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RESEARCH ARTICLE

Ambulatory Percutaneous Coronary Angioplasty: a safe resource for low-income countries

Licurgo Cruz [1*], Helio M. Grullon-Rodriguez[2], Yanely Lopez-Bencosme[2], Ka Ming Wu[2], Anthony Jose Gutierrez-Martinez[2]

1 Hospit al Metropolitano de Santiago, Juan Pablo Duarte Av km 28, Santiago de los Caballeros, 51000, Santiago de los caballeros, Dominican Republic
2 Escuela de Medicina, Facultad de Ciencias de la Salud, Pontificia Universidad Católica Madre y Maestra, Santiago de los Caballeros, Dominican Republic

* lcruz@homs.com.do

ABSTRACT

Background: Percutaneous coronary intervention (PCI) stands as the most employed coronary revascularization technique today. By the year 2020, more than 965,000 PCI procedures were performed in the United States. However, the growing demand for this procedure poses several challenges. It leads to a substantial occupancy of hospital beds, extended waiting times, increased procedural costs, and a heightened demand for healthcare personnel, all of which contribute to a reduction in the quality of care for patients with medical emergencies. Therefore, this research aims to assess the short-term safety of ambulatory percutaneous coronary intervention in carefully selected patients.

Aims: The primary objective of this study is to determine the short-term safety of implementing ambulatory percutaneous coronary intervention in a middle-income country.

Methods: This retrospective, single-center study was conducted in Santiago, Dominican Republic. The study population consisted of patients who underwent percutaneous coronary angioplasties between January and December 2022. Seventy patients who met the predefined inclusion criteria were included in the final sample. These patients were discharged within 24 hours of the procedure and subsequently contacted at 24-48 hours and 7-14 days post-procedure by the healthcare staff to monitor for any signs or symptoms of complications stemming from the intervention.

Results: The study identified a few complications, with no abnormalities reported in 98.6% of patients. Hematoma emerged as the most observed alteration, and no major adverse cardiac events (MACE) were recorded. From the patient's perspective, individuals expressed satisfaction with the same-day discharge throughout the follow-up period, which extended to 7-14 days post-procedure.

Conclusion: Ambulatory percutaneous coronary angioplasty was found to be a safe procedure, particularly in patients meeting specific low-case complexity criteria.

Keywords: percutaneous coronary intervention, ambulatory procedure, safety, Dominican Republic, ambulatory percutaneous coronary.

Introduction

Percutaneous coronary intervention (PCI) remains the most widely used coronary revascularization technique, with its prevalence steadily increasing. In 2020, over 965,000 PCIs were performed in the US [1]. We use this data as a reference point, considering the absence of statistical reports on this type of intervention in Latin America. This statistic underscores the significant strain on hospital resources, resulting in increased procedure costs and personnel demands, ultimately compromising the quality of care for patients with medical emergencies. Additionally, the surge in hospital admissions has led to extensive waiting lists for PCI, affecting a substantial number of patients.

Improvements in technology have significantly reduced the occurrence of major complications and shortened hospital stays following surgery. This progress now enables same-day hospital discharge following the procedure, known as ambulatory percutaneous coronary intervention (PCIa), particularly for carefully selected patients. This approach not only garners high patient satisfaction but also modestly reduces costs by nearly 50% [2,3].

A single-night hospital stay, under optimal sanitary conditions, carries a 0.5% risk of adverse reactions to medications, a 1.6% risk of infection, and adds to the anxiety of both family members and the patient [4]. In terms of safety, subacute stent occlusion typically occurs between the 2nd and 7th day post-procedure, rendering a hospital stay of fewer than 48 hours insufficient for addressing this concern [2,5]. Several studies, predominantly those employing the transradial approach, have confirmed the safety of PCIa [6,7,8]. The Elective PCI in Outpatient Study (EPOS) reported a 6.1% vascular complication rate at 24 hours for transfemoral PCIa with hemostasis achieved through manual compression [7]. A prospective multicenter study [8] reported a mere 0.19% rate of major cardiovascular adverse events within 24 hours of the procedure with early discharge.

The performance of PCI began to be documented less than two decades ago, and for years, European and American guidelines on myocardial revascularization did not address this topic. In 2005, the first investigations emerged, emphasizing the need for more data before generalizing the strategy [9].

