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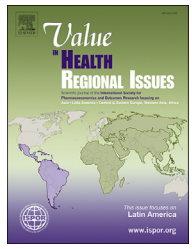

Economic Evaluation

Resource Utilization and Costs Associated With Percutaneous Coronary Intervention When Treating Patients With Acute Coronary Syndrome in the Mexican National Institute of Cardiology "Ignacio Chávez"

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ABSTRACT

Background: The treatment of acute coronary syndrome (ACS) using percutaneous coronary intervention (PCI) is a frequent intervention with a high economic impact. **Objective:** This study investigates the resource use and cost of PCI in Mexico where heart disease is a leading cause of death, and a large segment of the population does not have formal healthcare coverage. **Methods:** This retrospective observational study obtained resource utilization data from patient files and itemized costs from the pharmacy registry at the National Institute of Cardiology. Patients were aged >18 years, diagnosed with ACS, and treated with PCI and secondary prophylaxis with aspirin plus clopidogrel or prasugrel. Patients had a follow-up of >12 months at the institute. Statistical analysis was descriptive. **Results:** The sample included 156 patients (mean age: 58.66 years; male: 77.9%). Patients were diagnosed with ST segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction, and unstable angina 64.9%, 27.2%, and 7.9%, respectively. The mean (standard deviation [SD]) total medical cost was estimated to be $145 677 ($98 326) Mexican pesos 2018. The highest category of spending was surgical materials (mean [SD]: $47 834 [$32 569], comprising 32.8% of total costs); medications and access to the operating room represented 14.2% and 11.8%, respectively. Mean (SD) hospital stay was 9.07 (6.2) days; for the 11.5% of patients admitted to the intensive care unit, the mean (SD) stay was 4.61 (2.06) days. The mean cost of standard hospitalization was $12 572, or 8.6% of spending; intensive care unit hospitalization comprised 17.7% of total costs (mean: $25 802). The cost of the intervention is subsidized up to 95% for patients with a low social economic status, with the exception of surgical materials such as stents. This results in the highest burden component of the intervention being placed on the patient and not the institute. **Conclusion:** The mean cost per patient shows that PCI is an expensive procedure in Mexico. A lack of subsidies for surgical equipment places a high economic burden on the patient and represents a barrier of access for a vulnerable population that likely increases mortality and morbidity rates in those patients unable to pay for treatment and a potential high burden of debt for those who do pay.

Keywords: ACS, costing, hospital, Mexico, PCI.

Introduction

Acute coronary syndrome (ACS) includes ST-segment elevation myocardial infarction (STEMI), non–ST-segment elevation myocardial infarction (NSTEMI) and unstable angina (UA). Management of the condition consists of treating acute STEMI and preventing the progression of UA and NSTEMI into acute STEMI. To achieve this, treatment may include pharmacologic intervention or percutaneous coronary intervention to open coronary arteries and to restore arterial blood flow to the heart tissue.[1-3]

In Mexico, heart disease is one of the leading causes of death—along with diabetes for first and second place cause of death over the past decade.[4,5] In 2014, deaths associated with heart disease reached 121 178, or 19.2% of total deaths in the country, of which 82 129, or 13.0%, were associated with ischemic

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heart disease.[6] In 2008, this number was estimated at 11.1% of total deaths,[5] demonstrating an increasing trend that is likely linked to diabetes rates.[7] With its high impact in patient mortality and morbidity, ACS is an important area of investigation. As such, to facilitate research in Mexico, the National Registry of Acute Ischemic Coronary Syndromes (RENASICA) was established and conducted its first data collection and analysis in 2001.

