

**ORIGINAL RESEARCH ARTICLE****IS A CARDIAC CATHETERIZATION PROCEDURE AT HOSPITALS WITHOUT ON-SITE SURGICAL BACKUP SAFE?**SR Regmi^{1*}, BM Dhital¹, B Sharma²¹Department of Cardiology, Chitwan Medical College, Bharatpur, Chitwan, Nepal.²Department of Anesthesiology, Chitwan Medical College, Bharatpur, Chitwan, Nepal.***Correspondence to:** Dr. Shyam Raj Regmi, Cardiology Unit, Chitwan Medical College, Bharatpur, Chitwan, Nepal.Email: shyamregmi2003@gmail.com**ABSTRACT**

Percutaneous cardiac catheterization procedures have now become an established and preferable method. Initially, these procedures were performed at clinical sites with surgical backup as complication rates and need of urgent surgery were high. With the improvement in catheter technique, experienced operators and the development of new devices, overall complication rates of catheterization are low and emergency cardiac surgery has become an increasingly rare event. The aim of the study was to evaluate the procedural outcomes for cardiac interventions in a tertiary-level hospital without onsite cardiac surgery backup. This was a prospective descriptive study. All consecutive patients who were admitted for percutaneous cardiac interventions, including both diagnostic as well as therapeutic interventions, between September 2013 and August 2015 were included in this study. Total 692 percutaneous cardiac interventions were performed. The mean age was 61.9 ± 18.3 years. 439(63.52%) procedures were carried out in men. PCI was done in 189(27.31%). Percutaneous transvenous mitral commissurotomy was done in 49(7.08%) cases, coronary angiogram was done in 395(57.08%), permanent pacemaker insertion in 29(4.20%), peripheral angiogram in 16(2.30%), pericardiocentesis in 14(2.02%). Primary PCI was done in 62(32.88%). The most frequent indication for PCI was STEMI 106(56.16%). Complications like Post-procedural cardiogenic shock in 4 (2.11%) cases, arrhythmias and minor complications in 7 (3.70%), and death in 4 (2.11%) patients was witnessed. Similarly, periprocedural MI and contrast induced nephropathy (CIN) requiring dialysis stroke or transient ischemic attack were not noted. Cardiac tamponade was observed in 1 (2.02%) patient during PTMC. There was no need of emergency cardiac surgery Percutaneous cardiac intervention was feasible with acceptable complications in a tertiary-level hospital without onsite cardiac surgery backup.

Key words: Onsite cardiac surgery; Outcomes; Percutaneous cardiac interventions.**INTRODUCTION**

Percutaneous cardiac catheterization procedures have now become an established and preferable method for the diagnosis and treatment of most of the cardiac diseases. Initially, these procedures were performed at clinical sites with surgical backup as complication rates and need of urgent surgery were high. With the improvement in catheter technique, experienced operators and the development of new devices, overall complication rates of catheterization are low and emergency cardiac surgery has become an increasingly rare event.¹ Percutaneous coronary

interventions(PCI) and other cardiac catheterization procedures like PTMC(percutaneous transvenous mitral commissurotomy), (permanent pacemaker insertion(PPI) , coronary and peripheral angiogram, done without on-site cardiac surgery backup were as safe as procedures done with on site backup . It could be the good strategy to decrease door to balloon time in PPCI. The aim of the study was to evaluate the procedural outcomes for cardiac interventions in a tertiary-level hospital without on-site cardiac surgery backup.

METHOD

This was a prospective descriptive study. All consecutive patients who were admitted for percutaneous cardiac interventions, including both diagnostic as well as therapeutic interventions, between September 2013 and August 2015 at Chitwan Medical college, Bharatpur, Chitwan were included in the study. A total of 692 cardiac catheterization procedures were carried out in this period. Medical records of these 692 were reviewed. Ethical committee had approved for the study. Both written and informed consent were obtained. Simple procedure like temporary pacemaker insertion were excluded.

The primary outcome variables of the study were cardiac catheterization procedures like percutaneous coronary intervention (PCI), percutaneous transvenous mitral commissurotomy (PTMC), coronary angiogram (CAG), permanent pacemaker insertion (PPI), peripheral angiogram and pericardiocentesis procedures. The procedural outcomes included were arrhythmia requiring treatment, post procedure cardiogenic shock, stroke, heart block, contrast induced nephropathy requiring dialysis, cardiac tamponade required surgical drainage and severe mitral regurgitation requiring emergency mitral valve replacement after PTMC, minor complications, death and need for emergency cardiac surgery like coronary artery bypass graft surgery.

Cardiogenic shock was labeled as a clinical state of hypoperfusion, characterized by a systolic blood pressure <90 mm Hg and central filling pressure >20 mm Hg. Primary PCI was defined as the coronary intervention procedure for the treatment of acute STEMI performed in an emergency setting. Arrhythmia requiring treatment, i.e., ventricular tachycardia was diagnosed on three or more QRS complexes of ventricular origin at a rate exceeding 100 beats per min.²

All procedures were performed by standard methods as mentioned in Hand book of cardiac catheterization and intervention by Morten J Kern.³ Patients underwent diagnostic angiography followed by PCI of the infarct-related artery by both radial and femoral approach with single wall puncture

technique, using six French or seven French guiding catheters as appropriate. PTMC were performed with inoue balloon catheter and right femoral venous approach.³

The data collected included age, gender, past medical history of hypertension (systolic blood pressure ≥ 140 mmHg, and/or diastolic pressure ≥ 90 mm Hg, and/or on medication), dyslipidemia (fasting cholesterol ≥ 200 mg/dl and/or low density lipoprotein ≥ 130 mg/dl or on treatment), diabetes (defined as a fasting glucose >126 mg/dl or on treatment) and smoking; and the final indications and outcome were recorded. PCI success was defined as achievement of vessel patency to a residual stenosis <20% plus normal Thrombolysis in Myocardial Infarction (TIMI) three flow.² PTMC success was defined as more than 50% increment in mitral valve area after the procedure.

