# ACUTE AND LATE MAJOR ADVERSE CARDIAC EVENTS USING THE S7 CORONARY STENT

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***Objectives:*** To assess acute and late major adverse cardiac events (MACE) using the S7 coronary stent.

***Settings and Methods:*** A prospective, non-randomized trial where 406 patients with objective evidence of ischemia and a target vessel diameter ≥3.0 mm and ≤4.0 mm underwent percutaneous intervention (PCI) using an S7 stent. Patients were assessed for acute complications and followed for MACE for up to 6 months.

***Result:*** A total of 406 patients were involved and 437 lesions were dilated. The mean age was 57 years. They were 80.8% male and 23.9% diabetic. 29.5% had prior myocardial infarction. 54.8% had type $B_2$ + C lesions. There were no acute complications, including either acute or subacute thrombosis. All patients were dilated successfully with an increase in minimal luminal diameter from 0.7 mm ± 0.7 mm to 3.3 ± 0.6 mm (P=0.0005). Follow up at 6 months was available for 96.6% of patients. The rate of major adverse cardiac events was 8.5% and the rate of target lesion revascularization was 6.3%.

***Conclusion:*** Despite the complexity of the lesions being dilated, PCI using S7 stent has good acute angiographic results. The acute and 6-month events rate were low with optimal follow-up.

## Introduction

EARLY OBSERVATION TRIALS SHOWED THE FEASIBILITY and safety of stent implantation in humans.[1-3] The first trials to show conclusively the superiority of coronary stenting over conventional balloon angioplasty in clinical and angiographic outcome were the large prospective randomized trials BENESTEN 1[4] and STRESS.[5]

Both trials compared elective Palmaz-Schatz stent placement to elective balloon angioplasty. Later studies have compared stents of various design to the Palmaz-Schatz stent. Major adverse cardiac events (including death, ST or non-ST elevation myocardial infarction, bypass and redilatation) varied between 11.0% to 21%.[6-10]

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The S7 coronary stent is the latest in succession of Medtronic AVE stents. It is a flexible, and delivers with an optimal radio-opacity. This stent provides improved scaffolding and surface coverage. A prospective trial is planned in the Kingdom to assess the clinical use and major acute and late cardiac events rate.

## Methods

The study started on April 2001 and aimed to enroll 400 patients over a period of one year. Patients in the study met the following inclusion criteria:

1. Age above 18 years with objective evidence of ischemia (stable and unstable angina or a positive stress test).
2. A target vessel reference site ≥3.0 mm and ≤4.0 mm in diameter.
3. Target lesions in a native coronary artery with ≥60% and ≤100% stenosis.
4. A lesion length <30 mm.
5. Patient an acceptable candidate for coronary bypass surgery.
6. Patient consented to be in the trial.

**Exclusive criteria included:**

1. Significant unprotected left main disease and an untreated lesion ≥50% diameter stenosis in the target vessel remaining after the planned intervention.
2. Other medical illnesses (i.e. cancer or refractory congestive heart failure) that may cause the patient to be non-compliant with the protocol or that are associated with limited life expectancy.

Patients were loaded with ticlopidine and later clopidogrel. The femoral approach was used by the operators and only lately in few cases was a radial approach utilized. The lesion could be either dilated directly with a stent or predilatation was used according to the operators decision. The deployment pressure was left to the operator, as well as post-stent deployment dilatation. Patients were observed for 24 hours post-dilatation and followed as out-patients at monthly interval for 6 months. Repeated intervention was done only if there was objective evidence of ischemia. All patients were asked to take ticlopidine or clopidogrel for one month following stent deployment.

## Statistics

Data were analysed by the paired students t test using the Microsoft Excel statistical package and presented as mean±standard deviation. The level of statistical significance was set at $< 0.05$.

## Results

The 406 patients enrolled over the study period had the characteristics shown in Table 1. The mean age was 57±18 years. Most (80.8%) were male, 62.3% were smokers and 43.1% were hypertensive, while diabetes was found in 23.9%. 29.5% had prior ST elevation myocardial infarction and 11.8 had non-ST elevation myocardial infarction. 36.7% presented with unstable angina (Figure 1). The indication for intervention was elective for 51.0% of the cases. The operator felt that balloon dilatation was incomplete in 37.4% of the cases, while bail out stenting was done in 9.6% of the cases. 99.5% of the cases were done by the femoral approach. There were 437 lesions in the 406 patients. Table 2 shows the lesion characteristics. 54.8% of the lesions where type $B_2$ & c which indicates the complexity of the cases. Pre-procedure diameter stenosis was 87.5 ± 9.7 with minimal luminal diameter of 0.7±0.7 mm and the referance vessel diameter was 3.1±0.4. The assessment was done by quantative angiography. The lesion length was between 10 mm and 20 mm in 69.2% of the cases. Table 2 shows the vessel being dilated where in 48% of cases the left anterior descending artery was dilated. The location of the lesion was at the proximal segment in 46.2% of the cases where the mid segment was dilated in 48.1% of the cases. The distal segment was less as the vessel size should be ≥ 3 mm. Figure 2 shows the degree of tortuosity and calcification. Figure 3 shows the stent length, which is consistent with the lesion length. The diameter of the stent was 3 mm in 63.4% of the cases and 3.5 mm in 29.9% of the cases, which is consistent with the pre-planned size. In 74.4% of cases predilatation was done before stent placement, while in 25.6% of cases direct stenting was done. Figure 4 shows the stent delivery pressure where 73.6% were between 12 and 14 atmosphere which is considered high pressure deployment. In 93.3% of the cases no post-dilatation was required and variable balloons with a different compliance was used for the post dilatation.

