

Patient Selection for Percutaneous Closure of Patent Foramen Ovale with Transthoracic Color-Doppler Echocardiography Only. A Different Strategy

Percutaneous closure of patent foramen ovale (PFO) has been shown to reduce the rate of stroke recurrence following a cryptogenic stroke (CS). (1) Transesophageal Color-Doppler echocardiography (TEE) is recognized as the gold standard for diagnosing PFO; however, evidence suggests that transthoracic echocardiography (TTE) is a safe, non-invasive and effective method for PFO diagnosis. (2)

Our purpose was to compare the anatomical characteristics and the outcomes of percutaneous PFO closure in a group of patients diagnosed by TEE versus another group diagnosed by TTE.

A retrospective, descriptive, observational study was performed including patients undergoing percutaneous PFO closure following CS. Selected patients with CS had nuclear magnetic resonance imaging consistent with ischemic stroke, 24-hour Holter ruling out atrial fibrillation, normal Doppler ultrasound of neck vessels, lab tests ruling out procoagulant state as the cause of the ischemic event, and PFO with high risk criteria (large PFO, association with atrial septal aneurysm or septal hypermobility).

Two groups were determined, according to how PFO diagnosis was made. Group 1: patients diagnosed by TEE; Group 2: patients diagnosed by TTE who had not received TEE prior to the procedure.

Agitated saline injection test was performed in both groups. Before cannulation of the antecubital vein of the right arm, a 3-way stopcock was placed and 9 ml of saline mixed and shaken with 1 ml of previously aspirated blood was injected.

In the TTE group, the patient was placed in the left lateral decubitus position, and apical four-chamber views were used to observe right atrial filling and assess passage of bubbles into the left atrium. At least 3 injections were performed, at rest and with Valsalva maneuver.

When the diagnosis was made by TEE, mid-esophageal views ranging between 30-60 degrees were used. Patent foramen ovale diagnosis by both methods was defined as the passage of bubbles into the left atrium within 3 to 6 cardiac beats after the right atrium had been filled. (3)

All patients were monitored with TEE during percutaneous closure, under general anesthesia and mechanical ventilation.

Anatomical characteristics of PFO, such as atrial septal aneurysm (saccular deformity of the atrial septum ≥ 10 mm deep), length of the PFO tunnel, and size of the aortic edge and of the atrial septum, were compared between both groups, based on the intra-

procedural TEE. The size of the implanted device was also compared. Implantation success and need for transeptal puncture, when cannulating of the PFO was not possible, were also considered.

Categorical variables were expressed as percentage, and continuous variables as median and interquartile range. Categorical variables were compared using Fisher's exact test, and the Mann-Whitney non-parametric test for continuous variables. SPSS 17 statistical package was used for data analysis.

The study was carried out following the recommendations on clinical research and the Declaration of Helsinki. Informed consent was not requested as a review of clinical histories and echocardiographic records was performed. Privacy and confidentiality of patient data were protected. This study was approved by the Institutional Research Committee.

Between July 2017 and May 2019, 24 patients underwent percutaneous PFO closure. All the patients had CS diagnosis. Median age was 39.5 years (IQR 35.5 - 46.7 years) and 54.2% were women (13/24) (Table 1). In 12 patients, pre-procedure PFO diagnosis was made by TEE (Group 1), and in the remaining 12 patients by TTE (Group 2). The latter had not received TEE before the procedure. All patients had PFO, and 66.7% had an associated atrial septal aneurysm. Septum size was 19 mm (IQR 16-22 mm), tunnel length 7 mm (IQR 4.5-8 mm), and the aortic edge 8 mm (IQR 6-11 mm).

No anatomical differences in the atrial septum were found between the two groups at the time of percutaneous closure (Table 2) and the device was implanted in all patients without complications. Nit-Occlud® PFO (PFM Medical, Colonia, Germany) was the device used in all cases.

Our main finding has been that diagnosing PFO only by TTE with agitated saline test did not hinder the therapeutic approach, since there were no anatomical differences depending on the diagnostic method used at the time of the intervention.

Although TEE with agitated saline solution is the test of choice to diagnose PFO, it is not free from adverse reactions. The frequency of reported complica-

Table 1. Population characteristics.

