A., Diener H. C., Levy E. I., Pereira V. M., Albers G. W., Cognard C., Cohen D. J., Hacke W., Jansen O., Jovin T. G., Mattle H. P., Nogueira R. G., Siddiqui A. H., Yavagal D. R., Baxter B. W., Devlin T. G., Lopes D. K., Reddy V. K., du Mesnil de Rochemont R., Singer O. C., Jahan R.; SWIFT PRIME Investigators. Stentretriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. 2015 Jun 11; 372 (24): 2.285-95.

I) CONTROVERSY I: CARDIAC SURGERY AND CAROTID DISEASE

Even nowadays, some controversies arise at the time of treating patients with carotid disease and stroke in the context of a central concomitant cardiac surgery. It is also questionable if the endarterectomy or the carotid stenting significantly reduce the risk of ischemic stroke, especially in asymptomatic patients. This is mainly due to two reasons. The first one is that sometimes the causal relation between carotid stenosis and post-cardiac surgery ischemic stroke is difficult to identify. Some observe that the prophylactic endarterectomy would be performed in a reduced group of patients. (1) In most cases, carotid atheromatous disease would behave as a marker in the context of its vascular risk factors and ischemic stroke could be the result of aortic arch plaques during extracorporeal circulation (2-3) or secondary to the presence of postoperative arrhythmias, since up to 30% of patients show an AF (4-5). Second, the variability of the studies conducted, the age of the population under study, inaccurate patient inclusion and exclusion criteria, countless strategies to avoid ischemic stroke, both from the specific point of view of the surgical procedures to be performed (aortic cannulation, non-circulatory assistance surgery, oxygenators, arterial filters, etc.) and the carotid disease (optimization of medical treatment, anticoagulants, carotid stenting, endarterectomy, etc.) affect the number of neurological complications and hinder the proper interpretation of results. While some observational studies show acceptable outcomes in combined surgery (6), others do not succeed in doing so (7). Neurological complications associated with cardiovascular surgery are frequent, causing great morbidity, mortality and disability. These may be divided into type 1, which includes stroke, stupor and coma, and type 2, which refers to those affecting the cognitive function with memory impairment, orientation and/or confusion. Alterations in neuropsychological tests are common, with an incidence that ranges from 30% to 80%. (8) Intermediate manifestations are difficult to categorize.

Global stroke incidence associated with cardiac surgeries varies. Authors refer to values that range between 2.0% and 1.4%, depending on the kind of study (prospective and retrospective). (9)

The non-identification of the patients observed in the different studies should be highlighted. In many cases, neither previously

symptomatic or asymptomatic patients nor their bilateralism and rate of occlusion or partial stenosis are distinguished. In many of these situations (for example, full carotid occlusions), it is already known that endarterectomies or carotid stenting are not very useful. Patients with bilateral lesions would imply higher risk. In cases of asymptomatic carotid stenosis, it has not been observed an increase in the percentage of neurological complications or ipsilateral stroke related to cardiac surgery with extracorporeal circulation (ECC). (9) A meta-analysis found prevalence of stroke, death, and combined stroke and death in patients who underwent cardiac surgery and with carotid lesions higher than 50%, which were not subject to prophylactic endarterectomy of 7.4%, 4.8% and 8.3%, respectively. For patients with lesions between 80-99%, the incidence increased to 9.1%. However, these outcomes combine many of the cases that cannot be revascularized, thus increasing the risk of stroke. (11) Patients with neurological symptoms previously informed (transient ischemic attack or stroke) and with unilateral or bilateral occlusive lesions (and who would not benefit from prophylactic treatment) should be excluded. Throughout his review, Naylor details the risk of death, stroke (30 days) and prevalence of death/perioperative stroke in patients with carotid lesions between 50% - 99% and without prophylactic treatment, with 3.8% in each of the groups. (10)

Nevertheless, most strokes related to the performance of an open cardiac surgery would not seem to be associated with concomitant carotid stenosis. In cases of asymptomatic carotid stenosis, no increase in the percentage of ipsilateral neurological complications related to the cardiac surgery was observed. The causes of stroke in this context may be multifactorial, not only depending on the carotid lesion. Macro and micro embolization phenomena may be the result of surgical manipulation of the aorta or the heart chambers. Likewise, hypoperfusion phenomena may have a prevailing role. However, in cases of severe bilateral carotid stenosis, encephalic hypoperfusion may not occur during ECC. (12,13)

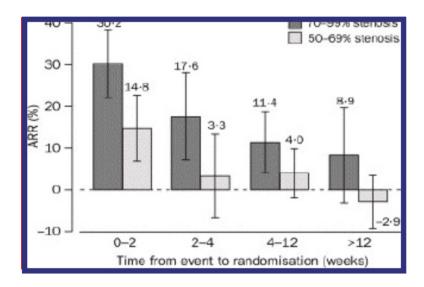
So far, there is no evidence that the endarterectomy benefit patients with asymptomatic carotid disease who must undergo a coronary surgery. (14) Some data suggest that combined surgery implies higher procedural risk (15) and thus, in most cases, a staged carotid procedure is preferred over cardiac surgery. Under these circumstances, the endarterectomy would be prioritized over stenting, since the latter would imply a greater delay for coronary acute revascularization due to the antiplatelet therapy and a higher risk of bleeding after cardiac surgery. The use of endovenous heparin *post-stenting* until cardiac surgery has not been tested. As this circumstance is accepted, stenting should not be considered a first strategy. (16)

REFERENCES

- 1.-Van der Heyden J., Suttorp M. J., Bal E. T., Ernst J. M., Ackerstaff R. G., Schaap J., et al. Staged carotid angioplasty and stenting followed by cardiac surgery in patients with severe asymptomatic carotid artery stenosis: early and long term results. Circulation 2007; 116: 2.036-42.
- 2.-Mandak J., Lonsky V., Dominik J., et al. Concomitant coronary and asymptomatic carotid artery disease in patients factor to myocardial revascularization. Acta Médica 1996; 39:31-34.
- 3.-Da Rosa Marcelo. P., Schwendler R., Lopes R., Portal Vera L. Open Access Carotid Artery Stenosis Associated with Increased Mortality in Patients who Underwent Coronary Artery Bypass Grafting: A Single Center Experience. The Open Cardiovascular Medicine Journal, 2013, 7, 76-81.
- 4.- Mathew J., Parks R., Savino J., et al. Atrial fibrillation following coronary artery bypass graft surgery. JAMA 1996; 276: 300 306.
- 5.- O'Neill B., Furlan A., Hobbs R. Risk of stroke in patients with transient post operative atrial fibrillation/flutter. Stroke 1983; 14: 133.
- 6.- Ricotta J. J., Char D. J., Cuadra S. A., Bilfinger T. V., Wall L. P., Giron F., et al. Modeling stroke risk after coronary artery bypass and combined coronary artery bypass and carotid endarterectomy. Stroke 2003; 5: 1212-7.
- 7.- Brown K. R., Kresowik T. F., Chin M. H., Kresowik R. A., Grund S. L., Hendel M. E. Multistate population-based outcomes of combined carotid endarterectomy and coronary artery bypass. J Vasc Surg 2003; 1: 32-9.
- 8.- Roach G., Kanchuger M., Mora C., et al. Adverse cerebral outcomes after coronary by pass surgery. N. Eng J. Med. 1996; 335: 1857 1863.
- 9.- Carotid Artery Disease and Stroke During Coronary Artery Bypass: a Critical Review of the Literature Naylor A. R., Mehta Z., Rothwell P. M., Bell P. R. F Eur J Vasc Endovasc Surg 23, 283–294 (2002).
- 10.- Stroke after Cardiac Surgery and its Association with Asymptomatic Carotid Disease: An Updated Systematic Review and Meta-analysis Naylor A. R., Bown M. J. Eur J Vasc Endovasc Surg (2011) 41, 607-624.
- 11.- Timaran C. H., Rosero E. B., Smith S. T., Valentine R. J., Modrall J. G., Clagett G. P. Trends and outcomes of concurrent carotid revascularization and coronary bypass. J Vasc Surg 2008; 48: 355-61.
- 12.- Ali I., Cummings B., Sullivan J. et al. The risk of cerebrovascular accident in patients with asymptomatic cortical carotid artery stenosis who undergo open heart surgery. Can J Surg 1998; 41: 374-378.
- 13.- Y. Li D. Walicki C. Mathiesen Strokes After Cardiac Surgery and Relationship to Carotid Stenosis Arch Neurol 2009; 66: 1091-6.
- 14.- 2011 Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease Thomas G. Brott Th $\rm G$ & cols Circulation. 2011;124: e54-e130.
- 15.- Dubinsky R. M. and Lai S. M. Mortality from combined carotid endarterectomy and coronary artery bypass surgery in the US. Neurology 2007; 68: 195-7.
- 16.- Shishehbor Mehdi H. Sridhar Venkatachalam, Zhiyuan Sun, M. S., y Jeevanantham Rajeswaran, Samir R. Kapadia, Christopher Bajzer, Heather L. Gornik, B. H. Gray, J. R. Bartholomew, Daniel G. C., Joseph F. Sabik III, Eugene H. Blackstone. A Direct Comparison of Early and Late Outcomes With Three Approaches to Carotid Revascularization and Open Heart Surgery, (J Am Coll Cardiol 2013; 62: 1948–56).

II) CONTROVERSY II: TIME FOR SURGERY IN PATIENTS WITH SYMPTOMATIC CAROTID ATHEROMATOUS DISEASE

The role of carotid artery endarterectomy (CAE) in symptomatic patients with extracranial carotid artery disease has been firmly established since the publication, during the 1990s, of the classical studies North American Symptomatic Carotid Endarterectomy Trial (NASCET) http://www.elsevier.es/es-revista-angiologia-294articulo-endarterectomia-carotidea-precoz-versus-diferida-90359406 - bibl and European Carotid Surgery Trial (ECST). (1,2) However, the time for the performance of a CAE after a neurological event has become a subject of controversy. Historically, literature had suggested that, after a stroke, a CAE needed to be performed 6 weeks following the ischemic event (3) to minimize the risk of postoperative complications such as brain edema and possible postoperative bleeding of the previous stroke. However, in 2004, the publication of a subgroup reanalysis of the NASCET and ECST studies (4) marked a turning point, questioning the historical paradigm that defers the CAE 6 weeks after the stroke. This study had concluded that patients with ≥ 70% symptomatic carotid artery stenosis benefited more if operated on within the first 2 weeks after the stroke.



Early surgery within the first 14 days after the stroke is the most effective measure to reduce the risk of new events in symptomatic patients (Class II Evidence A). Clinical conditions that may be limited by this indication are: post-stroke bad neurological condition (patients with consciousness deterioration, severe focal neurological deficit, extensive ischemic lesions, with edema or bleeding transformation or patient's clinical instability).



REFERENCES

- 1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatics patients with high-grade carotid stenosis. N Engl.J Med. 1991; 325: 445-53.
- 2. European Carotid Surgery Trialists' Collaborative Group. MRC European Carotid Surgery Trial. Interim results for symptomatic patients with severe (70-99%) or with mild (0-29%) carotid stenosis. Lancet. 1991; 337: 1.235-43.
- 3. Blaisdell W. F., Clauss R. H., Galbraith J. G., Imparato A. M., Wylie E. J. Joint Study of extracranial arterial occlusion. A review of surgical considerations. JAMA.1969; 209: 1.889-995.
- 4. Rothwell P. M., Eliasziw M., Gutnikov S. A., for the Carotid Endarterectomy Trialists Collaboration. Endarterectomy for symptomatic carotid stenosis in relation to clinical subgroups and timing of surgery. Lancet. 2004; 363:915-24.



ABSTRACT:

Introduction: In 1995, John Wolfe referred to a subgroup of patients that suffered from sudden critical ischemia, considering that these patients manifested themselves by changing oxygen requirements at tissue level, and called this stage subcritical limb ischemia. Likewise, he showed that these patients had a lower amputation rate as they had used the medical treatment as opposed to that of critical ischemia.

Aim: To define the subcritical limb ischemia, diagnostic methodology and to recommend surgical medical treatment.

Materials and method: The different procedural guidelines were evaluated, taking into account clinical and diagnostic parameters; evidence-based medicine recommendations were developed.

Results: We define subcritical limb ischemia as the clinical status of occlusive arterial disease, characterized by disabling claudication (generally less than 200 mins), without pain at rest and trophic lesions, with an ankle-brachial index (ABI) higher than or equal to 0.40, ankle pressure > 50 mmHG or O2 pressures in Hallux equal to or higher than 40 mmHg and non-invasive study showing occlusion in both tibial arteries.

Conclusions: Patients with subcritical ischemia constitute a patient group that deserves greater attention than those with stable claudication.

AUTHORS:

PAOLINI, JUAN ESTEBAN; MUÑOZ, ALBERTO; DEMICHELI, ELVIO; NASIF, JUAN MOISÉS.

CORRESPONDENCE: juanestebanpaolini@gmail.com

Firstly, we should inform the rest of the medical community of the clinical characteristics of this stage to detect patients that are included in this group, especially those medical specializations that treat elderly patients.

Palabras Clave: Peripheral arterial disease, subcritical limb ischemia, critical limb ischemia.

INTRODUCTION

The concept of critical limb ischemia¹ attempted to define the terminal stage of the peripheral arterial disease (PAD), whose most characteristic symptoms and signs are pain at rest, trophic lesions and gangrene. In a certain way, this definition tried to join the classifications made by Fontaine (1951)² and Rutherford (1980),³ but, due to statistical reasons and lack of clear evidence in trying to exclude damages caused by diabetic neuropathy, the authors excluded diabetic patients;¹ therefore, in 2014, the Society for Vascular Surgery proposed a new definition based on the so-called WIfI (Wound, Ischemia and Foot Infection),⁴ i.e., taking into consideration wound characteristics, ischemia level and foot infection, this being the way to include diabetic patients.

In 1995, John Wolfe⁵ referred to a subgroup of patients that suffered from sudden critical ischemia, considering that these patients manifested themselves by changing oxygen requirements at tissue level, and called this stage subcritical limb ischemia. Likewise, he showed that these patients had a lower amputation rate as they had used the medical treatment as opposed to that of critical ischemia. In 2007, White and Rutherford⁶ again attempted to redefine this group of patients, as a previous stage of critical limb ischemia, and stressed that, although these patients did not suffer from pain at rest, trophic lesions and tissue gangrene, they had an ankle-brachial index of 0.4, with the patients' advanced age as another relevant element. Different records have associated PAD in elder people with high morbidity and mortality rates.⁷⁻⁸

Between 25% and 30% of patients with symptomatic PAD are within this subgroup (higher than critical ischemia). They are obviously considered as population of high cardiovascular risk, as in the other PAD stages.

A recent study (SAGE)⁹ shows that there are 14 million patients with PAD in South America (from the published figures, Argentina, Brazil and Colombia represent 76%

of these patients), which will reach 23 million by 2030. Nowadays, patients with critical ischemia represent 1.3 million in this region (79% of them again in Argentina, Brazil and Colombia); therefore, this subgroup under study is deemed to be even greater.

We consider that this kind of patients increasingly requires our professional assistance, and due to this we have redefined clinical characteristics, proposing a differential diagnosis and possible treatments.

