# CARDIOVASCULAR AND METABOLIC SCIENCE

Continuation of the Revista Mexicana de Cardiología

2019



#### • Present and future of Asociación Nacional de Cardiólogos de México

- Mexican Position Statement on the Treatment of Atrial Fibrillation
- Evaluation of a scale to assess cardiovascular symptoms
- Total obstruction of percutaneous vascular accesses in acute coronary syndrome

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Referencias: 1. Setiawati A, Pohan T. Safety and Effectiveness of Candesartan and Candesartan/HCT Fixed Dose Combination in Patients with Hypertension. Acta Medica Indonesiana -The Indonesian Journal of Internal Medicine 2013; 45(3): 193-201. 2. Bramlage P, Buhck H, Zemmich C. Candesartan Cliexetii 30 gm/Hydrochlorothiazide 25 mg in Unselected Patients with High or Very High Cardiovascular Risk: Efficacy, Safety, and Metabolic Impact. Springer International Publishing Switzerland 2014: 1-9. 3. Mugellini A, Nieswandt V. Candesartan plus hydrochlorothiazide: an overview of its use and efficacy. Expert Opin. Pharmacother 2012;13(18):2699-2709. 4. Melian E. B., Jarvis B. Candesartan Cliexetii Julus Hydrochlorothiazide combination. A Review of its Use in Hypertension. Drugs 2002; 25 (5): 787-816. 5. Ohman K.P., Milon H., Valnes K. Efficacy and Tolerability of a Combination Tablet of Candesartan and Hydrochlorothiazide of Losartan and Hydrochlorothiazide in Patients with Maderate to Severe Hypertension Results of the CARLOS-Study1. *Clin Drug Invest* 2000; 19 (4): 239-246, 7. Scott L. J., McComack P, L. Olmesartan Medoxonii A Review of Its Use in the Management of Hypertension. *Drugs* 2008; 68 (9): 1239-1272. 8. Precio Máximo al Público Junio 2016.





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Referencias: 1. Jones P. H., Davidson M.H., E, et al. Comparison of the Efficacy and Safety of Rosuvastatin Versus Absrvastatin, and Parvastatin Across Doses (STELLAP Trial). The American Journal of Cartiology 2003; 92: 152-160 2. CoMkoch F., Stormhulvud C., Gardhi S.K. Impact of treatment with rosuvastatin and activastatin and activastatin and activastatin and activastatin and activates devices and buctomes evidence from the Archimodes-simulated clinical truats. Clinico/Economics and Ductomes 10: 57: 555-565. 3. Rehman A. Comparison of Law Pointson Tell. Stormhulvud C., Gardhi S.K. Impact of treatment with rosuvastatin in a trigh-resk Pakalatin Cohort An Open-Label Randomizot Triki, Jumari et Unico/Economics and Ductomes evidence and Stores and Sto



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Present and future of *Asociación Nacional de Cardiólogos de México* (ANCAM) Pedro Gutiérrez-Fajardo

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### Present and future of *Asociación Nacional de Cardiólogos de México* (ANCAM)

Presente y futuro de la Asociación Nacional de Cardiólogos de México (ANCAM)

Pedro Gutiérrez-Fajardo\*

#### Dear members:

This year, ANCAM will be celebrating 35 years from its foundation. In spite of being a young association, ANCAM has reached a significant advance and has a relevant regional, national and international position. It is important to recognize the brave, engaged, pluralistic and inclusive vision of ANCAM founders in order to get a cardiological association to interchange ideas, experiences, collaborations and continuing medical education to facilitate study, research, and knowledge diffusion to impulse cardiology in Mexico.

It is a privilege having the opportunity to communicate with you through Cardiovascular and Metabolic Science, continuation of Revista Mexicana de Cardiología, official journal of Asociación Nacional de Cardiólogos de México, A.C. (ANCAM). This first number will be available, for the first time in our story, in electronic format, accessing to the microsite: https://cardiovascularandmetabolicscience. org.mx. It will allow an easier access and consultation, as well as easier reception of submitted works for publication (electronic submission system). We hope this change, achieved after several process difficulties can increase scientific contributions from ANCAM fellowships, sister societies, clinical and basic cardiology professionals, cardiac surgeons and all of the allied scientists.

As an innovation in our Regional Meetings we will offer electronic inscription and general and particular evaluation after meetings in order to have actual feedback for future events. Certificate of assistance will be available on line, after fulfillment of a questionnaire. Also, healthy coffee break will be offered in our events in order to be concordants with our slogan: Preventing is our goal. Finally, due to our collaborators and available devices our meetings will be considered ANCAM Cardioprotected Events.

We will support ANCAM Chapters to get final transcendental results, including courses, updates and statements. Of a major importance is *Iniciativa por el Corazón de la Mujer*, a novel and unique chapter focused to specific actions linked directly to female open population, where different topics are presented to explain the importance of cardiovascular risk and diseases in women. With chapters support and participation of World Summit of Echocardiography, we will ensure a most successful National Congress in 2020, in Guadalajara, Jal.

Previously ANCAM has sent statements to The Senate, on taxes to sugar drinks. We recently sent a statement to both Chamber of Deputies and The Senate, on Cardiovascular effects on Cannabis sativa consumption. We are working on multidisciplinary approach statements on systemic hypertension, heart failure and sudden death that we hope they will be available soon.

I am sure that current collaborating work with focused goals, ANCAM will increase membership and international collaborating relationships that will allow a professional position to continue working with a global association vision.

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### Joint Mexican Position Document on the Treatment of Atrial Fibrillation

Endorsed by: Mexican National Association of Cardiologists (ANCAM), Mexican Electrophysiology and Pacing Society (SOMEEC) and Mexican Society of Cardiology (SMC)

Posicionamiento conjunto acerca del tratamiento para fibrilación auricular

Avalado por: Asociación Nacional de Cardiólogos de México (ANCAM), Sociedad Mexicana de Electrofisiología y Estimulación Cardiaca (SOMEEC) y Sociedad Mexicana de Cardiología (SMC).

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#### I. WHAT IS KNOWN ABOUT THE EPIDEMIOLOGY OF ATRIAL FIBRILLATION IN MEXICO? CAN IT BE CONSIDERED A PUBLIC HEALTH PROBLEM?

A trial fibrillation (AF) incidence and prevalence increase with age. Its prevalence is near to 2% in the general population, but it could be as high as 10% in those over 75 years.<sup>1,2</sup> Before the Mexican Registry of Atrial Fibrillation (ReMeFA) was published a market study was conducted in Mexico in 2007, finding that, for a population of 105,338,982 people the prevalence of cardiac arrhythmias was 2.4%, with tachyarrhythmias being the most common with 56% (1,402,453 people), of which, AF was the most frequent arrhythmia, occupying 60.7% of tachycardias (or a total of 851,489 cases).<sup>3</sup>

Today, we estimate that in Mexico, there are more than one and a half million people with AF, with a prevalence ranging from 0.43% in the 40-49 age group to 8.48% in those over 80 years old, for an average of 1.58% in a population over 40 years of age.<sup>3</sup> Permanent or chronic AF represents 51.5% (corresponding to 438,134, Mexicans). The ReMeFA<sup>4</sup> study was the first national multicenter registry, with clinical

follow-up of one year, in 1,201 subjects, on the comparison of AF treatment with a rhythm control strategy or with rate control. This study was carried out with the collaboration of 71 cardiologists and electrophysiologists. At one year follow-up, an incidence of 3% of ischemic cerebral vascular disease (CVD) was observed in the rate-control strategy, significantly higher than 1% in the rhythm control strategy (p = 0.04).<sup>2</sup> Worldwide, CVD is the second leading cause of death and the leading cause of disability.<sup>1</sup> CVD has become a health problem as a result of increased life expectancy and lifestyle changes, representing one of the leading causes of death in Mexico.<sup>2,3</sup> According to the Brain Attack Surveillance project in Durango, it is estimated that in Mexico the annual incidence of CVD is 232.3 cases per 100,000 inhabitants over 35 years of age, while its prevalence is eight cases of CVD per 1,000 inhabitants, a figure that increases to 18 cases per 1,000 in people over 65 years of age.<sup>5</sup> It is important to note that in recent years, CVD has occurred in younger people as a result of the continuing increase in risk factors, including unhealthy lifestyles and obesity. In a Pan American Health Organization report, indicators of premature vascular mortality (in people under 70) showed that in

Mexico the rate in non-diabetics was 10.7 per 100,000, compared to 3.3 and 5 per 100,000 in Canada and the USA, respectively.<sup>6</sup> Based on these results, we consider AF to be the most frequent tachyarrhythmia in Mexico with a high percentage of cerebral vascular disease, so it should be considered a public health problem in Mexico.<sup>6</sup>

#### I a. Importance of early diagnosis

AF is an independent risk factor associated with mortality, increasing it twice in men and 1.5 times in women;<sup>1</sup> mortality due to embolic events can decrease with oral anticoagulation but other causes of cardiovascular death such as heart failure or sudden death continue to be frequent despite adequate treatment, that is the reason why an early diagnosis is of utmost importance since AF can be asymptomatic (silent AF), and patients have it inadvertently, delaying proper treatment. The diagnosis of AF requires an event lasting at least 30 s and to be observed on an ECG, rhythm strip, or cardiac monitor, characteristically with the irregularity of RR intervals without clearly identifiable P waves or with visible «f» waves of fibrillation. An early electrocardiographic recording is cost-effective for documenting chronic forms of AF particularly in populations older than 65 years with a prevalence of up to 2.3%, obtaining a «necessary to treat number» of 70 to find one person with AF.<sup>1</sup> As for paroxysmal AF, the longer the record, the more likely it is to find silent events. Now the technology has evolved, so in Mexico, we already have 48hour recorders and implantable loop recorders whose duration is up to three years. The more we use these devices in high-risk patients, more likely to find AF and being able to start appropriate treatment earlier.<sup>4</sup>

#### II. ANTIARRHYTHMICS AVAILABLE IN MEXICO FOR RHYTHM CONTROL: HOW AND WHEN?

II a. Recent onset atrial fibrillation: conversion to sinus rhythm in an unstable patient

If the AF paroxysm is associated with «angina pectoris», pulmonary edema, low blood

pressure or shock, urgent electrical cardioversion should be practiced. It is recommended that the shock should be administered with the highest available energy: 200 joules biphasic or 360 joules monophasic. It is not suggested to proceed in stages by increasing from lower energies. The reason for this is to reduce the number of shocks, use a lower cumulative dose of energy, and reduce the anesthetic time. For thromboembolic prophylaxis, unfractionated heparin (bolus according to body weight followed by infusion) should be administered, followed by oral anticoagulation.<sup>1</sup> Although embolism risk might be increased because of the emergency nature of the condition.

