

CORONARY ARTERY DISEASE

Original Studies

Day Procedure Intervention is Safe and Complication Free in Higher Risk Patients Undergoing Transradial Angioplasty and Stenting. The Discharge Study

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Objectives: To assess the timeframe of postprocedural complications following transradial percutaneous intervention in selected nonlow-risk patients as a feasibility study for same day discharge. **Background:** Percutaneous coronary intervention (PCI) is traditionally performed as an inpatient procedure. Transradial access with its lower complication rate facilitates safe and same day discharge. We hypothesize that with current standards of pharmacotherapy and intervention, complications post transradial percutaneous coronary angioplasty even in a nonlow-risk patient cohort will be evident within 6 hr or occur more than 24 hr post procedure. Under these circumstances, overnight stay results in no improvement in patient safety. **Methods:** 2,189 patients underwent transradial PCI at our institution between January 2005 and June 2006. Of these 1,174 were assessed as intermediate or high risk and admitted postprocedure. The remaining 1,015 were assessed as low risk and discharged the day of procedure. All 1,174 inpatients were entered into our study database. Information was collected on patient demographics, angiographic characteristics, post procedural complications, and timing of post procedural events. **Results:** 1,543 ACC type B2 or C lesions were treated in 1,174 patients. All post-procedural complications were identified within 6 hr of the intervention or occurred more than 24 hr later when patients would have been discharged according to overnight admission protocols. **Conclusions:** Day case transradial percutaneous intervention with a 6-hr period of post procedure observation is a safe and feasible practice. The presence of higher-risk features should not be considered an absolute indication for overnight admission in patients considered clinically appropriate for discharge. © 2007 Wiley-Liss, Inc.

Key words: percutaneous coronary intervention (PCI); transradial cath (TRAD); complications adult cath/intervention (COMP); day case

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INTRODUCTION

Percutaneous coronary intervention is usually performed via the femoral approach as an inpatient procedure with overnight admission. This clearly impacts upon patient length of stay, increasing occupied bed days, and health care expenditure. Transradial access, however, with its lower complication rate facilitates safe same day discharge after percutaneous intervention [1–4]. This reduces hospital expenditure and max-

TABLE I. Criteria for Inpatient Stay

| |
|-----------------------------------------|
| Clinical indication |
| Access site complication |
| Nonaccess site complication |
| Chest pain/AMI |
| Hemodynamic instability |
| Persistant ECG changes during procedure |
| Angiographic indication |
| Last remaining vessel |
| Complex lesion/bifurcation |
| Suboptimal result |
| Dissection |
| Intracoronary thrombus |
| Major side branch jeopardy |
| Transient closure |
| Pharmacologic indication |
| IIB/IIIA inhibitor infusion |

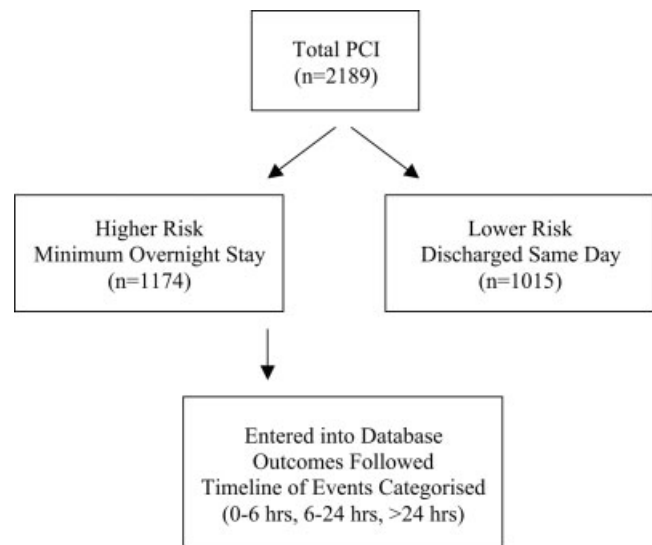
imizes bed utilization. From a patient perspective, it increases early ambulation and patient comfort and is therefore preferred by most patients [5,6].

Although European Percutaneous coronary intervention (PCI) guidelines do not address patient overnight stay, current ACC guidelines still recommend overnight stay. Radial day case PCI is however identified as an area requiring further study [7,8].

