Coronary Stents in the Management of Coronary Artery Disease Review of First 100 Stents

S C Ng, FSCAI*, Chen Sawatt, SRN, L K Foo, SRN, O Hitam, ASMLT, P G Khor, ASMLT, Y K Lee, ASMLT, *Consultant Interventional Cardiologist, Subang Jaya Medical Centre, Jalan SS12/1A, Subang Jaya, 47500 Petaling Jaya

Summary

This is a review of the first 100 coronary stents implanted for the indications of PTCA restenosis, acute or threatened closure and DeNovo lesions. The success rates were high and complications rates were low. Subacute stent thrombosis rates were low and stenting for DeNovo lesions in > 3.0mm arteries provide the best short and long term results. Six months restenosis rate was low. Stent assisted high pressure balloon angioplasty is an important advance.

Key Words: Coronary stents, DeNovo lesions, Good results, SAHBA, No anticoagulation

Introduction

Since the publication of our earlier study on 100 PTCAs in 1991[1], there has been much progress in the area of interventional cardiology, both internationally and locally. We have learnt more about the strength and weakness of atherectomy devices, laser devices and coronary stents. Large-scale randomized trials have helped us to understand the role of PTCA better. The RITA trial[2], EAST trial[3], CABRI trial, GABI[4] trial and many others, compared PTCA with bypass-surgery in single and multivessel CAD. The landmark ACME[5] trial compared the role of PTCA with medical treatment. It is evident from these trials that PTCA had many shortcomings including its failure to recanalise chronic total occlusion, its complication of acute or threatened vessel closure and of course restenosis after successful PTCA.

The problem of chronic total occlusion in coronary arteries remains with us. Whenever the guidewires cannot cross, the balloons or new devices cannot help. For the future, lasers hold promise but it is still too early to know whether it can break through the chronic total occlusion regularly and safely. High energy ultrasonic ablation of total occlusion is under intense investigation and seems to hold promise.

Acute and threatened closure was the fear of angioplasters since the inception of PTCA, prompting elaborate arrangements for in-hospital and in some institutions, even cross-city cardiosurgical backup. Currently, with the availability of perfusion balloons and particularly coronary stents, this bane of PTCA has been effectively neutralized. In many institutions, on-site "OT in - waiting" cardiosurgical coverage is no longer practised. In hospitals not familiar with coronary stenting, a policy of "next available OT" is practised. In "Stenting" centres, the coronary stents[6] provide very effective treatment for acute and threatened closures following PTCA, making on-site cardiosurgical backup no longer mandatory.

As for restenosis, the STRESS[7] (STent REStenosis) trial

(USA) and the BENESTENT[8] (BElgium-NEtherlands) trial (European) has shown that coronary stenting significantly reduced restenosis rates when compared to PTCA, even after 1 year. This means that currently of all the new devices and medications studied in our attempt to reduce restenosis, the Palmaz Schatz coronary stent, is the only device proven, both by the Americans and the Europeans. Not all coronary stents are the same. Both the STRESS and BENESTENT investigators had chosen to study the Palmaz Schatz (JJIS) coronary stent. With the positive results of these two multicentre trials, the Palmaz Schatz coronary stent is now FDA-approved for the indication of restenosis in the USA.

Therefore it is evident that coronary stent has solved many of the major weakness of plain old balloon angioplasty.

We therefore embarked on a "stent registry" in 1991 to study our patients' outcomes.

Method

This review includes all patients entered prospectively into the Stent Registry between 13.5.91 – 4.4.95. The demographics, details of stenting and outcomes, short and long term were reviewed. Patients were entered into the registry as they were done. All patients were followed-up from discharge till at least 7 days. The > 7 days follow-up was not 100% as many patients treated were from outstation. For those on follow-up, clinical assessment was done initially at 1 week, then 1 month and later at 3-monthly intervals. Stress ECG was performed at 3 months to 1 year and thereafter at yearly intervals. Coronary angiograms were performed if patients developed significant angina or a positive stress ECG. Restenosis data for this review should be seen in this light.