The RENASICA is a prospective and ongoing registry that includes patients with a diagnosis of ACS from across the country. Its primary objective is to investigate treatment strategies used in Mexico and to create a consensus on best practices. To meet this objective, RENASICA collects data on the types of interventions and pharmaceutical treatment used, their frequency of use, and the resulting efficacy and safety. The RENASICA's analysis has been presented in 3 main publications: RENASICA I (N = 4253) identifies risk factors and disease prognosis,[8] RENASICA II (N = 8098) observes the therapeutic approaches and hospital outcomes,[4] and RENASICA III (N = 8296) further describes current management and clinical outcomes.[9,10] Further subgroup analysis has subsequently been published using the RENASICA database.[11-15]

The RENASICA study provides valuable clinical knowledge for the Mexican medical community; however, the potential impact of its conclusions has not yet been studied in economic impact. Specifically, RENASICA III concludes that there is an urgent need to improve adherence to recommended guidelines, suggesting wide variation in the way patients are treated. Although clinically important, a wide variation in treatment protocols can result in unpredictable public system costs across institutes and hospitals.

Precise cost data are difficult to find in Mexico. Publications frequently use the Delphi panel method as a way of estimating costs; the method is also recommended by the government health technology assessment evaluating committee.[16] Nevertheless, although a panel may represent best practices of the physicians included in the study, in the case of wide variation in treatment practices such as that demonstrated by RENASICA III, it may not fully represent the clinical reality of the public health system. Similarly, the Mexican Institute of Social Security's (IMSS's) diagnosis-related groups (DRGs) are estimated using clinical guideline recommendations, secondary literature, and expert advice. In the IMSS, the cost for percutaneous cardiovascular procedures ranges from $98 134 to $229 761 Mexican pesos (DRG 249 and 248, respectively) and starts at $374 307 Mexican pesos for coronary artery bypass grafting with no complications (DRG 236) (costs adjusted to 2018).[17] Although these suggest that undergone percutaneous coronary intervention (PCI) represents a significant cost to the system, neither of the methods presented are designed to established confidence parameters.

Given the high volume of patients diagnosed with ACS nationally, this study suggests that precise resource and cost information will prove useful in 2 distinct manners. First and foremost, Mexico heavily weighs the cost-effectiveness and budget impact of new innovations during its approval process. Cost estimates based on observed data will aid and increase confidence in future decision making for the public healthcare system. Second, given that a large proportion of the population is not covered by social security and public health insurance, recognizing and quantifying the cost of highly prevalent procedures may assist public sector planning in identifying those patients who cannot access treatment owing to economic constraints, and in increasing access through various existing or new funding systems and financial aid schemes.

This retrospective observational study was designed to investigate the health resource utilization of patients treated for ACS in Mexico, specifically for patients who had undergone PCI. The study takes place at the National Institute of Cardiology "Ignacio Chávez" (NIC) in Mexico City, Mexico. By focusing on the mechanical intervention of PCI, a procedure performed for 31.8% of patients in the RENASICA I study,[8] it hopes to focus on higher cost and more frequent interventions.

Methods

This retrospective observational health utilization study obtained data from patient files and the pharmacy registry at the NIC, a tertiary-level specialized institute hospital funded by the Ministry of Health. The NIC is a national institute that treats patients with no formal employment and therefore no formal social security. Although limited essential medicines and procedures are covered by funding programs, patients are responsible for a large part of their healthcare costs, which are then offset by substantial subsidies if treated within a national institute. As such, the NIC has an itemized pharmacy registry that records all resource use to issue invoices to patients. Resources associated with treatment are categorized into the following groups: medication, laboratory tests, imagining tests, surgical equipment and medical devices, inpatient hospitalization, and hospital overheads (including doctor's fees).

The primary objective of the study was to calculate the average cost per patient in the primary intervention and the cost distribution according to resource category. Secondary analysis included identifying the characteristics of patients with costs that fell above the estimated average.

Patients

Patients with ACS, as defined by STEMI, NSTEMI, and UA, were considered if they had been treated with PCI as a primary intervention and required secondary prophylaxis with aspirin plus clopidogrel or prasugrel. Clopidogrel and prasugrel were considered the standard of care within the hospital. Patients were eligible if they were at least 18 years of age and had a minimum follow-up of 12 months at the institute. The 12-month follow-up was established to capture the frequency and cost of rehospitalizations. Exclusion criteria included patients who were treated with a thienopyridine other than prasugrel and clopidogrel during follow-up.