The most commonly cited reasons for overnight admission include surveillance for access site complications, periprocedural events, and target vessel closure in the first 24-hr post PTCA. The majority of these events are evident within 6 hr and the risk declines after this uneventful observation period [2,4]. Subacute stent thrombosis is the most feared complication prompting protocols for overnight admission, however this usually occurs 1–5 days postprocedure [9,10], when the patient would have been discharged anyway.

Prior studies have already demonstrated the safety of same day discharge in low risk patients who meet a list of predetermined criteria for day case transradial PTCA [1,2,4]. A recent prospective randomized study [11] demonstrated same day discharge after transfemoral PCI was safe and feasible in the majority of patients selected for day case PCI. Almost half of the eligible patients however were excluded, many for reasons that do not present obstacles for same day discharge in transradial procedures.

In this study, we elected to assess the timeframe of complications in a non low-risk group, with a minimum of 1 night stay following transradial PTCA. Specifically this was designed as a safety and feasibility study to address the hypothesis that even in a higher risk cohort, a peri-procedural adverse event will be evident within 6 hr or occur after the accepted overnight admission protocol. Under these circumstances overnight stay increases expenditure with no improvement in patient outcomes.

**Fig. 1. Study design.**

METHODS

Two thousand and eighty-nine patients underwent transradial PCI at our institution between January 2005 and June 2006. Of these 1,174 were admitted postprocedure, while 1,015 were assessed as low-risk according to accepted criteria (Table I) and performed as day cases. Previous studies [1,2,4] have already addressed the safety of day case PCI using similar criteria, and this study was designed to analyse the higher risk admitted cohort. All 1,174 patients admitted after transradial PCI were entered into our study database. Information was collected on patient demographics, angiographic characteristics, postprocedural complications, and timing of post procedural events (Fig. 1).

Radial PCI Technique

All patients referred for PCI were assessed for adequate collateral circulation via the Allens test. Sheath insertion was performed under local anaesthesia by the standard seldinger technique using either a Cook or Arrow kit (21-gauge needle, 0.018 in. guidewire). The left radial approach was used for graft studies and LIMA interventions. 6-Fr systems were used for the vast majority of procedures, with 7 Fr used on occasion for complex bifurcations or left main interventions. A vasodilating mixture of Verapamil 1mg and nitroglycerine 200 mcg was administered intra-arterially post sheath insertion as prophylaxis against radial spasm.

Anticoagulation Protocol

Heparin (5000 IU) was administered intravenously following successful sheath insertion. This was increased to 80–100 IU/kg (depending on operator preference) when the decision was made to intervene.

TABLE II. Baseline Characteristics

| | Admitted | | Discharged | | P |
|----------------------|-----------|----|------------|----|----------|
| | n = 1,174 | % | n = 1,015 | % | |
| Age (years) | 66 | | 66 | | NS |
| Sex | | | | | |
| Male | 889 | 76 | 780 | 77 | NS |
| Female | 285 | 24 | 235 | 23 | NS |
| Risk factors | | | | | |
| Hypercholesterolemia | 478 | 41 | 544 | 53 | P < 0.01 |
| Hypertension | 664 | 57 | 619 | 61 | NS |
| Diabetes | 230 | 20 | 220 | 22 | NS |
| Current smoker | 257 | 22 | 173 | 17 | P < 0.05 |
| Former smoker | 362 | 31 | 412 | 41 | P < 0.01 |
| Prior MI | 231 | 20 | 245 | 24 | NS |
| Prior PCI | 208 | 18 | 301 | 30 | P < 0.01 |
| Prior CABG | 59 | 5 | 81 | 8 | NS |
| Elective PCI | 197 | 17 | 521 | 51 | P < 0.01 |
| Urgent PCI | 635 | 54 | 485 | 48 | P < 0.05 |
| Emergent PCI | 342 | 29 | 9 | 1 | P < 0.01 |

All patients were pretreated with aspirin 81 mg and clopidogrel 75 mg/day with a 300–600 mg loading dose if clopidogrel naive. GP IIb/IIIa inhibitors were used depending on operator discretion. A 12-hr infusion post procedure mandated overnight stay. Following PTCA the ACT was checked and a further heparin dose given if the ACT was < 200 sec. The radial sheath was removed immediately with application of a haemostasis clamp. This was released in stages 1–2 hr post procedure, and removed 2–3 hr post procedure. A pressure dressing was then applied and the patients were fully ambulated depending on their clinical situation.