#### II b. Stable patient

Assuming that the corresponding thromboembolic prevention measures have been taken and that the heart rate is controlled with the isolated or combined use of betablockers, calcium channel blockers or digoxin, the clinician should assess whether it is reasonable to administer any antiarrhythmic drug to restore sinus rhythm. It is known that up to 50% of AF paroxysms may spontaneously remit within 24-48 hours.7 If AF persists after this period, pharmacological cardioversion with amiodarone (oral or preferably intravenous), propafenone or flecainide is indicated. Intravenous amiodarone is given at a loading dose of 5 to 7 mg/kg in 30-60 minutes, followed by a maintenance dose of 1.2 to 1.8 g/day until ten g<sup>1</sup> completed. The oral dose of propafenone is 600 mg in a single dose, and that of flecainide is 300 mg in a single dose. Sinus rhythm conversion occurs in 80-90% of cases within the first few hours.<sup>8</sup> It should be emphasized that sotalol, dronedarone, and digoxin are not indicated for conversion to sinus rhythm. If the episode becomes persistent despite the use of antiarrhythmics, electrical CV is indicated, preceded by a transesophageal echocardiogram to rule out intracavitary thrombus.1,9

#### II c. Maintaining sinus rhythm

Once the conversion to sinus rhythm has been achieved, the clinician should assess whether

it is appropriate to use an antiarrhythmic daily for the maintenance of sinus rhythm or whether it is preferable not to give preventive antiarrhythmic and choose to treat the episode with the «pill in your pocket» strategy.<sup>1,10</sup> For the maintenance of sinus rhythm it is indicated to use one of the following antiarrhythmics: propafenone, flecainide, sotalol, dronedarone or amiodarone. In the absence of structural heart disease, the use of propafenone or flecainide is recommended.<sup>10</sup> Sotalol may be used in the presence of ischemic heart disease. Dronedarone is indicated only for cases of paroxysmal AF, in the absence of heart disease and with preserved left ventricular ejection fraction. Amiodarone is considered a secondline drug due to its side effects; however, it is the most effective alternative for maintaining sinus rhythm.<sup>1</sup> In the case of heart failure, the use of amiodarone is recommended. For the last three drugs (sotalol, dronedarone, and amiodarone), the duration of the QT interval should be monitored.<sup>11</sup> A single dose of 600 mg propafenone or 300 mg flecainide is recommended for the «pill in your pocket» strategy.<sup>1,8,10</sup> Caution should be exercised due to the possibility that these two drugs may unmask the electrocardiographic signs of Brugada syndrome or convert atrial fibrillation into an atrial flutter with a paradoxical increase in ventricular response (less than 1% of cases).<sup>12</sup>

### II d. Recurrent atrial fibrillation (paroxysmal, persistent)

Unlike the first episode approach (or very sporadic recurrent cases), for recurrent cases of paroxysmal and persistent presentation, it is indicated to use antiarrhythmics for prevention. The therapeutic options are propafenone, flecainide, sotalol, dronedarone, and amiodarone. It should be emphasized that dronedarone is only indicated to prevent recurrence of paroxysmal or persistent AF that has lasted less than six months of evolution, in the absence of heart disease and with preserved left ventricular ejection fraction. AF ablation (radiofrequency or cryoballoon energy) should be considered as a first-line alternative for drugrefractory or symptomatic cases (at least one antiarrhythmic class Ic or III).<sup>1,13</sup>

### II e. Persistent atrial fibrillation (lasting more than a year)

This category was established to identify patients who may not benefit from a rhythm control strategy because AF is permanent, from those with a chance to convert to sinus rhythm. There are two therapeutic options: 1) facilitated electrical cardioversion with prior use of antiarrhythmics<sup>14</sup> and 2) AF ablation.<sup>1</sup> It is reasonable to proceed with facilitated electrical cardioversion with antiarrhythmic drugs as the first measure because if successful, although with early relapse, it demonstrates that the patient can maintain sinus rhythm and would be a suitable candidate for catheter ablation.<sup>1,13,14</sup>

#### II f. Immediate post-cardioversion recurrence

Electrical cardioversion is one of the cornerstones for rhythm control in AF. However, immediate recurrence or therapeutic failure, described in up to 26% of cases, limits its clinical application.<sup>15</sup> To increase the response rate, antiarrhythmics must be given before the electric shock.<sup>13,14</sup> The use of verapamil, amiodarone, or sotalol has been reported to decrease the incidence of immediate recurrence.<sup>13-16</sup> Other drugs such as ibutilide (not widely available in Mexico), vernakalant (not available in Mexico), and ranolazine (available in our country) have also shown benefit in this area.<sup>1,17</sup>

### II g. Delayed cardioversion (facilitated by antiarrhythmic)

It is indicated for persistent AF, mainly when the temporal progression is unknown or when a high probability of immediate recurrence is assumed. Amiodarone 600 mg per day administered for one month (total dose 16.8 g) is indicated for a better outcome. Pharmacological cardioversion has been observed to occur during loading dose in 16-18% of cases.<sup>1</sup> The success of electrical cardioversion is 88%. Besides, if cardioversion does not occur, the ventricular response of the heart rate during AF could be reduced (from 100 ± 25 to 87 ± 27.5 beats per minute [p ≤ 0.001]) by a negative dromotropic effect on the atrioventricular node.<sup>18</sup>

#### III. HOW TO MANAGE VENTRICULAR RATE CONTROL IN PERMANENT AF? WHAT IS THE ROLE OF AV NODE ABLATION WITH PACEMAKER IMPLANT?

Much that has been said about AF can be summed in three brief sentences: it is the most common arrhythmia, the easiest to diagnose and the most difficult to treat.<sup>19-21</sup> Another no less ominous peculiarity is that AF is a progressive disease,<sup>22</sup> and that it is a condition that contributes to its perpetuation.<sup>23</sup> In other words, the sooner we try to revert and achieve sinus rhythm, the higher the chances of success (to keep the patient in sinus rhythm).<sup>24</sup>

#### III a. Permanent (chronic) AF

Permanent AF is the one in which recovery of sinus rhythm is not possible.<sup>1,19</sup> The distinguishing feature of this phase of AF is the uncontrollable variability of the ventricular rate. It depends on the AV conduction and not on the sinus node function; it is the autonomic nervous system (sympathetic and vagal) that determines the AV conduction velocity and thus the ventricular frequency.<sup>25</sup> It is common to consider ventricular frequency analysis only with a resting electrocardiogram (EKG) record, however this is not quite right because of the circadian heart rate variations. On the other hand, vagal tone during the early morning hours can delay AV conduction and cause considerable and sufficient ventricular pauses to cause low brain perfusion with its consequences. The therapeutic possibilities are: pharmacological and interventional.<sup>26,27</sup>

#### III b. Pharmacological treatment

The main limitation of drugs comes from their AV node conduction slowing properties, thus inducing severe bradycardias without avoiding abnormally fast rates.<sup>28</sup> Antiarrhythmic drugs such as amiodarone are ineffective, as, by definition, sinus rhythm is not intended to be restored.<sup>29</sup> Beta-adrenergic blockers may delay AV conduction, but decrease the force of ventricular contraction.<sup>1</sup>

#### **III c. Interventional treatment**

Once it has been demonstrated that the patient has a very high ventricular rate variability and maintains a heart rate above 140/min, heart failure is an imminent threat,<sup>1,30</sup> Ablation of the AV junction and placement of a variable frequency ventricular pacemaker (VVIR) is the indicated option. The use of anticoagulants is imperative even in patients who have regained sinus rhythm after isolating the pulmonary veins, so there is no argument to avoid it.<sup>31,32</sup> Radiofrequency thermal injury of the AV junction causes an irreversible blockage. The injured tissue can be the AV node or the His bundle, and can be achieved either from the tricuspid ring or from the left ventricle.<sup>1</sup> The success of this procedure is very close to 100%, and the possibility of recurrence is practically null. The placement of a ventricular pacemaker is a routine procedure in any institution, with low risk and ventricular function improved by obtaining regularity of rate.<sup>1</sup>

In a series of patients from the Department of Experimental Medicine and Arrhythmias (UNAM) in the General Hospital of Mexico, 177 ablations of the AV junction with placement of a ventricular pacemaker have been carried out. All patients showed a ventricular rate variability greater than 140 bpm, when the normal is above 100 bpm. Many of them, during the 6-min walk test (6MWT), could not perform more than 250 meters. In 159 of the patients, ablation of the AV junction was achieved from the right atrium, and in 17 (10%) it had to be done from the left ventricle. In no case, there was a recovery of AV conduction. (unpublished data). This study concludes that ablation of the AV node is affordable and feasible in cases of permanent AF. Isolation of pulmonary veins should not be performed as an attempt to recover sinus rhythm, even if other options have been exhausted. Anticoagulation is mandatory in almost all patients with AF, regardless of its type.