Patients with interventions conducted between June 2011 and June 2013 were reviewed from the NIC hospital pharmacy database. Patients were randomly selected with a ratio of 50:50 being treated with prasugrel and clopidogrel, respectively.

Study Design

Clinical data were captured from patient files in a case report file that had been validated by the principal investigator against the hospital's patient files. The case report files were then monitored by a third-party reviewer. Variables collected included patient demographics, medical history, procedural characteristics, and resource use.

Once patients were identified, the list of costs associated with the primary intervention and hospital stay was requested from the hospital pharmacy. If subsequent hospitalizations were identified in the clinical file within the 12-month follow-up, the list of costs was solicited for each hospitalization.

Ethics approval was obtained and data capture respected international patient privacy regulations.

Statistical Methods

A descriptive analysis of all main variables was conducted. Mean, median, mode, and standard deviation (SD) were calculated for continuous variables; frequency and proportion were calculated

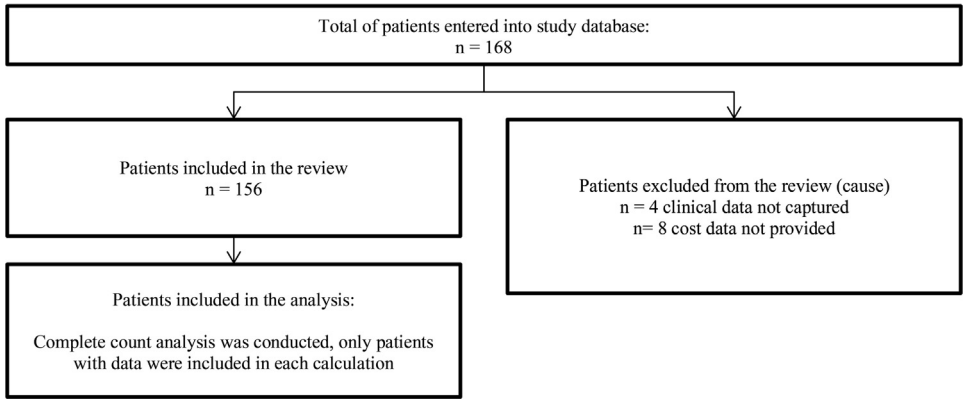

Fig. 1 – Patient flow.

for categorical variables. All measures were assessed using complete case analysis.

The primary outcome of the analysis was mean direct cost per patient of the primary intervention and per cost category; results are presented with the SD and 95% CIs assuming a normal distribution. Costs were categorized by medication, laboratory tests, imagining tests, surgical equipment and medical devices, hospitalization, and hospital overheads. Logistic regressions were used to test the ability of key categorical variables to predict higher than the estimated mean total cost; a significance level of 5% was considered for all analysis.

Analysis was conducted using Excel 2016 (Microsoft Corporation, Redmond, Washington); logistical regressions were conducted using the RealStats add-in.

Results

Study Population

The initial sample size of the study was 168 patients. Four patients were excluded owing to lack of clinical data and 8 owing to lack of cost data, for a final sample of 156 patients with complete data sets (Fig. 1). The demographic and clinical characteristics of the study are summarized in Table 1. For the sample size, the mean age was 58.66 years and 78% were male. The distribution of socioeconomic class was heavily weighted to lower classes (1 and 2 of 9), with 52.6% and 30.8% of patients receiving 95% and 90% subsidies on treatment, respectively.[14]

Table 1 – Descriptive statistics of patient demographics

Variables	Study group
Age in years, mean (SD)	58.66 (10.60)
Male, %	77.9
BMI score, mean (SD)	30.17 (4.36)
TIMI risk score, mean (SD)	3.41 (1.67)
GRACE risk score, mean (SD)	122.58 (32.34)
Systolic blood pressure, mean (SD)	136.58 (6.18)
Comorbidities, %	
Diabetes	42.9
Anemia	5.2
Hypertension stage 1 (140-159/90-99 mmHg)	57.7
Hypertension stage 2 (>160/100 mmHg)	2.6
Prior heart failure	10.5
Prior acute myocardial infarction	17.3
Moderate renal dysfunction, 30-60 mL/min	13.5
Arrhythmia*	3.2