DEFINITION

Clinical status of occlusive arterial disease, characterized by disabling claudication (generally less than 200 mins), without pain at rest or trophic lesions, with an ankle-brachial index (ABI) higher than or equal to 0.40, ankle pressure > 50 mmHG or O2 pressures in Hallux equal to or higher than 40mmHg and non-invasive study showing occlusion in both tibial arteries.

CLINICAL EXAMINATION

The essential characteristic is the so-called disabling claudication, which means such pain that prevents the patient from doing minimum tasks, considering it as decisive if it appears at 200 mins or less, comparable with Stage IIb in Fontaine classification² or Category 3 or Severe claudication in Rutherford classification.³

Several studies confirm that the usual symptomatology of arterial claudication and the typical pain are not always present in patients with PAD. Sometimes, patients suffer from these symptoms but do not look for medical assistance because they consider them typical pains of their age, with the advanced age (octogenarian, nonagenarian people, etc.) as one of the characteristics of this patient group.

In addition, there is still no adequate level of suspicion of this problem within the medical community, leaving out the verification of distal pulses and, in the absence of trophic lesions, little attention is paid.⁶

To further worsen the situation, many patients with a severe PAD walk very little or do not walk at all due to other diseases (osteoarticular pathology, COPD, etc.) or because they are not used to doing so, and make their clinical debut

at a very advanced stage of their disease. Therefore, they are often at the stage of subcritical ischemia.⁵⁻⁶

The most affected population is usually that of elderly patients, with other comorbidities (dyslipidemia, severe smoking, diabetes, chronic renal failure (CRDF)⁶. Special attention should be paid to younger women with diabetes, severe smoking and chronic renal failure, as a subgroup of risk.

Patients who have undergone failed previous endovascular or surgical treatments usually remain at a subcritical stage. Regarding hemodynamics and distal blood pressure, these subcritical patients have enough perfusion pressure to keep skin integrity, but in case of (major or minor) trauma, they are not able to reach cicatrization within a period of 3 to 4 weeks.

DIAGNOSIS

Diagnosis does not differ from current PAD guidelines:

Recommendation I¹⁰⁻¹¹

- a. The ankle-brachial index (ABI) is the first non-invasive study to be performed if a patient is suspected of suffering from subcritical limb ischemia. If the result is doubtful, the post exercise ABI (treadmill) with recommendation of *Grade 1 evidence A* should be added.
- b. In patients with diabetes and/or chronic renal failure, the doppler echocardiography is the complementary non-invasive study, confirming the anatomic compromise and subsequent use of contrasted methods such as the angio-tomography/angio magnetic resonance with renal protection and recommendation *Grade 1* evidence B.
- c. We suggest the angiography, if possible with digital substraction, to be prescribed for those patients that will invariably undergo an invasive treatment (whether endovascular, surgical or hybrid) (*Grade 1 evidence B*).

Measuring segmental pressures (including Hallux pressures) is another study that confirms the subcritical stage of the disease.

Each of these methods will be chosen according to the speed and availability of each service. We should not forget that these patients can rapidly evolve to critical ischemia.

We should have a high level of suspicion in the high-risk patients described above.

If we consider the ABI, these patients usually have indexes between 0.4 and 0.7.

Regarding the segmental pressures in Hallux, they are above 50 mmHg.

Due to the seriousness of the clinical picture, such measurements should not delay treatment if they cannot be verified.

TREATMENT

Medical Treatment

After it is confirmed that we have a special group of patients with a large number of associated risks, such as dyslipidemia, arterial hypertension, diabetes, CRF, severe smoking, osteoarthritis, obesity, heart disease, cerebrovascular atherosclerotic disease, etc., initial treatment seeks to stabilize and treat all the above-mentioned factors. However, we should recognize that it is a group of high risk of morbidity and mortality at a subcritical stage, which means that we cannot ignore this special feature hoping that, only with the improvement of the observed risk factors, we will be able to modify their situation. Therefore, we should regularly control the patient by modifying the different treatments as needed and individually adjust them according to the patient's needs. 10-11

The treatment for patients without critical ischemia usually consists of the control of risk factors, the use of statins, antiplatelet therapy, oral vasodilators, and walking exercises (better if supervised) for a period of 60 days. According to the response, the same treatment is continued or a more invasive treatment is implemented.

During the subcritical stage, patients are restrained by pain and there is an imminent risk of developing critical ischemia (pain at rest and/or trophic lesions). Therefore, treatment should be quick and effective, without any delay or therapeutic test period, as at the critical ischemia stage. Recognizing that revascularization is the best treatment, we should adapt to each patient's risks.

High-risk patients (diabetes, chronic renal failure or congestive cardiac insufficiency), or those who cannot be revascularized by surgical or endovascular means, first will receive medical treatment and then they will receive invasive treatment only upon failure of the former.

Recommendation II¹⁰⁻¹¹

- a) We recommend to stop smoking habits with the assistance of multidisciplinary teams (*Grade 1 Evidence A*).
- b) Aggressive treatment of dyslipidemia with statins (*Grade 1 Evidence A*).
- c) Levels of glycosylated hemoglobin (Hb G) < 6.5 (*Grade 1 Evidence B*).
- d) Antiplatelet therapy with acetylsalicylic acid (ASS) 75 to 325 mg/day (*Grade 1 Evidence A*).
- e) Use of clopidogrel as an alternative to ASS or in combined therapies, in patients with history of PAD or another arterial line, 75 mg/day (*Grade 1 Evidence B*).
- f) Use of cilostazol of progressive application reaching 200mg/day in those patients without congestive heart failure (*Grade 2 Evidence A*).
- g) Use of pentoxifylline in those cilostazol-intolerant patients or to whom it is contraindicated, up to 400 mg/ 3 times a day (*Grade 2 Evidence B*).
- h) We recommend the implementation of supervised walking exercises in triweekly walking sessions for 30 to 60 mins (*Grade 1 Evidence A*).

Pain management

This topic is developed in the Vascular Pain Management chapter.

USE OF PROSTAGLANDIN

The use of prostaglandin is deemed a medical treatment option. Although such use has not been supported yet by the Food and Drug Administration (FDA), many European and Asian publications confirm its usefulness in patients with critical limb ischemia. Considering that perhaps such a use in this patient group would have a better outcome since they are at a less severe stage, and especially for those patients that cannot be revascularized or have surgical high risk, intravenous E1 prostaglandin treatment is the best option.

Recommendation III¹²⁻¹³⁻¹⁴

Use of intravenous prostaglandin of up to 80 ug/day for 21 consecutive days, (*Grade 2 Evidence B*).

Revascularization

We consider it important in the defined patient group to exhaust medical treatment scopes. In case it does not improve the patient's symptoms after a period of 90 to 120 days (disabling claudication), we should choose the most appropriate therapeutic invasive method (endoluminal, open or hybrid surgery). This will depend on a detailed evaluation of each clinical case, considering the anatomy of the occlusive lesions, the available means and the experience of the intervening team.¹⁰⁻¹¹⁻¹⁵

We should take into consideration that, in those patients with lumbar spine arthritis, coxofemoral joint compromise, severe ischemic cardiopathy, unstable heart failure, morbid obesity, stroke or advanced renal failure, invasive treatment will not have any benefit or great changes with respect to claudication, increasing the risk of morbidity and mortality.¹¹

Some reports⁵⁻⁶ show that patients at subcritical stages experienced better results with invasive treatments than those patients suffering from critical limb ischemia. Also, we know that we generally find lesions that compromise more than one arterial line, making it difficult to choose the strategy to be followed,¹⁵ considering the need of inflow and outflow permeability, regardless of the invasive treatment chosen.

Recommendation IV

a) We recommend the invasive treatment for patients in whom the medical treatment has failed and the benefits of the treatment to be used exceed the possible risks of the selected procedure (*Grade 1 Evidence B*).

DISCUSSION

Pursuant to the paper by Wolfe and Wyatt,⁵ in comparing two patient groups, one with critical ischemia and the other with subcritical ischemia, it was found that, although in both groups there was a mortality rate of 26% regardless of the treatment used, in the subcritical ischemia group, 27% of patients with medical treatment did not show any progress (Fig. 1), given that, in 1997, the benefits of cilostazol, coupled with antiplatelet therapy, management of statins and effectiveness of programmed walking sessions had not been proven. Also, the definition of critical ischemia was not interpreted as it is today.⁴

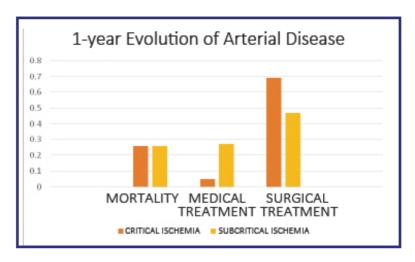


Fig 1: Modifed chart of Wolfe JHN and Wyatt MG.5

Considering the natural history of patients who generally suffer from intermittent claudication and only receive medical treatment over five years, the Guidelines of ACC/AHA¹⁶ show that 20% - 30% of patients progress to disabling claudication and only 1% - 3% progress to critical ischemia; the population that is really at a subcritical stage but is not assessed should be considered (Fig. 2).

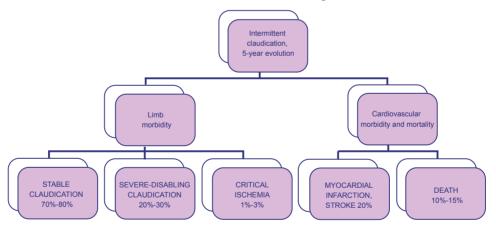


Fig 2 Modified chart of Hirsch AT, Haskal ZJ, Hertzer NR, ACC/AHA 2005. 16

According to the foregoing, we consider subcritical limb ischemia as a stage suffered by a substantial number of patients and is underestimated. Also, as we have already mentioned, the population with arterial limb diseases in Latin American countries is increasing, as well as the age of the population in our countries, meaning that subcritical limb ischemia may affect a larger number of patients.

Taking into account that in Fontaine² and Rutherford³ classifications this stage is not clearly defined, we propose to create a new one.

Peripheral arterial disease classification of the III End of the World Intersocieties Consensus (EWIC)

Although the existence of these patients has always been recognized, they were never classified as another category within traditional classifications.

If we consider Fontaine classification,² patients would be Stage IIb; if we consider Rutherford classification,³ patients would be Grade 3.

Therefore, we propose the following Peripheral arterial disease classification, taking into consideration symptoms (claudication severity), ankle-brachial index, O2 partial pressure of the affected foot toe, ankle systolic pressure and existence of trophic lesions and/or gangrene, thus defining four stages: (Chart 1)

Stage 1: Asymptomatic peripheral arterial disease.

Stage 2: Intermittent claudication.

Stage 3: Subcritical limb ischemia.

Stage 4: Critical limb ischemia.

STAGES	A/B Index	Claudication	PO2mmHg	Ankle Systolic Pressure	Trophic Lesions
1 Asymptomatic PAD	>0.8	> 600 m	> 60 mmHg	>100 mmHg	-
2 Intermittent Claudication	0.8-0.6	600 -200 m	60-40 mmHg	70-100 mmHg	-
3 Subcritical Limb Ischemia	0.6-04	= 200 m</td <td>40-30 mmHg</td> <td>50-70 mmHg</td> <td>-</td>	40-30 mmHg	50-70 mmHg	-
4 Critical Limb Ischemia	< 0.4	Pain at Rest	< 30 mmHg	< 50 mmHg	8,348

Chart 1: PAD classification of the III EWIC.

CONCLUSIONS

Patients with subcritical ischemia constitute a patient group that deserves greater attention than those with stable claudication. Firstly, we should inform the rest of the medical community of the clinical characteristics of this stage to detect patients that are included in this group, especially those medical specializations that treat elderly patients.

If we could compare ischemic cardiopathy with PAD patients, we would establish the following groups: those suffering from stable angor/intermittent claudication v. minimum effort angor/ subcritical ischemia v. unstable angor/critical ischemia.

Perhaps the assistance and control of these patients would allow early detection of patients with critical ischemia, thus reducing morbidity and mortality rates. Also, the definition of this patient group allows to better assess the different treatments that are applied currently.

Considering that the expected outcomes are better than those in critical patients. ■

REFERENCIAS

- 1). Bell P. R. F., Charlesworth D., De Palma R., Jamieson C. (1982) The definition of critical ischaemia of a limb. Br J Surg 69: 52.1
- 2). Fontaine R., Kim M., Kieny R. Die chirurgische Behandlung der peripheren Durchblutungsstörungen. Helvetia Chirurgica Acta 1954;5/6:199-533.
- 3). Rutherford R. B., Baker J. D., Ernst C., Johnston K. W., Porter J. M., Ahn S., Jones D. N. Recommended standards forre port sdealing with lower extremit yischemia. Revised version. J VascSurg 1997;26:517-538.
- 4). Mills J. L. Sr., Conte M. S., Armstrong D. G., et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification base don wound, ischemia, and foot infection (WIff). J Vasc Surg 2014 Jan; 59 (1): 220-34.
- 5). Wolfe J. N., Wyatt M. G.: Critical and sub critical ischaemia. Eur J Vasc Endovasc Surg 13: 578-582, 1997.
- 6). White J. V. 1, Rutherford R. B., Ryjewski C. Chronic subcritical limbischemia: a por ly recognized stage of critical limbischemia. Semin Vasc Surg. 2007 Mar; 20(1):62-7.
- 7). McFalls E. O., Ward H. B., Moritz T. E. et al. Coronary-artery revascularization before elective major vascular surgery, CARP Trial. N Engl J Med. 2004; 351: Dec 30; 351 (27): 2795-804.
- 8). Steg P. G., Bhatt D. L., Wilson P. W. et al. One-year cardiovascular eventrates in out patients with a thero thrombosis, REACH Registry. JAMA 2007. Mar 21; 297(11):1197-206.
- 9). The SAGE GROUP: Reports that Approximately 14 Million People in South America suffer from Peripheral Artery Disease, July 09, 2013–10: 30 AM Eastern Dayligth Time, Atlanta (Business Wire).
- 10). Paolini J. E., Lamelza V. H., Demicheli E., Nasif J. M. y col. Manejo de la Enfermedad Arterial de los Miembros Inferiores 1st End of the World Intersocieties Consensus (EWIC). Fundación Craveri. 2012Cap 5: 57-73.
- 11). Society for Vascular Surgery Practice Guide lines for Atherosclerotic Occlusive Disease of the Lower Extremities: Management of Asymptomatic Disease and Claudication JVS Supplement S. March 2015 Volume 61.
- 12). Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) JACC Vol. 61, No. 14, 2013 April 9, 2013:1555–70.
- 13). Creutzig A., Lehmacher R., Elze Meta-analysis of randomised controlled prostaglandin E1 studies in peripheral arterial occlusive disease stages III and IV, European Journal of Vascular Medicine Vasa Aug 2004, Vol. 33, Issue 3, pp. 137-144.
- 14). Mlekusch, Schillinger, Sabeti, Al-Awami, Gschwandtner, Minar, Effects of intravenous prostaglandin E1 on arterial compliance: a randomized controlled trial Vasa Jan 2013,Issue. 7 pp. 131-136.
- 15). Dormandy J., Rutherford R. B.: Management of peripheral arterial disease (PAD). Transatlantic Inter-Society Consensus (TASC). J Vasc Surg 31 (Pt2): S170, 2000.
- 16). Hirsch A. T., Haskal Z. J., Hertzer N. R., Bakal C. W., Creager M. A., Halperin J. L., et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborativereportfrom the American Association for Vascular Surgery/ Societyfor Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Societyfor Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Forceon Practice Guidelines (Writing Committee to Develop Guide lines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; Transatlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation 2006; 113: e 463-654.