#### IV. WHAT IS THE CLINICAL BENEFIT AND WHAT IS THE PURPOSE OF PULMONARY VEINS ISOLATION IN AF?

In general, there is no definitive cure for AF; the therapeutic goal is to control symptoms, delay

disease progression, and prevent a cardiovascular event.<sup>33</sup> Electrical isolation of the pulmonary veins when there is recurrence with drug treatment is the most effective strategy for maintaining sinus rhythm and keeping the individual asymptomatic.<sup>1,33</sup> Invasive electrophysiological treatment is relatively recent; it began when it was discovered that premature atrial contractions from the pulmonary veins were responsible for initiating AF; which led to the establishment of the selective elimination of these ectopic foci as a therapeutic goal.<sup>33</sup> Currently, the strategy is broader, trying to make electrical isolation of all pulmonary veins, from the antrum and not from the ostium to avoid side effects such as pulmonary stenosis. Other cases with a more advanced disease require different ablation strategies such as supplemental lesion in the left or right atrium, or even both, as well as in the superior vena cava or cavotricuspid istmus.<sup>1,33</sup> AF is a progressive disease, starting with tachycardia of the pulmonary veins (they usually arise from there, but they can be originated in other sites) that initiates AF; however, AF produces more AF with a remodeling, not only anatomical but also electrical process of the atria. If AF is prolonged enough, it becomes a biatrial disease with fibrosis, electrical remodeling, and dilation of both atria that causes rotor systems that support it, making it finally permanent.<sup>34-36</sup> Technology and knowledge have evolved, thus, 74% of the patients submitted for radiofrequency catheter ablation have sinus rhytm at a one-year follow-up.<sup>1,33</sup> AF ablation is recommended in paroxysmal, persistent and long standing persistent AF refractory or intolerant to antiarrhythmic drugs; it may also be considered as the first line in symptomatic paroxysmal AF.<sup>1</sup> The therapeutic objective it is to create a series of lesions that prevent AF starting by eliminating the triggering extrasystoles or modifying the substrate that maintains it.<sup>1,33</sup> Currently, ablation strategies depend on the type of AF; if it is paroxysmal AF, the success rate is higher, since the isolation of the pulmonary veins is sufficient to maintain sinus rhythm.<sup>1,33</sup> On the other hand, if it is persistent AF, the success rates are lower; in these cases the therapeutic strategy is broader, requiring different ablation lines and searching for rotors not only in the left atrium but also in the right atrium, and even in other

thoracic veins such as the coronary sinus, caval veins or Marshall's vein.<sup>1,33,36</sup> This complexity leads to a significant reduction of the long-term success rate, requiring two or more procedures to make it more likely that the patient maintains sinus rhythm. Because of these results, patients with paroxysmal AF are now preferred for early intervention. Scientific evidence shows that the main prognostic factor for maintaining sinus rhythm is achieving complete electrical isolation of the pulmonary veins. In advancing stages the posterior wall, also plays an essential role in the maintenance of sinus rhythm, as a therapeutic goal.<sup>1,33,34</sup> The techniques employed can be two, with RFCA by using irrigation catheters or with cryoballoon ablation (CBA); the latter was limited only for paroxysmal AF, but nowadays, it is safe to perform it in persistent AF with the advantage of being a less operator-dependent procedure, with a faster learning curve and above all, fewer complications than RFCA,<sup>1</sup> with comparable results in comparative studies.<sup>1,33,37</sup> In centers of high experience, it can give results of up to 85% of patients free of AF at follow-up in 12 months.<sup>38</sup> In Mexico, in the series published by the Instituto Nacional de Cardiología<sup>39</sup> (Clínicas Mexicanas de Cardiología) of RFCA, in a period of eight years, in patients with paroxysmal AF, there is a 78% success rate at a 12-month follow-up in a total of 121 patients. CBA in the first experience in Mexico from 2013-2014 in a multicenter study (unpublished data, from Hospital Ángeles Interlomas, CMN Siglo XXI, CMN 20 de Noviembre and Servicios de Salud del Estado de Puebla) with 52 patients, exclusively with paroxysmal AF, the CBA was successful in 78% of cases with an 18-month follow-up.

#### V. WHEN AND HOW SHOULD ANTITHROMBOTIC PROPHYLAXIS BE GIVEN IN THE SUBJECT WITH ATRIAL FIBRILLATION? ANTI-PLATELET DRUGS, VITAMIN K ANTAGONISTS, DIRECT ORAL ANTICOAGULANTS, AND LEFT ATRIAL APPENDAGE OCCLUDERS

#### V a. AF is a cause of stroke

The presence of AF has long been associated with the development of cerebral and systemic

(pulmonary, limb, coronary, renal and visceral) embolism.<sup>40</sup> Initially, only AF secondary to valvular disease, usually rheumatic heart disease, was considered thrombogenic,<sup>41</sup> but since the Framingham study, AF of non-rheumatic origin is also recognized as a cause of embolism.<sup>42</sup>

> V b. The prevention of embolisms in «valvular» AF should be performed with vitamin K antagonists (VKA)

For embolic risk purposes, «valvular» AF is considered to be the one associated with moderate or severe mitral stenosis or in the presence of a mechanical valve prosthesis.<sup>43</sup> Although acetylsalicylic acid (ASA) was initially used in patients with rheumatic heart disease,<sup>44</sup> subjects with valvular AF should now be anticoagulated with VKA, either acenocoumarin or warfarin.<sup>1,45</sup> The dose is that necessary to achieve an INR between 2.0 and 3.0, except for patients with mechanical valve prostheses that require INR between 2.5 and 3.5. Direct oral anticoagulants (DOAC) should not be used in valvular AF until the results of studies supporting this practice are available.<sup>46</sup> To improve the time in therapeutic intervals it is

recommended to: 1) establish anticoagulation clinics<sup>47</sup> and 2) self-monitoring of the INR with portable devices.<sup>48</sup>

V c. CHA<sub>2</sub>DS<sub>2</sub>-VASc score and options for prevention of embolisms in «non-valvular» AF

For patients with AF not associated with mitral stenosis or a mechanical valve prosthesis, a choice can be made between antiplatelet drugs, VKA or DOAC. Antiplatelet agents have the weakest effect in preventing embolism.<sup>49</sup> In a meta-analysis of randomized studies (Hart RG et al), the relative risk reduction of stroke with ASA compared to placebo was calculated at 19% while with VKA was 64%.<sup>50</sup> It is important to note that based on the results of the ACTIVE-W study, dual antiagreggation therapy (e.g. ASA and clopidogrel) is not recommended over oral anticoagulation.<sup>51</sup>

The decision of which drug should be used in the prevention of cerebral infarction can be based on the use of the CHA<sub>2</sub>DS<sub>2</sub>-VASc<sup>1,52</sup> score (*Table 1*). For individuals with no points, (no risk factors, considered «low risk» by not observing any embolic event in a follow-up year) it is possible to choose: not

CHA <sub>2</sub> DS <sub>2</sub> -VASc	Score	HAS-BLED	Score
C (congestive heart failure) = left-sided heart failure	1	H = hypertension	1
H = Hypertension	1	A = impaired liver or kidney function	1 each
A $(Age) = \geq 75$ years	2	S(Stroke) = cerebral vascular disease	1
A(Age) = age 65  to  74  years	1	B(Bleeding) = bleeding	1
D-diabetes mellitus	1	L ( <i>Labile INR</i> ) = highly variable INR (outside therapeutic intervals)	1
S ( <i>Stroke</i> ) = previous stroke	2	E ( <i>Elderly</i> )	1
S = Sex category V = peripheral vascular disease	1	D(Drugs) = drugs  or alcohol	1 each
Risk of cerebral infarction:		Risk of bleeding in patients with AF with indication coagulation:	of oral anti-
<ul> <li>Low = 0</li> <li>Intermediate = 1</li> <li>High = 2</li> </ul>		<ul> <li>Low = 0</li> <li>Intermediate = 1-2</li> <li>High = 3 or more</li> </ul>	

Table 1: Risk factors for cerebral infarction included in the «CHA<sub>2</sub>DS<sub>2</sub>-VASc» score and hemorrhagic risk factors included in the «HAS-BLED» score.

to give treatment; in those with a score of 1 («intermediate risk» of 0.6% of an embolic event per year) if it is male or 2 if it is female, they benefit more with oral anticoagulation with VKA or DOAC.<sup>1</sup> The HAS- BLED or ATRIA scales can be used to assess the risk of bleeding (*Table 1*).<sup>53</sup>

For individuals scoring 2 or more on the  $CHA_2DS_2$ -VASc scale («high risk», 3% embolic event per year) there is no doubt that formal anticoagulation with VKA or DOAC is required. There are currently three DOACs available in Mexico: dabigatran, rivaroxaban, and apixaban. Their mechanism of action is inhibition of thrombin (dabigatran) or inhibition of factor Xa (rivaroxaban and apixaban).<sup>54</sup>

Each has a different dosage, which varies with the individual's age (in the case of apixaban) and kidney function (all). None can be used in cases of renal failure with creatinine clearance less than 15 mL/min. For a complete review of DOAC including dosages, how to start them, switching from VKA to DOAC, drug interactions, and bleeding management, the clinical practice guidelines of the European Heart Rhythm Association are highly recommended.<sup>55</sup>

#### V d. Left atrial appendage occluders (LAAO)

LAAO is an interventional option for the prevention of embolism that so far is only indicated for patients with high embolic risk and who have some contraindication to receive VKA or DOAC.<sup>56</sup>

Outside of this select group of patients, implanting these devices as substitutes for anticoagulation does not yet have sufficient evidence. The most recent results on costbenefit analysis using dedicated statistical models (e.g. Markov's stochastic decision model) have yielded contradictory results.<sup>57</sup> However, several studies are ongoing and are expected to produce positive results for occluders.<sup>58</sup> Like any invasive procedure, its efficacy in preventing stoke should be weighed against possible complications of its implant.

#### VI. FINAL REMARKS

AF, in its different forms, is considered to be the most frequent tachyarrhythmia in

Mexico and should be considered as a public health problem. Its treatment includes «rhythm control» with a few antiarrhythmic drugs available in Mexico for this purpose. Ventricular rate control can be achieved with drugs or some interventional procedures, included AV junction ablation with a VVIR pacemaker implant. The role of pulmonary vein isolation is undoubted for clinical relief of symptoms with many ongoing studies on the possible effect on morbi-mortality. Thromboprophylaxis is a key and integral part of the management of any patient with AF. Recently, CENETEC (National Center for the Technical Excellence in Health, Health Ministry of Mexico) published guidelines on anti-thrombotic treatment of AF.59

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### Validity, sensitivity and specificity of a scale to assess cardiovascular symptoms

Validez, sensibilidad y especificidad de una escala para evaluar los síntomas cardiovasculares

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#### **Keywords:**

Validity, screening, symptoms, cardiovascular diseases.

#### Palabras clave:

Validez, tamizaje, síntomas, enfermedad cardiovascular.

