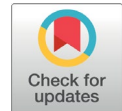




ORIGINAL ARTICLE



Sigle-center, observational, prospective study describing same-day discharge implementation for uncomplicated elective percutaneous coronary intervention by radial approach: Study protocol

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KEYWORDS

Angioplasty
Coronary disease
Costs and cost analysis
Patient discharge

ABSTRACT

Objectives: The primary objective of the study will be to evaluate the safety and describe the initial experience of implementing early discharge (on the same day) of coronary patients from the Unified Health System undergoing elective, uncomplicated, transradial percutaneous coronary intervention. The secondary objective will be to assess the impact on the direct cost per patient compared to previously known data from the classic hospital stay used (hospital overnight).

Methods: Observational and prospective study of patients undergoing elective uncomplicated transradial percutaneous coronary intervention with early discharge, respecting the inclusion and exclusion criteria. Follow-up of patients will be carried out to prove the safety of the new strategy in the population of the Unified Health System and to compare the direct costs between overnight stays and discharge on the same day. This will be the first study dedicated to primarily evaluating the safety of early discharge after elective uncomplicated transradial coronary angioplasty, validating this protocol in the population of the Brazilian public health system.

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This study was conducted at the Faculty of Medicine of Itajubá and Hospital de Clínicas de Itajubá.

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INTRODUCTION

Cardiovascular diseases (CVD) are the leading causes of death worldwide and have been treated as a severe public health problem for decades, leading to mortality rates progressively decrease over time¹. This reduction is mainly due to optimized drug treatment guided by guidelines and myocardial revascularization². Percutaneous coronary angioplasty is currently the primary modality of revascularization, reaching a ratio of 3 angioplasty to 1 coronary artery bypass graft in the last two decades³. In the United States of America, an annual expenditure of 60 billion dollars is estimated to treat these patients⁴. In turn, these same data can be projected to a greater or lesser extent for all other countries in the world, including Brazil. However, the lack of accurate data and the regional heterogeneity of quality and access to treatment for coronary artery disease (CAD) in Brazil makes it difficult to give precise values to this scenario. Therefore, the continuous search for optimizing the health care management of this group of patients is vital to public health systems, positively impacting the cost/benefit ratio and their accessibility to quality treatment.

In this complex and multifactorial equation of health analysis from an economic point of view (Table 1)⁵, the standard, potentially modifiable numerator, and with a direct impact on the economic costs of treatment, is the average length of hospital stay for a given disease or intervention (Figure 1)⁶.

In this context, we still have the hospital stay as the standard practice for the observation of patients after uncomplicated elective coronary angioplasties worldwide⁷. However, aiming at cost reduction and greater availability and turnover of hospital beds, the idea of short-stay protocols emerges, made possible by the increasingly widespread use of the transradial approach (TRA) and its relationship with the reduction of bleeding complications at the puncture site, as well as major adverse cerebral and cardiovascular events (MACCE)^{8,9}.

The early discharge strategy (EDS) is based on the patient's discharge undergoing percutaneous coronary intervention (PCI) on the same day. It can optimize the turnover of hospital beds, improve the cost-effectiveness of the treatment of CAD, and is a reality in

the daily life of other surgical medical specialties. For example, according to the North American report of uncomplicated outpatient elective surgeries, 50% of cholecystectomies, 70% of transurethral prostatectomies, and 90% of hernioplasties are discharged on the same day, compared to only 4.7% in angioplasties with stent implantation¹⁰.

Compared to the hospital stay, named here as the classic strategy (CE), the EDS showed a reduction in costs per patient treated by 50%¹¹⁻¹³. It is also noteworthy that early discharge was shown, in previous studies, to be feasible, safe, with improvement in the quality of health care and patient satisfaction and was not related to a higher risk of cardiovascular events. Therefore, the body of evidence places this strategy at the center of the measures to optimize the cost-effectiveness of percutaneous treatment of CAD^{11,13-17}.

Another clear point for the EDS is the short-term clinical outcomes safety, equivalent to the CS, since the most immediate post-procedural cardiovascular events such as myocardial infarction (MI), acute occlusion of the treated vessel, hemorrhagic complications, and acute stent thrombosis, in addition to being infrequent, usually occur within the first six hours after PCI^{18,19}.