Statistical Analysis

Continuous variables are presented as means and categorical data are presented as numbers and percentages. Statistical comparison of categorical data was performed by a statistician using the z-test for equal proportions with bonferroni correction for multiple analyses.

RESULTS

All 1,174 patients were entered into our database for statistical analysis. Baseline characteristics were representative of a standard cardiology population and are outlined in Table II. The mean patient age was 66, with 76% of the study population male. Twenty-percent had evidence of prior myocardial infarction, and 23% had prior revascularisation (percutaneous or surgical). As expected in this nonrandomized admitted cohort there was some demographic differences from our discharged cohort, although the age, sex, and incidence of diabetes and hypertension were similar between groups.

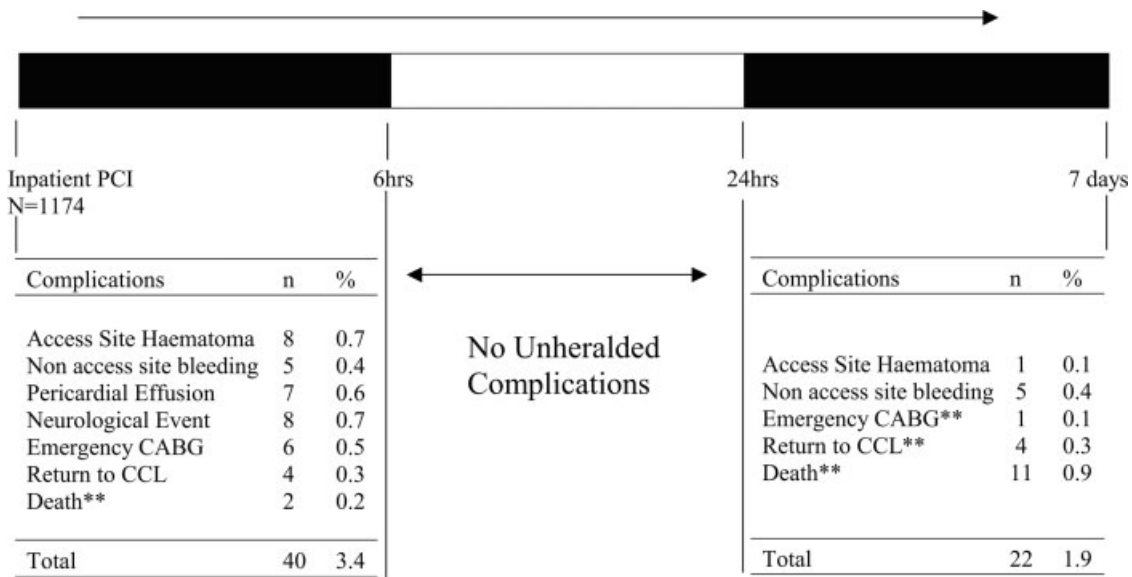
TABLE III. Angiographic Characteristics

| | n = 1,174 | % |
|------------------------------------|-----------|----|
| Left main disease | 18 | 2 |
| 1-vessel disease | 486 | 41 |
| 2-vessel disease | 405 | 34 |
| 3-vessel disease | 265 | 23 |
| Vessel of PTCA | | |
| LAD | 464 | 40 |
| LCX | 208 | 18 |
| RCA | 426 | 36 |
| Left main | 24 | 2 |
| Ramus | 25 | 2 |
| Branch (OM/Diag) | 153 | 13 |
| SVG | 25 | 2 |
| LIMA | 3 | 0 |
| Type of lesion treated (n = 1,543) | | |
| A | 15 | 1 |
| B1 | 264 | 17 |
| B2 | 756 | 49 |
| C | 508 | 33 |
| Single vessel PTCA | 909 | 77 |
| Multivessel PTCA | 265 | 23 |
| Lesion/patient | 1.31 | |
| Vessel/patient | 1.13 | |

Procedure indication was emergent in 29% [acute presentation with transfer directly to cardiac catheter laboratory (CCL)] urgent in 54% (acute presentation stabilised with transfer to CCL during index hospitalisation) and elective in 17% (Table II). The proportion of urgent and emergent cases was significantly higher in the cohort admitted overnight and the proportion of elective cases was significantly lower, confirming this as a higher risk group based on presentation.