VARICOSE VEIN SURGERY BY RADIOFREQUENCY ABLATION:

IMMEDIATE AND 6-MONTH POSTOPERATIVE EVALUATION OF THE TREATMENT FOR GREAT SAPHENOUS VEIN INSUFFICIENCY

ABSTRACT:

Introduction: The so-called internal saphenectomy has been the standard surgical treatment for many years. The advent of the treatment of venous insufficiency by thermal ablation in the 90's introduced the possibility of performing minimally invasive procedures, with the radiofrequency ablation of the saphenous vein among these options.

Aim: To evaluate prospectively and by Doppler scanning the radiofrequency ablation treatment for great saphenous vein insufficiency.

Materials and method: Between April and December 2015, a longitudinal prospective study was conducted on 50 cases (31 women, 19 men; 19 - 80 years old, with a median of 51 years) treated for chronic great saphenous vein insufficiency with varicose vein surgery by endovenous radiofrequency ablation. The treatment indication included the following patients according to the Clinical, Etiologic, Anatomic and Pathophysiologic (CEAP) classification: CEAP2 (n=31), CEAP3 (n=3) and CEAP4a (n=16). Twenty five of the 50 patients treated were associated with micro-incision phlebectomy of insufficient epifascial tributaries in the treated leg. All patients were controlled at the clinic, where a Doppler scan was performed on them to check the closure of the great saphenous vein treated and they were examined for pain and other complications.

AUTHORS:

LEGUIZAMÓN, M.;

ARLORO, V.;

PAOLINI, J. E.:

GIRALDEZ, N.;

FROSCH. M.:

MÉNDEZ M. S.:

COHEN, C. I.;

LAMELZA, V.

Peripheral Vascular Surgery Service of Sanatorio Dr. Julio Méndez, City of Buenos Aires.

CORRESPONDENCE: mail: cvascularobsba@gmail.com

Results: The clinical remission of the effects of the great saphenous vein insufficiency treated was observed from the first month after treatment in all patients. At the same time, a Doppler scan found that 62% (n=31) of patients had great saphenous vein occlusion 2 cm from the saphenofemoral junction. No patient presented deep venous thrombosis or thrombus migration. As to follow-up, 36% (n=18) received follow-up care for nine months and 64% (n=32) for six months. Using the verbal numerical scale for pain assessment, 86% (n=43) of patients said they felt no pain, 2% (n=1) had mild pain, 10% (n=5) felt moderate pain and 2% (n=1) suffered from severe pain. As for procedure-related complications, 2 patients presented infection on the puncture site that was treated with antibiotics. 4 patients felt pain that required a combination of NSAIDs and pregabalin for its resolution, while 2 patients were treated with a centrally acting analgesic, NSAID and pregabalin for its treatment. Ecchymosis at the thigh level was observed in 2 cases.

Conclusions: The results obtained in relation to the closure of the insufficient great saphenous vein and the clinical remission of symptoms in all cases make varicose vein surgery by endovenous radiofrequency ablation a safe and effective technique. While reported complications are comparable to the results published for endovenous treatments, they correspond to the beginning of the learning curve for the procedure.

Keywords: Endovenous thermal ablation, varicose vein surgery by radiofrequency, superficial venous insufficiency.

INTRODUCTION

Since Friedrich Trendelenburg's description¹ of his operative technique of great saphenous vein ligation in 1891, open surgical therapy has been the mainstay of the treatment of patients with symptomatic chronic venous insufficiency. John Homans in 1916 advocated the technique of ligation of tributaries at the saphenofemoral junction², and Keller³ and Mayo⁴ promoted the saphenous vein stripping technique in the early 1900. Recently, minimally invasive endovenous techniques that reduce postoperative complications and improve recovery time and quality of life in comparison with standard surgical techniques have been introduced for the treatment of varicose pathology.¹ Our working group has applied the technique of

endovenous radiofrequency ablation for the treatment of great saphenous vein insufficiency. The purpose of our work was to prospectively evaluate by Doppler scanning the immediate and 6-month results of the radiofrequency ablation treatment for great saphenous vein insufficiency.

MATERIALS AND METHODS

Radiofrequency ablation is the controlled denaturation of collagen in the vein wall by heat, with the consequent collapse of its lumen.¹ To this end, a 7F endovenous radiofrequency ablation catheter 100 cm long connected to a RF energy generator is used.

In the period between April and December 2015, a longitudinal prospective study of clinical follow-up was conducted by collecting information about 50 patients diagnosed with great saphenous vein insufficiency by ultrasound scan that underwent radiofrequency ablation surgery in our Service. The treated population consisted of 31 women and 19 men between 19 and 80 years, with a median of 51 years. Clinic postoperative controls were performed for 6 months to evaluate the clinical response and ultrasonographic changes in order to verify the degree of procedure-induced thrombosis of the great saphenous vein.²

The selection of patients with symptomatic venous insufficiency was based on the Clinical, Etiologic, Anatomic and Pathophysiologic (CEAP) classification and included CEAP1 to CEAP4 stage patients with irregular response to medical treatment, in whom saphenofemoral junction and/or great saphenous vein insufficiency, with or without collaterals, was observed by ultrasound scan (Figure 1).

CEAP classification for chronic venous disease

C0 No visible or palpable signs of venous disease

C1 Telangiectasies or reticular veins

C2 Varicose veins

C3 Edema

C4a Pigmentation and eczema

C4b Lipodermatosclerosis and atrophie blanche

C5 Healed venous ulcer

C6 Active venous ulcer

Eight of the 50 patients had received previous treatment with sclerotherapy in other institutions, 2 with microsurgery and 1 with both procedures. Initial medical treatment included elastic compression stockings (mostly with 8/15-mmHg

compression), associated with oral venotonics (diosmin-hesperidine) and a change of habits of the patient (exercises, change of footwear, no prolonged standing position, rest in the Trendelenburg position). Doppler scanning was used as the diagnostic method, determining reflux time above 500 milliseconds and saphenous vein diameter over 25 mm³.

For the preoperative evaluation, standard pre-surgical studies were performed with laboratory tests, including blood count and coagulation profile, and basic cardiac evaluation. The studies of all patients showed acceptable parameters, with low surgical risk.

Surgical technique

The procedure was performed at an operating room on all patients and under spinal anesthesia in 38 patients, local anesthesia associated with neuroleptanalgesia in 10 patients and general anesthesia in 2 patients (Figure 2). An ultrasound mapping was performed on the great saphenous vein at premalleolar level and at the saphenofemoral junction. The affected saphenous vein was acceded at pre-malleolar level or at the middle third of the leg by ultrasound-guided puncture (n=30) or by pre-malleolar dissection (n=20) (Figure 3). A 7F introducer with hemostatic valve and, through it, an endovenous RF ablation catheter (ClosureFast) connected to the generator were placed using the Seldinger technique. The position of the end of the catheter was controlled by ultrasound scan as it must be 2 cm below the saphenofemoral junction.4 A tumescent solution (250 ml of saline solution with 20 ml of lidocaine 2%) was infiltrated along the saphenous vein to compress the vein over the catheter and to protect the saphenous nerve, skin and subcutaneous cell tissue from its heat. The generator was set at a temperature of 120°, with pulses of a maximum of 20 seconds. It has a security system that supports a maximum of 25 watts of power to reach this temperature and, from that level, it is disabled to avoid thermal complications in the patient. Endovenous ablation was performed under a proximal to distal approach; to this end, two cycles of ablation were used in the first segment of the great saphenous vein and in the segments with insufficient perforating veins. It was very important not to apply radiofrequency below the upper third of the leg to prevent damage to the nerve.

A phlebectomy of varicose epifascial tributaries was performed in 25 cases using the Müller technique, and a ligation of the saphenofemoral junction associated with varicose vein surgery was performed in 2 cases.⁵ Once the

procedure was completed, the induced thrombosis was checked by ultrasound scan and compression bandaging of the whole lower limb was applied.

A first postoperative control was performed at the outpatient clinic 7 days after the intervention to assess the clinical response. Subsequent controls took place after 30, 60, 90 and 180 days and included Doppler scanning performed by members of the team to determine the evolution of the venous occlusion and to track possible complications.

RESULTS

Out of the 50 patients operated on, 5 needed 24-hour hospitalization and the rest were outpatients with hospital discharge on the day. Two of the hospitalized patients were operated on in both lower limbs and the remaining 3 presented irregular anesthesia recovery, requiring more observation time.

Thirty-nine patients did not have postoperative pain and resume their usual activities between 5 and 21 days later (Figure 4).

The most common complications included: hypoesthesia on the front of the operated leg in 14 patients, with spontaneous resolution; infection of the puncture site (3 patients); neuralgia in ankle (3 patients); hematoma (2 patients); anesthesia in ankle (2 patients); malleolar collection (1 patient) and telangiectasies (1 patient) (Figure 5).

Ultrasound scanning control showed thrombosis of the saphenous vein in 90% of patients, mostly as from 2 cm from the saphenofemoral junction (31 patients), 9 patients as from 4 cm, 3 cases as from 15 cm from the junction, 2 cases as from 10 cm from the junction, 4 cases as from the lower third of the thigh. Reflux was found in none of the cases with recanalization (Figure 6).

The medical discharge with vocational rehabilitation occurred after 15 days in 25 patients, after a week in 7 patients, after 3 weeks in 7 patients, and after longer periods in the rest due to postoperative complications (Figure 7).

DISCUSSION

Chronic venous insufficiency is a prevalent disease largely affecting the labor force with significant social and economic consequences.

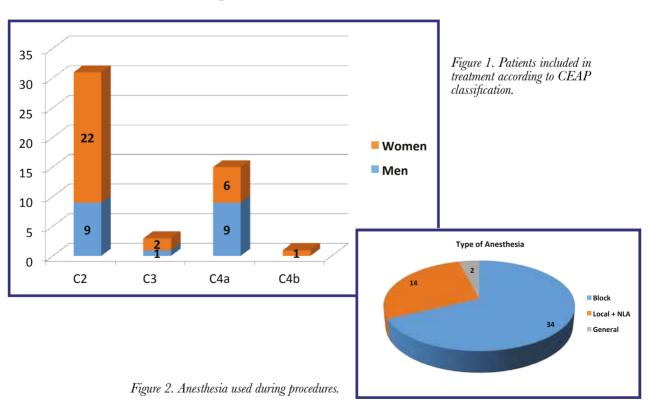
Varicose vein surgery by radiofrequency is an outpatient alternative to the conventional procedure. Its advantages include being a minimally invasive procedure without incisions in most cases and with a lower incidence of postoperative complications, such as hematoma and surgical site infections.⁶ Postoperative pain, absent in most cases, is said to be considerably milder if present, leading to faster recovery and vocational rehabilitation.⁷

With the appropriate surgical technique, induced thrombosis occurs distally 2 cm from the saphenofemoral junction, with minimum risk of deep vein thrombosis secondary to the procedure.⁸ Almost no significant differences are found between ultrasound scanning controls in immediate and late postoperative periods, so skipping the former could be considered in the future.⁹

These results translate into the clinical improvement of all the evaluated patients despite variations in their controls.¹⁰

CONCLUSION

The results obtained in relation to the closure of the insufficient great saphenous vein and the clinical remission of symptoms in all cases make the varicose vein surgery by endovenous radiofrequency ablation a safe and effective technique. While reported complications are comparable to the results published for endovenous treatments, they correspond to the beginning of the learning curve for the procedure.



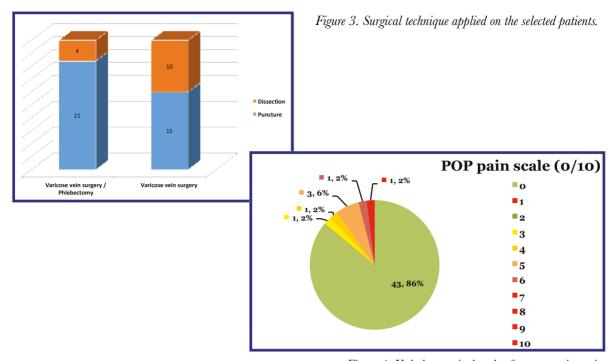


Figure 4. Verbal numerical scale of postoperative pain.

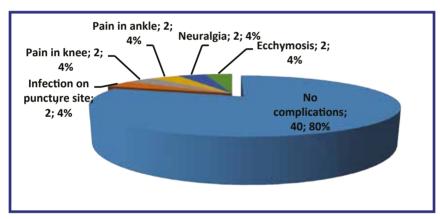


Figure 5. Complications presented in postoperative controls.

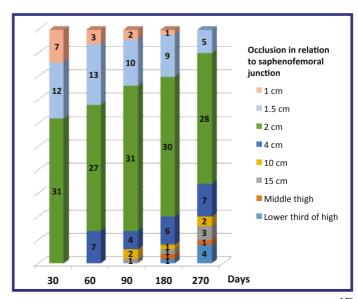


Figure 6. Control of venous occlusion in relation to the saphenofemoral junction as verified by Doppler scanning.

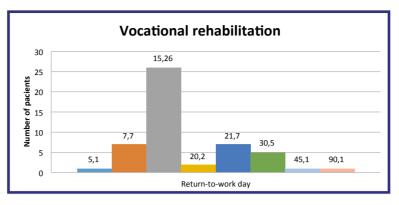


Figure 7. Vocational rehabilitation after surgery, in days.