In 2020, the Society for Cardiovascular Angiography and Interventions (SCAI) finally endorsed PCIa, if quality and safety standards in ambulatory surgical centers (ASCs) matched those in hospitals [10,11]. While PCIa may already be occurring in some parts of Latin America and the Caribbean, like Trinidad and Tobago, showing procedural success rates with no major early complications and the potential for in-hospital savings of up to $1480 USD per patient [12], the available information remains limited. The Dominican Republic (DR), for instance, has yet to undertake any studies on this procedure. Given the safety and potential economic benefits, middle-income countries like the Dominican Republic could significantly benefit from implementing this intervention, enhancing patient experiences, reducing costs, and managing health system resources more efficiently.

Although PCIa may be underway in certain parts of Latin America, research validating this practice remains scarce. In the DR, no research on the subject exists. Consequently, our objective is to describe the short-term safety of ambulatory percutaneous coronary intervention in selected patients, evaluate the cost-benefit of PCIa in the DR, and provide insights into potential complications associated with short-term ambulatory angioplasty.

Methods

This prospective single-center study spanned one year, from January 2022 to December 2022. The study population comprised patients who underwent percutaneous coronary angioplasties at Hospital Metropolitano de Santiago (HOMS), Dominican Republic, during this period. A prior evaluation of this intervention found that around 50% of patients undergoing angioplasty meet the criteria for an outpatient protocol. Additionally, 13.8% of those observed experienced some form of complication, none of which were severe or necessitated extended hospital care. The COVID-19 pandemic led to 159 angioplasties at HOMS being performed conservatively. With a margin of error of 5%, a precision of 95% resulted in a sample calculation of 86 patients. Extending the calculation to account for a 10% margin of error, the final

number of patients selected would be 95. However, equipment failures in the center and a national physician's strike limited patient flow in the last months of data collection, resulting in a final sample of seventy patients who met the inclusion criteria: the need for an elective procedure, a Left Ventricle Ejection Fraction greater than or equal to 35%, the angioplasty not being performed in the bifurcation or trunk of the left coronary artery, and recuperation occurring in proximity to the health center where the procedure took place.

Participants were provided with information about the study along with an informed consent form. Only those who agreed to the terms gained access to the questionnaire and received verbal instructions on managing potential complications at home. Data collection occurred at four intervals: immediately before the procedure, during recovery after treatment, 24-48 hours post-procedure, and 7-14 days after the intervention. The first two intervals involved direct interaction with patients in the non-invasive cardiology unit, while follow-ups at 24-48 hours and 7-14 days were conducted by telephone.

Table 1. Inclusion criteria to define low chance for complication.

Patient characteristics
1. Being outpatient
2. Less than 75 years old
3. Left Ventricular Ejection Fraction equal or of more than 35%
4. Patient within a 45-minute travel radius of the hospital
5. No psychiatric condition such as delirium or confusional syndrome
Patient characteristics
1. No evidence of dissection
2. No hemodynamic instability
3. No electrocardiographic changes post-procedure
4. No prolonged angina post-procedure
5. No evidence of thrombosis
6. No presence of multivessel disease
7. Procedure duration of less than 1 hour
8. Optimal angiographic result
9. Lack of decompensation of underlying diseases

The inclusion criteria, as outlined in Table 1, identified patients at low risk of short- or medium-term complications. Procedural success and safety were defined as achieving PCI without major adverse cardiac events (MACE). Major adverse cardiac events before hospital discharge encompassed all-cause death, stroke, and/or myocardial infarction (MI). Procedural complications included the need for immediate hospital admission, major bleeding, coronary perforation, vascular access-site complications, and other complications like dyspnea and chest pain. The need for immediate hospital admission was defined as any cause of readmission within 24 hours following medical discharge. Major bleeding was characterized by any bleeding leading to a drop in hemoglobin levels of 1.24 mmol/L (20 g/L or greater) or more, or bleeding necessitating transfusion or surgical intervention. Coronary perforation was identified by brisk extravasations of blood and dye beyond the artery wall. Vascular access-site complications were defined as access-site bleeding followed by the formation of a hematoma [14].