Age	39.5 years (35.5-46.7 years)
Hypertension	12.5%
Hypercholesterolemia	8.3%
Smoking	4.2%
Large patent foramen ovale (more than 20 bubbles)	75%
Atrial septal aneurysm	66.7%
RoPE Score	8 points (7-9 points)

RoPE: Risk of Paradoxical Embolism

Table 2. Anatomical features of the septum, size of implanted devices, and implantation strategy.

	Group 1 (TEE)	Group 2 (TTE)	P value
ASA (%)	55	75	0.40
Tunnel size (mm)	7	7	0.55
Aortic edge (mm)	8.5	7.5	0.49
Septum size (mm)	19	17	0.55
Device size (mm)	30	30	0.23
Transseptal puncture (%)	0	8	0.99

ASA: Atrial septal aneurysm

tions is about 2.15%. (4) Compared with TEE, sensitivity and specificity of TTE using second harmonic imaging is greater than 90% for the diagnosis of PFO. (2) It may even be more sensitive than TEE in certain circumstances, such as in heavily sedated patients unable to undergo a proper Valsalva maneuver or in patients who cannot tolerate esophageal intubation for a long time. (5)

Its extensive availability and low cost should also be pointed out. In patients with CS, a possible etiological cause is the presence of aortic plaques, which could be very difficult to visualize with TTE, especially when located in the descending thoracic aorta. However, plaques should be searched mainly in patients >50 years of age since their prevalence in younger patients is very low. (6)

When planning the percutaneous closure of atrial septal defects, the use of TEE is recommended to assess the feasibility of such approach. This includes interatrial shunting, the need to determine the size of the defect, the proper edges for implantation, and to rule out associated lesions. (3) However, the anatomical variability is less remarkable in PFO.

The anatomical features compared in our study are those that mainly influence the choice of device size at the time of implantation (e.g., the need to cover the atrial septal aneurysm (ASA), or the size of the device not larger than the size of the septum due to risk of erosion) or the septum approach (through the PFO tunnel or by transseptal puncture in very long tunnels).

Our study had a limited number of patients and was carried out in a single center; however, we believe that this strategy can be employed, since TTE with agitated saline solution is a low-complexity diagnostic test, which is performed in most echocardiography laboratories with positive cost/benefit ratio and no negative influence at the time of percutaneous closure device implantation.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

Ethical approval

Not applicable.

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Rev Argent Cardiol 2020;88:267-268. <http://dx.doi.org/10.7775/rac.v88.i3.16589>

Routine Blood Salvage with Cell Saver During Elective Cardiac Surgery

In cardiac surgery, different approaches have been developed to reduce allogeneic transfusions. Operative recovery of blood with cell saver is one of these approaches, despite its routine use is still questioned. (1-4)

The purpose of this study was to confirm whether the routine use of cell saver during elective cardiac surgery can improve hematocrit and hemoglobin levels at discharge, and also reduce blood product consumption.

An intervention study with a quasi-experimental design was conducted on a series of adult patients who underwent cardiac surgery in a community hospital in 2017 and 2018. Patients undergoing any type of elective cardiac surgery with cardiopulmonary bypass

were included, divided into two consecutive series of 43 and 45 subjects each. In the first series, intraoperative blood salvage with cell saver was used routinely, but it was not used in the following time series (“non-cell saver” group).

The cell-saver group underwent intraoperative cell salvage with autologous transfusion of red blood cells at the end of the procedure, and external transfusion as required. Blood loss from skin incision to skin closure was salvaged with a single-lumen suction tube and washed with heparinized 0.9% saline (10 U/ml infused at 83 ml/h) connected to a closed collection reservoir (Dideco®).

Salvaged blood was washed, and red blood cells were suspended in saline until a hematocrit of about 60% was achieved. The suspension was transferred to a sterile collection bag, and was administered with a standard blood infusion set. Salvaged red blood cells were transfused upon skin closure.

In the control group without cell saver, bleeding from the skin incision to its closure was either aspirated and discarded or salvaged with the heart-lung machine during perfusion.

The defined threshold for homologous red blood cell transfusion was hemoglobin < 8 g/dl or hematocrit < 23%. In patients with excessive blood loss and hemodynamic instability, blood was administered at the discretion of the attending team. Platelets and coagulation products were transfused at discretion and by thromboelastometry (ROTEM®) test support. A comparative analysis based on the use –or not– of cell saver was carried out, evaluating the basal hematometric variables (hematocrit and hemoglobin) before surgery and before hospital discharge, as well as blood product consumption. The protocol was approved by the Institutional Review Board, and all patients consented to the use of cell saver.