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#### ABSTRACT

**Objective:** To analyze the validity, internal consistency, sensitivity and specificity of a scale of cardiovascular symptoms (ESCV-10). Material and methods: Two studies were carried out in which confirmatory factorial analyses were done, the Cronbach alpha and omega of the scale were calculated, and ROC curves were estimated. In addition, criterion validity was analyzed using different standards in two studies. In study 1, 151 apparently healthy public transport drivers participated, from whom total cholesterol, LDL, HDL, glucose, triglycerides, and blood pressure were obtained, which were used as proxy bio-markers of cardiovascular health status. The sample of study 2, were cases of diagnosed ischemic heart diseases, reported in a public hospital (n = 57), which were paired with healthy people with similar sociodemographic characteristics (n = 69) for comparative purposes. Results: The 2 studies showed a replica of the unifactorial structure of the scale and good psychometric properties in general, in particular by eliminating 2 items (ESCV-8). Although in study 1 the scale was correlated weakly with biomarkers, in study 2 it discriminated effectively between heart and healthy patients and showed levels of acceptable sensitivity and specificity (> 80% and > 70% respectively). Conclusions: In general, the findings showed that the scores of the proposed scale of cardiovascular symptoms (ESCV), in particular in its 8-item version, has psychometric validity and acceptable levels of sensitivity and specificity, so that it could be used reliably, as an initial screening tool for cardiovascular health. Future findings and perspectives are discussed.

#### RESUMEN

**Objetivo:** Analizar la validez, consistencia interna, sensibilidad y especificidad de una escala de síntomas cardiovasculares (ESCV-10). Material y métodos: Se realizaron dos estudios en los que se efectuaron análisis factoriales confirmatorios, se calculó el alfa de Cronbach y omega de la escala, y se estimaron curvas ROC. Adicionalmente, se analizó la validez de criterio empleando diferentes estándares en dos estudios. En el estudio 1 participaron 151 conductores de transporte público aparentemente sanos, de quienes se obtuvieron niveles de colesterol total, LDL, HDL, glucosa, triglicéridos y tensión arterial, los cuales fueron utilizados como biomarcadores proxy del estado de salud cardiovascular. En la muestra del estudio 2, participaron casos diagnosticados con cardiopatía isquémica en un hospital público (n = 57), los que fueron emparejados con personas sanas de similares características sociodemográficas (n = 69) con fines comparativos. Resultados: En los dos estudios se evidenció una réplica de la estructura unifactorial de la escala v buenas propiedades psicométricas en general, en particular al eliminar dos ítems (ESCV-8). Aunque en el estudio 1 la escala correlacionó débilmente con los biomarcadores, en el estudio 2 discriminó eficazmente entre cardiópatas y sanos, y mostró niveles de sensibilidad y especificidad aceptables (> 80 v > 70%, respectivamente). Conclusiones: En general, los hallazgos muestran que los puntajes de la escala de síntomas cardiovasculares (ESCV) propuesta, en particular en su versión de ocho ítems, tienen validez psicométrica y aceptables niveles de sensibilidad y especificidad, por lo que puede utilizarse de manera confiable como instrumento de tamizaje inicial para la salud cardiovascular. Se discuten hallazgos y perspectivas futuras.

#### INTRODUCTION

Cardiovascular diseases (CVD) are the leading cause of morbidity and mortality

in the world and it is known that more people die every year from CVD than from any other cause. According to the World Health Organization,<sup>1</sup> just in 2015, an estimated 17.7 million people died from CVD, which represents 31% of the total deaths recorded in the world. Some estimates indicate that an acute myocardial infarction occurs every four seconds and a cerebral vascular event every five seconds, and at least one in three people lose their lives due to some pathology related to CVD.<sup>2</sup>

More than three quarters of CVD deaths occur in low and middle-income countries, particularly in Latin America, ischemic heart disease and CVD represent 8.96 and 6.11% respectively of the causes of death in the region, and these chronic problems along with diabetes, cause more deaths in Latin America than in the United States of America and Canada.<sup>3</sup>

In México, the National Institute of Statistics and Geography (INEGI)<sup>4</sup> reported 141,619 deaths from cardiovascular diseases and 101,877 from ischemic heart disease, which together accounts for 34.63% of all deaths in 2017. Some studies with a population registered at IMSS (government health insurance) in Mexico have found that since 1990 there has been a decrease in the prevalence of lethality and mortality due to CVD, however it is recognized that there is not a decrease in incidence yet.<sup>5,6</sup> This agrees with statistics of the Organization for Economic Cooperation and Development, which shows that México does not have the highest death rate due to this cause among the member countries of this organization, but it ranks second with the highest percentage of incidence rates between 1990 and 2011.7

As in any public health problem, cardiovascular diseases require screening measures for a more simple and rapid detection and with a positive relationship in terms of effectiveness/cost and efficiency/ time. In this sense, questionnaires and subjective self-reports of illness can represent an additional relevant contribution to physical medical examinations and laboratory tests, especially at the level of primary or secondary prevention. These questionnaires and scales do not substitute any clinical diagnosis properly, but they should be understood as general screening tests, and in this sense, their usefulness can be an advantage at prevention level, as long as their validity, sensitivity, and specificity are acceptable. The self-reports scales of subjective symptoms have been a useful and widely used measures in the assessment of different health problems and especially have been useful in the field of epidemiological research because of the logistical facilities they represent.

However, for the specific case of CVD, the use of questionnaires or self-report scales are scarce in the literature, perhaps due to the nature of such diseases that represent underlying alterations of blood vessels that are often asymptomatic and their first manifestation can be directly a heart attack or a cerebrovascular event.<sup>8</sup> Some studies have found weak or absent relationships between the subjective selfreport and the clinical diagnosis of CVD or its risk factors; for example, Tenkorang,<sup>9</sup> and Dave<sup>10</sup> located inconsistencies between selfreported hypertension and the one obtained in biometric data (sensitivity of 33%); Similarly, Molenaar et al<sup>11</sup> in a population-based prospective study, obtained for self-reports only a sensitivity of 33.3% in the case of hypertension, and 58.9% for diabetes mellitus type II. On the other hand, Natarajan et al<sup>12</sup> and Dey et al,13 found that self-reported hypercholesterolemia also has low levels of sensitivity (44 and 57.5% respectively).

Notwithstanding the foregoing, in a German study, the medical condition of more than 7,000 participants was assessed by means of physical and laboratory examinations at the same time as the subjective self-report of diseases such as hypertension, diabetes, cardiac arrhythmias and angina pectoris. Among others; they found substantial levels of agreement between both measurements with significant percentages ranging from 83 to 96%.<sup>14</sup> In another study,<sup>15</sup> they found sensitivity levels of up to 92% in the subjective self-report of hypertension, and others have also found reasonable consistencies, including Hispanic populations,<sup>16</sup> which means that there are still inconsistencies in the literature regarding this topic.

Several authors have pointed out that the accuracy of a subjective self-report of the medical condition of the same patient may be influenced by factors such as: age, sex, race, knowledge and understanding of relevant medical information, memory capacity, disposition to communicate what it feels and, of course, the specific cardiovascular disease or risk in question.<sup>10,12-14,17</sup>

Although some authors agree that the subjective self-report is slightly more consistent for diabetes than any other disease, <sup>10,18</sup> other follow-up studies showed that the self-report is a better predictor of the incidence of cerebrovascular accident (CVA) and myocardial infarction (MI), compared to those obtained in other diseases.<sup>14,19</sup>

This has some relation with what has been obtained in experimental studies of cardiovascular activation response, where for several decades it has been concluded that the subjective cardiovascular self-report provides a more accurate indicator of the overall level of arousal of the whole body in relation to that obtained in other specific biomarkers.<sup>20,21</sup> So perhaps the perception of the health of the heart in a global way is more accurate than the one present in some of its risk factors separately.

In this sense, Bowlin et al<sup>22</sup> have suggested combining different repeated measures in a single indicator to improve the sensitivity and specificity of CVD self-reports, which may partly explain the limited results of previous studies that have used a single measurement or an only question to assess the self-report of a disease, such is the case of questions like «Do you suffer from hypertension?». In psychometrics it is well known that the accuracy of a measurement using a single question is weak, and therefore the use of «scales» of subjective self-report through the use of several items (which can be summative) allows not only to ensure a greater a view of what is valued, but the content validity is increased and greater consistency is obtained in the measurement, which gives rise to the concept of reliability. Reliability theory is based on the assumption that a score observed in a particular value of a random variable represents all possible scores that could have been repeatedly reported by a person.<sup>23</sup>

The available literature does not show any proposal for validation of a self-report scale with several items that explore cardiovascular symptoms for the overall assessment of heart disease, which is of great need and can represent great advantages for population screening. Among the benefits of having a tool of this nature are: 1) low cost, 2) speed and ease of identification of possible risk without large logistical deployments, 3) decrease in the use of specialized human resources and devices, 4) avoidance of invasive procedures, 5) ease of people having global and first-hand information about their possible cardiovascular risk, especially in cases where another form of medical assessment is inaccessible, and 6) the possible availability of a scale of cardiovascular screening for research purposes in large samples.

Given the above, the present work has two objectives: the first one is to propose a scale of self-report of cardiovascular symptoms and analyze their psychometric properties through the analysis of internal consistency (reliability) and its factorial structure (construct validity); and second, to explore the criterion validity of the scale through correlation analysis with different cardiovascular indicators, estimating in turn the sensitivity and specificity through ROC curves.

To achieve these objectives, two studies were carried out with designs and samples that were distinguishable in nature: the first study in a sample of apparently healthy people from whom various biomarkers of their cardiovascular health were obtained as validation criteria, and a second comparative study of cases (with cardiopathy) and not cases (healthy), which are described below.

#### MATERIAL AND METHODS

Study 1. Study of validity in apparently healthy people

#### Participants

An open and voluntary convocation was made to approximately 300 public transport drivers in the city of Cuernavaca, Morelos, who were invited to a screening to know their health that included the filling of the proposed scale of cardiovascular symptoms (ESCV) and the taking of blood samples. N = 151 apparently healthy drivers who did not know their cardiovascular health participated. This group was chosen because it belongs to the occupational group

most vulnerable to cardiovascular diseases according to the statistics described by the Mexican Institute of Social Security (IMSS).<sup>24</sup> Informed consent was obtained from the participants and blood samples were taken in accordance with NOM-253-SSA1-2012 for the disposition of humal blood and its components, and extracted by certified personnel assigned to the department of medical services of the Autonomous University of the State of Morelos (UAEM). Informed consent was signed and at all times the ethical procedures corresponding to the Declaration of Helsinki,25 the UAEM regulations, and corresponding regulations were followed. 100% of the participants were male, with an average age of 36.09 years (SD 9.48), 25.2% had primary school, 55.6% secondary, 18.5% high school and 0.7% undergraduate. 83.4% lived with a partner.