Results

Table 2. Sociodemographic summary

	Total	Female	Male	P-value
	N=70	N=29	N=41	
Diabetes:	48.6% [36.4%;60.8%]	41.4% [23.5%;61.1%]	53.7% [37.4%;69.3%]	0.441
Hypertension:	90.0% [80.5%;95.9%]	82.8% [64.2%;94.2%]	95.1% [83.5%;99.4%]	0.118
Dyslipidemia:	50.0% [37.8%;62.2%]	55.2% [35.7%;73.6%]	46.3% [30.7%;62.6%]	0.627
Smoker	21.4% [12.5%;32.9%]	20.7% [7.99%;39.7%]	22.0% [10.6%;37.6%]	1
Alcohol consumer	27.1% [17.2%;39.1%]	17.2% [5.85%;35.8%]	34.1% [20.1%;50.6%]	0.196
Family history of heart disease:	30.0% [19.6%;42.1%]	27.6% [12.7%;47.2%]	31.7% [18.1%;48.1%]	0.916
Non-previous PCI:	62.9% [50.5%;74.1%]	62.1% [42.3%;79.3%]	63.4% [46.9%;77.9%]	1
NYHA Classification:				0.005
Class II	1.43% [0.04%;7.70%]	3.45% [0.09%;17.8%]	0.00% [0.00%;8.60%]	
Class III	20.0% [11.4%;31.3%]	3.45% [0.09%;17.8%]	31.7% [18.1%;48.1%]	
Class IV	78.6% [67.1%;87.5%]	93.1% [77.2%;99.2%]	68.3% [51.9%;81.9%]	
Angioplasty Indication:				0.784
NSTEMI	4.29% [0.89%;12.0%]	3.45% [0.09%;17.8%]	4.88% [0.60%;16.5%]	
Stable ischemic disease	14.3% [7.07%;24.7%]	10.3% [2.19%;27.4%]	17.1% [7.15%;32.1%]	
Unstable angina	81.4% [70.3%;89.7%]	86.2% [68.3%;96.1%]	78.0% [62.4%;89.4%]	

Summary descriptive table by groups of "sex", p-value <0.05 is deemed to be statistically significant comparing females and males. NSTEMI: Non-ST-Elevation Myocardial Infarction, NYHA Classification: New York Heart Association

Functional Classification, PCI: Percutaneous coronary intervention.

Table 3. Outcomes measured in safety and satisfaction.

	Total *N=70*	Female *N=29*	Male *N=41*	P-value
Need for immediate hospital admission:	14.3% [7.07%;24.7%]	17.2% [5.85%;35.8%]	12.2% [4.08%;26.2%]	0.731
Asymptomatic post-angioplasty	100% [94.9%;100%]	100% [88.1%;100%]	100% [91.4%;100%]	
Hematoma at arterial punction site:	1.43% [0.04%;7.70%]	3.45% [0.09%;17.8%]	0.00% [0.00%;8.60%]	0.414
Electrocardiogram without changes:	100% [94.9%;100%]	100% [88.1%;100%]	100% [91.4%;100%]	
Chest pain at 24-48 hours:	4.92% [1.03%;13.7%]	5.41% [0.66%;18.2%]	4.17% [0.11%;21.1%]	1
Dyspnea at 24-48 hours:	3.28% [0.40%;11.3%]	2.70% [0.07%;14.2%]	4.17% [0.11%;21.1%]	1
Chest pain at 7-14 days:	3.28% [0.40%;11.3%]	5.41% [0.66%;18.2%]	0.00% [0.00%;14.2%]	0.515
Dyspnea at 7-14 days:	6.56% [1.82%;15.9%]	5.41% [0.66%;18.2%]	8.33% [1.03%;27.0%]	0.643