ACS indicates acute coronary syndrome; BMI, body mass index; GRACE, Global Registry of Acute Coronary Events; SD, standard deviation; TIMI, thrombolysis in myocardial infarction.
* Supraventricular tachycardia and ventricular tachycardia.

Clinical Characteristics

The distribution of ACS within the treatment group was 64.9%, 27.2%, and 7.9% for STEMI, NSTEMI, and UA, respectively. A total of 10.5% of patients had prior heart failure, and 17.3% had prior acute myocardial infarction. The mean (SD) body mass index was calculated as 30.17 (4.36). The mean (SD) thrombolysis in myocardial infarction risk score for UA/NSTEMI was reported as 3.41 (1.67), and the mean (SD) Global Registry of Acute Coronary Events risk score was 122.58 (32.34). Comorbidities reported included 5.2% of patients with anemia, 13.5% with poor renal function, 57.7% with stage 1 hypertension (140-159/90-99 mmHg), 2.6% with stage 2 hypertension (>160/100 mmHg), and 42.9% with diabetes mellitus.

Procedural Characteristics

Procedural characteristics of the PCI are summarized in Table 2. Of the sample, 42.3% of patients were admitted in the emergency

Table 2 – Descriptive statistics of procedural characteristics

Variable	%
Emergency department admission	42.3
Thienopyridine loading dose at admission*	88.5
Vessels treated	
1	71.8
2	18.6
Stents used	
0	8.0
1	61.6
2	22.5
≥3	8.0
Drug-eluting stent used	50.4

* Patients who were treated with a thienopyridine other than prasugrel and clopidogrel during follow-up were excluded from the study.

Table 3 – Average total cost and distribution costs of patients treated with PCI (MXN Pesos 2018)

Variables	Mean	95% Inf	95% Sup	Median	SD
Total cost	$145 677	-$47 041.20	$338 395.71	$122 962	$98 326
Surgical material	$47 834	-$16 000.75	$111 668.86	$40 010	$32 569
Surgery time	$17 242	-$5 768.09	$40 252.28	$17 701	$11 740
Medicines	$20 725	-$70 175.95	$111 625.62	$4090	$46 378
Imaging tests	$7738	-$14 562.42	$30 038.10	$5047	$11 378
Laboratory tests	$12 758	-$5757.78	$31 274.38	$11 703	$9447
Hospitalization	$12 572	-$19 741.30	$44 884.45	$8312	$16 486
Intensive care	$25 802	-$21 613.07	$73 216.66	$20 972	$24 191
Other	$1007	-$15 768.69	$17 782.22	$0	$8559

Inf indicates inferior; MXN, Mexican; PCI, percutaneous coronary intervention; SD, standard deviation; Sup, superior.

department, whereas the remaining patients had elective surgery. At admission, 88.5% of patients were treated with a loading dose of either clopidogrel or prasugrel.

The mean (SD) number of vessels treated was 1.21 (0.41), with 71.8% and 18.6% of patients receiving treatment for 1 and 2 vessels, respectively. Of the sample, 61.6% and 22.5% of patients received 1 and 2 stents, respectively; the type of stent used was split evenly (50/50) between drug-eluting and bare-metal stents. A total of 21.8% of patients reported a complication associated with a primary PCI. Results were not powered to show the statistical difference between the types of complications and therefore are not shown; however, because they were treated in the primary hospital admission, all costs were included in the average total cost.

Of the 156 patients in the sample, there were 6 incidences of rehospitalization within 12 months. Of these cases, 4 were associated with ACS; as a result, the cost of rehospitalization was not reported in the analysis.