A total of 88 patients were included, 43 with cell saver and 45 without cell saver. Mean age was 67.2 (SD: 12.8) years, and 70% were men. Baseline clinical characteristics were similar in both groups (Table 1).

Thirty-day mortality was 4.7% and 4.4% ($p = 1.000$) for cell-saver and non-cell-saver groups, respectively. The rate of reoperation for bleeding was similar in both groups: cell saver 2.3% versus non-cell saver 4.4% ($p = 1.000$). The average volume of salvaged red blood cells with the cell saver was 473 ml (SD: 264). Table 2 compares the data on bank blood product consumption and blood values at discharge for each group.

In this quasi-experimental study, no benefit was found with the use of cell saver to reduce the average volume of red blood cells transfused during elective cardiac surgery in adults, or to reduce platelet consumption. On the contrary, a higher consumption of fresh frozen plasma was found in the group of operated patients using cell saver. This finding supports the theory of some authors who argue that cell saver would generate dilutional coagulopathy secondary to the removal of platelets, plasma, and coagulation factors. (5)

A recently published systematic review (2019) concluded that the use of cell saver would not have an impact on the rates of red blood cell, platelet and fresh frozen plasma transfusion; however, this should be interpreted taking into account the substantial heterogeneity between the results of the included studies ($I^2 = 60\%$). (6)

In conclusion, the use of cell saver as a routine strategy to reduce red blood cell consumption during elective cardiac surgery showed no benefit in optimizing hematometric values at discharge or in the consumption of blood products during hospitalization.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

Ethical approval

Not applicable.

Table 1. Baseline characteristics

Characteristics	Cell-saver group (n: 43)	Non-cell-saver group (n: 45)	<i>p</i>
Age in years, mean (SD)	68.0 (12.4)	65.4 (11.0)	0.301
Male subjects, n (%)	31 (72)	34 (76)	0.712
EuroSCORE II (%), mean (SD)	2.8 (6.4)	2.8 (8.2)	0.978
Hematocrit (%), mean (SD)*	40.8 (4.2)	40.3 (5.3)	0.623
Hemoglobin (g%), mean (SD)*	13.5 (2.0)	13.7 (1.6)	0.649
Coronary surgery, n (%)	22 (51)	25 (56)	0.680
Valve surgery, n (%)	18 (42)	15 (33)	0.267
Other surgeries, n (%)	3 (7)	5 (11)	0.632

SD: Standard deviation. *Correspond to hematocrit and hemoglobin values before surgery.

Table 2. Bank blood product consumption and hematometric values at discharge

Variable	Cell-saver group (n: 43)	Non-cell-saver group (n: 45)	<i>p</i>
Volume of transfused red blood cells in ml, median (IQR)	300 (0-600)	300 (0-300)	0.562
Volume of transfused fresh frozen plasma in ml, mean (SD)	130 (329)	5 (30)	0.022
Transfused platelet units, mean (SD)	1 (1.9)	0.3 (1.5)	0.150
Hematocrit (%), mean (SD)	30.4 (3.1)	31.4 (3.7)	0.168
Hemoglobin (g%), mean (SD)	10.0 (1.1)	10.2 (1.4)	0.368

SD: Standard deviation. *Correspond to hematocrit and hemoglobin values before surgery.

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Rev Argent Cardiol 2020;88:268-270. <http://dx.doi.org/10.7775/rac.v88.i3.15969>

Effect of Antiplatelet Therapy on Suboptimal Reperfusion

In ST-segment elevation acute coronary syndrome (STE-ACS), the main purpose is restoration of blood flow in the responsible artery and microvascular reperfusion as soon as possible, thus limiting the extent of irreversible injury.

Suboptimal reperfusion (SOR) is associated with greater infarct size, increased rate of left ventricular dysfunction, and increased mortality rate. (1) It is defined by partial ST-segment depression (< 50%) after pharmacological or mechanical reperfusion.

The causes of SOR are persistent stenosis or thrombosis, dissection or coronary spasm, distal microembolism, acute stent thrombosis, no-reflow phenomenon, reperfusion injury, endothelial cell edema, and myocyte inflammation. (1-4)

We recently published an analysis (4) in which we observed that SOR incidence in a STE-ACS registry was 8.6%, with significantly increased in-hospital mortality in this subgroup of patients [17.6 vs 1.8%, SOR vs optimal reperfusion (OR), $p = 0.007$].