Although this strategy is well documented in randomized studies and meta-analyses, all these studies originate in developed countries with a sample derived from a population with a better socioeconomic and educational level when compared to the Brazilian population, therefore, not yet validated in the population using the Public Health System (SUS)^{11,12,14,16,20-22}. Thus, the rationale for our study lies in describing the initial experience of implementing early discharge in coronary patients from SUS undergoing elective, uncomplicated PCI by TRA, analyzing its safety and direct savings generated when compared to the classic discharge strategy. Another fact that makes this study even more relevant is the possibility of a shorter average length of stay, optimizing the use of hospital beds, with greater accessibility to highly complex public health care. Furthermore, in times of the COVID-19 pandemic, same-day discharge can become a synonym for savings and an essential tool to continue treating patients with CAD without overloading hospital beds²³. Finally, it is noteworthy that this strategy is endorsed in international guidelines^{7,24,25}.

Table 1 – Types of economic analysis in health according to each study's outcome measure and unit of measure.

Type	Effectiveness unit	Cost unit	Final unit
Cost-effectiveness	Years of life saved Complications prevented	Currency (\$)	\$/years of life saved
Cost-utility	Quality-Adjusted Life Years (QALYS)	\$	\$/QALY
Cost-minimization	-	\$	\$
Cost-benefit	Conversion to currency (\$)	\$	\$

Source: Silva EN et al. 2016⁵.

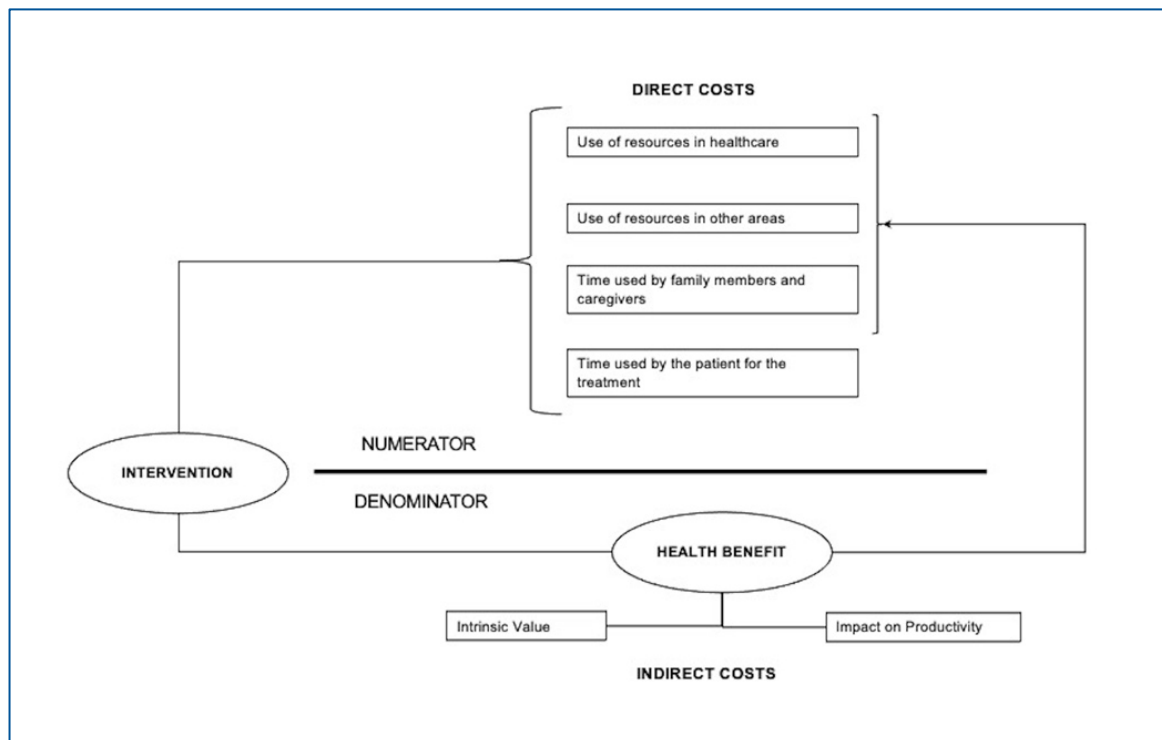


Figure 1 – Costs of a health intervention. Modified from Shepard DS et al., 1996⁶.