**Table 1:** *Patient Demographics*

| | |
|---|---|
| Mean age (yr) | 57 |
| Sex | (80.8%) male<br>(19.2%) female |
| Number of lesions | 437 |
| Smokers % | 62.3 |
| Hypertension % | 43.1 |
| Hypercholesterolaemia % | 49.0 |
| Positive family history of CAD % | 28.1 |
| Prior Q-wave MI % | 29.5 |
| Prior non-Q-wave MI % | 11.8 |
| Diabetes % | 23.9 |
| History of PTCA % | 3.2 |
| History of CABG % | 4.2 |
| Unstable angina % | 36.7 |
| MI less than 3 days ago % | 17.0 |

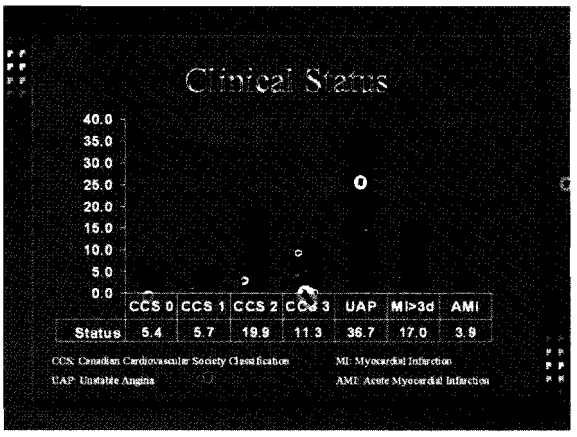


**Figure 1.** Clinical presentation of patients.

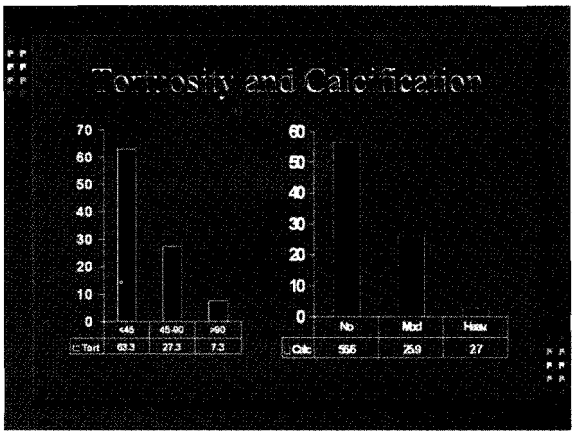


**Figure 2.** The degree of tortuosity and calcification.

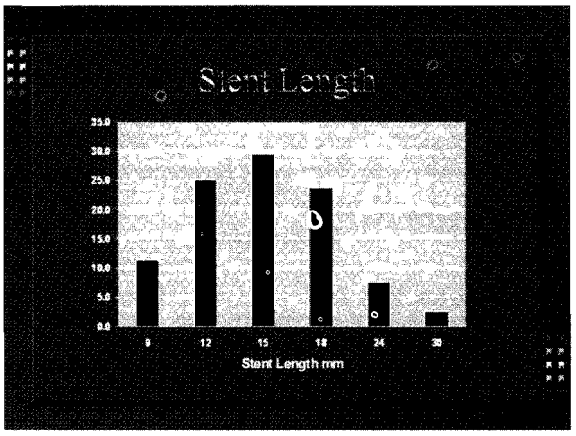


**Figure 3.** The stent length used.

**Table 2:** *Lesion Characteristics*

| | |
|---|---|
| Pre-procedure reference Vessel diameter (mm) | 3.1 + 0.4 |
| Pre-procedure MLD (mm) | 0.7 ± 0.7 |
| Pre-procedure diameter stenosis (%) mean + SD | 87.5 ± 9.7 |
| Lesion length %<br>> 5 mm<br>5 - 9.9 mm<br>10 - 14.9 mm<br>15 - 19.9 mm<br>20 - 24.9 mm<br>> 25 mm | <br>1.1<br>20.8<br>48.6<br>20.6<br>6.9<br>1.9 |
| Lesion location %<br>LAD<br>Circumflex<br>RCA | <br>48<br>24<br>27 |
| Lesion type %<br>A<br>B1<br>B2<br>C | <br>8.6<br>36.6<br>40.9<br>13.9 |

## Acute angiography results and in hospital follow-up

All patients were dilated successfully and the stent placed at the planned site. Figure 5 shows pre- and post-minimal luminal diameter, which has increased from 0.7±0.7 mm to 3.3±0.6 mm (P = 0.0005) and diameter stenosis reduced from 87.5±9.7 to 2.2±8.9. Less than 10% had local hematoma and in 1.4% it was more than 10 cm. There were no acute or subacute thromboses.