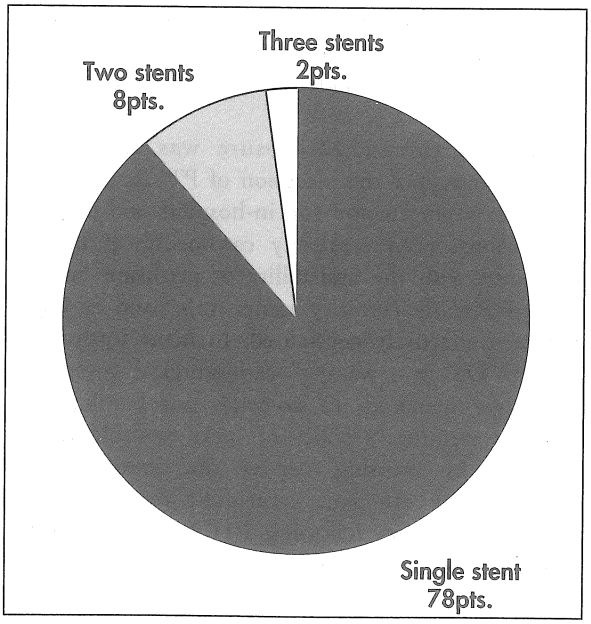

Fig. 1: Allocation of stents

Population

One hundred coronary stents were implanted from 13.5.91 – 4.4.95, in 88 patients. Seventy-eight patients had single stents and 10 patients had multiple stents. Eight patients had two stents and 2 patients had three stents. (Fig. 1). The mean age was 56.1 years (range 37-81 yrs). There were 76 Chinese, 8 Indians, 3 Malays and 1 Frenchman. The M:F ratio is 5.3:1. All stents implanted were ≥ 3.0mm with 70 = 3.0mm stents, 5 = 3.25mm, 20 = 3.5mm, 4 = 4.0mm, 1 = 5.0mm stents (Fig. 2). Fifty-four stents were placed in the LAD, 31 stents in RCA, 11 stents in LCx, 3 stents in SVG and 1 stent in LMS (protected) (Fig. 3). As for indications, 62 stents were placed DeNovo, 26 stents were placed because of threatened or acute closure, and 12 stents were placed for PTCA restenosis

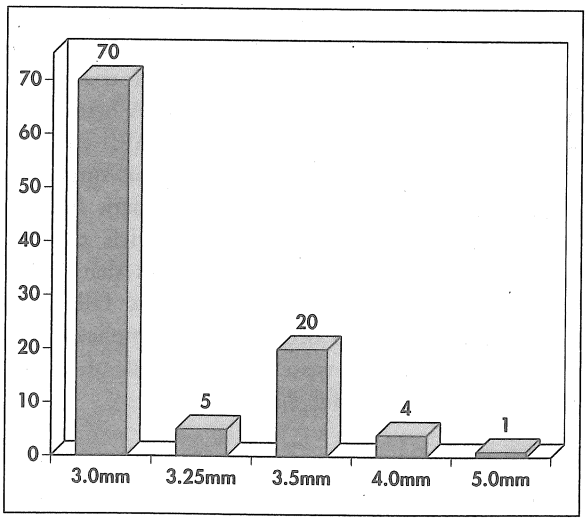

Fig. 2: Size of stents

(Fig. 4). DeNovo stenting is defined as the placing of a coronary stent in a lesion which had not had previous angioplasty. The minimal luminal diameter of the vessel must be ≥ 3.0mm. Acute or threatened closure is defined as a major dissection flap either acutely closing the vessel or threatening to close the vessel, with less than TIMI 3 blood flow.