Study design

An observational, prospective, and descriptive study of the first 100 patients from SUS who underwent elective PCI not complicated by TRA in a high-complexity hospital. All patients included in the pilot study will undergo telephone follow-up 24 hours and 30 days after the procedure, being questioned about the puncture site, precordial pain, readmissions to other health institutions, and other possible complications. In addition, face-to-face follow-up should be performed 7±2 days after the procedure to assess the presence of radial pulse (Figure 2).

Objectives

- Primary objective: To analyze the safety of implementing the early discharge protocol in patients undergoing elective, uncomplicated, and transradial PCI
- Secondary objective: Comparing direct economics between the early and classic discharges strategies.

METHODS

Study design

Elective patients (of outpatient origin) admitted for elective, uncomplicated, and TRA PCI will be included in the study. The study will be carried out in the interventional cardiology service of the Hospital de Clínicas de Itajubá (HCI), a quaternary hospital, accredited by the Public Health System for highly complex procedures, in addition to serving private patients or those coming from supplementary health insurance, located in the South of the State of Minas Gerais. It is responsible for the direct care of the micro-

region of Alto Sapucaí, with about 300,000 inhabitants, and indirectly receives patients from all over the south of the state.

Definitions used

- Elective PCI: Coronary angioplasty performed in an elective patient or ad-hoc angioplasty (a therapeutic intervention that can be performed simultaneously as the diagnostic procedure) in a low-complexity patient²⁴.
- Minor and major bleeding complications: Based on classification types 0 to 1 and 3 and 5, respectively, by the Bleeding Academic Research Consortium (BARC)²⁶. Type 0: no bleeding; Type 1: Mild bleeding that does not require medical evaluation or induce the patient to seek medical evaluation. Major bleeding complications: Type 3a-c: fall in baseline hemoglobin $\geq 5\text{g/dL}$, bleeding requiring intervention, cardiac tamponade, hemorrhagic shock, central nervous system bleeding; Type 5a-b: fatal bleedings likely or definitely related to the procedure.
- Vascular complications related to the puncture site: include symptomatic arterial occlusion, fistulas, pseudoaneurysms, arterial dissections, and perforations.
- Multivessel coronary artery disease: Obstructive involvement $\geq 70\%$ in two or more major epicardial coronary arteries or $\geq 50\%$ or more in the left main coronary artery (LM).
- Major adverse cardiovascular and cerebrovascular events (MACCE): Include stroke, death, non-fatal acute myocardial infarction, target vessel revascularization, and emergency myocardial revascularization surgery²⁷.
- Repeated target vessel revascularization:

Need for new revascularization of the vessel already treated due to recurrence of symptoms. The responsible obstructive lesion is somewhere in the previously treated vessel and is not necessarily the same previously

treated target lesion²⁷.

- Multivessel PCI: Angioplasty performed on two or more obstructive lesions in the same target vessel or on two or more coronary vessels.

