Day Case Discharge of patients treated with Drug Coated Balloon Only Angioplasty for de novo coronary artery disease: A Single Centre Experience

Short title: Protocol for day case DCB-only angioplasty

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Abstract

Objective: To report our initial experience with Drug Coated Balloon (DCB) only angioplasty and propose a protocol to achieve this safely.

Background: There are no articles published in the literature currently regarding the safety of same day discharge in patients treated with DCB-only angioplasty.

Methods: Retrospective review of all our patients treated with DCB-only angioplasty from Sept 2017 to April 2018 with identification of potential complications relating to same day discharge.

Results: A total of 100 consecutive patients who underwent elective DCB-only angioplasty for de novo coronary artery disease and were discharged on the same day as the procedure were included. In 99% no cardiac symptoms relating to the procedure requiring urgent hospitalisation or urgent investigations were identified. One patient was readmitted the next day requiring stenting of the previously treated lesion. Our 30 day mortality was zero. Some 97 hospital bed days were saved with 100 patients treated.

Conclusion: Elective day-case DCB-only angioplasty according to our local protocol is safe and cost-effective and should be considered for the majority of the patients.

Keywords: DCB-only angioplasty, day case

Introduction

Drug coated balloon (DCB) only angioplasty in de novo coronary lesions, is an alternative to routine elective drug eluting stent implantation (DES) (1) (2) (3) . In our institution this constitutes 44% of all elective, urgent and emergency PCI. Given the constant pressures on hospital beds, there is an increasing demand for fast and efficient, yet safe turn-around of all elective patients, ideally as day cases. Although there is ample evidence for same day discharge

in patients receiving an intra coronary stent, no prior study has reported on this strategy in DCB-only de novo angioplasty (4) (5). An important safety consideration, particularly with DCB only angioplasty, is acute vessel closure due to a higher risk of coronary dissection, which will usually be apparent peri-procedurally and will necessitate emergency treatment (6) (7). The default position to defer discharge to the following day is therefore readily understandable particularly where an intracoronary stent has not been deployed to scaffold the vessel. In this article we report our experience with same day discharge following DCB-only angioplasty from a high-volume UK centre and propose a protocol to achieve this safely.

Methods

We identified all patients who underwent elective DCB angioplasty at the Norfolk and Norwich University Hospital between September 2017 and April 2018 and were discharged on the day of their procedure. A local protocol had been proposed for guidance (Figure I) but ultimately the decision for same day discharge was left to the Consultant Interventional Cardiologist in charge of the patient's care. In our institution elective patients can be considered for same day discharge following balloon angioplasty if they fulfil the following criteria:

1) They are pain-free

2) There are no new changes on the post-PCI ECG

3) There is no more than type B coronary artery dissection as defined by Rahman et al. (8), and

4) Absence of high-risk procedural features (such as coronary perforation, occlusion of significant side branch, vascular complications)