REFERENCES

- 1. Trendelenburg F. Über die Unterbindung der Vena saphena magna bei Unterschenkelvaricen. Beiträge zur klinischen Chirurgie. 1891; 7: 195–210.
- 2. Homans J. The etiology and treatment of varicose veins and ulcers based upon a classification of these lesions. Surg Gynecol Obstet 1917; 24: 300-5.
- 3. Keller W. L. A new method of extirpating the internal saphenous and similar veins in varicose conditions: a preliminary report. N Y Med.J 1905; 82: 385-6.
- 4. Mayo C. H. Treatment of varicose veins. Surg Gynecol Obstet. 1906; 2: 385-388.
- 1. Kabnick, L., Todd, B., Endothermal Heat Induced Thrombosis (EHIT). 38th Annual Vascular and Endovascular Issues, Techniques and Horizons (VEITHsymposium), November 16–20, 2011, New York City.
- 2. Van der Velden S. K., Lawaetz M., De Maeseneer M. G., Hollestein L., Nijsten T., Van de Boss R. R. Predictors of recanalization of the great saphenous vein in randomized controlled trials 1 year after endovenous thermal ablation. Eur J Vasc Endovasc Surg. 2016 Aug; 52 (2): 234-241.
- 3. Berardi, H., Ciccioli, A. Examen Doppler de la insuficiencia venosa de miembros inferiores: consenso entre especialistas. Rev Argent Radiol. 2015; 79 (2): 72 79.
- 4. Sadek, M., Kabnick, L., Rockman, C., Berland, T., Zhou, D., Chasin, C., Jacobowitz, G., Adelman, M., Increasing ablation distance peripheral to the saphenofemoral junction may result in a diminished rate of endothermal heat-induced thrombosis. J Vasc Surg Venous Lymphat Disord. 2013. Jul; 1(13): 267-62.
- 5. Siribumrungwong, B., Noorit, P., Wilasrusmee, C., Attia, J., Thakkinstian, A., A systematic Review and Meta-analysis of Randomised Controlled Trials Comparing Endovenous Ablation and Surgical Intervention in Patiens with Varicose Vein. EuropeanJournal of Vascular and Endovascular Surgery 44 (2012) 214 223.
- Puggioni A., Kalra M., Carmo M., Mozes G., Gloviczki P. Endoveonus lasertherapyand radiofrecuencyablation of the great saphenous vein: analysis of early efficacy and complications. J Vasc Surg 2005 Sep; 42 (3): 488-93.
- 7. Younger, J., McCue, R., Mackey, S. Pain Outcomes: A Brief Review of Instruments and Techniques. Curr Pain Headache Rep. 2009 Febrruary; 13 (1): 39 43.
- 8. Sadek, M., Kabnick, L., Rockman, C., Berland, T., Zhou, D., Chasin, C., Jacobowitz, G., Adelman, M., Increasing ablation distance peripheral to the saphenofemoral junction may result in a diminished rate of endothermal heat-induced thrombosis. J Vasc Surg Venous Lymphat Disord. 2013 Jul; 1 (13): 267-62.
- 9. Todd, R., Kabnick, L., Perioperative Duplex Ultrasound Following Endothermal Ablation of the Saphenous Vein: Is it Worthless? J Invasive Cardiol 2014; 26 (10): 548 550.
- 10. Yin H. Y.,Ohe H. J., Hwanq J. K., Kim S. D., Kim J. Y., Park S. C., Kim J. I., Won Y. S., Yun S. S.,Moon I. S. Radiofrecuency ablation of varicose veins improves venous clinical severity score despite failure of complete closure of the saphenous vein after 1 year. Asian J Surg, 2016 Jul 1.pii; S1015-9584 (16) 30034-3,doi: 10,1016/j.asjsur.2016.03.400.



ARTICLE

65TH ANNIVERSARY OF THE ARGENTINE ASSOCIATION OF ANGIOLOGY AND CARDIOVASCULAR SURGERY

AUTHOR:

DR. EDUARDO F. PATARO

The constant evolution of humans as thinking and intuitive beings has allowed for the development of knowledge in pursuit of the cure of the individual. Along such an uncertain way, many times it was believed that the climax of knowledge had been reached. Therefore, at the beginning of the twentieth century, Jean Faure stated that "surgery has achieved such a point of perfection that any future acquisition will be insignificant". Vicente Pataro said that time had corrected Faure's statement, and one of the branches of surgery clearly responsible for this has been cardiovascular surgery.

Sixty-five years for a medical association seem to be enough time to evaluate its track record. However, it is not easy; intrinsically, the obliterating pathology still punishes man and forces to take giant evolutionary steps, beyond our professors' imagination, in search of relief with less invasive and clearly better tolerated procedures. The Society, then the Association, had to adapt not only to the present change from the professional super-specialty but also to the socio-economic transformations our country went through.

"The balance of a doctor is not possible without the exchange of knowledge that eliminates the blindness of impulse with no perspectives and perfects and standardizes the true procedure."

Miguel Ángel Lucas.

THE ORIGIN OF THE ARGENTINE SOCIETY OF ANGIOLOGY (SOCIEDAD ARGENTINA DE ANGIOLOGÍA)

In Argentina, the interest in vascular surgery can be observed in the hard work of its pioneers and perhaps Aquiles Pirovano was the one who, at the beginning of the twentieth century, gave a huge boost to vascular surgery with his work. In the late 1920s, Enrique Finochietto had 26 medical records on aortic aneurysms, In 1952, these two
men, Albanese and
Pataro, together
with an enthusiastic
group of renowned
angiologists,
physicians and
cardiologists, decided
to found a society
comprising their
knowledge to create a
discussion.

their repair and management, and Rene Leriche's approach to enervating surgery in France took hold of the surgery service of Hospital Rawson. In 1942, Ricardo Finochietto and two of his young disciples, Alfonso Albanese and Vicente Pataro, presented their experience in the surgical treatment of arterial hypertension to the National Academy of Medicine (*Academia Nacional de Medicina*). According to his writings, Pataro's interest in vascular surgery awakened after he met Julio Diez and witnessed a lumbar ganglionectomy at Hospital Pirovano.

In 1952, these two men, Albanese and Pataro, together with an enthusiastic group of renowned angiologists, physicians and cardiologists, decided to found a society comprising their knowledge to create a discussion, training and outlook forum for the management and study of cardiovascular diseases.

For two years (1952-1953), Alfonso Albanese presided over the Society, which received international recognition during the Second International Congress of Angiology held in Lisboa in September 1953 under the chair of Joao Cid Dos Santos, in which Pataro participated as representative of the South American Chapter and the Argentine Society of Angiology (Sociedad Argentina de Angiología). In its first twenty five years, the Society grew noticeably, with the best angiology groups of the country among its members, and was presided over by surgeons, angiologists and cardiologists (including Alfredo Buzzi, Jorge Parano, Elías Sales, Antonio Perreta). It promptly gained international significance in the Congress of the International Vascular Society in 1969 and the Latin American Congress in 1978 under the chair of Rubén Siano Quiroz. Together with Mario D'Angelo, I witnessed Siano's efforts to hold such an event with success during the hard times our country were going through. It was possible thanks to his tireless work capacity.

Two milestones should be mentioned. The first one is the Journal of Angiology (Revista de Angiología) founded in 1952 under the direction of Diego Zavaleta, today known as the Argentine Journal of Cardiovascular Surgery (Revista Argentina de Cirugía Cardiovascular). Its development was not easy, it underwent many changes – all aimed at keeping it updated – and finally in 1966 an Editorial Committee, an Editorial Board and a group of Associated Editors were created to publish, in March 1967, the first number of the Argentine Journal of Angiology (Revista Argentina de Angiología) with Dr. Eduardo Kitainik as director and Dr. Miguel Ángel Lucas as Deputy Director. The second great landmark is undoubtedly the Argentine College of Angiology (Colegio Argentino de Angiología), which was founded on November 30, 1966 at the

initiative of Delfin Vilanova (the then Head of the Vascular Surgery Service in Room VI of Hospital Rawson) and was directed by Samuel Rascovan. Our Society was then presided over by Dr. Eduardo Kitainik and I was one of the privileged students of the 1971-1972 program under the direction of the ineffable "Chango" Almonacid. Forty years later, I am pleased to participate as teacher in an updated college that applies current learning concepts. The program is now annual with two modules: a core one and a peripheral one.

The creation of the Argentine College of Cardiovascular Surgeons (Colegio Argentino de Cirujanos Cardiovasculares -CACCV) in 1975 under the presidency of Dr. René Favaloro was a new perspective in the history of the now called Association. The College would cover the need of its members for social security, medical and legal fees, and, essentially, union representation. The competition was perhaps in the training area, in which the Association of Angiology wanted to keep its inherited degrees for the development of the area. Although the relationship between the College and the Association had its ups and downs with clear disagreements, mutual respect was always present, as stated by Dr. Gerónimo Guastavino in his speech during the inaugural ceremony of Luis Molteni as president of the College: "... We all have high expectations for the capacity and intelligence resulting from the union of the Argentine College of Cardiovascular Surgeons and the Argentine Association of Angiology". It was the year 2001.

From the union of ethical and scientific values, the College and the Association today keep the characteristics predicted by their founders: the protection of cardiovascular surgeons, the spread of knowledge about the specialization, the training of young surgeons, and the certification of their associated professionals and members throughout the country.

These 65 years of the Association of Angiology may be divided into three periods. The first one extends until the 1980's, when the clinical-surgical orientation of the then Society started to feel the effects of the super-specialty. The advent of extracorporeal surgery promptly spread throughout our country, leading to the formation of teams of cardiologists, surgeons, anesthetists, internists and therapists. A gap then opened between cardiac surgeons and peripheral vascular surgeons. Many professionals moved to different societies – some already existed, others were new. At the beginning of the last decade of the twentieth century, peripheral vascular surgery seemed to have achieved its maximum level of development. The attendance to the meetings of the Argentine Medical Association (Asociación

The creation of the Argentine College of Cardiovascular Surgeons (Colegio Argentino de Cirujanos Cardiovasculares - CACCV) in 1975 under the presidency of Dr. René Favaloro was a new perspective in the history of the now called Association.

Médica Argentina), of which we were an affiliate, decreased and gradually we were relegated to distant offices of the old building on Santa Fe street.

In 1982, the Society began to hold its congresses every four years in connection with the Argentine Congress of Surgery and today maintains this frequency while holding annual conferences between congresses. Although program differences have been kept and the Association of Angiology has two days to develop its program activities, the Congress of Surgery makes its great infrastructure available for the organization of our congress, which, despite the wide offer of annual conferences, maintains its scientific value and distinction as shown by the latest excellent comments made by specialty professionals.

Almost in the 1990's, the idea of merging the Association of Angiology with the then Society of Cardiovascular and Thoracic Surgery (Sociedad de Cirugía Torácica y Cardiovascular), which was also affected by the crisis and the diversity of its members, stemmed from previous joint conferences. The project was expected to be implemented in the 1992 Conferences to be held at Patio de la Madera in the city of Rosario. Roberto Pittaluga was the then president of the Society of Cardiovascular and Thoracic Surgery. In the end, the pro-independence feeling prevailed and the Congress was successfully held in that city of the province of Santa Fe with Frank Veith as the foreign guest of honor. A year later, the Society Cardiovascular and Thoracic Surgery became the Society of Thoracic Surgery (Sociedad de Cirugía Torácica).

Finally, I think the last stage is closely related to the achievements of Juan Carlos Parodi. The extraordinary development of vascular surgery based on the new endovascular approach created new vascular surgeons, "hybrids" as Parodi named them, who not only know about anatomy and surgical techniques but also handle catheters, guides and balloons and interpret hemodynamics and medical imaging, with the great advantage of knowing the evolutionary history of degenerative vascular diseases and the suitable therapeutic solution to implement because of their training.

After 65 years, the Association of Angiology has survived its mentors and has walked together with three bright generations of Argentine vascular surgeons. Today, it faces a new scientific outlook, globalization, flows of information, and the fast development of new techniques. Our young disciples are in the presence of fascinating medicine with apparently unimaginable boundaries, hard and enviable work ahead. Aware of their aptitudes, I do not think I am wrong when I say that we are celebrating the first 65 years of the Association of Angiology.

DR. EDWARD B DIETHRICH — 1935-2017

Dr. Edward ("Ted") Diethrich (Fig. 1), arguably one of the most influential cardiovascular surgeons of our time, passed away on February 23, 2017. He was 81 years old.

He received the M.D. degree in 1960 at the University of Michigan, and remained in the state for Surgical Residency (in Ann Arbor and Detroit). He then moved to Houston to train as a cardiovascular and thoracic surgeon at Baylor College of Medicine under Dr. Michael E. DeBakey. He remained there as a junior Faculty and Attending until 1971, playing an important role in pioneering cardiac surgery developments with Dr. DeBakey and his team, including heart transplantation and many others. And it was obvious to anyone paying attention that Dr. Diethrich rapidly emerged as an extremely skilled surgeon and innovator.

In 1971, he left Texas and moved to Phoenix, Arizona where he founded the Arizona Heart Institute (AHI) which became the first free-standing center dedicated to the prevention, diagnosis, and treatment of cardiovascular diseases. From inception and until recently, he led the AHI Hospital as Medical Director and Chief of Cardiovascular Surgery, and AHI's nonprofit research organization, the Arizona Heart Foundation that propelled Arizona Heart to national and international prominence with an impressive series of *firsts*, such as establishing the nation's first cardiac catheterization lab in 1979.

Cardiac surgery was at the center of Ted Diethrich's early career. Famously he invented the sternal saw which became a standard tool for median sternotomy all around the world, AUTHOR: FRANK J CRIADO, MD, FACS, FSVM

CORRESPONDENCE: frankjcriado@gmail.com

and made important contributions to the bubble oxygenator among many other important contributions. His notoriety in the field took a giant leap forward when he and the AHI cardiac surgery team were first in history to broadcast on live television an open-heart coronary bypass operation in the year 1983.

His insight and genius led to another first: the development and installation of ceiling-mounted fluoroscopic/angiographic capabilities in the operating room – reportedly picking up the idea in its primordial form while visiting at a hospital in Munster, Germany in the mid 1980s. So, he was instrumental in the early development of the "hybrid suite" many years before the term was even coined.

Research, education, and training were integral components of Dr. Diethrich's activities. He wrote more than 400 scientific papers, several textbooks, and many lay publications, in addition to producing hundreds of educational videos and films. At AHI, he trained and mentored legions of surgeons and other cardiovascular specialists from around the world, and he was a world traveler where he demonstrated new techniques and ideas at innumerable meetings and events. Personally, Ted was a complex multifaceted man: a musician and sportsman, inventor and entrepreneur, film producer and media personality. And a dog lover.

He was the most competitive and driven person I have ever come across in my own life, equipped with a degree of dexterity and self-confidence that were enjoyable to watch could up-close. And I was fortunate to have had the opportunity to do so many times, especially in the late 1980s and 1990s. Attending AHI's first International Congress in February 1988 (in Scottsdale, AZ) changed my life - in more ways than one. It was then and there that I met Ted Diethrich, and was exposed for the first time to the idea of a less-invasive future for vascular surgery and for our specialty overall. Only a few months later (in 1988), I could refine my interventional percutaneous skills at AHI scrubbing with Ted in a number of cases performed in his endovascular suite (Fig. 2). I found the concept of "the surgeon's cath lab" so powerful and compelling, that I went all out to develop such capabilities at MedStar Union Memorial Hospital in Baltimore. The suite was built the same year (in the Fall), and Ted came to Baltimore (Fig. 3) to join me and our team as we announced and celebrated the formation of the endovascular unit and our imaging operating room (Fig. 4) - only the second hospital in the USA to have such capabilities at that early date.

But the opportunities to get to know Ted Diethrich and work more closely with him were just around the corner. The formation and founding of the ISES (now ISEVS) International Society in 1992 (Figs. 5-7) and of the Journal of Endovascular Surgery (now JEVT) 1 year later provided such context.

Ted Diethrich will be remembered and celebrated for many years to come. I feel incredibly fortunate to have had the opportunity to intersect with such a man. Truly one-of-a-kind, irreplaceable, unforgettable. ■



Fig. 1: Dr. Edward B. "Ted" Diethrich.



Fig. 2: Dr. Criado and Dr. Diethrich performing an endovascular procedure at the Arizona Heart Institute in Phoenix in 1988.



Fig. 3: at the Inaugural Celebration of the new Endovascular Unit and Imaging Operating Room at MedStar Union Memorial Hospital in Baltimore in December 1988.

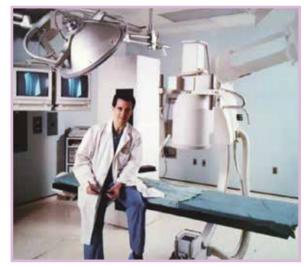


Fig. 4: Dr. Criado photographed in the newly constructed Imaging Operating Room (1988).



Fig 5: Ted Diethrich handing Dr. Criado the Certificate of membership in the newly formed ISES Society (during AHI Congress, February 1993).