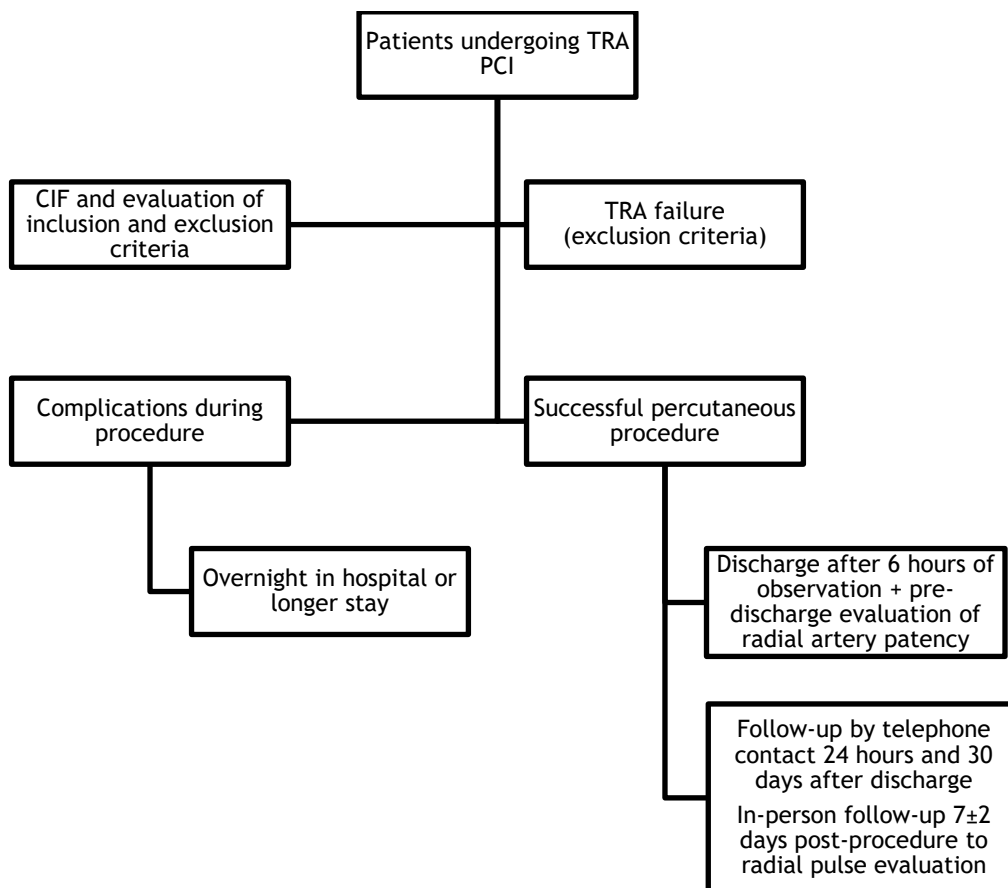


Figure 2 – Study flowchart. TRA - transradial approach; PCI - percutaneous coronary intervention; CIF - consent informed form.

Inclusion and exclusion criteria (Table 2)

The decision for the early or classic discharge strategies is left to the judgment of the multidisciplinary team formed by the clinical and interventional cardiologist, always considering the following criteria:

- Inclusion criteria: Criteria related to the procedure and the patient's clinical condition: elective PCI by uncomplicated TRA. Criteria related to the patient's socioeconomic characteristics: Patients with a good level of understanding of the procedure, post-procedure care (rest), warning signs for bleeding from the puncture site, and adequate family support and who can return to the hospital in case of complications in less than 30 minutes.

- Exclusion criteria: Exclusion criteria related to the procedure or clinical condition of the patient where studies of predictors of mortality associate them with an increase in this²⁴: Acute coronary syndromes, peri- and post-procedure complications: "No or Slow Flow" phenomenon (acute reduction of epicardial coronary flow after artery clearance, in the absence of spasms, thrombi, residual lesions, and arterial dissection)²⁸, suboptimal angiographic result (side branch occlusion,

stent edge dissections visible on angiography), hemodynamic instability or electrocardiographic changes related to acute ischemia, angina lasting post-procedure, renal dysfunction pre-procedure (characterized by a serum creatinine greater than 1.5 mg/dL), ejection fraction ≤ 30% or signs of decompensated heart failure or functional class ≥ III. Exclusion criteria related to the patient's socioeconomic characteristics: difficulty understanding the procedure and post-procedure care, inadequate family support, or housing far from the hospital (more than 30 minutes).

Ethical issues

The study protocol was approved by the Research Ethics Committee (REC) of the Faculty of Medicine of Itajubá with approval number 3.517,324 (CAAE: 15337019.6.0000.5559). It will only be started after applying the informed consent form (ICF) to each participant, following the Principles of the Singapore Declaration on Research Integrity. The publication of results will be done in a way that does not personally identify each participant. All data will remain in possession of the leading investigator until the time of publication.

Table 2 – Inclusion and exclusion criteria.

Inclusion criteria	
Related to the procedure and clinical picture: Elective patients Feasible transradial route Low complexity procedure angiographic success Absence of signs of periprocedural infarction: lasting angina associated with electrocardiographic changes	Related to socioeconomic characteristics: Good level of understanding of the procedure, post-procedure care, and warning signs for bleeding from the puncture site Effective family support Means to return to a hospital in <30 minutes
Exclusion criteria	
Related to the procedure and clinical presentation: Acute coronary syndromes Transradial access failure "no/slow reflow" phenomenon Sub-optimal angiographic result: side branch occlusion, edge dissections, or clinical or electrocardiographic signs of periprocedural myocardial infarction FEVE \leq 30% IC functional class \geq III Serum creatinine >1.5mg/dl	Related to socioeconomic characteristics: Patients with difficulty in understanding the post-procedure care. Patients without effective family support Patient unable to return to a hospital in <30 minutes

LVEF - left ventricular ejection fraction; CHF - heart failure.