Furthermore, in the multivariate analysis, we observed that high leuko-glycemic index (LGI) and his-

tory of prior revascularization were significantly associated with SOR. Other authors observed that in a series of 1,005 consecutive patients with STE-ACS undergoing primary angioplasty, the independent predictors of SOR were prior infarction, Killip and Kimball (KK) 3-4, diabetes, TIMI flow <2 pre-angioplasty, and TIMI <3 post-angioplasty.

In turn, Mahmoud et al. (2019) (5) found that the independent predictors of SOR were pre-angioplasty hyperglycemia and increased white blood cells (similar to our findings) associated with technical variables related to the angioplasty procedure, such as thrombus formation and number of balloon inflations.

The present analysis evaluated the antiplatelet therapy received, both on admission and maintenance doses, among patients who presented SOR and OR. A cohort of 197 patients with STE-ACS and angioplasty presented 180 cases with OR, and 17 with SOR.

Table 1 shows patient baseline characteristics. All patients in both groups received some antiplatelet treatment –aspirin in 95% of the SOR group, and in 98% of the OR group. The mean loading dose of aspirin in the SOR group was 280 ± 28.0 mg vs. 325 ± 9.9 mg in the OR group ($p = 0.11$).

Regarding the use of clopidogrel, the mean loading dose was 356 ± 35.6 mg in the SOR group versus 460 ± 11 mg in the OR group ($p = 0.0023$). There is little evidence of a relationship between the type and dose of the antiplatelet regimen used and the incidence of SOR, but based on our findings we believe there is an association with greater incidence of SOR in patients receiving a less potent antiplatelet regimen prior to reperfusion treatment.

Platelet aggregation would play a key role. Roule et al. (6) found that patients who were associated with SOR continued to have residual platelet reactivity after ticagrelor loading doses. We believe that our findings provide an alternative or additional explanation to the classical concept that higher doses of P2 and 12 are associated with a lower rate of myocardial infarction or death, due to a reduction in thrombotic events associated with the antiplatelet effect of thienopyridines.

Our study has the limitation of insufficient data to analyze the effect of new antiplatelet drugs, such as prasugrel or ticagrelor, so further studies will be necessary to test this hypothesis in order to clarify these results and those mentioned and published by other researchers; (2-4) that is, the occurrence of SOR is associated with a significant increase of in-hospital mortality. However, the hypotheses on SOR diagnosis are still controversial.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

Ethical approval

Not applicable.

Table 1. Baseline characteristics of OR vs. SOR patients

	OR	SOR	Odds ratio	p
N = 197	180 (91.37%)	17 (8.62%)		
Age	59.8 ± 11.5	60.6 ± 13.8	-	0.794
Age > 70 years	36 (20.45%)	5 (29.41%)	1.62 (0.53 - 4.89)	0.360
Male sex	137 (76.1%)	12 (70.6%)	1.33 (0.44 - 3.98)	0.567
Diabetes	26 (14.4%)	6 (35.3%)	3.21 (1.09 - 9.43)	0.026
Smoking	76 (42.2%)	4 (23.5%)	2.37; (0.75 - 7.57)	0.196
Hypertension	105 (58.3%)	12 (70.6%)	1.69; (0.57 - 5.00)	0.441
Prior myocardial infarction	14 (7.8%)	4 (23.5%)	3.60; (0.08 - 0.95)	0.056
KK 3/4 on admission	10 (5.75%)	2 (11.8%)	2.26 (0.45 - 11.3)	0.280
Prior revascularization	12 (6.7%)	5 (29.4%)	5.76; (1.74 - 19.07)	0.008

KK: Killip and Kimball.

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Circulatory Support and Extracorporeal Membrane Oxygenation in Transcatheter Aortic Valve Implantation

Severe aortic stenosis (SAS) is the most common valve disease in elderly patients. As many of these patients have several comorbidities and high risk for conventional surgery, transcatheter aortic valve implantation (TAVI) has been developed as an option. (1)

While TAVI is a proven and safe procedure, it presents risks associated with technical aspects, which are difficult or impossible to anticipate (vascular or ventricular trauma), and others that are specific to the patient, some of which can be prevented in order to avoid an unfavorable prognostic impact. (2)

An 82-year-old diabetic patient with SAS, ejection fraction of 15%, and history of aortic valve replacement, was hospitalized for heart failure, requiring inotropic support and mechanical ventilation, with prohibitive risk for conventional surgery (EuroSCORE II 70.5%). The case led to surgical team consensus of using TAVI as therapeutic approach. Due to the preoperative condition and the high chance of hemodynamic intolerance during the procedure, a circulatory support device (extracorporeal membrane oxygenation, ECMO) was used.