Fig. 6: meeting of the Executive Committee of the ISES Society in the early 1990s.



Fig. 7: ISES Founders.



TRIBUTE

FRIEDRICH WILHELM MOHR: HOW I KNEW HIM

The Bonn era:

In 1978, in the wake of a German programme for academic advancement, I obtained an approval from the University of Bonn Chief of Cardiovascular Surgery, Prof. Gerhard Kirchhoff, to undertake my residency in that specialty.

It was on a warm summer morning in July 1979 that I arrived to the service. The Chief introduced me in rounds at 7.30AM. There he was, also commencing his residency, albeit

German style, meaning before having undertaken general surgery, the slim, athletic and cheerful young man, on year after medicine school graduation, Friedrich Wilhelm Mohr.

I remember clearly Prof. Kirchhoff inquiring about my residence, which was the university guest accommodation, in the middle of the forest. I attended by foot, and so Fitty suggested I should get a bicycle. A couple of days later, one Saturday

afternoon he offered to join me to the Ring, or downtown, to buy one. And so we did. I got a used Peugeot, he bought another one, and then he headed off to celebrate where one always does in Germany: the Kneipe, that is, a pub. He told me about his girlfriend, Anita, pediatry resident in the city of Cologne in that moment, and about his parents who had fled dramatically from East Germany towards the Bundesrepublik (Federal Germany). On that day, a friendship emerged that is still lasting.

AUTHOR:

DR. ROBERTO BATTELLINI

CORRESPONDENCE: robertobattellini@hotmail.com



Battellini at the day of Mohr's farewell.

I was already
specialised in General
Surgery... Myself at
my 33 years gave
my best to pass my
knowledge to the
youngest.

At the beginning, we would speak in English. Although I had undertook a one year German language intensive course at the Goethe Schule of Buenos Aires, I realised this only helped me communicate in a tourist way. Equipped with positive predisposition towards this stranger of the Rhine area, all members of service, headed by Mohr, kept tolerating and perfecting my "bad German" on a daily basis. I was already specialised in General Surgery with two years in Peripheral Vascular, which gave me an advantage in operations, and so I made the most to teach what I knew and strike up friendship with everyone.

Shortly after arriving to Bonn, thanks to the international mentality of Prof. P. G. Kirchhoff, I was invited, together with the German group, to a long weekend on board of a sailing ship, property of a friend of the Chief, Herr Kalender. With great agility, Fred climbed to the highest of the mainmast to photograph everyone. It was a "chique" weekend, strolling around villages of the Dutch Ijselmeer. Each one of these events would deepen our friendship, which later continued in the operating room. Myself at my 33 years gave my best to pass my knowledge to the youngest. Joint duty was a challenge for our youth. One time, after 36 hours without sleeping, we operated and reoperated a peripheral vascular patient whose bypass became occludedagain and again, which we kept unclogging. As we left the operating room having successfully concluded the operation after the third time, we saw the female ICU physicians weeping for us. It is without saying that during these I taught him and let him does as much as possible. Very shortly after arriving to Bonn, Fred invited me to visit his parents one weekend. His father's anecdotes about the war on the Russian front and his subsequent escape to East Germany captivated me. They lived in a village constructed in the 16th century, and which had survived Allied bombing. Those wood and mud constructions fascinated me. Fred told me that when women went to church on Sundays, men would wait for them having a few drinks at the bar around the corner. We travelled there in a Volvo sport, license plate BN-AN 12 that I will always remember. In Germany, one can have their own initials on cars, and I believe this ANone was because of Anita, his great love.

Once a week we went to play tennis with other friends (Walter Koch, Axel Buchmueller) indoors in a "Halle" in the winter, or at the outdoor University of Bonn courts in the summer, which were located in the forest. However, the beer after was more sought after than the competition, and we enjoyed it more than any other of the week.

On Saturday mornings we went to the market of the main square, the Marktplatz, to do what in Germany is almost a religion for singles: to buy fresh vegetables for the rest of the week. Also, due to our working hours, this was our only chance to pre-emptively avoid having to rely on noodles for the whole week. We also frequently took our cameras, and played artists. Fred even bought a processor camera to start a photographic laboratory at his house.

Carnival time in Bonn and the Rhine zone is something very special, and so it was to us. There was special food at the hospital, and after we went dancing to Stieffel, a Bierlokal where everyone danced with everyone, and one met new girls. Fred, always with Anita.

Bicycle expeditions were another highlight of life in Bonn. Not only among us, but also sponsored by the Chief of the Service, Prof. Kirchhoff, twice a year we would cycle 70 kilometres (43 miles) along the Rhine banks. Additionally, cardiac technicians would do a grill (barbeque) in the middle of the forest during a break. In other occasions, we would visit wine cellars fortasting. And so, at midnight, with everyone sober, of course, we would finish these Fahrradtours. Favourite routes were the banks of the Rhine, or towards Koenigswinter, a village in front of Bonn, reached by crossing the ferry.

Speaking of grillparties, this custom began in Fred's house at Haydn 55, on an excellent balcony. Of course, I offerd my gifts as a gaucho, which were welcomed. Mohr senior, who was like my own "German father", was one of those who congratulated me.

It was winter of 1980, and I did not know how to ski. Fred proposed to go to Switzerland for 15 days together, to BernerOberland. It was one of the greatest experiences in my life, the mountain, the snow and the falling down, until I finally learnt. Anita Mohr was my teacher after the skiing classes were over. It was the end of a golden era of youth mixed with work and life enjoyment. We also made various excursions to go windsurfing on the Konstanz and Bodensee seas, and the island of Sylt.

The reader might think there was more fun than work. We were both not married yet, although I was already divorced. Almost at the end of my stay Fred had to operate his first abdominal aortic aneurysm, and he asked for my assistance. It was a sign of friendship of his part, greeted by pleasure from my part to operate with this promising young man, still unknown globally.

Anita Mohr was
my teacher after the
skiing classes were
over. It was the end of
a golden era of youth
mixed with work
and life enjoyment.
We also made
various excursions
to go windsurfing
on the Konstanz and
Bodensee seas, and
the island of Sylt.

In 2009, my hour had come: I won the competition for Chief in the Italian Hospital of Buenos Aires, thanks to my formation in Leipzig.

Intermezzo:

I returned to Argentina, because, although I had an offer from Prof. Kirchhoff, I had deep family responsibilities with my two older children. During those years, Fred visited the country many times, and visited me at Mar del Plata, where I had created the first ever Service for cardiac Surgery to the South of La Plata, near Buenos Aires. So we visited a few estancias (country estates), and went horseback riding, the only sport in which I fared better than him. All those years we kept contact through letters, telling each other how we were faring in our respective places. Until 1995, when I received a phone call from Fitty. After greeting me he offered me to visit him at Leipzig. It was during this visit that he offered me the post of Oberarzt, that is a Staff position, an offer I could not refuse after having seen the Herzzentrum.

The Leipzig era:

Fitty was now married to Anita and had two wonderful sons, Maxi and Philip. I had married again, with Norma. Our hours of leisure became hours of family meetings. Laika, the dog Fitty bought for the children, became a family symbol. And it also became a symbol of the friendship between our families, as she was always there to greet us as we arrived for visits at the Mohr residence. The other hours, those of work, became geometrically increasing intense for us both. On many weekends, Fred would go back to his hometown Wichmannsdorf, a village where he inherited a house at a lake. There, our children fished together, and even pulled a fish so big that I insisted on eating it, despite everyone telling us it would not taste good at all. Even after my efforts with plenty of garlic and lemon, it tasted of mud, and so had to contemplate eating burgers.

One Christmas eve in Leipzig, we did not have a Weihnachtsmann (Santa Claus) for Mauro, so Mohr offered to dress up and bring the presents in from the back door. My son Mauro, of 7 years, recognized him: he was wearing the same boots from just before. We laughed about it many times later. Still, it was a great human gesture. In 2002, Fred gave me a special present: Anita's 1995 Volvo, which I complimented on many occasions. Despite having replaced it with a new Mercedes, Anita was not entirely happy, as the car was full of good memories. By the way, I still drive this car today on the streets of Buenos Aires.

In spite of the great seriousness imposed by our line of work, and our hours, Fred never missed the opportunity to organise parties and events, with locations ranging from the local pub, the Kaiser Napoleon, to the Cospudenerlake, where the Herzzentrum has an annual bicycle race.

In 2006, he spearheaded the efforts to bring the Olympic Games to Leipzig. We organised public events ("Leipzig Hope") and demonstrations all over the city. In the end, London beat us.

In 2009, my hour had come: I won the competition for Chief in the Italian Hospital of Buenos Aires, thanks to my formation in Leipzig. On the 9th of October 2009, with Fred, we attended the commemoration of the 20th anniversary of the fall of the Berlin Wall at Augustusplatz. It was a procession that included candles. For me, it also meant a high emotional goodbye to Leipzig.



Conclusion:

Fred is a leader, not only within hospital, but outside of it. The barbeques at his residence were a sign of his devotion to caring about his workers and guests. He is a master, not only of surgery, but of human relations, and I am honoured to say he saw the same quality in my father when he visited Argentina.

After a profound friendship in Bonn, we both showed wisdom to continue it in Leipzig, even when one of the friends was the boss. Mohr always pushed everyone to excel beyond the level of professional, leading but also inspiring confidence during the rougher times. It is for this reason that I owe my position as chief at the Italian Hospital to him, just as many others who are writing in this book owe him their new positions of leadership.

If we read Dale Winbrow's great poem, "The Guy in the Glass", I believe Fred has passed the test, he can look at himself. ■



"Mohr among greatest" (from behind), surrounded by Yacoub, Carpentier, Favaloro and Jatene, and Borst at the background.



SCIENTIFIC LETTER

IMPLEMENTATION OF A VASCULAR AND ENDOVASCULAR SURGERY SERVICE AT THE HOSPITAL NACIONAL DE CLÍNICAS IN CÓRDOBA

AUTHORS:
ALLENDE, JOSÉ N.ª
CATI, JUAN M.*
MOLINELLI, LEANDRO
BARRERAS*

- ^a Angiology and Hemodynamics Department Coordinator, Hospital Nacional de Clínicas, Córdoba.
- * Members of the Angiology and Hemodynamics Department, Hospital Nacional de Clínicas, Córdoba.

CORRESPONDENCE: josenorbertoallende@gmail.com

This scientific letter presents the results of a new work program implemented for the treatment of peripheral vascular lesions at the Hospital Nacional de Clínicas in Córdoba. Patients began to receive assistance under this program in August 2014. The task force consisted of three vascular surgeons specialized in endovascular techniques. At the beginning of the program in 2014, the delay in outpatient appointments was 60 days. When the doctor requested an angiography, the patient needed to apply for the relevant authorization in order to get an appointment by referral to another institution. After the study, the patient needed to arrange a new appointment with the vascular surgeon, which represented a major delay for treatment.

The hospital has a room that works as a hybrid operating room which meets the radio-protection and asepsis standards and has Philips Allura FD10 equipment received as a donation. The new program allowed to increase the weekly time for outpatient assistance (four days per week) and to reduce the initial appointment delay from 60 to 12 days, with the consequent increase in vascular and endovascular therapeutic/diagnostic procedures (n = 420) (Figure 1.)

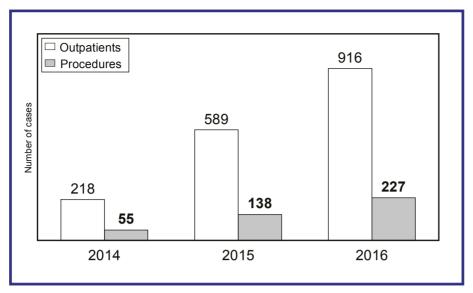


Figure 1. Distribution of the number of outpatient appointments and the number of procedures on a year basis (n = 1723).

In case a patient needed an angiography, the maximum time for its performance was reduced to less than 5 days; however, this must be improved. Once the diagnostic study is finished, the team decides on the therapeutic plan to follow, optimizing its implementation and reducing the delay.¹⁻² The number of peripheral angioplasties increased due to the possibility of rising the number of lower limb angiographies for the detection of new cases (Figure 2.)

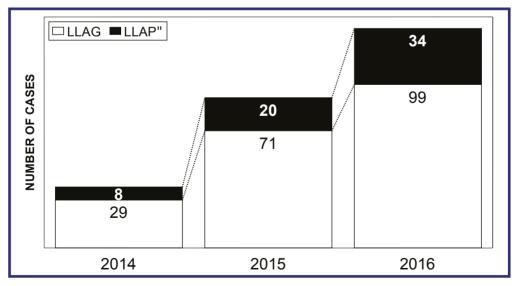


Figure 2. Distribution of cases according to lower-limb angiography (LLAG) / angioplasty (LLAP) (n = 261.)

Fourteen abdominal aortic aneurysms, two of them juxtarenal, were treated endovascularly, and the number of carotid angioplasties also rose (Figure 3.)

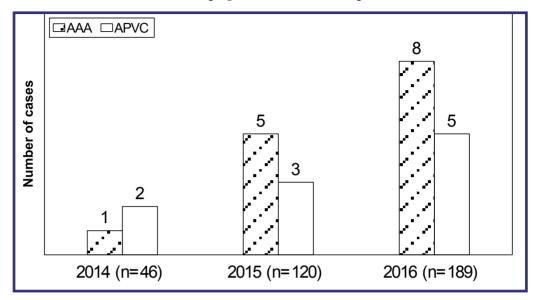


Figure 3. Abdominal aortic aneurysms (AAA) and angioplasties of neck vessels (ANV) treated (n = number of patients treated per year) (n = 355.)

Since the implementation of the program, the total number of open vascular surgeries has also increased (total 71; 44 of them in 2016) (Figure 4.)

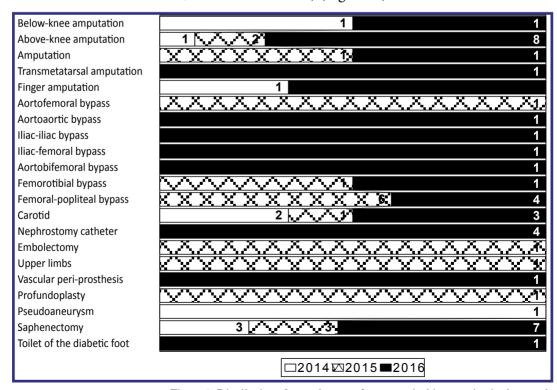


Figure 4. Distribution of cases by type of open surgical intervention in the sample analyzed (n = 71.)

Finally, a comparison was made of the major amputations performed in the Service; a decrease between 2014 and 2016 was noted, although so far the difference has not been significant (1/9 vs 2/44, p = 0.435) (Figure 5.)

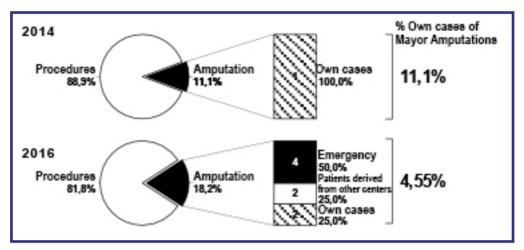


Figure 6. Comparative distribution of procedures according to cases of major amputation in 2014 (n = 9) and 2016 (n = 44.)