Methodology

- Pre-procedure: After clarifying the research and obtaining the informed consent, patients will be submitted to a form in the form of a parallel medical record (Appendix 1). For each patient, socioeconomic, clinical, and peri- and post-procedural variables should be collected through the parallel medical record. Afterward, patients should undergo a pre-procedural physical examination, which consists of the assessment, by pulse oximetry ipsilateral to the procedure, of the patency of the palmar arch using the Barbeau Technique: placing a pulse oximeter on the patient's thumb awaiting the appearance of the plethysmographic wave; then, the radial and ulnar arteries are compressed until the sign disappears; releasing only the ulnar artery, the curve returns, confirming its patency, and its non-reestablishment is interpreted as an insufficient palmar arch, contraindicating the procedure through this route²⁹.
- PCI: This should be performed by an interventional cardiologist specialized in TRA. The research subject will not be submitted to the procedure because of the investigation but on medical advice. The PCI must follow the HCl's protocols.
- Post-procedure: As long as they do not present complications, all participants who undergo early discharge (6h post-procedure) will require the assessment of the radial pulse through palpation before discharge. Patients should be advised to seek medical attention if necessary.
- Post-discharge follow-up: It should be carried out 24 hours and 30 days after the procedure by telephone and in-person contact at 7 \pm 2 days after the procedure, when, through an appointment, the patient will be questioned about possible complications (such as chest pain, bleeding in the puncture site, acute cardiovascular complications and need for hospital care)

and will be examined to assess the presence of a radial pulse, in its presence we will submit patients to the "reverse" Barbeau technique: while the ulnar artery is compressed, oximetry is observed in the patient's thumb, to assess the patency of the radial artery, if the curve disappears, the radial pulse palpated on physical examination is of retrograde origin from the ulnar artery via the superficial palmar arch³⁰.

Statistical analysis

Clinical variables will be collected through a parallel medical record (Appendix 1) and used in the sample characterization. Numerical data will be analyzed for normality using the Kolmogorov-Smirnov test. Quantitative variables will be expressed as mean and standard deviation or median and interquartile range, depending on their distribution. Categorical variables will be expressed in absolute numbers and frequency measures.

Adverse outcomes

The adverse outcomes in the study will be related to the invasive coronary procedure itself, that is, the complications inherent to percutaneous coronary interventions and will be used as safety elements of the strategy:

- Bleeding (BARC Classification): Type 1 - mild bleeding translated as a small hematoma without the need for any medical response to the event; Type 2 - bleeding greater than expected by the procedure, requiring non-surgical medical intervention, hospitalization, imaging studies, and not meeting Type 3 or 5 criteria; Type 3a - bleeding associated with a drop in basal hemoglobin of 3-5 g/dL, any need for transfusion; Type 3b - bleeding with a fall in basal hemoglobin > 5 g/dL, need for surgical medical intervention, vasoactive drugs; Type 3c - intracranial or

intraocular bleeding identified by imaging tests; Type 5a - probably fatal bleeding not confirmed by autopsy but with clinical suspicion; Type 5b - definitively fatal bleeding confirmed with autopsy or imaging study²⁶.

▪ In-stent thrombosis: defined by the time of presentation criteria in acute (< 24 h after stent implantation), sub-acute (between 24 h and 30 days), late (between 30 days and 1 year), and very late (> 1 year). Clinical criteria in definitive when thrombosis is identified by imaging or autopsy; probable when there is death within 30 days of stent implantation, regardless of the procedure time when findings of ischemia or acute myocardial infarction are found in the territory of the implanted stent; possible when death occurs 30 days after the procedure³¹.

▪ Allergic reactions: Classified in Grade I - mild symptoms related to one of the organs: cutaneous, upper airway, ocular conjunctiva; Grade II - symptoms related to two organs mentioned in grade I; Grade III - moderate symptoms related to the lower respiratory tract, gastrointestinal; Grade IV and V related to anaphylaxis: severe manifestations of upper and lower airways as well as circulatory collapse³².

Schedule

The schedule will be carried out as shown in Table 3.

Table 3 – Recruitment schedule and evaluations.

Períodos do Estudo	Study Phases						
	adm	PP	PCI	5h	24h	7d	30d
Recruitment							
Eligibility	X						
ICF	X						
Interventions							
SDD		X	X	X			
Evaluations							
Safety outcomes		X			X	X	X
RAO						X	

adm: admission; PP: parallel medical record; PCI: percutaneous coronary intervention; h: hours; d: days; ICF: application of the free and informed consent form; SDD: same-day discharge; RAO: radial artery occlusion.