Resource Utilization and Costs

All costs are presented in Mexican pesos (2018). Mean (SD) medical resource utilization of the primary intervention was $145 677 ($98 326). The highest area of spending was surgical materials with a mean (SD) of $47 834 ($32 569), representing 32.8% of total costs. Cost of medications and access to the surgery room comprised 14.2% and 11.8% of the overall cost, respectively. The mean costs and distribution of costs are presented in Table 3.

The mean (SD) hospital stay was 9.07 (6.2) days, and of the 11.5% of patients who were admitted to intensive care unit, the mean (SD) stay was 4.61 (2.06) days. The mean cost of standard hospitalization represented 8.6% of total spending, whereas intensive care unit hospitalization made up an additional 17.7%.

Logistic regressions were conducted on the variables of age, sex, renal function status, hypertension status, and diagnosis; however, explanatory power for differences in costs were not found to be significant (Table 4).

Discussion

This is the first health resource utilization and cost study completed in Mexico on patients diagnosed with ACS having undergone PCI and can been seen as a step forward in identifying the resources required of the system and the individual costs of treatment for the patient. Ischemic heart disease is a highly prevalent illness in Mexico[5] with a large clinical and budget impact, yet it appears that an examination of its economic impact has yet to be conducted. Specifically, cost-effectiveness analysis is an important part of the access decision-making processes in Mexico; however, data on the real costs are lacking. Current evaluations are reliant on costs estimated using clinical guidelines and at times expert panels; DRGs have also been published and estimate cost per event for best-practice care. Nevertheless, consensus methods are not designed to estimate the variability or the statistical robustness of an outcome, which seems at odds with evidence demonstrating that a wide variety of treatment practices are used across Mexico. This variation seems to be reflected in the results of this study, where the mean direct costs ranged enormously for a primary intervention. Access decisions that do not incorporate this diversity in treatment protocols and costs could therefore be misguided. On a positive side, however, this seems to suggest great potential for improved efficiencies through standardization of care.

Furthermore, although Mexico is generally accomplished at assessing cost-effectiveness and developing clinical guidelines

Table 4 – Exploratory subgroup analysis of key clinical and demographic variables

Variables	Categories	Coefficient	*P* value
Age in years	Age groups: 4-49; 50-59; 60-69; ≥70	-0.006	.749
Sex	M/F	0.863	.074
Diabetes	Yes/No	0.088	.809
Renal function	Normal (>60 mL/min); Moderate (30-60 mL/min)	0.794	.099
Hypertension	Stage 1 (140-159/90-99 mm Hg); Stage 2 (>160/>100 mm Hg)	0.163	.622
Diagnosis	STEMI, NSTEMI, UA	-0.026	.875

M/F indicates male/female; NSTEMI, non-STEMI; STEMI, ST segment elevation myocardial infarction; UA, unstable angina.

based on best practices, for the population without social insurance, it is the personal budget impact and its resulting barrier to access to healthcare that is of most importance. This study estimated valuable information on the categories of costs associated with the overall procedure. The calculated mean cost per patient of $145 677 pesos or $7559 USD (rate of 0.05189; October 2018) show that PCI is a costly procedure in Mexico. As previously mentioned, however, patients are subsidized according to economic capacity, making the procedure attainable for many. Regardless, what frequently goes unmentioned is that at the NIC, the full cost of stents and surgical material may be charged to the patient regardless of their assigned social economic status.[18] This becomes an important consideration for patients and physicians at the NIC because over 30% of resources used for a PCI is allocated to the purchase of surgical equipment and, in particular, stents. In contrast, social security institutions for employee citizens offer healthcare free at the point of access.

In context, the national minimum daily salary in Mexico is $88.36 pesos (general rate; 2018),[19] and most patients treated at the NIC are evaluated as low social economic class; over 80% in this study are from socioeconomic class 1 and 2 of 9. As a result, the patients in this study were responsible for an average of 48 000 pesos each (Table 3). Although cost sharing can be beneficial in producing a downward effect on the overall and potentially unnecessary demand of services,[20,21] the extraordinary economic burden placed on the uninsured users of the national institutes represents a barrier of access.