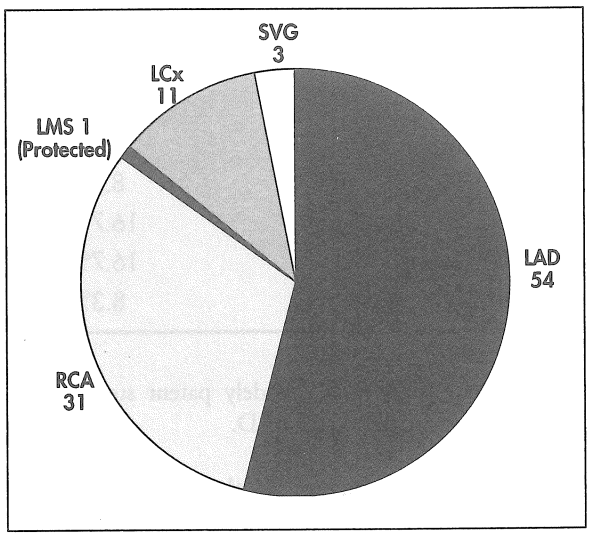

Fig. 3: Stent vessel distribution

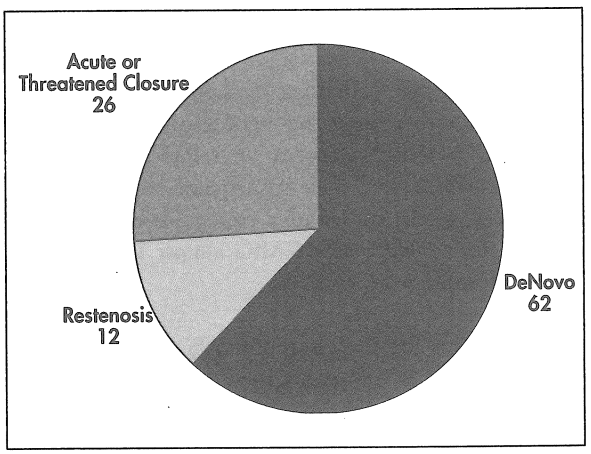

Fig. 4: Indications for stents

Results

Success in PTCSA (Percutaneous Transluminal Coronary Stent Angioplasty) is defined as the successful implantation of the coronary stent(s) at the target site without death, emergency CABG (within 24 hours) and AMI (within 24 hours) with a residual stenosis of ≤ 10%. Subacute stent thrombosis (SAST) is defined as acute thrombosis of the coronary stent 24 hours to 10 days post-stent implantation.

Table I
Overall results

Success	:	95%
Failed	:	5%
Em.CABG	:	2%
Death	:	2%
SAST	:	6%
AMI	:	8%
Acute closure	:	2%
Restenosis (Total)	:	9%
Restenosis (> 6 months FU)	:	11.2%

In line with these definitions, we implanted 95% of our stents successfully. There were 5 failures. Two patients underwent emergency CABG because of acute closure following PTCA, when stent implantations were unsuccessful. There were 2 deaths, one following SAST, (when the patient's relative refused an emergency PTCA). The second death was probably related to the angiogram procedure. The SAST rate was 6% and the AMI rate was 8% (Table I).

Over a minimum follow-up of 6 weeks, the clinical restenosis rate was 9%. One patient developed significant angina but refused a stress ECG or coronary angiogram. Over a minimum follow-up period of 6 months (73 patients with 80 stents) the clinical restenosis rate was 11.2%.

On subgroup analysis by indications, the results were even more revealing. In the patients who had coronary stent implanted (intention to treat) for acute or threatened closure, the success rate was 92.3%. The emCABG rate was 7.7%. The death rate was 0%. The SAST 11.5%. The failure rate was 7.7%. The AMI rate was 19.2% and the clinical restenosis rate was 19.2%. In the restenosis group, the respective rates were 91.7%, 0%, 8.3%, 16.7%, 8.3%, 16.7% and the

Table II
Results by indications

Complications	Indications		
	DeNovo (62 stents)	Acute closure (26 stents)	ReStenosis (12 stents)
Success	98.4%	92.3%	91.7%
Failure	1.6%	7.7%	8.3%
Em.CABG	0%	7.7%	0%
Death	1.6%	0%	8.3%
SAST	1.6%	11.5%	16.7%
AMI	1.6%	19.2%	16.7%
Clinical restenosis	4.8%	19.2%	8.3%

clinical restenosis rate was 8.3%. The best results were obtained when coronary stents were implanted electively in DeNovo lesions. The success rate was 98.4%, the emCABG 0%, death rate 1.6%, SAST 1.6%, failure rate 1.6%, AMI rate 1.6% and the clinical restenosis rate was 4.8% (Table II).

Among the minor complications, bleeding in the groin (puncture-site bleed) was the most common. There were 7% of minor groin bleed, defined as a groin hematoma not requiring blood transfusion and a 4% incidence of major bleed defined as groin bleeding requiring blood transfusion. One patient had a life-threatening GIT bleed, 2 days post-stenting requiring the cessation of IV heparin and PO Warfarin. He suffered subacute stent thrombosis which was successfully treated with PTCA and he is now 2 1/2 years post-stenting and well. One patient had aspirin-induced GIT bleed, 2 weeks post-stenting and was successfully managed medically.

Conclusion

The stent registry allowed us to study the outcome of our patients following coronary stenting.

The first Palmaz Schatz (JJIS) coronary stent was implanted on 13.5.91. A check coronary angiogram of this patient in April '95 for new chest pains showed a widely patent RCA with a widely patent stent. There is new disease in the distal LAD.