#### Instruments

The cardiovascular symptoms scale (ESCV) was initially developed with 10 items (*Table 1*), considering the traditional or more well-known symptomatology in case of circulatory discomfort, cardiac rhythm disturbances, high blood pressure, heart failure, and angina. It was designed with four response options: 1 (Never), 2 (some occasions = up to once a month), 3

#### Table 1: Proposed scale of cardiovascular symptoms (ESCV).

- 1. Have you felt the sensation of shortness of breath when making an effort like climbing stairs? I
- 2. Swelling, either in the legs, feet, ankles or knees
- 3. Rapid palpitations
- 4. Feeling that «your heart is jumping»
- 5. Chest pain
- 6. Headaches
- 7. Ringing in the ears
- 8. Have you seen bright spots or lights?
- 9. Have you felt sudden weakness or will you faint?
- 10. Have you felt pain in your chest before an effort that has caused you to stop?

#### Source: own creation.

Note: the instructions were «indicate how often you have the following symptoms in the last months».

(many occasions = several times a week) and 4 (always = every day). The value of the scale was divided by the number of items in order to clearly identify the average frequency of presentation of symptoms.

In addition to the application of the proposed scale, as proxy indicators of cardiovascular health biomarkers of well known CVD risk factors were obtained, which would allow to discriminate the validity of the scale even in healty subjects. This way, blood samples were obtained under normal conditions with the criterion of 12 hours of fasting to obtain values of total serum cholesterol, low-density lipoprotein cholesterol (LDL cholesterol), high-density lipoprotein cholesterol. (HDL cholesterol), glucose and triglycerides, which were measured with commercially available techniques, modified according to the recommendations given in the Third Report of the Panel of Experts of the National Cholesterol Education Program (NCEP) on the Detection, Evaluation, and Treatment of Cholesterol Elevated Blood in Adults.<sup>26</sup> For the determination of «cases», it was used the cut off point suggested by the NOM-037-SSA2-2012 for the prevention, treatment an control of dyslipidemias. Likewise, the weight and height were taken to evaluate the Body Mass Index (BMI) and the blood pressure (BP) was taken by means of an OMRON automatic wrist, model HEM-63INT (oscillometric method with measurement limits ranging from 0 at 299 mmHg, with a precision of pressure within  $\pm 3$ mmHg and memory of 60 measurements with date and time), the monitor model is the HEM-63INT, which is backed by the cardiology society following the protocol of estimated points of Schnall et al.<sup>27</sup> The lifestyle was also considered through the affirmations: «I have a fatty diet», «I exercise at least 30 minutes until sweating» and «I smoke», with four response options ranging from: «Never», «Once per month», «Several times per week» and «every day».

#### Procedure

In a first step, descriptive and dispersion statistics were calculated, and in order to obtain the highest certainty of the internal consistency of the scale, Cronbach's alpha  $(\alpha)^{28}$  was calculated by complementing it with

Table 2: Descriptions of the variables in study 1.									
	Min.	Max.	Mean	σ	Skewne	ss (error)	Curtosi	s (error)	High prevalence (%)
Scale ESCV (10)	1.00	2.60	1.41	0.36	1.169	0.197	0.792	0.392	-
Scale ESCV (8)	1.00	2.88	1.47	0.39	1.239	0.197	1.432	0.392	-
Systolic AP	93.50	162.00	121.04	10.53	0.922	0.202	1.941	0.401	17.2
Diastolic AP	56.00	106.00	78.57	7.72	0.612	0.202	1.488	0.401	15.2
BMI	17.26	46.85	29.89	4.97	0.389	0.197	0.600	0.392	86.1
Glucose	65.00	293.00	102.19	39.73	3.511	0.200	12.321	0.397	28.5
Total cholesterol	96.00	293.00	196.57	38.97	0.160	0.200	-0.235	0.397	41.7
Triglycerides	44.00	970.00	225.28	152.22	1.998	0.200	5.174	0.397	66.9
HDL	20.00	64.00	35.70	7.68	0.881	0.200	1.237	0.397	78.8
LDL	46.40	220.90	127.47	32.21	0.373	0.200	0.017	0.397	17.2
Exercise	1.00	4.00	1.88	0.85	0.697	0.198	-0.194	0.394	-
Smoke	1.00	4.00	1.90	1.11	0.906	0.197	-0.624	0.392	-
Fatty diet	1.00	4.00	2.16	0.83	0.511	0.197	-0.131	0.392	-

Note: The cut-off points to determine the prevalence were taken from NOM-037-SSA2-2012, being higher than normal levels  $\geq$  at 120/80 for TA, from 25 for BMI, 100 mg/dL for glucose, 200 for total cholesterol, 150 for triglycerides, 40 for HDL, 160 for LDL.

its confidence intervals (CI)<sup>29</sup> and the omega coefficient ( $\omega$ ), which has been recommended for cases in which the assumption of tau equivalence is violated.<sup>30</sup> The minimum acceptable value of both coefficients was 0.70.<sup>31</sup> To test its psychometric validity and the unidimensionality of the scale, a confirmatory factorial analysis (CFA) was carried out with structural modeling using the EQS software version 6.2. The robust estimation method was used by the Satorra Bentler adjustment for non-normality in the data.<sup>32</sup> The most acceptable fit indices were used according to recent literature, and Kline's suggestions<sup>33</sup> were followed with respect to cut-off points, where a satisfactory fit index was  $\geq$  a 0.90 for the CFI and B-NNFI, while which should be < 0.10 for RMSEA and SRMR. For comparison between models, the adjustment differences test of  $\chi^2$  was used and to verify differences between Cronbach's alphas, the Lautenschlager and Meade method<sup>34</sup> was used. Finally, seeking to prove the convergent validity of the scale, correlation coefficients rs (Spearman) were obtained between the proposed scale (ESCV) and cardiovascular risk markers; likewise, the sensitivity and

specificity of the scale were estimated using ROC curves with the software SPSS version 23.

#### **RESULTS (STUDY 1)**

With respect to the proposed scale of 10 items, the descriptive statistics showed an average of 1.41, which in the frequency scale refers to symptomatology between «never» (1) and «some occasions» (2). The asymmetry indicators showed a positive bias, which together with the kurtosis in relation to their errors, indicate low frequencies and lack of compliance with the assumption of normality. It is worth mentioning that some respondents (n = 9) showed understanding difficulties in items 9 (sudden weakness or going to faint) and 10 (chest pain in the face of exertion that causes them to stop). The item-total correlations (not shown by space issues) showed that the lowest relations were precisely with items 9 and 10 (r = 0.49and r = 0.43 respectively), which also had the lowest means (1.24 and 1.15 respectively), thus showing some psychometric difference with the rest of the items, so it was decided to also try a version of the scale without those two items (ESCV10 vs ESCV 8) (Table 2).

Eventhough it was not the main objective of this work it is worth it to point out that the descriptive statistics show a prevalence of total cholesterol in the drivers of 41.7%, which was higher than the general population. Likewise, the prevalences of the body mass index (86.1%) and triglycerides (66.9%) in the participants were also high, although the prevalences of other biomarkers such as blood pressure were not so high.

With respect to the psychometric behavior of the scale, the internal consistency indices showed that the 10-item version obtained a  $\alpha$  = 0.80 (Cl 0.73-0.85) and a  $\omega$  = 0.85; while for the 8-item version a  $\alpha$  = 0.78 (IC 0.70-0.83) and a  $\omega$  = 0.84. These coefficients were satisfactory, including the minimum value within the confidence interval, and without statistically significant differences between them ( $\chi^2$  = 0.27, p = 0.60). On the other hand, the fit indices of the confirmatory factor analyses showed the expected one-dimensional structure satisfactorily, but only

for the 8-item version (CFI = 0.96, B-NNFI = 0.94 and RMSEA  $\leq$  0.04), which confirmed the limited contribution of items 9 and 10 to the psychometric performance of the scale and the greater effectiveness of the 8-item version. In this respect, the comparative  $\chi^2$  between Satorra Bentler indices showed a statistically significant difference (p = 0.003) between both models (version ESCV-8 vs ESCV10), being in principle, more acceptable in the 8-item version ( $\chi^2 = 25.96$ , p = 0.16). In general, the factorial loads were moderate to high (0.42-0.87) in almost all the items in both versions (*Table 3*).

As for the convergent validity of the proposed scale, both versions correlated in similar ways, with some cardiovascular risk indicators, although, the 8-item version (ESCV-8) showed slightly superior correlations. Meaningul statistical correlations (low magnitude, although) were observed with high fat diets, exercise frequency, low density cholesterol (LDL), high density cholesterol

Modelby itemBentler/CFIRMSEASRMRB-NNFIalpha (CI 95%)( $\omega$ )( $\omega$ )( $p$ )ESCV-101 = 0.67 $\chi^2 = 60.10/35$ 0.870.060.070.830.80 (0.73-0.85)0.85items2 = 0.46 $p = 0.005$ $3 = 0.84$ $4 = 0.79$ $5 = 0.46$ $6 = 0.45$ $7 = 0.37$ $8 = 0.42$ $9 = 0.45$ $34.19$ ( $p = 0.003$ )( $p = 0.003$ )( $p = 0.003$ )( $p = 0.003$ )ESCV-81 = 0.67 $\chi^2 = 25.92/20$ 0.960.040.050.940.78 (0.70-0.83)0.84items*2 = 0.46 $p = 0.16$ $3 = 0.87$ $4 = 0.80$ $5 = 0.43$ $6 = 0.43$	Table 3: Confirmatory factor analysis and internal consistency of the ESCV scale (study 1).										
items $2 = 0.46$ $p = 0.005$ 3 = 0.84 4 = 0.79 5 = 0.46 6 = 0.45 7 = 0.37 8 = 0.42 9 = 0.45 10 = 0.38 $(p = 0.003)$	Model			CFI	RMSEA	SRMR	B-NNFI		-	70	Dif. $\alpha$ $\chi^2$
items* $2 = 0.46$ $p = 0.16$ 3 = 0.87 4 = 0.80 5 = 0.43 6 = 0.43		2 = 0.46 3 = 0.84 4 = 0.79 5 = 0.46 6 = 0.45 7 = 0.37 8 = 0.42 9 = 0.45		0.87	0.06	0.07	0.83	0.80 (0.73-0.85)	0.85		0.27 (p = 0.60)
7 = 0.35 8 = 0.39		2 = 0.46 3 = 0.87 4 = 0.80 5 = 0.43 6 = 0.43 7 = 0.35		0.96	0.04	0.05	0.94	0.78 (0.70-0.83)	0.84		