Given the increase of population aging and the high prevalence of the peripheral vascular disease, the assistance of seniors by a specialized team that provides them with solutions with vascular or endovascular techniques according to the need of the patient is of utmost importance.³

REFERENCES

- 1. Mustapha J. A., Díaz-Sandoval L. J., Summers M., Saab F. Building a Comprehensive CLI Program: The multitasking, multidisciplinary team approach to addressing this multilevel disease. Endovascular Today. JANUARY 2017 VOL. 16, NO. 1.
- 2. Neily J., Mills P., Young-Xu Y., Carney B., West P., Berger D., Mazzia L., Paull D., Bagian J. Association between implementation of a medical team training program and surgical morbidity. JAMA. 2010; 304(15): 1693-1700.
- 3. Hull L., Bicknell C., Patel K., Vyas R., Van Herzeele I., Sevdalis N., Rudarakanchana N. Content Validation and Evaluation of an Endovascular Teamwork Assessment Tool. Eur J Vasc Endovasc Surg, Volume 52, Vol. 1, July 2016, Pág. 11-20.



AUTHORS:

TEA ACUFF, MD

CORRESPONDENCE: Mail de contacto: tacuff@swbell.net

What you wanna see?

Evidence based medicine (EBM) assumes the cloak of science, but almost nothing it espouses is scientific. Most particularly EBM transforms all symbolic or mathematical findings into semantic language and classes that often distorts the grain of true that the scientific method symbolically yields to us. There is a reason that mathematical analysis of experimental trials are only done by "intent" (randomization) and not in "occurrence". For the most part EBM equates and thus confuses the two.

Let me briefly and sardonically present a few cornerstones of EMB for examples. The following examples are not referenced as my quarrel is not so much with those that would offer these concepts as pearls but those of us that accept the pearl as real.

NON INFERIOR

"If it's non-inferior and less invasive, it must be better." Although the nouns have been dropped, this is a modern version of a logical prove of god. Science is not syllogism. If syllogisms make science, I can well be science's author. We offer it to push an agenda.

BEST PRACTICE

We are still knee deep in agenda. There may be some difference between a single technology moving in roughly a convergent direction, and biology (ever notice that we turned the tree of evolution off its pyramid) moving divergently. If we would be biologists, how can we pick the best species or most adaptive? Maybe we are rather just unwitting idiots of our favorite industry. I'm open to that view, but if we rally must choose the best car or truck, and use it for everything, we must be busily engineering the medical Yugo.

CLASSIFICATION OF EBM

We might as well quote Bible verses. There is no scientific law that classifies information in such an academic and scholastic format. The Krebs cycle is just as valid whether it was tested in a multicenter randomized trial or shared between labs on the back of a napkin. Small wonder that the scholastic researcher hopes to be a "partner" of the multimillion euro trial that will ensure academic and society chairmanship. It may be the most pedantic thing we do.

STS DATABASE

The king of mathematical and symbolic pretense masquerades as scholarship. If we were selling our wares in the local farmers market, we likely would be able to trade for comparable or even advantageous benefits. But we have to come up with a database to sell our wares virtually, and we (most of us) will surely lose our shirts as well as our farms. Its not like we are unfamiliar with data. In some ways we were the pioneers or proteges of database analysis, but now that we stuff it all into a big sausage maker and ask the sausage technocrats its ingredients we accept any explanation. More importantly it is a propriety database that we own, if at all, in name only. We have lost all control to the nobles and king, while we serve the feudal lords. We believe in this virtual monarchy. When we measure 1, 2 or 3 variables, say, arterial BP in a post op patient, we are much more critically involved. When the BP goes down, we seldom assume it has to be a BP problem despite what the numbers may "say". We may treat the BP but actively look for other and more critical explanations to change the result. But when we mix 40 variables together in our national databases, and have the statisticians pull out the answer, we proclaim, defend, and submit to the answer. We even allow that the same answer is a universal (as it gets) truth for any patient and any surgeon. At the bed side we would find the same manner of data

We can't change kings.
We have to rethink monarchy.

analysis of our BP monitor dangerous and sophomoric. We are observing and responding to the wrong cues post hoc.

We all see the dissonance that spawns my irreverence, even if you may not follow the direction I am going in my discontent. Trust me or just yourself. We can unwind the layers of contradictions of each of the above with each having its own book. That is not my desire even if that is the current solution:make it better. We all have directions we would go if we were king. We can't nibble around the definitions, slap the discontents, and hang the cheaters to improve this hubris. This is who we are if based on evidence.

We can't change kings. We have to rethink monarchy. ■



PERSPECTIVES

CACVS VASCULAR SYMPOSIUM 2017 - PARIS, FRANCE: PERSONAL INSIGHTS AND OPINIONS JAN 19-21, 2017

At the end of another impressive and successful CACVS Symposium in Paris under the steady visionary leadership of Jean-Pierre Becquemin, I thought it might be interesting to encapsulate and tightly summarize some of the key messages I came out with – at least on the arterial side. There was also a robust Venous program I will not comment on.

-Branched endograft technologies and technical strategies for aortic arch repair and TAAA are now evolving rapidly. Significant progress continues to be reported, but much of it remains near-experimental and in the early stages. Much more work remains to be done, experience gained, and mid/long-term results achieved and analyzed before any of this becomes anything close to a new standard of care. And of course, these procedures should and tend to be confined to a few centers of excellence with the necessary case volume and resources that constitute a pre-requisite.

-TEVAR treatment of type B aortic dissection moves forward and attracts lots of attention. But despite considerable developments in the definition and evidence for high-risk factors underlying indications for intervention in uncomplicated dissection, uncertainties and doubt persist, with some noted experts still entrenched in the historical posture of only offering treatment for classic-complicated type B cases and nothing beyond that... Additionally, there is emerging evidence suggesting that long-term results of TEVAR for aortic dissection may be less than stellar...

AUTHOR:

DR. CRIADO, FRANK J.
miembro del Colegio
Estadounidense de Cirujanos,
miembro de la Sociedad para
la Medicina Vascular

CORRESPONDENCE: frankjcriado@gmail.com

Stay tuned.

-Indications for elective treatment of AAA, 5.0cm versus 5.5cm – smaller (4.5-5.0) for female patients. Little progress here despite the available level-1 evidence in favor of 5.5cm. Many surgeons everywhere still cling on to the 5.0cm historical standard.

And by the way, the 5.5cm indication applies to men! Not to female patients.

Striking differences in indication thresholds and AAA repair rates amongst countries around the world, and AAA-related mortality were brought to our attention, and discussed at some length. Most remarkable are the differences between the U.K. and the U.S., with British AAA patients facing a 2-3X higher risk of death from their aneurysm!

-Iliac-branch devices for hypogastric artery revascularization in the setting of EVAR (and treatment of hypogastric aneurysms) have arrived! These technologies (available from at least 3 different manufacturers) are clearly becoming well established and seem to achieve a high degree of success, in exchange for an acceptable-level increase in procedure time and technical complexity.

Coiling and exclusion of the hypogastric arteries is rapidly becoming a thing of the past, with a much diminished role as we move forward.

-Likewise, *Percutaneous EVAR* is here to stay, now adopted by an increasingly larger number of stent-graft operators everywhere. Decreasing device profiles, and advances with percutaneous arterial closure techniques and devices are the 2 permissive factors underpinning such shift. The "classic" surgical cut-down approach to EVAR will be relegated to only a few cases in the future (when P-EVAR proves unfeasible or contraindicated). It will become an infrequent thing to do indeed.

-Access from above or antegrade to the visceral and thoraco-abdominal aorta is being used increasingly for complex endograft repair including Ch-EVAR, F-EVAR, and Branched TAAA procedures. Without claims of consensus, use of a graft conduit sewn to the axillary artery would appear to be emerging as the more popular and perhaps best technique for antegrade introduction of multiple long sheaths.

-Impressive advances with Ch-EVAR and F-EVAR strategies notwithstanding, increasingly voiced is the view that open surgical repair should still retain an important role in the treatment of juxta-renal and other complex AAAs on patients who are medically fit for major aortic surgery.

-type II endoleaks remain controversial, with one entire segment of a session devoted to discussing whether they should ever be treated – even in the face of an enlarging aneurysm sac! Not that rupture cannot occur, but some experts maintain that such risk is so very low... that any intervention might be more dangerous than the natural history of untreated type IIs.

Stay tuned for this as well.

-Despite considerable advances with F-EVAR repair, *Ch-EVAR techniques* retain their appeal in many circumstances, especially now when we have more robust data and clinical evidence. And the fact that it has received CE Mark approval for use with the Medtronic Endurant stent-graft. So this is now on-label approved therapy for complex AAA disease.

-As to the carotid arteries: evidence continues to pile showing the *extraordinarily low risk of stroke with asymptomatic stenosis* – even with hemodynamically critical stenosis. More and more surgeons would seem to be shifting to the view that – with few exceptions – symptomatic disease "only" should be treated with an intervention.

In terms of carotid stenting: *mesh-covered stents* represent a significant technological advance and will become the new standard. But the *real game changer may well be cervical access with flow reversal (Silk Road Neuroprotection System)*, a concept that surgeons are rapidly embracing at this time.

-Switching gears to the aorto-iliac and lower extremity vasculature, there is no longer doubt that *severe aortic bifurcation and bilateral common iliac artery disease is best treated with covered stents*. The available evidence is solid and it is real.

Paclitaxel-based devices are emerging as the undisputed champions in the infrainguinal arteries, especially the SFA. DCB angioplasty has become a game changer of sorts, although DES stents also play an important role – particularly

for complex extensive SFA occlusions where many experts feel DES stenting should be used, not DCB.

Advances with atherectomy were examined as well. Many still favor atherectomy over other options, including its use in combination with DCB for some complex lesions (such as ISR). The recent addition of OCT image-guided directional atherectomy (by Avinger) was mentioned as an example of a most interesting new technology to pay attention to in the near future.

And that's a wrap! ■



OFFICIAL LECTURE

ENDOVASCULAR VENOUS PROCEDURES IN THE DEEP VENOUS SYSTEM

ABSTRACT:

Introduction: Nowadays endovascular venous procedures in the deep venous system (DVS) are well known. They are used in both acute and chronic lesions. Their most common use in acute lesions is with filters to prevent pulmonary embolism (PE) and in the deep vein thrombosis (DVT) of the iliofemoral sector to prevent damage caused by the later appearance of the post-thrombotic syndrome (PTS). In the chronic disease, their use seems to be justified in severe cases of chronic venous insufficiency (CVI) and, in recent vears, we have seen that the number of procedures has also increased noticeably as their results are very encouraging. Also, thanks to a better understanding and more accurate add-on studies, there is a rise in the treatments of the pelvic congestion syndrome, which, as we know, through the so-called leak points, often manifests itself with varicose veins in the lower limbs, among other symptoms.

Aim: To make a literature review of the different aspects of endovascular procedures in the deep venous system and to add personal experience.

Materials and methods: The following issues were addressed: Vena cava filters / Pharmacomechanical thrombolysis for iliofemoral DVT / Venoplasty of post-thrombotic iliac vein lesions / Venoplasty of NON-thrombotic iliac vein lesions / Endovascular treatment of the pelvic congestion syndrome.

Conclusions: The development of the different endovascular treatments for the venous system has caused changes in all aspects, thus increasing survival and reducing morbidity, which exceeds the limits of conventional surgery.

AUTHORS:

DÁNDOLO, MARCELO ADRIÁN Presented during the 43th Conference on Angiology and Cardiovascular Surgery Argentine Association of Angiology and Cardiovascular Surgery

Sheraton Hotel, Buenos Aires, Argentina November 14-17, 2016

CORRESPONDENCE: mandandolo@gmail.com

FIRST PART

INTRODUCTION

Nowadays endovascular venous procedures in the deep venous system (DVS) are well known. They are used in both acute and chronic lesions. Their most common use in acute lesions is with filters to prevent pulmonary embolism (PE) and in the deep vein thrombosis (DVT) of the iliofemoral sector to prevent damage caused by the later appearance of the post-thrombotic syndrome (PTS). These procedures today are supported by an increasing number of users. In the chronic disease, their use seems to be justified in severe cases of chronic venous insufficiency (CVI) and, in recent years, we have seen that the number of procedures has also increased noticeably as their results are very encouraging. Also, thanks to a better understanding and more accurate add-on studies, there is a rise in treatments of the pelvic congestion syndrome, which, as we know, through the so-called leak points, often manifests itself with varicose veins in the lower limbs, among other symptoms.

Therefore, in this lecture, we will deal with procedures for acute diseases:

- 1) Vena cava filters.
- 2) Pharmacomechanical thrombolysis for iliofemoral DVT

And for the chronic pathology:

- 1) Venoplasty of post-thrombotic iliac vein lesions
- 2) Venoplasty of non-thrombotic iliac vein lesions.
- 3) Endovascular treatment of the pelvic congestion syndrome

VENA CAVA FILTERS:

Brief history of the interruption of the inferior vena cava

In 1784 John Hunter performed the first ligature of the femoral vein in a patient with thrombophlebitis. (1) In 1868 Trousseau suggested the ligation of the inferior vena cava (IVC) as probable treatment for the interruption of the way of production of pulmonary embolism (PE). Bottini is who in 1893 prevented PE with the ligation of the IVC but did not report its success. (1) These techniques have been performed for years: first, the ligation of the bilateral common femoral vein with an unacceptable incidence of PE as well as the sequels of venous stasis in the lower limbs. Then, the ligation of the IVC, frequently performed until the end of the 1960s, seemed to be more successful in controlling PE. (1) However, this technique also delivered unacceptable results in terms of high postoperative mortality rate, recurrent PE and post-thrombotic sequels in the lower limbs.

To mention some statistics which led to the disuse of these procedures, mortality ranged from 19% to 39%, reaching 41% in case of patients with underlying heart diseases (2,3), while 40% of lower limb edema, 20% of varicose veins, 14% of disabling venous claudication and 6% of ulcers were reported. (2) In the light of these data, it was understood that the limitation of the cardiac output after ligating the IVC in patients with heart diseases was what increased the mortality rate (4), which, in addition to the recurrence rate, led to conceive techniques to filter emboli without interrupting it. Thus, IVC sutures were used for more than a decade with plications, foldings with staples and clips externally applied to create limited blood flow, filtering clots in caval circulation. The Adams-DeWeese clip stood out at that time. (5,6) The rapid obstruction of external devices was observed on shortterm follow-up, thereby their use declined quickly after the logical advent of intravenous devices. (7)

The first device that gained popularity was the umbrella of Kazi Mobin-Uddin, but the appearance of some problems, such as a high rate of IVC thrombosis (36% to 47%), the formation of thrombosis proximal to the device, 3% recurrent PE and occasionally its migration to the pulmonary artery, were evidenced in the short term. This device was recalled in 1986 due to its high rate of complications with the advent of much more reliable second-generation devices. (8,9,10)

Indications for the placement of vena cava filters (VCFs)

VCF placement indications are divided into absolute and relative. The following table shows the indications accepted in different current consensus statements and papers, and below some highlights will be detailed.