	Total N=70	Non-previous PCI N=37	Previous PCI N=24	
Patient satisfaction 24-48 hours post-procedure:				0.658*
(2) Dissatisfied	8.20% [2.72%;18.1%]	4.17% [0.11%;21.1%]	10.8% [3.03%;25.4%]	
(3) Neutral	4.92% [1.03%;13.7%]	8.33% [1.03%;27.0%]	2.70% [0.07%;14.2%]	
(4) Satisfied	24.6% [14.5%;37.3%]	25.0% [9.77%;46.7%]	24.3% [11.8%;41.2%]	
(5) Very satisfied	62.3% [49.0%;74.4%]	62.5% [40.6%;81.2%]	62.2% [44.8%;77.5%]	
Patient satisfaction 7-14 days post-procedure:				0.181*
(1) Very dissatisfied	3.28% [0.40%;11.3%]	0.00% [0.00%;14.2%]	5.41% [0.66%;18.2%]	
(2) Dissatisfied	4.92% [1.03%;13.7%]	4.17% [0.11%;21.1%]	5.41% [0.66%;18.2%]	
(3) Neutral	4.92% [1.03%;13.7%]	12.5% [2.66%;32.4%]	0.00% [0.00%;9.49%]	
(4) Satisfied	19.7% [10.6%;31.8%]	16.7% [4.74%;37.4%]	21.6% [9.83%;38.2%]	
(5) Very satisfied	67.2% [54.0%;78.7%]	66.7% [44.7%;84.4%]	67.6% [50.2%;82.0%]	

Summary descriptive table by groups of "sex", only 1 of the immediate admissions had a PCI-associated component described as "transitory and self-limited elevation of ST post-procedure". P-value <0.05 is deemed to be statistically significant compared to females and males. *P-value comparing patients with previous PCI and non-previous PCI.

A predominant characteristic among patients was a history of cardiovascular disease, notably arterial hypertension, affecting 82.8% of women and 95.1% of men (table 2). Concerning the classification of angina pectoris, most patients fell into class IV (93.1% of women and 68.3% of men), with a statistically significant gender difference (p=0.005).

Other noteworthy observations include the fact that 37.9% of women and 36.6% of men had previously undergone angioplasty. In terms of procedural specifics, radial vascular access was the primary choice in many cases (98.6%). Most patients received pre-dilatation, with the anterior descending artery being the vessel of primary focus (50%). The average contrast volume utilized was 186 ± 35.2 ml, while the mean stent length and diameter measured 26.8 ± 13.4 and 2.63 ± 0.39 mm, respectively.

Reasons for admission were categorized into three groups: unstable angina, stable ischemic disease, and ACS without elevated ST. It is noteworthy that many patients with unstable angina were women (86.2%), while most cases of stable ischemic disease occurred in men (17.1%).

Complications were infrequent during arterial puncture examination, with 98.6% of patients reporting no alterations and hematoma being the most observed complication (1.43%). In the post-procedural evaluation, most patients were asymptomatic, experiencing no chest pain or shortness of breath. Some participants did report other symptoms, such as pain at the site of arterial puncture. Regarding medication administration, most patients received a combination of Clopidogrel and aspirin, with only a small fraction receiving ticagrelor. During follow-up, most patients remained asymptomatic 7-14 days after angioplasty, although some reported angina or shortness of breath.

Discussion

Our findings strongly support the safety and feasibility of ambulatory PCI, particularly in low-risk patients within the Dominican Republic's healthcare system. Importantly, the remarkably low minor complication rate of 1.4% with no major complications reaffirms the safety profile of this procedure. This approach holds significant promise in healthcare systems with limited

resources, as it enables more efficient resource utilization by curtailing hospitalization to less than 24 hours. Moreover, this approach yields economic benefits and has the potential to bridge the gap between healthcare system capacity and demands, which is especially valuable in low-income healthcare systems.

Previous research consistently reinforces the safety and advantages of performing PCIa in carefully selected patients, including those with complex coronary lesions [8]. The concept of same-day discharge from the hospital also represents a substantial cost-saving strategy for hospital resources [7,15]. It is crucial to underscore that an overnight hospital stay (lasting ≥ 2 days) not only escalates costs but also escalates the risk of adverse drug reactions in 3.4% of patients and infection in 11.1% [4]. With ambulatory percutaneous coronary intervention, we effectively mitigate this cumulative risk while preserving patient safety.

It is pertinent to acknowledge that prior studies often excluded patients with specific conditions. In contrast, our study employed criteria targeting low-risk conditions, characterized by minimal periprocedural complication risks [16]. It is essential to maintain a standardized approach to patient selection to realize the logistical and resource benefits of PCIa, even in elective PCI. Therefore, any alterations to the inclusion criteria should be preceded by careful evaluation within a similar safety research framework.