Angiographic characteristics are outlined in Table III. A total of 1,543 lesions were treated in 1,174 patients. As expected in this inpatient non low-risk risk group 90% of lesions were type B2 or C. The majority of type A or B1 lesions were discharged home the day of procedure and therefore did not meet inclusion criteria for this study. Postintervention complications are outlined in Figure 2. A total of 13 patients (1.2%) had bleeding complications within 6 hr of their procedure. Five of these (0.4%) were minor nonaccess site bleeding requiring no intervention or transfusion. Eight of these (0.7%) were access site hematomas. Only one of these eight required intervention—surgical repair of a radial artery laceration. No bleeding complication occurred between 6 and 24 hr.

A total of eight patients (0.7%) suffered neurological symptoms post percutaneous intervention. Four (0.3%) were transient minor symptoms with no abnormality on CT head. Four (0.3%) had definite cerebrovascular accidents, three with persisting neurological deficits. In all of these cases the diagnosis was made during or immediately after the procedure.



*One return to CCL and one death both with clinical deterioration observed within 6 hrs
 ** See table IV & V for details

Fig. 2. Timeline of complications after transradial intervention in 1,174 higher risk inpatients.

A total of six patients (0.5%) went for urgent bypass surgery post PTCA. All were performed immediately due to procedural complications (dissection, propagating thrombus). No patients proceeded to CABG with unforeseen complications within the 6–24 hr timeframe.

A total of five patients (0.4%) returned to the CCL within 24 hr during their index hospitalization. Two had an unrecognized dissection related to the initial procedure, which required stenting. Three were found to have an unchanged angiographic appearance with TIMI III flow. Only one patient returned between 6 and 24 hr post PCI. This patient had a guide dissection during his initial procedure, which propagated the entire length of his RCA, requiring multiple stents. This would have excluded him from even the most aggressive same day discharge protocol He had recurrent pain post procedure, with no changes on repeat angiography 7 hr later and no further intervention required.

Seven patients (0.6%) had post-procedural pericardial effusions requiring drainage. One was related to perforation from a temporary pacing wire inserted for complete heart block during an acute infarct PCI. Six were presumed due to vessel perforations. All were clinically evident within 6 hr.

Complications more than 24 hr after PCI are detailed in Table IV. Six patients (0.5%) had late bleeding complications relating to warfarin or antiplatelet therapy.

Five were significant requiring intervention (3 GI bleeds with endoscopy, one pulmonary haemorrhage, and one epistaxis requiring nasal packing).

Four patients returned to the CCL outside of 24 hr. One had loss of a small RV branch impinged during the initial procedure with no intervention required. Three had acute stent thromboses more than 24 hr post intervention and of these two were related to modification of antiplatelet agents for a coincident operation (appendix and abdominal aortic aneurysm).

One patient underwent urgent bypass surgery outside of 24 hr after a failed PTCA with recognized dissection was initially managed expectantly, with sudden onset of pain 24-hr post procedure.

A total of 14 patients (1.2%) in this higher risk cohort died after PCI during their index hospitalization (Table V). Thirteen of these were acutely unstable on presentation and all 14 were identified clinically within 6 hr as being clearly unsuitable for same day discharge. Only one patient died between 6 and 24 hr and this patient was critically unwell within 6 hr and on inotropes within 1 hr of the intervention.

DISCUSSION

This study challenges the long held axiom that all angioplasty should be performed as an inpatient procedure with overnight stay. Our data confirms the hypothesis that even in a non low-risk patient cohort,

TABLE IV. Late Complications in 1,174 Inpatients After 24 hr

| | <i>n</i> | % | Event |
|-------------------------|----------|-----|----------------------------------------------------------------|
| Access site haematoma | 1 | 0.1 | Forearm haematoma after starting warfarin |
| Nonaccess site bleeding | 5 | 0.4 | GI bleeding (3) epistaxis (1) pulm haemorrhage (1) |
| Emergency CABG | 1 | 0.1 | Dissection during failed PCI managed expectantly |
| Return to CCL | 4 | 0.3 | Stent thrombosis (3) loss of small impinged RV branch (1) |
| Death | 11 | 0.9 | Haemodynamically unstable from time of procedure (see Table V) |
| <i>Total</i> | 22 | 1.9 | |