It is indeed heartening to see that we have a 95% success rate with a low mortality rate of 2%. Of these two deaths, one was probably related to catheter trauma and the other from cardiogenic shock following SAST in an RCA stent for a restenotic lesion.

All the stents that had subacute stent thrombosis had repeat PTCA to reopen the stent except for the man whose family refused consent for rePTCA. Four were easily recanalised and their subsequent recoveries were uneventful while one had a re-occlusion and was actually sent to emergency CABG almost 10 days post-stent implantation.

The clinical restenosis rate of 9% overall is very gratifying as it is low enough to be comfortable. In fact in the DeNovo group, the restenosis rate is only 4.8%. Clinical restenosis is a practical way of assessing long-term stent results. Patients come for PTCA and coronary stenting either because of chest pain (angina) or a positive stress ECG. If after coronary stenting, they are asymptomatic with a negative stress ECG, it can be safely assumed stent is clinically patent and functional. Routine post-stent angiogram to look for angiographic restenosis, is not necessary and not practical. It is akin to conducting

routine angiogram for males aged 40-65 years to look for significant CAD – something impractical and rather unclinical.

There is then the question of follow-up rate which does affect the clinical restenosis rate. Perhaps because coronary stents are something new, the follow up rate is 85-90%, making the clinical restenosis rate of 7% fairly reliable.

Looking at the results, the best short and long term results are in those with stenting for DeNovo lesions in ≥ 3.0mm vessels. In such patients a higher success rate, a very low complication rate, with a clinical restenosis rate of only 4.8% was achieved. The most difficult group was those whose stents were placed for an acute threatened closure (about 25%). Here the success rate was lower with higher complications. This of course was attributed to the fact that the coronary stent was placed in a "beat-up" artery wall which was obviously red hot with very angry platelets waiting to generate thrombosis and complications. This will make a strong case for interventional cardiologists to place stents more readily for acute or threatened closures.

Finally, it is important to point out that the last 15 stents in this registry were placed with the new technique of stent-assisted high pressure balloon angioplasty (SAHBA) without anticoagulation and also without intravascular ultrasound guidance. This, of course is following the good work of Dr A Colombo[9] in Milan. The results thus far is very gratifying. Optimisation of stent implantation is possible with stent-assisted high pressure balloon angioplasty (SAHBA) and it obliviates the need for anticoagulation, thereby avoiding the risk of bleeding. Patients can be ambulated and discharged earlier, thereby saving costs. Although intravascular ultrasound (as advocated by Dr Colombo) is nice to have, our initial 15 patients in this SAHBA protocol has shown that perhaps it is not mandatory.

Acknowledgements

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References

1. Ng SC, O Hitam, Chen Sawatt. Percutaneous transluminal coronary angioplasty in the treatment of coronary artery disease - the local experience ; review of 100 cases. Med J of Mal 1991;46 : 59-67.

2. RITA Trial Participants. Coronary angioplasty versus coronary artery bypass surgery: the Randomised Intervention Treatment of Angina (RITA) trial. Lancet 1993;341 : 573-80.

3. King B III, Lembo NJ, Weintraub WS, *et al.* A randomised trial comparing coronary angioplasty with coronary bypass surgery. New Engl J Med 1994;331 : 1044-50.

4. Hamm CW, Reimers J, Ischinger T, Rupprecht HJ, Berger J, Bleifield W. A randomised study of coronary angioplasty compared with bypass surgery in patients with symptomatic multivessel coronary disease. New Engl J Med 1994;331 : 1037-43.

5. Parisi AF, Folland GD, Hartigan P. A comparison of angioplasty with medical therapy in the treatment of single vessel coronary artery disease. New Engl J Med 1992;326 : 10-6.

6. Serruys PW, Keane D. The bailout stent: is a friend in need always a friend indeed? Circulation 1993;88 : 2455-7.

7. Fischman DL, Leon MB, Bain DS, *et al.* A randomised comparison of balloon expandable-stent placement and balloon angioplasty in the treatment of coronary artery disease. New Engl J Med 1994;331 : 496-501.

8. Serruys PW, de Jaegere P, Kiemeneij F, *et al.* A comparison of balloon expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. New Engl J Med 1994;331 : 489-95.

9. A Colombo, Hall P, Nakamura S, *et al.* Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1995;91 : 1676-88.