From the patient's perspective, our results highlight a consistently positive response throughout the procedure (Figure 1). Ensuring this positive patient experience is pivotal to the procedure's success. Pre-procedure information, personalized follow-up, and vigilant observation in the event of complications are all factors that may contribute to a Hawthorne effect, potentially contrasting the conditions in our study with real-world scenarios. Hence, we advocate for the adoption of a patient-centered healthcare model, particularly in low- and middle-income countries, departing from the traditional paternalistic model. Informed patient consent and comprehension of the procedure are fundamental pillars for the success of this intervention in such settings [17,18].

One aspect that could influence safety is patient adherence to treatment, particularly antiplatelet therapy. It is noteworthy that all patients reported perfect adherence until the last follow-up. To contextualize the external validity of this finding, we attribute this high adherence rate to several factors, including robust social and family support, the relatively advanced age of most patients, and their acute awareness of the severity of their condition—all of which are positively associated with treatment adherence. However, it is advisable to identify patients facing family conflicts, those with lower educational levels, individuals experiencing depression, and diabetic patients with depression for targeted interventions to enhance treatment adherence [19].

It is important to acknowledge that there are areas for improvement in future research. Notably, this was a single-center study, which limits its representativeness. Despite being conducted at a private center, it is worth noting that a significant proportion of these procedures in the country are performed in privately owned centers. The method of patient selection was not randomized but followed a sequential first-come-first-serve approach. Additionally, limited resources constrained the ability to observe patients over an extended period. Moreover, the absence of a control group means that our study cannot conclusively establish the effectiveness of the intervention, with its primary focus being on safety. Lastly, the study was impacted by equipment failures at the center and a national physician's strike, which curtailed patient flow in the latter stages of data collection. On a positive note, the study demonstrated the rapid adaptability of outpatient procedures by healthcare personnel, garnered high patient receptivity, and contributed valuable satisfaction data—a largely underexplored area in prior research.

Conclusion

Ambulatory percutaneous coronary intervention emerges as a viable option to enhance life-saving services within a cost-efficient and safe environment, particularly in low and middle-income countries. Future research endeavors aim to explore the expansion of inclusion criteria and provide a more comprehensive understanding of the economic impact. The collective evidence from our results and their discussion offers ample

rationale for the implementation of PCIa within healthcare systems, highlighting its potential to minimize patient complications and yield clear economic advantages.

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DISCLOSURES

There are no conflicts of interest to report.

IMPACT ON DAILY PRACTICE

Percutaneous coronary intervention is undeniably a widely utilized coronary procedure. However, the burgeoning demand for this intervention presents a set of challenges, encompassing a significant occupation of hospital centers, prolonged waiting times, escalating procedure costs, and a heightened demand for healthcare personnel. Ambulatory percutaneous coronary intervention has emerged as a viable solution to enhance life-saving services within a cost-effective and secure environment, resulting in heightened patient satisfaction levels—especially in low- and middle-income countries. Consequently, it leads to a reduction in hospital occupancy and costs, rendering the procedure more affordable and effectively diminishing waiting lists.

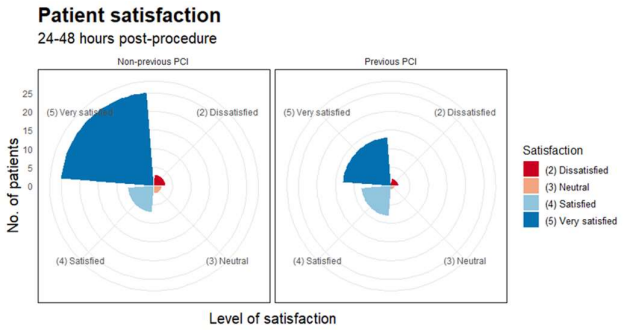

Figure 1. Patient satisfaction after the procedure with and without a previous percutaneous coronary intervention

Figure 1. With maintained proportions of satisfied patients over dissatisfied patients, this graph allows us to estimate the expectations of the patients who previously underwent coronary angioplasty. In both groups, a predominantly positive satisfaction is maintained. Thus, we propose to use the implementation of the ambulatory modality of the procedure as a step, in favor of optimizing care focused on human quality in favor of improving clinical outcomes as well as the user's perspective.

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