TABLE 1: Indication for the insertion of a VCF (1,11)

Absolute indications	DVT or PE documented in patient with anticoagulation contraindication
	Recurrent PE in patient with (Ineffective anticoagulation)
	Anticoagulation complications forcing interruption
	Immediately after a pulmonary embolectomy
Relative indications	Large floating iliofemoral thrombus demonstrated in a high-risk patient
	Iliofemoral thrombus spreading despite adequate anticoagulation
	Chronic PE in a patient with pulmonary hypertension and pulmonary heart disease
	Patient with DVT and poor cardiopulmonary reserve
	Septic PE
	Patient with high risk of anticoagulation complication (severe ataxia, falls)
	Poor compliance with anticoagulant medication
	Difficulty to establish the therapeutic anticoagulation

Absolute indications are those which today are accepted unequivocally when the named case comes up. Elaborating on the absolute indications referred to in Table 1, the most common anticoagulation contraindications are in patients with recent bleeding episodes such as gastrointestinal bleeding and hemorrhagic stroke, in patients in immediate postoperative period after major surgery, mainly neurological, and finally in patients suffering from blood dyscrasia such as thrombophilia, hemophilia, etc. Meanwhile, inadequate anticoagulation in patients with PE occurs in approximately 18% of cases. These are the patients in whom we must place the VCF, but we must continue with anticoagulation as this therapy showed a lower incidence of IVC occlusion and therefore of post-thrombotic syndrome (PTS). According to different case studies, anticoagulation complications are present in a 10%-18% range, with hemorrhagic stroke, gastrointestinal bleeding, postoperative bleeding, skin rash and heparininduced thrombocytopenia as the most common ones.

Relative or case-selective indications (1) are those in which we adapt the VCF indication to the pathology of the patient and the moment of his/her illness. Usually discussions arise among the participating doctors as they try to agree on the therapeutics that offers the patient greater guarantees. Those listed in Table 1 are the most frequent and supported ones according to consensus statements. (11) Special mention should be made of septic PE, which for some authors falls within VCF indications (1,11) and for others is a VCF contraindication (12,13). Particles generated in septic processes from infected heart valves, peripheral septic thrombophlebitis and infected venous catheters or other less frequent infectious processes such as chronic mastoiditis, osteitis and oropharyngeal bacterial processes with subsequent thrombophlebitis of internal jugular vein (Lemierre's syndrome) are not potentially infective for inert materials commonly used in the manufacture of filters such as stainless steel or titanium; on the contrary, animal studies showed that thrombi trapped in devices with proper antibiotic treatment were sterilized. (14) A study of 175 patients with sepsis at the moment of VCF placement makes clear that mortality is not related to the placement of the VCF but to the ongoing disease and also that anticoagulation and VCF patients had a low rate of recurrent PE (1.7%) and were better than those with no VCF (15). We believe that acting with certainty based on current evidence on the subject is not possible.

SCIENTIFIC EVIDENCE

It should be stressed that classic indications have hardly changed over the years; however, current indications have little weight in terms of evidence-based medicine and are governed more by the belief of what should be done and what leaves the attending doctor with a clear conscience than by scientific evidence, possibly by the small number of patients. This scientific evidence was taken from the eighth edition of the American College of Chest Physicians guidelines for the treatment of venous thromboembolic disease. (16) The grades of evidence in the indication of VCFs for DVT cases are the following:

- In patients with deep venous thrombosis, the routine use of inferior vena cava filter is not indicated (Grade 1A).
- The use of inferior vena cava filter is indicated in patients with deep venous thrombosis who present contraindication to anticoagulation therapy due to risk of bleeding (Grade 1C).
- Patients with DVT who have received a vena cava filter as an alternative to anticoagulation should receive conventional anticoagulant treatment once the risk of bleeding is resolved (Grade 1C).

And for PE cases, the grades of evidence are the following:

- In patients with pulmonary thromboembolism, the routine use of inferior vena cava filter is not indicated (Grade 1A).
- The use of inferior vena cava filter is indicated in patients with pulmonary thromboembolism who present contraindication to anticoagulation therapy due to risk of bleeding (Grade 1C).
- Patients with pulmonary thromboembolism who have received a vena cava filter as an alternative to anticoagulation should receive conventional anticoagulant treatment once the risk of bleeding is resolved (Grade 1C).

Studies following the publication of these guidelines compare the degree of support to them in relation to results. Thus, recent studies establish the comparison between the clinical characteristics and outcomes of patients who have received a VCF by following the above-mentioned recommendations or not, concluding that data did not support the use of a VCF without following the recommendations of the American College of Chest Physicians guidelines (16, 17) in patients without prior DVT and tolerant to anticoagulation therapy, these having a low risk of developing PE. From what was learnt, we see that knowledge on this subject is dynamic or

there is no definition yet. In the CHEST AT9th guidelines, the conclusion is that permanent VCFs increase the risk of DVT and decrease the risk of PE including fatal PE and have no effect on venous thromboembolic disease (VTD, combination of DVT and PE) or on mortality, based on the PREPIC study. In relation to the update of the CHEST AT9th guidelines (39), and based on the recent publication of the PREPIC 2 trial (40), we find new changes. The PREPIC 2 trial states that VCFs used for 3 months do not reduce the recurrence of PE, including the possibility of fatal PE, in anticoagulated patients with PE, DVT and additional risk factors. As we see, this is opposed to CHEST AT9th. What is affirmed then in the update of CHEST AT9th guidelines is that, for patients with DVT or PE who are treated with anticoagulants, the use of a VCF is not recommended (Grade 1B). (39)

PROPHYLACTIC VCF INDICATIONS

There is a new group of indications promoted since 2005 (18) that gave rise to an increase in the rate of VCF placement in the last years. These indications divide into two groups and are: 1) PE prophylaxis in patients with diagnosed DVT, and 2) true prophylaxis, patients with no DVT or PE (venous thromboembolic disease, VTD) but with high risk. Table 2

TABLE 2. Prophylactic VCF indications (18)

Patients with DVT but no PE (PE prophylaxis)	Patients with reduced lung function who would not tolerate a pulmonary embolism
	Iliofemoral thrombus spreading
	Recent deep venous thrombosis (DVT)
	A history of recent major surgery
	Pregnancy with proximal DVT (depending on the trimester)
	Thrombolysis patients
	After a thrombectomy of iliofemoral thrombosis
Data : : : : : : : : : : : : : : : : : :	Patients with single or multiple trauma
Patients with high risk of PE (true prophylaxis)	Prolonged immobilization or paralysis
	Patients who underwent major surgery and with anticoagulation contraindication or ineffectiveness
	In cases of gastric surgery for morbid obesity
	Hypercoagulability
	A history of venous thromboembolic disease
	Cases of tumor malignancy, especially in patients undergoing chemotherapy treatments
70	After venous reconstructions or endo procedures

78

These prophylactic indications are based on the use of short-term devices, i.e. temporary or removable VCFs, which we will see below, and are subject to revisions that will arise from future studies.

VCF CONTRAINDICATIONS

Contraindications to the placement of VCFs are few and are summarized in Table 3.

TABLE 3. VCF contraindications. (11)

There is no venous access available for the implant
There is no place available for the placement of the VCF

Some authors include a marked decrease in platelets as a contraindication, but it should be noted that this situation may be temporary or correctable; others, as already mentioned, include septic PE.

TYPES OF FILTERS:

VCFs can be classified according to the time they remain in place; thus, those which will never be removed are called permanent. Removable are those which will remain for a limited period corresponding to the time that the anticoagulation contraindication and PE risk last, taking into account that, if this period extends on average for more than three weeks, its removal will be convenient to avoid complications. The last group consists of filters that remain attached to the catheter attached to the patient's skin and are used when there is certainty that the time that it will be needed is extremely short. Table 4 presents this classification and the ones most used in the different types.

Permanent	Greenfield (stainless steel 1988, titanium 1991)
	VenaTech
	Bird's Nest
	Simon Nitinol
Removable	Günther Tulip
	Optease
	Nitinol recovery
	Ella filter
Temporary	Filcard
	Tempofilter

Table 4. Classification of VCFs.

Today it is possible to add to the classification an additional type of VCFs: the **convertible ones**. These devices can pass from "active" to "inactive" mode with a simple percutaneous maneuver, thus turning into a stent. This avoids dangerous maneuvers to remove the filter. Current related studies are still few. (11) The filter is called **Vena Tech Convertible** and is not available in our country for now; we should wait for the results of its use although the conceptual idea of this device is tempting. What is interesting and positive about this

design is the initial report of fewer IVC wall lesions during conversion as compared to the extraction of removable VCFs and that it is possible to be left in "active" mode for a longer time with an average of 121 days. (41)

To choose the appropriate VCF for each case, first we should know the characteristics of the devices most used and available in our country. Thus, we could search for an "ideal" VCF with the following characteristics: Low profile, easy insertion, high biocompatibility, prolonged durability, non-corrosive, non-ferromagnetic, non-thrombogenic, removable or convertible. (12) These characteristics were achieved by most current devices, but there are still a few not achieved to obtain the "ideal" VCF, which are: 100% IVC patency, 0% PE recurrence, 0% migration rate, 0% IVC perforation rate.

The most outstanding features of the devices most commonly used are highlighted below. The first one is the titanium Greenfield vena cava filter, which is delivered with a 12-F catheter through a 14-F sheath via the jugular or femoral vein, although, given the large French size (device diameter), the femoral via is preferred if the case allows so. In addition, it has fixation hooks that have reduced the migration rate. (19,20) The VenaTech vena cava filter is a cone-shaped VCF introduced in 1986, which is sealed and made from Phynox. This material has similar properties to those of Elgiloy alloy, a material used in temporary pacemaker guidewires. It has radial teeth for the stabilization of the cone with hooks to reduce the possibility of migration of the device. (1) They are usually delivered via the right jugular vein with a 12-F introducer. This VCF is described for use in large IVC. (21) The VenaTech LP (low profile) vena cava filter with a 6-F introducer has recently been launched; the material used, Phynox, has not changed and its purpose is still the same, i.e. for large IVC, as it reaches an unfolded diameter of 40 mm. However, the FDA so far has approved it for 28-mm IVC. (22)

The **Bird's Nest vena cava filter** is a VCF devised for two basic purposes: the filtration of emboli and large IVC (maximum 40-mm diameter). After undergoing changes to its initial presentation, it has a 12-F introducer formed by V-shaped guidewires connected by an uneven swarm of guidewires. The follow-up of its use showed a 1.3% PE rate, a 4.7% IVC occlusion rate and an 85.3% high rate of asymptomatic IVC penetration. (23)

The **Simon Nitinol vena cava filter** is made from a nickel-titanium alloy; as a characteristic, this material is

flexible when cooled and takes the rigid form previously given at body temperature. (1) The design of this VCF is also particular, with a 28-mm diameter dome of eight handles and the bottom similar to the Greenfield-type VCF with hooks to fix to the IVC. It is an attractive device given its characteristics and acceptable French size, but case studies have not delivered very encouraging results. In a detailed report of 44 implant cases with 6-month follow-up, 4% of recurrent PE, 1% of mortality and 20% of IVC occlusions were observed. (24)

As for removable VCFs, first a brief comment will be made on the **Optease vena cava filter**. It is made from nickeltitanium alloy, its shape consists of two cages facing each other with side hooks, and its delivery system is extremely practical as the VCF is sheathed in a cartridge and can be introduced via femoral or jugular vein. Also, the profile is low: 6 French. On the other hand, it has a hook to be removed with the appropriate maneuver. The removal kit has a higher diameter: 8 F. It is recommended for IVC of less than 30 mm in diameter. Its retrieval is safe if done within 23 days after its implantation. Like the **Trapease vena cava filter** (permanent but of similar shape and features), it is criticized for a high thrombosis rate perhaps due to the inadequate filtration of small clots leading to its occlusion and much contact with the IVC endothelium, which may make its removal difficult. (25)

The Günther Tulip vena cava filter has been used in Europe since 1992 and in the United States was approved in 2001. Made from Elgiloy, it has a retrieval hook and fixation hooks. Its use was reported also in the superior vena cava (SVC). The results of studies are somewhat contradictory; however, a study on 75 Günther Tulip VCFs in 49 cases presented the successful removal of the VCF only in 35 cases (81%) because, in the other 14 cases, large thrombi were found trapped. The average implant time was 8.2 days. Moreover, 16% and 22% tilting was observed in the VCFs retrieved and in the VCFs not retrieved, respectively, after 30 months. (26)

The **nitinol recovery vena cava filter** is one of the newest devices approved, has hooks for fixation to the IVC wall, is delivered by a 6-F device and its retrieval device is 10 F. This VCF is recommended for IVC of less than 28 mm in diameter. It is a promising device and its initial results are good. (27)

The **Ella vena cava filter** is another removable device available in our country. It has a 7-F sheath and is easy to unfold. It is recommended for IVC of up to 35 mm in

diameter. However, in our experience, this device migrated to the right ventricle of the patient and we were able to retrieve it endovascularly without consequences 20 days after implantation.

VCF USES IN SPECIAL SITUATIONS

There are a number of situations that have increased the use of VCFs in the last years; some of these were briefly discussed when reference was made to prophylactic indications. Thus, we will refer first to patients with severe polytraumatism. In these patients, the risk of DVT is estimated at 58% and the risk of PE is unknown. Of these, around 14% have anticoagulation contraindication, in which case the placement of VCFs is proposed. It is estimated that those who benefit most would be those with spinal cord lesions. This indication has advantages and disadvantages. Regarding the former, we can say that we obtain effective PE prevention and that the VCF would act as an effective bridge until the moment in which we can anticoagulate the patient. As a disadvantage, a higher incidence of DVT was evidenced in patients with VCFs. (28,29)

Another situation of growing interest is the prevention of PE in bariatric surgery. This surgery is considered of high risk and papers support the use of VCFs with good results. Removable VCFs are always used and this maneuver is performed in the fourth postoperative week. (30)

A challenge for the operator is when the thrombus ascends through the IVC compromising the renal veins; this contingency forces an atypical placement over them. Other situations requiring this high placement are the thromboses of the renal veins, DVT and pregnancy with anticoagulation contraindication, and recurrent embolism in a patient with proper infrarenal VCF placement which forces the placement of a second VCF but this time suprarenal.

As regards pregnancy, the implantation of removable filters in the inferior vena cava is indicated when there is absolute contraindication to anticoagulation, PE despite proper anticoagulation therapy, heparin complications such as thrombocytopenia and DVT or PE close to delivery (from 1 to 2 weeks). As anticoagulation must be suspended before and immediately after delivery to minimize the risk of bleeding, this being the period of extension of thrombosis and PE, protection would be given through the insertion of the removable filter in high-risk patients. The protection provided by inferior vena cava filters to prevent fatal PTE

varies between 98% and 99%. (31) The VCF for a pregnant patient is recommended to be removable and be placed suprarenally via the jugular vein. (32) The abdomen of the mother should be protected and exposure to radiation should be limited. In experienced hands, with minimum exposure time, the chances of fetal consequences are almost nil.