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Table	4: Correl	lations (r	Spearma	an) betwe	en the ES	CV and	the select	ed cardio	ovascular	markers	(study 1).		
	1	2	3	4	5	6	7	8	9	10	11	12	13
1. ESCV-8 items	1.000												
2. ESCV-10 items	0.991**	1.000											
Systolic AP	-0.115	-0.130	1.000										
Diastolic AP	-0.051	-0.058	0.768**	1.000									
BMI	0.002	-0.018	0.272**	0.286**	1.000								
Glucose	0.003	-0.003	0.096	0.068	0.163*	1.000							
Total cholesterol	0.167*	0.157	0.168*	0.195*	0.109	-0.122	1.000						
Triglycerides	0.020	0.015	0.286**	0.268**	0.063	0.042	0.531**	1.000					
HDL	0.179*	0.173*	-0.098	-0.086	0.020	-0.022	0.230**	-0.356**	1.000				
LDL	0.213**	0.207*	0.040	0.083	0.131	-0.117	0.847**	0.178*	0.343**	1.000			
Exercise	-0.289**	-0.285**	-0.024	-0.092	-0.150	-0.028	0.070	0.011	-0.039	0.015	1.000		
Smoke	0.048	0.039	0.112	0.151	-0.017	0.032	0.062	0.186*	-0.080	-0.004	-0.172*	1.000	
Fatty diet	0.293**	0.305**	0.034	0.149	0.022	-0.046	0.176*	0.116	0.048	0.201*	-0.228**	0.076	1.000

\* p < 0.05

\*\* p < 0.01

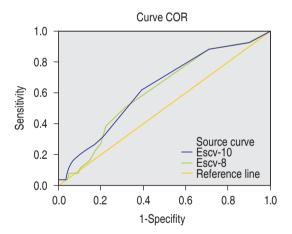


Figure 1: ROC curves of sensitivity and specificity of ESCV-8 and ESCV-10 (study 1).

(HDL) and total cholesterol, the last one only in the 8-item version. Even that a higher number of correlations were expected, the ones obtained were in the expected directions, with the only exception of the HDL correlation, which was positively correlated with other lipids (*Table 4*).

LDL cholesterol was chosen as a possible standard to estimate the sensitivity and specificity of the scale since it was the cardiovascular risk indicator with the highest correlation and the most objective of the criteria with which it correlated the proposed scale. For the ESCV-10 version, there was an area under the curve (AUC) = 0.61 not significant (95% CI = 0.49-0.72), and for the ESCV-8 the ROC curve obtained indicated AUC = 0.63 which was statistically significant (95% CI = 0.51-0.74), which represented greater accuracy compared to the 10-item version (*Table 1*). The Youden index was calculated to obtain the optimal cut-off point in each scale,<sup>35</sup> being 1.45 for the ESCV-10 (sensitivity = 0.50 and specificity = 0.69) and of 1.43 for the ESCV-8 (sensitivity = 0.61 and specificity = 0.61), both very close to the obtained means (*Figure 1*).

For a better reflection of the present work, the discussion and conclusion of both studies (1 and 2) were carried out jointly at the end, so that the study is described below 2.

### Study 2. Validity of the scale in healthy public sector workers and cardiologists

#### Participants

Being an investigation of instrumental validity, a comparative measure was considered between «cases» and «no cases» for this second study. A

total of 119 people participated, of which n =57 were patients with ischemic heart disease hospitalized for public sector workers located in Mexico City, who were designated as «cases» when clinically diagnosed by a cardiologist of the hospital. Additionally, and using the population origin of «public sector workers» as criteria, the «matching» strategy was used, locating apparently healthy people with similar sociodemographic characteristics to confirm the «no cases» group (n = 69). All the participants signed informed consent and the same research regulations with human beings followed in study 1 were respected. Cramer's V analyzes by sex, age, marital status and schooling showed no statistically significant differences between these two groups (Table 5).

#### Instrument

The same scale of cardiovascular symptoms was used in its version of 8 (ESCV-8) and 10 items (ESCV-10) (*Table 1*).

Table 5: Sociodemographic profile of participants in study 2.								
	С	ase	No	case	Te	otal	V.C	
	n	%	n	%	n	%	V Cramer (p)	
Age (years)								
Up to 45	11	19.3	18	26.1	29	23.4		
46-54	20	35.1	35	50.7	55	43.7	0.24 (ns)	
55-64	23	40.4	13	18.8	36	28.6	0.21 (115)	
More than 65	3	5.3	3	4.3	6	4.8		
Sexes								
Male	46	36.5	46	36.5	92	73.0	0.15 (ns)	
Female	11	8.7	23	18.3	34	27.0		
Civil status								
Single	4	3.2	10	7.9	14	11.1		
Married	44	34.9	50	39.7	94	74.6		
Free union	4	3.2	4	3.2	8	6.3	0.16 (ns)	
Divorced	2	1.6	4	3.2	6	4.8		
Widowed	3	2.4	1	0.8	4	3.2		
Scholarship								
Primary	7	12.3	7	11.3	14	11.8		
Secundary	13	22.8	13	4.8	16	13.4		
High School	14	24.6	16	25.8	30	25.2	0.28 (ns)	
Graduate	20	35.1	29	46.8	49	41.2		
Postgraduate	3	5.3	7	11.3	10	8.4		

#### Procedure

In order to fulfill the sample requirement necessary for the psychometric analysis (n =10 x item), both groups (n = 119) responded to the proposed scale of cardiovascular symptoms and proceeded with the same previous analyzes of study 1: descriptive statistics were calculated and of dispersion, the internal consistency of the scale was estimated by means of the Cronbach alpha coefficient ( $\alpha$ ) and omega ( $\omega$ ), confirmatory factorial analyzes (CFA) were carried out to verify the structural unidimensionality, then point biserial correlations were estimated as measures of size of effect and differences through t-tests to verify the expected discrimination (criterion validity) between heart disease and healthy participants, and finally, the sensitivity and specificity of the scale was estimated using ROC curves, locating the cut-off point using the Youden index.

#### **RESULTS (STUDY 2)**

The confirmatory factorial analyzes that sought to prove the same one-dimensional structure of the scale, showed acceptable fit indices for the 8-item version (CFI = 0.93, B-NNFI = 0.90, RMSEA = 0.09) and less acceptable for the version of 10 items (CFI = 0.92, B-NNFI = 0.89, RMSEA = 0.09). Likewise, although the Satorra Bentler fit indexes were inadequate in both versions (p < 0.05), it has been observed that this can be due to large sample sizes or strong correlations between the indicators, so as corrected additional fit index<sup>33</sup> a lower value than three in the ratio between the coefficient  $\chi^2$  and the degrees of freedom (gl) has been suggested, a criterion that was fulfilled in the two versions. Notwithstanding the foregoing, the  $\chi^2$  test of differences between both models was statistically significant (p = 0.01), thus showing a relative improvement in the 8-item version. In both versions, the factorial loads were moderate to high (0.46-0.88) in all the items. In the internal consistency we found a  $\alpha$  = 0.87 and  $\omega$  = 0.90 for the 10-item version, and for the 8-item version it was 0.84 and 0.88 respectively, without statistically significant differences in the  $\alpha$  of the 2 versions (p = 0.31), which together can confirm a

	Table	6: Confirmatory	y factor	analysis ar	nd interna	al consisten	cy of the ESCV sca	ale (study 2	2).	
Model	Factor loading by item	χ² Satorra Bentler/	CFI	RMSEA	SRMR	B-NNFI	α = Cronbach's alpha (CI 95%)	Omega (w)	Dif. χ <sup>2</sup> (p)	Dif. $\alpha$ $\chi^2$
ESCV-10 items <sup>‡</sup>	1 = 0.75 2 = 0.50 3 = 0.85 4 = 0.56 5 = 0.79 6 = 0.48 7 = 0.52 8 = 0.49 9 = 0.69 10 = 0.68 e6-e7 (0.38)	$\chi^2 = 69.12/34$ p = 0.0003	0.92	0.09	0.07	0.89	0.87 (0.82-0.90)	0.90	30.14 8 (p = 0.01)	1.01 (p = 0.31)
ESCV-8 items <sup>*,‡</sup>	1 = 0.76 2 = 0.52 3 = 0.88 4 = 0.54 5 = 0.75 6 = 0.49 7 = 0.52 8 = 0.46 e6-e7 (0.38)	$\chi^2 = 38.98/19$ p = 0.004	0.93	0.09	0.08	0.90	0.84 (0.70-0.83)	0.88		

<sup>‡</sup> Covariances were released between the errors of items 6 & 7 by modification indexes.

\* Without items 9 & 10.

high internal consistency or reliability in both versions (Table 6).

The t-test of differences between cases and non-cases showed statistically significant differences in both versions of the total scale (ESCV10 and ESCV8) in practically all items (except item 2), thus demonstrating greater symptomatology in people diagnosed with heart disease in comparison to healthy ones, which confirms the scale's ability to discriminate them. On the other hand, the point biserial correlations were of moderate to high magnitude, thus confirming the criterion validity of the scale, even with a stronger and clearer tendency than in study 1 (*Table 7*).

Finally, the ROC curve analyzes in this second study showed, for the ESCV-10 version, an area under the curve (AUC) = 0.81 statistically significant (Cl 95% = 0.73 - 0.88, p = 0.0001), a sensitivity of 84% and specificity

of 70%, with the cut-off point of 1.80 (Youden index = 0.50). For the ESCV-8 version, the ROC curve obtained indicated an AUC = 0.80 which was also statistically significant (95% CI = 0.72-0.88), a sensitivity of 80% and specificity of 70% with a cut-off point of 1.80 (Youden index = 0.50), similar to that obtained in the 10-item version (*Figure 2*).

#### DISCUSSION

The main purpose of this study was to analyze the validity of a proposed scale to measure cardiovascular symptoms in two ways: by analyzing its factorial structure and internal consistency, on the one hand, and on the other, its convergence with external criteria of cardiovascular health, allowing in turn to explore its sensitivity and specificity in two different studies. The first study involved apparently healthy people who were unaware of their cardiovascular health, and as validity criteria, different biomarkers were used as cardiovascular risk factors, and in the second study, as a comparative validation strategy, healthy and patients with heart disease were evaluated.