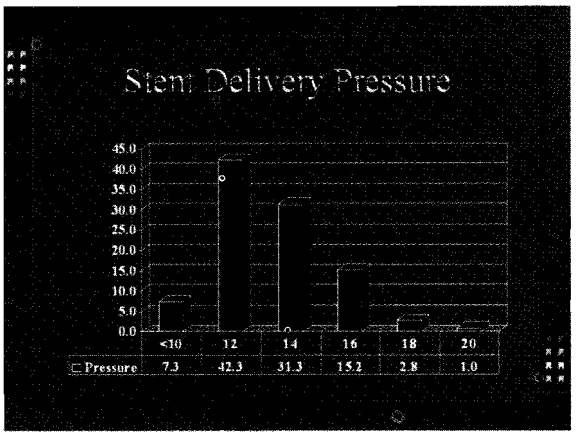


**Figure 4.** The stent delivery pressure.

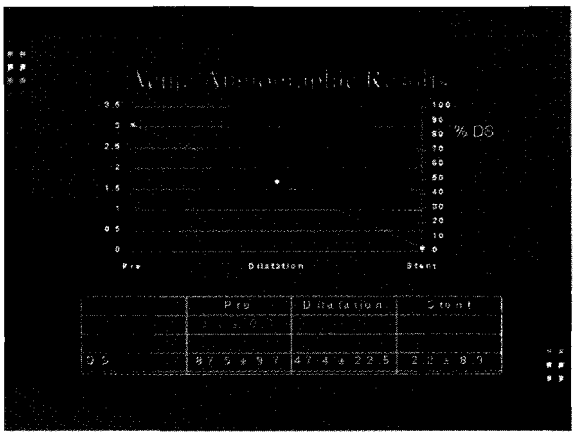

**Figure 5.** Acute angiographic results.

**Table 3:** *Major Adverse Events Up to 6 Months*

| Event | Number (%) |
|---|---|
| Death | 2 (0.5) |
| Q-wave MI | 2 (0.5) |
| Non-Q-wave MI | 5 (1.2) |
| CABG target vessel | 5 (1.2) |
| CABG non-target vessel | 3 (0.7) |
| Re-PTCA target lesion | 20 (5.1) |
| PTCA non-target lesion | 9 (2.3) |
| Combined MACE at 180 days | 8.5% |
| TLR at 180 days | 6.3% |

## Long term follow-up

392 patients (96.6%) were followed up to 6 months. Table 3 shows the major adverse cardiac events at 6 months. There were 2 patients who died during the follow-up period (0.5%). The cause of mortality were progressive heart failure and sudden cardiac death. Re-intervention was required in 20 patients (5.1%) at the target lesion and 5 patients (1.2%) required bypass surgery at the target vessel. The combined MACE at 6 months were 8.5% and TLR 6.3%.

## Discussion

This large prospective clinical trial was done on a group of patients with complex lesions and showed that percutaneous coronary intervention (PCI) using the S7 stent has a good acute and long-term outcome. The percentage of diabetic patients in this study was less than what we have reported before.[11] This can be explained by the fact that the reference diameter of the lesion treated is 3 to 4 mm, which is a relatively large diameter compared to a diabetic who has diffuse disease. There are several reasons for the dramatic increase in coronary stenting. Stents provide predictable, excellent angiographic results, improve the safety of PCI by successfully treating abrupt and threatened closure, and improve long-term clinical outcome by reducing restenosis.[12] The mechanical characteristics of the new stent (flexibility and scaffolding) are better than the old design. The new stent has a low elastic recoil, which is a good parameter for a low restenosis rate of the stent.[13] The radial force under pressure of the new stent shows excellent results.[14] There were no acute or subacute thromboses in our study as patients were loaded with ticlopidine or clopidogrel compared to other studies where other protocols were used.[15-17]

Looking at comparative studies of different stent designs, Baim et al[9] compared the multi-link stent versus Palmaz-Schatz stent for treatment of coronary stenosis and the 9-month event rate was 15.1% versus 16.7%, respectively.

Jorgensen et al[18] compared the NIR stent versus the Palmaz-Schatz stent for treatment of coronary stenosis. The MACE rate was 15.9% versus 11.9%, respectively.

The result of our study showed a low MACE as compared to the previous studies, which indicates a better design in the stent used, and better preparation with ticlopedine or clopidegrel. As well the deployment pressure used in this study was high as compared by other studies.

This study represents a local experience with selected patients using the latest available stent and technique which showed a better out come than other reported studies. There is no similar studies has been carried locally with such large prospective cohort.

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