Arterial-venous cannulation of the femoral vessels (with 21F venous cannula and 17F arterial cannula (MAQUET AG, Hechingen, Germany) was performed. A Sapien prosthesis (Edwards Sapien XT, Edwards Lifescience, Irvine, Ca) was implanted. As during the procedure, the patient developed extreme bradycardia and deep cardiogenic shock, circulatory support with ECMO (CardioHelp®, MAQUET, Hechingen, Germany) was provided. This allowed the procedure to be completed successfully (Images A and B) and the patient was transferred to ICU under drug and respiratory support.

Once the echocardiography revealed myocardial functional recovery, the device and the drug and respiratory support were successively weaned, a process demanding 96 hours. Several case reports such as the present one, together with two clinical series, pose the usefulness of this strategy in selected patients. Husser et al. reported 18 cases of prophylactic use of ECMO, which represent 8% of total TAVI performed with 97% implant success and 7% mortality at 30 days, while Seco et al. performed 11 ECMO in 100 TAVI patients, with one death (9%). (3, 4)

Stretch et al. reported an increase in the use of mechanical circulatory support in patients over 80 years of age, which rose from 6.2% between 2004 and 2007 to 11.9% between 2008 and 2011. The question is whether the lack of mechanical circulatory support availability could become ethically unacceptable, and even legally controversial, given the increasing growth of TAVI procedures. (5, 6) The indications for prophylactic use of ECMO during TAVI include severe ventricular function impairment, pacemaker intolerance

prior to implantation, and hemodynamic instability prior to or during induction of anesthesia and the concomitant angioplasty of the main coronary artery, to prevent severe complications that could compromise the success of the procedure and patient survival. The feasibility of this strategy has been demonstrated in selected cases. (3-5)

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

Ethical approval

Not applicable.

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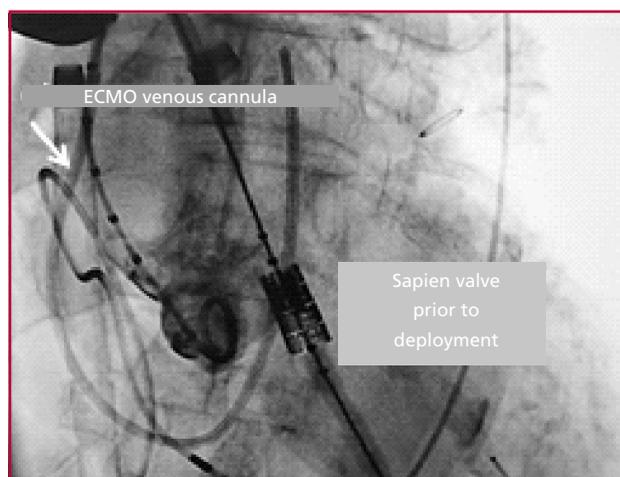


Fig. 1. Image of Sapien prosthesis prior to deployment. The venous cannula can be observed in the inferior vena cava.

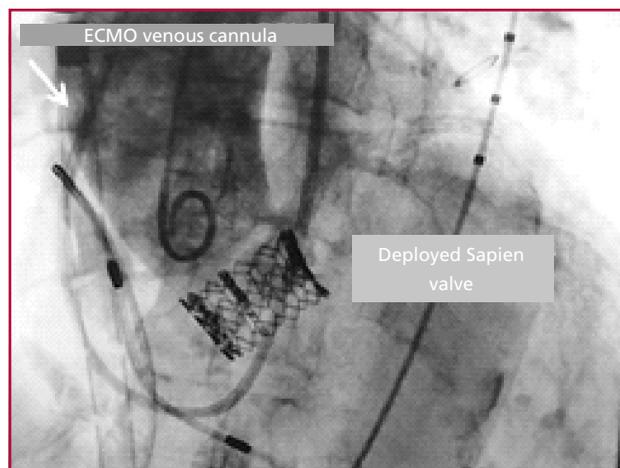


Fig. 2. Deployed Sapien prosthesis in aortic position.