The initial exploration of the first study showed two psychometrically vulnerable items (9.- «He has felt sudden weakness or that he is going to faint» and 10.-«He has felt pain in the chest before an effort that has caused him to stop»), so it was decided to try an 8-item version (ESCV-8), in addition to the original version of 10 items (ESCV-10), in which the same validity scans were performed.

With regard to the reliability of the scale, the calculations of omega ( $\omega$ ) and alpha Cronbach ( $\alpha$ ) showed a fairly satisfactory internal consistency of the two versions, in both studies. The value  $\omega$  reached a value of 0.90 which is considered «high» and on the other hand, the minimum value in the confidence intervals of  $\alpha$  was always greater than 0.70, that is, that even the lowest value estimate possible in the population parameter (with 95% certainty) achieves the minimum recommended to consider this coefficient as

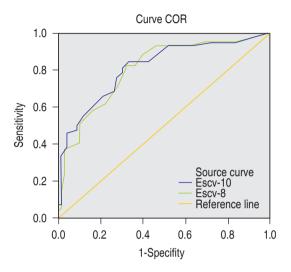


Figure 2: ROC curves of sensitivity and specificity of ESCV-8 and ESCV-10 (study 2).

	Cases $(n = 57)$		No case	s (n = 69)			
Items	Mean	σ	Mean	σ	T de Student (p)	Point biserial correlation (r)	
<ol> <li>Have you felt the sensation of shortness of breath when making an effort like climbing stairs?</li> </ol>	3.0702	1.06670	1.8261	0.98454	-6.79 (p = 0.0001)	0.52 (p = 0.0001)	
2. Swelling, either in the legs, feet, ankles or knees	2.0328	1.16462	1.7391	1.00955	-1.49 (p = 0.13)	0.13 (p = 0.13)	
3. Rapid palpitations	2.9002	0.91523	1.8261	0.89042	-6.65 (p = 0.0001)	0.51 (p = 0.0001)	
4. Feeling that «your heart is jumping»	1.8596	1.14078	1.2464	0.60405	-3.65 (p = 0.0001)	0.32 (p = 0.0001)	
5. Chest pain	2.7018	1.08504	1.3043	0.62554	-8.61 (p = 0.0001)	0.63 (p = 0.001)	
6. Headaches	2.4386	1.22500	1.9130	0.99616	-2.60 (p = 0.010)	0.23 (p = 0.009)	
7. Ringing in the ears	2.1930	1.20176	1.6522	0.85451	-2.85 (p = 0.005)	0.25 (p = 0.004)	
8. Have you seen bright spots or lights?	2.2982	1.14899	1.6806	0.86570	-3.34 (p = 0.001)	0.29 (p = 0.009)	
9. Have you felt sudden weakness or will you faint?	2.1723	1.07189	1.5362	0.81493	-3.68 (p = 0.0001)	0.32 (p = 0.0001)	
10. Have you felt pain in your chest before an effort that has caused you to stop?	2.3684	1.17461	1.3478	0.76362	-5.64 (p=.0001)	0.46 (p = 0.0001)	
Total version ESCV-8	2.4368	0.68403	1.6485	0.60233	-6.79 (p = 0.0001)	0.53 (p = 0.0001)	
Total version ESCV-10	2.4072	0.71150	1.6132	0.55122	-6.79 (p = 0.0001)	0.53 (p = 0.0001)	

#### Table 7: Differences between items of the ESCV scale between cardiac and healthy participants (study 2).

acceptable.<sup>28,31</sup> With the above, it can be concluded that the scores of the proposed scale have satisfactory internal consistency, reliability or accuracy in both versions.

Regarding factorial validity, confirmatory analyzes generally confirmed a one-dimensional structure of the scale in both versions, although the adjustment indices obtained and comparison of Satorra Bentler adjustment between models, showed that the 8-item version had better psychometric performance in the two studies. In particular, the 8-item version in study 1 (apparently healthy people) had the highest adjustment indices, which fall within the most demanding criteria<sup>36</sup> (e.g. CFI = 0.96, RMSEA = 0.04). On the other hand, study two showed a marginal to acceptable compliance in the adjustment indices despite the release of the covariance restriction between the errors of items 6 and 7, in particular the RMSEA (0.09), which refers to the amount of variance not explained by the model by degree of freedom. One possible explanation for this is the heterogeneity of the participants (with heart disease and healthy) who had to mix for reasons of maintaining statistical power in the factor analyzes. Notwithstanding the above, considering both studies, the indices were acceptable in general (in particular the ESCV-8 version) and although the factorial loads were heterogeneous, they were always higher than 0.40 in all the analyzes, which shows a good representation of the construction of all the indicators and their evident structural validity.

Regarding criterion validity or convergent, study 1 showed that ESCV-8 had significant correlations with 5 of the 11 cardiovascular risk indicators evaluated in the participants and the ESCV-10 with 4 of 11, however, the correlations were of low magnitudes. The area under the curve (AUC) was only 0.61 for the ESCV-10 and did not reach statistical significance, and although in the ESCV-8 it did reach significance, it was barely 0.63, with a sensitivity of 0.61 and specificity of 0.61, so that using a cut-off point of 1.43 (ESCV-8), approximately 61% of the participants had a «high» score ( $\geq 1.43$ ) when the biomarker (LDL) was abnormal and 61 % had a «low» score (< 1.42) when it was normal. This means that 39% of the participants who had pathological levels in the chosen biomarker

had a low score on the scale, which shows a weak convergent validity when CVD risk factors were used as criterion (particularly LDL), this was just in the case of the «apparently healthy» participants in study 1.

In study 2, a more forceful validity scenario was presented, since the scale in its two versions and each one of the items managed to discriminate in an outstanding way to healthy and unhealthy people with similar sociodemographic characteristics, and the specific biserial correlations showed effects of moderate to high magnitude when cardiovascular disease was used as a criterion, thus confirming the criterion validity of the scale. The area under the curve was above 80% with statistical significance, and the specificity was 70% in both versions, the sensitivity was slightly higher in the 10-item version (84 vs. 80), so using a point of cut of 1.80, more than 80% of patients with heart disease had high scores, while 70% of participants who were healthy had low scores, this means that at most 20% of patients with heart disease (using the ESCV-8 version) obtained low scores, which means a satisfactory sensitivity at the screening level, of the proposed scale.

The vulnerable criterion validity found in study 1 (unlike study 2), recalls the inconsistency in the literature of the accuracy of self-reports to assess the objective medical condition of people, however, this may perhaps be explained in part by the traditional influence of social desirability or willingness to communicate the symptoms in the participants, who were all men in a work context where culturally it is inappropriate to show weakness (public transport drivers). Notwithstanding the foregoing, it could also be valid to interpret that the proposed scale of cardiovascular symptoms allows more discernment of cardiovascular disease in more chronic and/or more advanced stages and not in people with CVD risks factors, since the biomarkers used in this study do not represent a cardiovascular disease by itself but just a «proxy», and also they were taken in a transectional way, without the certainty that their values were maintained over time, and therefore, that high levels of any of them mean a chronic condition (eg: high blood pressure  $\neq$  hypertension). Also,

these results could be expected since some studies have shown low sensitivities (around 33%) in the case of hypertension 9-11 and between 44 and 57% for biomarkers such as hypercholesterolemia,<sup>12,13</sup> while for cardiac arrhythmias and clinically diagnosed angina pectoris have found sensitivities above 80%14 and above all, in the case of more serious diseases such as cerebrovascular accidents or myocardial infarctions.<sup>14,19</sup> This is consistent with the present work in the sense that the scale proposed was able to better discern when the criteria were participants diagnosed with the specific disease of coronary heart disease by a certified cardiologist (and the respective clinical trial cabinet) (study 2), that when only some blood markers of the apparently healthy participants were considered, which they could be very non-specific (unstable levels) and at the same time very general (cardi o-metabolic in general) (study 1), which also confirms what was said by Mackay et al<sup>20</sup> and Cacioppo et al<sup>21</sup> on the accuracy of the self-report as a better indicator of overall cardiovascular health of a person (arousal level) and at the same time, it is a specific indicator (cardiovascular and not any metabolic alteration).

It is worth discussing that the apparent dysfunction of items 9 and 10 that led to the formulation of an 8-item version with better psychometric performance may be due to an error detected in its design, as they are the only ones that include two or more simultaneous affirmations in its content: 9.-weakness-faint-, and 10.-pain-effort-stop-. Given the above, it is suggested to rethink it in future studies and to assess its elimination, since its indicators of internal consistency and validity in general, show the possibility of improvement.

#### CONCLUSIONS

Finally, it can be concluded that, in general, the proposed scale presents satisfactory construct and convergent validity as a screening measure, although we consider that further future studies are necessary. In the meantime, in particular the ESCV-8 version could be used for screening or cardiovascular health screening in general populations with the reserves of the case, considering the advantages already mentioned (costs, speed, resources, etc.), and with cut-off points. that could place people in the following categories: «without risk» up to 1.43; «possible risk» of 1.44 to 1.79 and «high risk» of 1.80 and up.

#### Limitations

One of the main limitations of this work is related to the heterogeneity and size of the sample, particularly in study 2, although the evidence of validity obtained in these two studies, both criterion and construct, does not seem to be affected by this vulnerability. Study 1 showed the lack of incorporation of measures of social desirability as methodological control, which would give greater certainty of the contribution of this to the explained variance and the psychometric performance of the scale in general, which should ensure future studies. In the study 2 the possible impact of recall bias was not evaluated in cardiac patients, so this should be studied in the near future Likewise, the intrinsic limitation of the transectional design made it impossible to detect the discriminative capacity of the scale towards future cardiovascular health outcomes, so that follow-up studies are recommended to consolidate a predictive validity of the proposed scale.

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# **Total obstruction of percutaneous vascular accesses in acute coronary syndrome.** Case report

Obstrucción total de los accesos vasculares percutáneos en el síndrome coronario agudo. Reporte de caso

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#### **Keywords:**

Peripheral arterial disease, multisite artery disease, acute coronary syndrome.

#### Palabras clave:

Enfermedad arterial periférica, enfermedad arterial de múltiples sitios, síndrome isquémico coronario agudo

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Received: 26/03/2019 Accepted: 30/07/2019 ABSTRACT

Multisite artery disease (MSAD) is common in patients with atherosclerosis involvement in one vascular bed, including the coronary arteries. The clinical presentation depends on the site and the severity of affected vascular territory as well as the time of disease developed. The therapeutic approach includes addressing the specific symptoms of any affected location and evaluates the risk associated with a specific lesion, in addition to manages the implementation in order to control cardiovascular (CV) risk factors. We present an unusual case of a patient with unstable angina and total obstruction of the vascular accesses (radial and femoral) that precluded the percutaneous coronary revascularization. Subsequently, through non-invasive CV imaging, the possibility of coronary artery bypass grafting (CABG) surgery was ruled out as there were no revascularizable coronary anatomy due to severe and diffuse atherosclerotic disease in coronary arteries.