These considerations open the door to policy questions outside of PCI on the number of patients who make the final decision of whether or not to go ahead with a recommended procedure purely for economic reasons, and for those who do elect to undergo the procedure, the potential of significant debt remains.

The cost data of this study are considered to be of high quality. Specifically, the data collected included an itemized list of resources provided by the NIC. In Mexico, healthcare is included in employment-provided social security. Those who are unemployed or those with no formal employment are able to receive care in federally funded hospitals, such as the NIC, but are required to contribute to treatment costs according to social economic capacity, as established on a scale of 1 to 9, with the lowest classification receiving subsidies of 95%.[18,22] As such, resource use is collected and stored for accounting purposes. It is unlikely that such detailed data would be found outside of an institute hospital. The applicability of the current results to other health institutions in Mexico is not straightforward; however, they may be considered a reasonable or even conservative estimate. Comparisons of international registries suggest that the Mexican population has traits unique to the country. In particular, the patient population with diabetes was found to be higher in RENASICA when compared with almost all international registries, including the Global Registry of Acute Coronary Events, CREATE, and National Registry of Myocardial Infarctions.[11,13] The current study reflects this tendency, with 43% of patients having diabetes versus 42% in RENASICA II. Although the current study is not powered to detect clinical differences, the similarities between RENASICA and the current analysis in patient characteristics suggest that the economic results could be reflective of the RENSICA population.

Furthermore, the NIC is a highly regarded reference hospital, with 207 hospital beds and over 2500 new cases annually.[23] Literature suggest that the optimal number of hospital beds at which institutes are able to push down costs as a result of economies of scale is from 200 to 400.[24,25] As such, although the detail and data on allocation of costs in this study are singular to the NIC, the results of the study show that PCI is likely to be as expensive in any specialty hospital nationwide, and potentially more costly in nonspecialized hospitals.

The aforementioned cost characteristic is further supported when considering the most recent actualization of the IMSS DRGs (2014), which serve as an indication of the institutes' estimated costs.[17] Adjusted to 2018, the DRGs range from $98 134 to $229 761 for a percutaneous cardiovascular procedure with bare-metal stent and no complications (DRG 249) and major complications (DRG 249), respectively. The diagnostic group of each DRG is not a direct comparison with the inclusion criteria included in this study; however, we suggest that this further demonstrates that the calculated average cost of the current analysis is comparable and potentially conservative.

Finally, this study tested basic key variables to begin an initial exploration of variables that would predict higher than average cost, as defined by the estimated mean total cost. No variables were identified; however, this is more likely due to the sample size and further analysis on the topic is merited.

The limitations of the study are related to the small sample size and the inclusion criteria of 12-month follow-up. The scarcity of data due to the small sample limited the ability to compare subgroups and identify high-cost patients. The mandatory follow-up time likely produced a bias toward less complicated cases by excluding those cases where death occurred before 12 months or the patient was lost from the system. This bias is further supported by the low number of patients who were rehospitalized within 12 months, which is not congruent with the literature.[26,27] A further source of bias is the high overall costs identified, which may result in a proportion of the population that is unable to enter the system or to stay in the system due to economic constraints. In discussions with the treating physician, it was commented that a percentage of patients treated at the hospital remain in debt or on a payment scheme, but that to avoid the demands of immediate payment, patients may avoid returning to the hospital where initially treated and seek aid elsewhere. We consider it likely that the lack of statistical difference in costs among STEMI, NSTEMI, and UA is due to these biases.

Finally, the study focuses on patients treated with PCI within the diagnostic of ACS. If the current study is used as a basis, a more detailed analysis of the tendencies and clinical outcomes described will provide valuable information due to the high incidence rate of this disease/procedure. Of more importance, in our opinion, future investigation should look to expand the objective patient population, the study size, and the number and affiliation of public institutes included to calculate more universally applicable results.

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