TABLE V. Deaths

| Admission diagnosis | Cause of death |
|------------------------|----------------------|
| UAP | Cardiac arrest |
| STEMI aspiration | Respiratory failure |
| NSTEMI | Cardiac arrest |
| STEMI VF arrest | Cardiogenic shock |
| STEMI CHB | TPW perforation |
| NSTEMI VF arrest | Cardiac arrest |
| ruptured AAA | Multiorgan failure |
| STEMI | Cardiogenic shock |
| VF arrest | Hypoxic brain injury |
| NSTEMI exac COAD | Respiratory failure |
| Aortic dissection | Multiorgan failure |
| cardiogenic shock | Multiorgan failure |
| VF arrest | Hypoxic brain injury |
| Arrest post AAA repair | Cardiogenic shock |

complications between 6 and 24 hr post transradial percutaneous coronary angioplasty are exceedingly rare. Only two patients in this study had post-procedural events between 6 and 24 hr after their intervention, and in both, clinical deterioration was evident within 6 hr. After a 6-hr period of observation most nontarget vessel complications are evident, and most target vessel closures will occur more than 24 hr post procedure. An additional period of overnight inpatient observation rarely leads to the diagnosis of unsuspected adverse events.

A similar study looking at a low risk day case cohort from this institution found no impact on patient outcomes after same-day-discharge, with no episodes of sub-acute target vessel closure within the first 24 hr [1]. This is consistent with findings from other radial centers advocating day case PCI in low risk patients [2–4].

The definition of low risk PCI is however a changing field. Many studies used to identify predictors of post procedural complications or target vessel closure were performed prior to current standards of pharmacotherapy and improvements in procedural equipment and techniques. In the current era of stent technology, and aggressive platelet inhibition, sub-acute complication rates even in complex cases are low.

This study of the higher risk inpatient transradial PCI cohort demonstrates similar findings to our low risk outpatient cohort, despite adhering to a set of cri-

teria designed to capture higher complication rates in the first 24 hr. Ninety percent of patients in this study had a lesion type of B2 or above. Eighty-four percent were urgent or emergent cases. Treated lesions per patient averaged 1.31, 23% were multi vessel PCI, and all possessed one or more clinical or angiographic characteristics identified as risk factors for post procedural complications. Despite this no patient had a significant unheralded complication between 6 and 24 hr post PCI.

Neurological event rates were higher than in other angiographic series, however this number is artificially elevated since all neurological events were admitted and there were no events in the discharged cohort. All occurred within 6 hr of the procedure. Three were clearly procedure related cerebrovascular accidents with persisting neurological deficits (0.3%). Four (0.3%) were presumed to have had procedure related TIAs—three with transient diplopia, and one transient vertigo each with a normal CT head. One (0.1%) had transient hemiparesis resolving over 36 hr.

There were three cases of stent thrombosis all more than 24-hr post-procedure. Two of these were in patients who required operations during their index hospitalization reinforcing the risk of the perioperative procoagulant state to patients with non-endothelialized stents.

The superiority of transradial intervention in minimizing access site complications is also highlighted by this study, with no retroperitoneal haemorrhages, only one radial perforation requiring intervention (<0.1%), and only nine patients (0.8%) suffering significant forearm haematomas. This is much lower than the 2–4% access site complication rate of the femoral approach [5].

In summary, as the acceptance of day case PCI increases without an increase in patient morbidity or mortality, guidelines for same day discharge are expanding. Patients previously thought to be unsuitable are now being reconsidered. Bivalirudin is emerging as an option to reduce the need for prolonged IIBIIIa infusions. Some authors are suggesting the use of bolus only IIBIIIa inhibition in higher risk patients to avoid the overnight admission mandated by a 12 hr infusion [12]. The absence of significant complications in the 6–24 hr period in this study supports these

moves. Further prospective randomized analysis is planned in the follow-up “discharge trial,” however, data from this feasibility study suggests that initial non low-risk risk criteria mandating overnight stay, while understandably conservative may be loosened to allow an even higher same day discharge rate.

CONCLUSION

Day case transradial percutaneous intervention with a 6-hr period of post procedure observation is a safe and feasible practice. Transradial percutaneous intervention with higher risk features should not be considered an absolute indication for overnight admission in patients considered clinically appropriate for discharge.

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