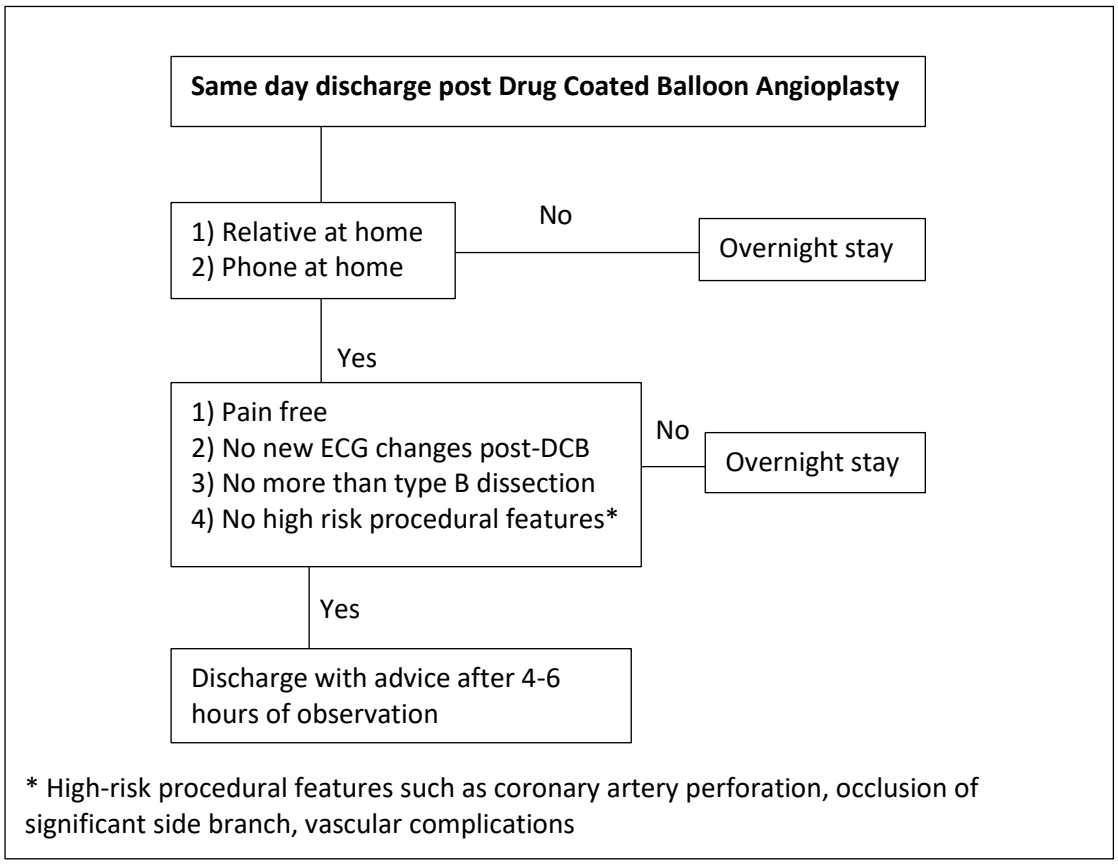

Figure I: Flow diagram for elective drug coated balloon angioplasty patients

All patients were routinely contacted via telephone post-discharge to identify any complications relating potentially to the procedure. Institutional approval was received for use of data for the purposes of this manuscript. Survival data was obtained from the Office of National Statistics, a national registry where all deaths are reported.

Results

One hundred consecutive patients with a total of 113 de novo lesions and 10 in-stent re-stenosis lesions were included (eight patients had in-stent restenosis only whilst two had both in-stent restenosis and de novo disease, giving a total of 105 de novo only lesions in 92 patients). The baseline characteristics demonstrate the unselected nature of the patients; 30% had diabetes mellitus, 41% had a previous myocardial infarction, 56% had undergone previous PCI, 9% had

undergone coronary artery bypass grafting surgery (CABG), 55% had hypertension and 69% were current or ex-smokers, as shown in table I. Women were under-represented comprising only 19% of the cohort. However, this is in keeping with the general relative proportion of women undergoing PCI in the UK over the last few years, which is 25%(9).

Table I: Demographics of patients undergoing elective day – case Drug Coated Balloon Angioplasty	
Number of patients	100
Mean Age (years) +/- SD	67 ±10.3
Females	19
Diabetes	30
Previous Myocardial Infarction	41
Previous PCI	56
Hypertension	55
CABG	9
Smoking history (current/previous)	69
PCI: Percutaneous Coronary Intervention, CABG: Coronary Artery Bypass Graft. SD: Standard Deviation	

Table I: Demographics of patients undergoing elective day – case Drug Coated Balloon Angioplasty

The greater majority of procedures (97%) were completed via the transradial route. The drug coated balloons used were SeQuent Please NEO, 2-4mm in diameter and 10-40mm in length. A total of 140 drug coated balloons were used, 91 with diameter >2.8mm and 49 with diameter <2.8mm, as shown in tables II and III. Two experienced operators (SCE/IM) reviewed all the

angiograms and graded the severity of the treated lesions according to the ACC/AHA classification system (A-C).(10) A total of 52.0% were type C coronary lesions, 36.6% were type B and only 11.4% were type A lesions. All procedures were also reviewed for any visible dissections which were graded according to the National Heart, Lung and Blood Institute (NHLBI) classification.(8) Out of 123 treated lesions, 62 (50.4%) had no angiographic evidence of dissection, 18 (14.6%) had type A dissection, 42 (34.1%) had type B dissection and 1 (0.8%) had type D dissection, which had not been appreciated during the procedure or the time of discharge, as shown in table IV.

Table II: Angiographic details of patients undergoing elective day-case Drug Coated Balloon Angioplasty	
Number of lesions	123
Lesion type	
A	14 (11.4%)
B1	23 (18.7%)
B2	22 (17.9%)
C	64 (52.0%)
Bifurcations	28
Heavy calcification	26
Chronic total occlusions	7
Thrombus	1
Small vessel (<2.8mm) Non-small vessel (>2.8mm)	49 91
Vessel treated / out of 123 lesions	
LMS	2 (1.6%)

LAD	57 (46.3%)
Diagonal	7 (5.7%)
LCx	22 (17.9%)
Marginal	10 (8.1%)
Intermediate	3 (2.4%)
RCA	21 (17%)
Vein graft	1 (0.8%)
DCB: Drug Coated Balloon, LMS: Left Main Stem, LAD: Left Anterior Descending, LCx: Left Circumflex, RCA: Right Coronary Artery.	