#### RESUMEN

La enfermedad arterial de múltiples sitios es común en pacientes con afección ateroesclerótica en un lecho vascular, incluyendo las arterias coronarias. La presentación clínica depende del sitio y gravedad del territorio vascular afectado, así como del tiempo de desarrollo de la enfermedad. El abordaje terapéutico se centra en considerar los síntomas específicos de cualquier localización afectada v evaluar el riesgo asociado con la lesión específica, así como implementar el manejo para el control de los factores de riesgo cardiovascular (CV). Presentamos un caso poco habitual sobre un paciente con angina inestable y obstrucción total de los accesos vasculares (radial y femoral) que imposibilitó la revascularización coronaria percutánea. Posteriormente, a través de estudios de imagen cardiovascular no invasivos, se descartó la posibilidad de una cirugía de revascularización coronaria al no contar con anatomía coronaria revascularizable secundario a la enfermedad ateroesclerótica severa y difusa de las arterias coronarias.

#### **INTRODUCTION**

MSAD is defined by the simultaneous presence of clinically relevant atherosclerotic lesions in at least two main vascular territories. This condition is common in patients with atherosclerosis involvement in one vascular bed with association ranging from 10 to 15% in patients with coronary artery disease (CAD) and up to 60 to 70% in patients with arterial disease of the lower extremities.<sup>1</sup> MSAD shares risk factors with other CV diseases. Smoking is the strongest risk factor, followed by previous history of smoking and type 2 diabetes, conferring this last factor five times greater risk for limb amputation and three times greater for mortality.<sup>2</sup> The increase risk of CV morbimortality is well established in patients with peripheral artery disease (PAD). An anklebrachial index (ABI) of  $\leq$  0.90 is commonly used in clinical practice to diagnose PAD<sup>3</sup> and is associated with approximately twice the 10year total mortality, CV mortality, and major coronary event rate compared with the overall rate in each Framingham risk score category.<sup>4</sup> Best medical therapy focuses on controlling CVS risk factors with pharmacological measures as antihypertensives, antiplatelets, and lipid-

#### **CASE REPORT**

A 67-year-old male with a history of chronic smoking, type 2 diabetes (T2D), and supracondylar amputation of the right pelvic limb (due to complications of diabetic foot in 2015). He was admitted to the emergency

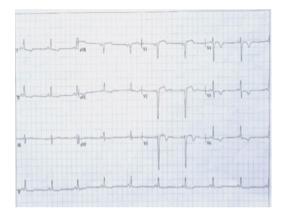
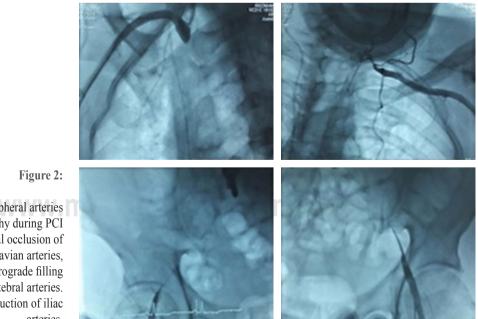


Figure 1: 12-lead electrocardiogram: sinus bradycardia with septal necrosis and antero-lateral subepicardial ischemia.

department due to a progressive pattern of angina pectoris that began three weeks before admission. The initial electrocardiogram (ECG) confirmed anterolateral subepicardial ischemia (Figure 1). Furthermore, the transthoracic echocardiography showed anterior and anteroseptal hypokinesia, with left ventricular ejection fraction of 44%. The cardiac biomarkers were normal, categorizing it as unstable angina with GRACE 102 points. Continuous monitoring and anti ischemic drugs with dual antiplatelet therapy, anticoagulation and high dose statin were started based on the international guidelines of non-ST-elevation acute coronary syndrome (NSTE-ACS).6,7 However, the angina symptoms were recurrent despite the pharmacological treatment. Therefore, he was transferred to the cardiac catheterization room. During the intervention, it was necessary to perform a puncture of both radial and femoral arteries, finding total obstruction at the level of both subclavian and proximal common femoral arteries by angiography (Figure 2), precluding percutaneous coronary revascularization. He was transferred to the coronary care unit to optimize anti-ischemic drugs and stabilize the angina events. Subsequently, non-invasive cardiovascular imaging were performed. The coronary computed tomography angiography



Peripheral arteries angiography during PCI attempt: total occlusion of both subclavian arteries, with anterograde filling through vertebral arteries. Total obstruction of iliac arteries.



Figure 3: Coronary angiotomography: diffuse disease whit significant stenosis of left anterior descending (LAD) artery and left circumflex artery. LAD artery with maximum diameter of 1.3 mm in its mid segment with poor distal filling.

(CTA) identified diffuse coronary artery disease without distal targets and the anatomy not amenable for CABG (Figure 3). The CTA of the aorta and other large blood vessels anatomically identified the sites of total peripheral arterial obstruction (Figures 4 and 5). Finally, he was a candidate for medical treatment with dual antiplatelet therapy, beta-blocker, nitrate, angiotensin-converting enzyme inhibitor, and high dose statin in addition to cardiac rehabilitation for control of risk factors and changes in lifestyle. In the last cardiological consultation one year after the event, the patient continued smoking eight cigarettes a day and denied cardiological symptoms in his daily activities.

#### DISCUSSION AND LITERATURE REVIEW

In general, the risk of MSAD increases considerably with age, it is estimated a prevalence of 2% at the age group of 40 to 50 years and 32.5% at the age group of 91 to 100 years.<sup>8</sup> Combining the CVS risk factors exposure, being an active smoker increases the risk (odds ratio) of 2.72 times more, 1.88 for type 2 diabetes, 1.55 for systemic arterial hypertension, and 1.19 for hypercholesterolemia.<sup>9</sup> These patients with MSAD who suffer NSTE-ACS have an increased risk for CVS mortality during their hospitalization, as well as medium and long term compared to those with isolated CAD. Similarly, the risk of CV mortality increases if more arterial territories are affected.<sup>10-12</sup> The therapeutic approach should be decided on a case-by-case basis with a multidisciplinary team and giving preference to the symptomatic vascular site. It has not been shown that routinely detection of the disease in additional asymptomatic vascular sites improves its prognosis or changes the therapeutic behavior.<sup>1</sup> The only randomized clinical trial «AMERICA» designed to evaluate the impact on the prognosis of the systematic screening for MSAD in patients with high-risk CAD (three vessel

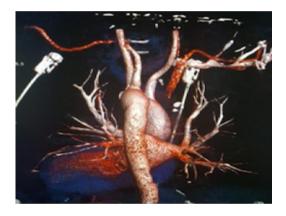
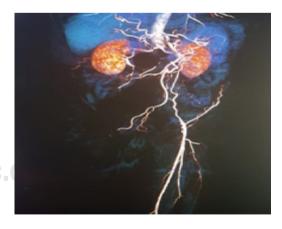


Figure 4: Reconstruction 3D angiotomography: chronic thrombosis of both subclavian arteries.



**Figure 5:** Reconstruction 3D angiotomography: aortoiliac occlusive disease with chronic thrombosis of both iliac arteries and anterograde filling by collateral circulation.

CAD and/or with ACS at age greater than 75 years), does not show any significant benefit in primary composite endpoint including death, any ischemic event leading to rehospitalization or any evidence of organ failure.<sup>13</sup> Within the spectrum of NSTE-ACS, unstable angina is defined as myocardial ischemia at rest or minimal effort in the absence of myocardial necrosis<sup>6</sup> and compared with myocardial infarction, has a lower risk of mortality.<sup>14</sup> NSTE-ACS international guidelines establish the time for conducting diagnostic percutaneous coronary angiography in patients with recurrent angina despite pharmacological treatment and recommends an immediate invasive strategy in less than two hours.<sup>6,7</sup> The radial artery access in percutaneous coronary intervention (PCI) is preferred over femoral artery in patients with PAD. The reason behind this is that femoral access in PAD patients is an independent risk factor for developing major vascular complications, in other words, complications requiring surgical vascular intervention for resolution.<sup>15</sup> The current surgical practice is based largely on an anatomical definition of complete revascularization and aims to derive all epicardial vessels with diameter equal to or greater than 1.5 mm with luminal reduction greater than 50% in at least one angiographic view. The complexity of coronary anatomy and clinical comorbidity was associated with incomplete revascularizations that had a significant increase in mortality.<sup>16</sup> Data on patients with ACS not susceptible to revascularization due to severe and diffuse CAD or without distal bedding are scarce. Available observational studies included mainly patients with stable CAD and refractory angina. Although the prognosis vary due to characteristics of the patient factors such as age, previous CABG or PCI, left ventricular dysfunction, and congestive heart failure, in the largest cohort in the literature consisting of patients with CAD referred specifically for refractory angina who were not amenable to coronary revascularization had significantly higher mortality rate (14.8% vs 6.6%, p =0.004) compared to completely revascularized patients at the three-year follow-up.17 If coronary anatomy is not suitable for revascularization, the goal is to intensify

medical therapy for angina relief and improve quality of life.<sup>18</sup> In addition, individuals who change their behavior (quit smoking and modify diet and exercise) after ACS are at substantially lower risk of repeat cardiovascular events. Persistent smoking and non-adherence to diet and exercise had a 3.8-fold increased risk of myocardial infarction, stroke and death compared with never smokers who modified diet and exercise.<sup>19</sup>

#### CONCLUSIONS

MSAD has a high prevalence worldwide. This condition is strongly associated with morbidity and mortality due to coronary and cerebrovascular disease. Given the devastating consequences of these pathologies, it is of utmost importance to continue spreading information about cardiovascular diseases. The main goal is to educate the population with primary prevention tools, as well being able to recognize early manifestations of arterial diseases and thus reduce the number of patients diagnosed in advanced stages.

**Conflict of interest:** The authors declare to have no conflict of interest.

**Protection of people and animals:** The authors declare that no experiments have been carried out for this research in humans or animals.

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