Descriptive statistics of different variables of the sample population were computed. Means and standard deviations (SD) were calculated for quantitative variables. Categorical variables reported in percentages for the gender, history of dyslipidemia, diabetes, hypertension and smoking, and complications were considered. Frequency of complications were noted as the primary outcome of the study. The statistical package for social sciences version 13.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. P values less than 0.05 were considered to be statistically significant.

RESULTS

Total 692 percutaneous cardiac interventions were performed. The mean age was 61.9 ± 18.3 years. 439(63.52%) procedures were carried out in men. PCI was done in 189(27.31%). Percutaneous transvenous mitral commissurotomy was done in 49(7.08%) cases, coronary angiogram was done in 395(57.08%), permanent pacemaker insertion in 29(4.20%), peripheral angiogram in 16(2.30%), pericardiocentesis in 14(2.02%).

Primary PCI was done in 62(32.88%). The most frequent indication for PCI was STEMI 106(56.16%). Complications like Post-procedural cardiogenic shock in 4 (2.11%), arrhythmias and minor complications in 7 (3.70%), and death in 4 (2.11%) patients was

witnessed. Similarly, periprocedural MI and contrast induced nephropathy (CIN) requiring dialysis stroke or transient ischemic attack were not noted. cardiac tamponade was observed in 1 (2.02%) patient during PTMC. There was no need of emergency cardiac surgery.

Table 1: Patients profile

Male	439(63.52%)
Female	253 (36.48%)
Diabetes (PCI)	80(42.46%)
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Hypertension(PCI)	90(47.94%)
Smoking (PCI)	98(52.01)
Dyslipidemia (PCI)	62(32.87%)

Table 2: Procedures

Coronary Angiogram	395(57.08%)
Percutaneous coronary intervention(PCI)	189(27.08%). (Primary PCI in 62 (32.88%)
Percutaneous transvenous mitral commissurotomy(PTMC)	49(7.08%)
Permanent pacemaker insertion(PPI)	29(4.20%)
Peripheral angiogram	16(2.31%),
Pericardiocentesis	14(2.02%).
Total	692(100%)

Table 3: Complications

Cardiogenic Shock/death	4(2.11%)
Periprocedural MI	0 (0%)
CIN requiring dialysis	0 (0%)
Arrhythmias requiring treatment	7(3.7%)
Stroke	0 (0%)
Minor complications	7 (3.7%)
Mitral regurgitation requiring MVR	0 (0%)

DISCUSSION

The number of PCI procedures has increased considerably in Nepal in recent years. Till date there are only ten hospitals in Nepal that are equipped with a cardiac catheterization laboratory facility. Among them, only three hospitals have onsite cardiac surgery.

PCI has undergone tremendous growth over the past two decades and become a safe and effective procedure, and also has proven to be superior to thrombolysis for reperfusion.^{2,4} Initially, PCI was performed at clinical sites with surgical backup as complication rates and need of urgent surgery were high. With the improvement in catheter technique, experienced operators and the development of new devices, overall complication rates of PCI are low and emergency cardiac surgery rates resulting from PCI procedure are at 0.2%.⁵ Intraatrial septal puncture during PTMC sometimes complicated with cardiac tamponade due to left atrial free wall puncture. This procedure is also complicated with development of iatrogenic severe MR after balloon inflation and needs emergency mitral valve replacement.³

Wu and colleagues,⁶ showed in-hospital mortality of 1.8% while in our study the in-hospital mortality was 2.11%. This result was comparable to other centers with in site cardiac surgery back-up in primary PCI. Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases. Among four deaths, one patient died because of massive pericardial effusion most probably due to right ventricular free wall rupture after successful PCI to RCA. Rest three patients who died had AMI complicated with cardiogenic shock and had multivessel disease. Despite undergoing PCI stenting to the culprit vessel, they did not improve from cardiogenic shock. As compared to the Melbourne Interventional Group (MIG) Registry,⁷ in which 38% patients underwent PCI for UA/Non STEMI, followed by stable CAD 34% and STEMI 23%, our study had high proportion of patients with STEMI, i.e., 56.16%.

Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery. None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after primary PCI.

Eight studies examined nonprimary PCI at sites with

and without on-site surgery. The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study showed a lower mortality at the facility without on-site surgery. However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias. Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial⁸ randomized over 18,000 patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively. High-risk patients were excluded, as was the use of atherectomy devices. The 6-week mortality rate was 0.9% without and 1.0% with on-site surgery. The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively. The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly. A similar, but smaller randomized study of non-emergency PCI was performed in Massachusetts hospitals. The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days. Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery. Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery.^{9,10,11} Our study data regarding mortality and complications was consistent with the data of most of these clinical trials.

CONCLUSION

Though having on-site cardiac surgery back up might enhance operator confidence and sometimes useful for medico legal purpose, Percutaneous cardiac intervention was feasible with acceptable complications in a tertiary-level hospital without on-site cardiac surgery backup. The most common indication for PCI was STEMI. Despite having no cardiac surgery backup, in-hospital mortality and

other complications following cardiac procedure were acceptable in our cardiac catheterization laboratory.

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