Table II: Angiographic details of patients undergoing elective day-case Drug Coated Balloon Angioplasty

Table III: Procedural characteristics of patients undergoing elective day-case Drug Coated Balloon Angioplasty	
Access Radial Femoral	 97 3
Number of DCBs used	140
DCB diameter Mean Range	 2.99mm Min = 2, Max = 4mm
DCB Length range	10-40mm
Average DCB Length	23.25mm
Average Fluoroscopy time	14.6minutes

Average Contrast Volume (SD)	129.6 ±48.6ml
Radiation skin dose	1091 mGy
DCB: Drug Coated Balloon, SD: Standard Deviation	

Table III: Procedural characteristics of patients undergoing elective day-case Drug Coated Balloon Angioplasty

Table IV: Core lab analysis elective day-case Drug Coated Balloon Angioplasty	
Dissection type	
No angiographic dissection	62 (50.4%)
A	18 (14.6%)
B	42 (34.1%)
D	1 (0.8%)

Table IV: Core lab analysis elective day-case Drug Coated Balloon Angioplasty

According to the Office of National Statistics, a national body where all deaths are recorded by law, our 30-day mortality was zero. The overall complication rate was 1%. There were no vascular complications and no cases of contrast nephropathy reported. In cases at risk of contrast nephropathy, we routinely undertake all necessary steps to minimise the risk with adequate intravenous pre-hydration and limited use of contrast. Our average contrast volume of 130mls justifies this reassuring result. During our follow-up telephone contact, nighty-nine patients did not report any cardiac related symptoms requiring urgent hospitalisation or urgent investigations. One patient was admitted the day after the procedure with cardiac chest pain, ECG changes and serial troponin rise of 150, 160 and 148 ng/L (normal <14). Urgent angiography revealed TIMI II flow in the target vessel requiring stent implantation. The patient

made an uneventful recovery and was discharged home the next day. Retrospective review of the index procedure demonstrated a type D dissection that had not been previously appreciated due to suboptimal imaging.

Discussion

Acute vessel closure due to coronary artery dissection is one of the most significant complications of balloon angioplasty. Early studies have shown that type A and B coronary artery dissections if left untreated have good long term outcomes.(11) This is the first study to report on same day discharge in consecutive patients undergoing DCB-only angioplasty and propose safe criteria to achieve this (figure 1). The case mix of the patients included supports that this can be achieved across all patients with multiple comorbidities and complex lesions.

DCB is an emerging interventional strategy in the extensive armamentarium of Interventional Cardiologists both in the elective and emergency setting. (12) The existing pressures on hospital beds nationally exacerbated by the winter crises places greater emphasis on more efficient utilisation of inpatients beds for our elective patients without compromising unduly on patient safety. Our study confirms that day-case DCB angioplasty is safe, with zero 30-day mortality, and carries a low complication rate in an unselected patient population and can improve cost-effectiveness. After one hundred consecutive patients, ninety-seven days in hospital were saved. With an excess bed day of £306 according to 2015-16 reference costs published from the Department of Health, UK, we estimate that day-case DCB angioplasty can save about £296 per procedure in the UK. (13) Recent data from the United States demonstrate that same-day discharge after PCI is associated with larger cost savings of $5128 per procedure, (7) while transradial same-day discharge PCI in Canada was associated with savings of Can$ 1,141 mainly due to the extra night for overnight hospital stay. (8) Obviously, the economic

benefits of day-case DCB angioplasty will be of greater relevance in countries with more expensive overnight hospital stays.

The retrospective nature of our work from a single-centre is a limitation as it can introduce referral bias. However, we are a large tertiary referral centre providing cardiac intervention to a population in excess of one million and we included consecutive patients to ensure recruitment bias is minimised. The strength of our study is that it represents real world data and that we included and followed up all (consecutive and unselected) patients who met the inclusion criteria during our study duration. Therefore, we believe that our conclusions can easily be generalised to patients undergoing elective DCB-only angioplasty in other institutions.

Conclusion

Our study has shown that where DCB can be used for the treatment of de novo coronary artery disease, same day discharge of all elective patients according to our protocol can be considered and is cost-effective.

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