In patients with neoplasia, there is no evidence that they benefit from the use of VCFs. Perhaps we should assess its use in patients with a diagnosis of recent metastasis and a history of PE or episodes of neutropenia with reasonable life expectancy and quality of life. (33)

Finally, in patients whose transfer is contraindicated or represents an unacceptable possibility of complications due to their underlying pathology, implantation assisted only by ultrasound, either transabdominal or intravascular, has been proposed. This type of implants in the intensive care unit at the patient's bedside (bedside placement) has the difficulty of interpreting the anatomy of the IVC without radiological confirmation. (34)

VCF REMOVAL INDICATIONS

Many papers and authors support the need to remove the VCF once the period of PE risk is over. (1,11,35,36,37,38) The reasons provided are simple. On the one hand, in most patients the risk of PE is limited in time as it is linked to a momentary pathology and this is reinforced when the treated patient is a young person with prolonged life expectancy. (1)

The PREPIC study (35) gave great impetus to the removal of VCFs. The study was a randomized clinical trial intended to assess the overall effectiveness of the use of VCFs. During an 8-year follow-up, it effectively evaluated 396 patients who randomly received VCFs or not. VCFs were of four different types and all patients received low-molecularweight heparin (LMWH) or unfractionated heparin (UFH). V/P grammagraphies were performed at the beginning and clinical evaluations were conducted during follow-up. It was demonstrated that, in the VCF group, the incidence of PE at the beginning (short term) was lower (1.1% vs 4.8%) but two years later it reached the same level without differences. As for DVT, the recurrence rate was 20.8% in the VCF group vs. 11.6% in the group without VCFs. This led to consider the VCF as a strong risk factor for recurrent DVT and prompted the use of removable VCFs.

In 2015, the results of the PREPIC 2 study were published. The study sought to identify a subgroup of patients with

acute venous thromboembolic disease (VTD) in which the risk of early recurrence was so high that perhaps the placement of a temporary VCF could improve clinical outcomes as opposed to standard anticoagulation only. The sample consisted of 399 patients with PE associated with VTD (DVT or superficial thrombosis) who had ≥1 additional recurrence risk factor (age > 75 years old, active Ca, RV dysfunction, etc.). Patients were assigned randomly to the placement or non-placement of a removable VCF with 3-month recovery; all patients received anticoagulation for \geq 6 months. There was no differences in the primary result of recurrent symptomatic PE in 3 months (3% vs.1.5%; P = 0.50); neither were significant differences after 6 months. The authors concluded that, in patients with high PE recurrence risk, the temporary placement of a removable VCF should not be performed routinely.

VCFs generally should be reserved for patients with anticoagulation contraindications. The authors acknowledge that the applicability of these results to certain subgroups of patients (including those with massive PE) is uncertain. (40)

Thus, we could consider the removal of VCFs according to the recommendation presented in Table 5. (37)

Table 5. When to consider the removal of the VCF.

Patient with low PE risk (clinically significant

a. Patient with venous thromboembolic disease (VTD) Anticoagulant therapy for at least two or three weeks

No clinical evidence of progressive or recurrent VTD

b. Patient without VTD (VCF used prophylactically)
Prophylactic anticoagulation therapy or VTD risk factors solved

By normal duplex scan of lower limbs without evidence of DVT

Patient compliant with the use of medication and follow-up

Life expectancy of more than 6 months

Unlikelihood of returning to a VTD state

The patient wants the removal of the VCF

Of course in addition to following these recommendations to indicate the removal of the VCF, we should take certain precautions such as having the appropriate material, being within the removal period suggested by the manufacturer of each type of VCF and performing at the beginning of the removal a venacavogram in which we make sure that there

are no large thrombi trapped in the VCF. As regards the exact moment of removal, on average we should not exceed three weeks after implantation since it was observed that after this period IVC lesions increase when the device is removed. If we want to remove the VCF and we need to exceed three weeks, the suggested alternative is to reposition the VCF above or below the primary placement site so as to have three more weeks and avoid the firm adhesion of the device to the vein wall.

However, the VCF removal rate is low. In 80% of cases, VCFs are not removed (38) and, while in our country there are no related statistics available, the non-removal rate is supposed to be even higher. This is due to the lack of patient follow-up by the operator after solving the emergency and, in our country, the economic difficulty derived from the cost of removing materials is important. Regarding follow-up, in some countries records of operators are kept for the operators themselves to be responsible for the removal when it is indicated.

We believe that the prophylactic indication of filters in certain patients should be a priority over the later discussion on their maintenance or removal. The incidence of long-term complications in patients with removed VCFs and in patients with unremoved VCFs should be a reason for prospective studies.

COMPLICATIONS OF VCFs

VCF complications can be divided into three groups: 1) complications related to the VCF placement technique, tilting frequently; 2) complications related to failures in PE prevention due to the small size of thrombi but generally causing non-fatal PE; or 3) long-term complications related to the VCF itself. The latter are very common and include: VCF migration or fracture, VCF thrombosis, erosion of a strut on the IVC wall with penetration into neighboring structures. Penetration into the IVC wall is a very frequent situation, presented by about 25% of VCFs placed. However, in general it is asymptomatic and only a few cases of symptomatic patients with penetration into neighboring structures such as aorta, pancreas, duodenum, right ureter or column are reported. Penetration is due to different causes including respiratory movements, aortic pulsatility and spinal misalignment, etc. (42)

OUR EXPERIENCE

Between 2004 and 2015, we placed 56 VCFs in a 120-bed hospital: 22 in men (40%) and 34 in women (60%). The

average age of patients was 53 years old (24 - 96 years old). The access way was the internal jugular vein in 31 cases (55%) and the femoral vein in 25 cases (45%). As for the placement indications of the sample, 42 cases corresponded to anticoagulation contraindications in patients with DVT, 6 cases were due to inefficient anticoagulation, 3 cases related to anticoagulation complications, and finally 3 cases were grouped as "others" since they do not correspond to absolute VCF placement indications. VCF placement indications in the latter were 2 cases of right kidney cancer with invasion of the IVC and 1 case of femoral DVT of right lower limb with term pregnancy and proven recent PE. Labor was started, the VCF was placed and subsequently a c-section was performed.

The FVC types used were permanent in 19 cases and removable in 37. The highest percentage was the Ella filter model (21), followed by Greenfield (16), Optease (8), Günther (8), Simon Nitinol (2) and VenaTech (1). It should be made clear at this point that in most cases we did not choose the type of VCF to be used, we just decided if they were permanent or removable. In the second half of the sample, we preferred to ask routinely for removable and lowprofile VCFs and then to determine whether they would be removed or not. From the sample of 37 removable VCFs, we only retrieved 6 (16.2%). The low extraction rate was due to difficulties in the follow-up of these patients as they are patients with an interdisciplinary treatment and most cases are not led by the vascular surgeon. Follow-up was possible in 39 cases for 5 days to 64 months. As for complications, we had VCF migration to the right ventricle with asymptomatic patient in 1 case, with successful endovascular extraction of the VCF. There were no complications in the extraction of VCFs. Three patients died during follow-up of causes unrelated to the VCF: one 96-year-old patient in the immediate postoperative period after a hip surgery and two patients with neoplasia.

REFERENCES:

- 1. Rentenwald JE, Greenfield LJ, Henke PK, Wakefield TW. Procedimientos de obstrucción de la Vena Cava. Rutherford, Cirugía Vascular, sexta edición. 2006. 152:2198-2216.
- 2. Nasbeth D, Moran J. Reassessment of the role of inferior vena cava ligation in thromboembolism. N Engl J Med 1965. 273:1250-1253.
- 3. Amador E, Ting K, Crane C. Ligation of inferior vena cava for thromboembolism. JAMA 1968. 206:441-443.
- 4. Miller TD, Staats BA. Impaired exercise tolerance after inferior vena cava interruption. Chest $1988,\,93{:}776{-}780.$
- Adams JT, De Weese JA. Partial interruption of inferior vena cava with a new plastic clip. Surg Gynecol Obstet. 1966. 123:1087-1088.
- 6. Hye RJ, Mitchell AT, Dory CE, et al. Analysis of transition to percutaneous placement of Greenfield filters. Arch surg 1990. 125:1550-1553.

- 7. Askew AR, Gardner AM. Long-term follow-up of partial cava occlusion by clip. Am J Surg 1980. 140:441-443.
- 8. Cimichowski GE, Evans RH, Zarins CK, et al. Greenfield filter versus Mobin Uddin umbrella: The continuing quest for ideal method of vena caval interruption. J Thorac Cardiovasc Surg 1980. 79:358-365.
- 9. Mobbin—Uddin K et al: A vena cava filter for the prevention of pulmonary embolus. Surg Forum 1967; $18:\!209\text{-}211$
- 10. McIntyre AB et al: A ten year follow-up study of the Mobbin Uddin filter for vena cava interruption, Surg Gynecol Obstet 1984; 158:513-516.
- 11. John A. Kaufman, MD, Thomas B. Kinney, MD, Michael B. Streiff, MD, Ronald F. Sing, DO, Mary C. Proctor, MS, Daniel Becker, MD, MPH, Mark Cipolle, MD, PhD, Anthony J. Comerota, MD, Steven F. Millward, MD, Frederick B. Rogers, MD, David Sacks, MD, Anthony C. Venbrux, MD. Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. J Vasc Interv Radiol 2006; 17:449 459.
- 12. Lucas LF, Lucas MA. Interrupción de la Vena Cava. Rev Arg de Cir Cardiovasc Dic, Ene, Feb2004/2004 Vol II N° 4:236-242.
- 13. U.S. Food and Drugs Administration, Center for Divices and Radiological Help: Guidance for cardiovascular intravascular filter 510 (K) submissions. Online at: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm073776.htm
- 14. Peyton JW, Hylemon MB, Greenfield LJ, et al: Comparison of Greenfield filter and Vena Caval ligation for experimental septic thromboembolism. Surgery 1983. 93:533-537
- 15. Greenfield LJ, Proctor MC. Vena Caval Filter use in patients with sepsis: Results in 175 patients. Arch Surg 2003. 138:1245-1248
- 16. Kearon Clive; Kahn Susan R; Agnelli Giancarlo; Goldhaber Samuel; Raskob Gary E; Comerota Anthony J; Antithrombotic therapy for venous thromboembolic disease: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008; 133(6 Suppl): 454S-545S.
- 17. P. Singh, H. M. Lai, R. Guidelines and the use of inferior vena cava filters: a review of an institutional experience. Journal of Thrombosis and Haemostasis 2008; 31.
- 18. Robert B. Rutherford, MD Prophylactic Indications for Vena Cava Filters: Critical Appraisal. Semin Vasc Surg 2005; 18:158-65
- 19. Greenfield LJ, Cho KJ, Pais SO, Van Aman M. Preliminary clinical experience with titanium Greenfield vena cava filter. Arch Surg. 2003. 124:657-659.
- $20.\ Greenfield\ LJ,\ Cho\ KJ,\ Tauscher\ JR.\ Evolution\ of\ hook\ design\ for\ fixation\ of\ the\ titanium\ Greenfield\ filter.\ J\ Vasc\ Surg\ 1990.\ 12:345-353.$
- 21. Millward SF, Aquino JJr, Peterson RA. Oversized inferior vena cava: Use of single Vena Tech-LGM filter. Can Assoc Radiol J. 1996. 47:272-274.
- 22. Kinney TB. Update on inferior vena cava filters. J Vasc Interv Radiol. 2003. 14:425-440. 23. Nicholson AA, Ettles DF, Paddon AJ, Dyet JF. Long-term follow-up of bird's nest IVC filter. Clin Radiol. 1999. 54:759-764.
- 24. Dorfman GS. Percutaneous inferior cava filters. Radiology. 1990; 174:987-992.
- 25. U.S. Food and Drugs Administration, Center for Devices and Radiological Health: MAUDE database. Online at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm.
- 26. Wicky S, Doenz F, Meuwly JY, et al. Clinical experience with retrievable Günther Tulip vena cava filters. J Endovasc Ther. 2003 10:994-1000.
- 27. Asch MR. Initial experience in humans with a new retrievable inferior cava filter. Radiology. 2002. 225:835-844.
- 28. Rosenthal D et al. Role of prophylactic temporary inferior vena cava filters placed at the ICU bedside under intravascular ultrasound guidance in patients with multiple trauma. J.Vasc.Surg. 2004.vol 40.5: 958-964.
- 29. Langan e et al. Prophylactic inferior vena cava filters in trauma patients at high risk: Follow –up examination and risk/benefit assessment. J Vasc Surg. 1999 vol 30, 3:484-490
- 30. Giancarlo P et al. Safety, feasibilty, and outcome of retrievable vena cava filters in high risk surgical patients. 2007. J. Vasc Surg. Vol 45, 4:784-788.
- 31. Vicario M. Enfermedad tromboembólica venosa en el embarazo. 2010. Flebología y Linfología-lecturas vasculares. 13:788-796.
- 32. Kawamata K et al. Experience of temporary vena cava filters inserted in the perinatal period to prevent pulmonary embolism in pregnant women with deep vein thrombosis. 2005. J vasc Surg. Vol 41; 4: 652-656.
- 33. Jules Lin, Mary C. Factors associated with recurrent venous thromboembolism in patients with malignant disease. J. Vasc Surg May 2003; 37(5):976-83.
- 34. Passman M et al. Bedside placement of inferior vena cava filters by using transabdomianl duplex ultarsonography and intravascular ultrasound imaging 2005 J Vasc. Surg 42; 5:1027-1032.
- 35. PREPIC. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. Circulation 2005; 112:416–422.

- 36. Merino B, Brizuela JA, Mengíbar L, Salvador R, Revilla A, Carpintero L, Gonzalez Fajardo JA, Vaquero C. Evidencia científica en la indicación de Filtro de Vena Cava Inferior: Revisión bibliográfica; Rev Española de Inv Quir. 2009. Vol XII 1:37-39
- 37. Kaufinan JA. Guidelines for use of retrievable Vena Cava Filters. 2007. Interv Cardiology 52-54.
 38. Riyad Karmy-Jones MD; Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients. Journal of Trauma-Injury Infection & Critical Care Jan 2007; 62(1):17-25.
 39. Clive Kearon, MD, PhD; Elie A. Akl, MD, MPH, PhD; Joseph Ornelas, PhD; Allen Blaivas, DO, FCCP; David Jimenez, MD, PhD, FCCP; Henri Bounameaux, MD; Menno Huisman, MD, PhD; Christopher S. King, MD, FCCP; Timothy A. Morris, MD, FCCP; Namita Sood, MD, FCCP; Scott M. Stevens, MD; Janine R. E. Vintch, MD, FCCP; Philip Wells, MD; Scott C. Woller, MD; and COL Lisa Moores, MD, FCCP; Antithrombotic Therapy for VTE Disease CHEST Guideline and Expert Panel Report. 10th edition. CHEST 2016; 149(2):315-352.
- 40. Mismetti P, Laporte S, Pellerin O, et al; and the PREPIC 2 Study Group. Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism: a randomized clinical trial. JAMA.2015;313(16):1627-1635. 41. E.J. Hohenwalter, J. Stone, P. O'Moore, S.J. Smith, J. Selby, Jr., R.J. Lewandowski, S. Samuels, P. Kiproff, D. Trost, J. Handel, E. Gandras, D.C. Madoff, A. Vlahos, W.S. Rilling, Muliticenter trial of the VenaTech convertible filter: a novel approach to IVC filtration. Journal of Vascular and Interventional Radiology. February 2015. Volume 26, Issue 2, Supplement, Pages S5–S6.
- 42. Junaid Y. Malek, Christopher J. Kwolek, Mark F. Conrad, Virendra I. Patel, Michael T. Watkins, R. Todd Lancaster, Glenn M. LaMuraglia. Presentation and Treatment Outcomes of Patients With Symptomatic Inferior Vena Cava Filters. Annals of vascular surgery. January 2013Volume 27, Issue 1, Pages 84–88