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Virtual Cardiology Outpatient Clinic in a Public Hospital During the COVID-19 Pandemic

The COVID-19 pandemic has generated health measures such as interruption of in-person work activities, social confinement, and suspension of scheduled medical services. (1, 2) "Hospital El Cruce - Néstor Kirchner" is a high-complexity tertiary care center that is part of a public health network in the south of the Greater Buenos Aires Area.

A system of referral and counter-referral of patients operates through the network, so that most patients return to their referring institutions after hospitalization or diagnostic-therapeutic interventions. A lower proportion of patients are followed-up by hospital physicians, due to complex diseases that may require additional procedures or rehospitalizations.

Thus, outpatient clinics receive a reduced number of patients depending on the hospital services provided, with scheduled appointments and full schedules for several months. As of March 20, with the provision of the pandemic lockdown by national authorities, the hospital's outpatient clinic was interrupted. (2)

In the first week of April, we started a telephone follow-up program for patients with scheduled appointments, which was then followed by a system designed for patients who had smartphones or computers suitable for that practice. (3-5) The Department of Telemedicine created a virtual consultation procedure within the current regulatory framework (Resolution 2018-189-APN-SGS#MSYDS / DI-2019-1-APN-DNSIS#MSYDS), adapted to the mandatory,

preventive lockdown (Decree 260/2020; 297/2020) due to COVID-19. (3, 4)

The teleconsultation process consists of a list of patients being followed up by the Service, to be interviewed virtually. This requires: 1) ability to understand the procedure, 2) availability of appropriate technology, 3) agreement with the new form of consultation. First-time consultation and preoperative risk patients were excluded.

Telemedicine advises patients on how to download and operate the application to be used (Cisco Webex). At this point, the informed consent is read, clarifying basic points such as: 1) differences with in-person consultation, 2) environment and conditions to be achieved prior to the consultation, 3) need for an accompanying person (excluding condition), and 4) clarification that emergencies are attended in the traditional way (not by teleconsultation). Before reading the informed consent, patients must show their National Identity Card in camera to certify their identity, and the presence of a witness is also required. This is recorded and included in the patient's medical history, as authorization to participate in the virtual doctor's clinic. (5)

Connection tests through telemedicine are made, and patients are finally informed about the scheduled date and time for the virtual appointment.

Physicians affected to their clinics took over teleconsultations with access to the electronic medical record from the hospital or from their home when, based upon their health history, they were considered at potential risk of complications by COVID-19. Consultations were prospectively recorded with a series of parameters to evaluate the impact of the process and the situation of patients.

Between April 7 and June 2, 2020, we achieved consultations with 230 of the 264 patients scheduled (86.8%). Ninety-two percent were scheduled consultations, 10% were patients followed up by the Department's heart failure program, 4.5% were recent discharges, and 2.3% were patients with angioplasty and drug-eluting stenting in the last six months.

Call responses were tabulated as grateful 226 (98.3%), indifferent 4 (1.4%), and upset 1 (0.4%). Clinical problems in progress were detected in 33 patients (14.3%): 7 with progression of heart failure, 10 with angina pectoris, and 16 with inadequate control of blood pressure. Two of them required hospitalization and interventions. Medication adherence was asked, and 42 patients (18.3%) reported having discontinued one or more prescribed drugs. The reasons were: forgetfulness (n = 2), lack of prescription (n = 26), financial reasons (n = 16), lack of drug delivery from health insurance plan (n = 5), and lack of drug delivery in the primary health care center (n = 6). The sum is over 42 because 13 patients referred more than one reason.

In conclusion, the rapid transformation from in-person to virtual consultation made it possible to

complete 86.8% of scheduled visits. The technical possibility of accessible electronic medical records and the institutional support for medical services through telemedicine facilitated the health care program implementation, which was highly valued by almost all of the patients. Despite the lack of face-to-face contact, this system was able to detect decompensation in 14.3% of cases and medication discontinuation in 18.3%, due to different reasons that reveal a complex reality that may have been hidden under interruption of in-person consultations. Teleconsultation was satisfactory for both patients and health care professionals. (6)

This experience targeted a low-income population with barriers to virtual contact, but in most cases everyday technology was enough to find solutions that adapted to the requirements of the teleconsultations.

Acknowledgements

We wish to thank Dr. Mariano Maydana and Dr. Mauricio Potito.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

Ethical approval

Not applicable.

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