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Indications about the contributions of each author:

Conception and design of the study: BLJ, CNM
 Analysis and interpretation of data: JBB, GSLMA
 Data collection: BLJ, CNM, MAS, JBB, GSLMA
 Writing of the manuscript: JBB, GSLMA, BLJ, CNM
 Critical revision of the article: BLJ, CNM
 Final approval of the manuscript*: BLJ, CNM, MAS, JBB, GSLMA
 Statistical analysis: JBB, GSLMA
 Overall responsibility: BLJ
 *All authors have read and approved of the final version of the article submitted to Rev Cienc Saude.

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Annex 1 - Parallel medical record

PARALLEL FORM	
PILOT STUDY: SAME-DAY DISCHARGE IMPLEMENTATION FOR ELECTIVE PERCUTANEOUS CORONARY PROCEDURES PATIENT VARIABLE PATIENT'S INITIALS: _____ PATIENT'S NUMBER: _____ TELEPHONE NUMBER: _____ MARITAL STATUS: _____ GENDER: _____ AGE: _____ EDUCATION: _____ WEIGHT: _____ HEIGHT: _____ CAPITAL COMPANION: () YES () NO ECONOMIC CONDITIONS: _____ CLASS: _____	
COMORBIDITIES: () SAH () PAOD () AMI () DM WITH INSULIN () STENTS () DLP () DM II () JICA () SMOKING () CABG () HF - NYHA: ____	
PROCEDURE DATE: _____ PICTURE SITE COMPLICATIONS: () YES () NO WHICH? PERI-PROCEDURE CARDIOVASCULAR EVENTS: () YES () NO WHICH? PRE-PROCEDURE EXAMS: <ul style="list-style-type: none"> • HB: • HT: • PLATELETS: • UREA • CREATININE: • LVEF: • MIBI: • ERGOMETRIC TEST: • Arteries with major / moderate obstructive involvement by AngioTC: • CORONARY AngioTC (CALCIUM SCORE): • PRE-PROCEDURE TEST WITH PULSE OXIMETRY: 	
MEDICINES IN USE:	
PATIENT'S COST: <ul style="list-style-type: none"> • SDD COST: • NSDD COST: 	
FOLLOW UP: <ul style="list-style-type: none"> • AFTER 24 HOURS DISCHARGE: • AFTER 7 DAYS: • AFTER 30 DAYS: 	
PROCEDURE VARIABLES ELECTIVE: () YES () NO AD-HOC: () YES () NO UNSTABLE ANGINA: () YES () NO NSTEMI: () YES () NO STENTS: <ul style="list-style-type: none"> • NUMBER OF CORONARIES ARTERIES TREATED: • NUMBER OF STENTS PER VESSEL: • STENT TYPE: () BMS () DES 	
ARTÉRIA TRATADA: () LAD () CX () RCA () DG () MG () RPD () RVP <ul style="list-style-type: none"> • RELEASE ATM: • BIFURCATION: () YES () NO MEDINA'S CLASSIFICATION: • TÉCNICA UTILIZADA: • PRE-DILATATION: • POST-DILATATION: • POST-DILATATION ATM: 	
CONTRAST DYE VOLUME: PROCEDURE TIMES: A. VESSEL PUNCTURE UNTIL CATHETERIZATION: B. CATHETERIZATION UNTIL SHEAT REMOVAL: C. TOTAL TIME:	
CLOPIDOGREL 600MG: () SIM () NÃO PERI-PROCEDURE DRUGS: PRE-DISCHARGE RADIAL PULSE WITH INVERTED OXIMETRY TEST	

SAH systemic arterial hypertension, DM diabetes mellitus, POAD peripheral obstructive arterial disease, CVA stroke, CHF congestive heart failure, NYHA New York Heart Association, AMI acute myocardial infarction, DLP dyslipidemia, HB hemoglobin, HT hematocrit, MIBI myocardial scintigraphy, CT Angio tomography of the coronary arteries, SDD same-day discharge, NSDD overnight, LAD left anterior descending artery, CX circumflex artery, DG diagonal branch, MG left marginal branch, RPD right posterior descending branch, RVP right posterior ventricular branch, ATM atmosphere.