

EARLY OUTCOMES FOLLOWING 797 CORONARY STENT PROCEDURES —

Our Experience at the Armed Forces Institute of Cardiology and National Institute of Heart Diseases Rawalpindi

AFSAR RAZA, AZMAT HAYAT, NADIR KHAN, A. H. SIDDIQI, K. RAJA, A. M. KYANI,
W. AHMAD, H. SHAFIQ, S. I. MAJEED, M. HAQ, S. AZIZ, M. M. H. NURI

SUMMARY

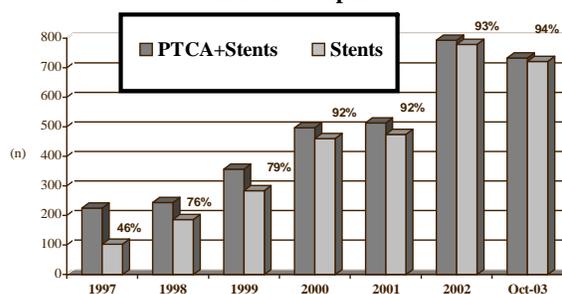
Objectives: To evaluate safety and in-hospital clinical end points in a consecutive series of 715 patients who underwent coronary stent implantation in our center. **Methods:** Armed Forces Institute of Cardiology coronary stents database was used to analyse retrospectively the procedural results, deaths, non-Q and Q wave myocardial infarction (MI) following 797 PTCA procedures in 715 patients during August 2002 - July 2003. **Results:** 1064 stents were deployed in 797 coronary artery lesions (Type B 59%, Type C 32% and Type A 9%) in 715 patients (87% males). Patients with single vessel coronary artery disease (SVCAD) were 44 %, double vessel coronary artery disease (DVCAD) 38 % and triple vessel coronary artery disease (TVCAD) 18%. Direct stenting was done in 734(69%) cases. Indications for stent implantation were 70% denovo, 12 % acute coronary syndrome (ACS), 8% total occlusion, 4% acute dissection, 3 % grafts, 2 % restenosis, and 0.8% subacute thrombosis (SAT). Over all procedural success was obtained in 786 (98.6 %) cases. In-hospital clinical events include 6 deaths (0.8 %), 12 MI (1.7 %), 8 SAT (1.1 %) and bleeding complications in 13(1.8%) cases. **Conclusions:** In our series, stent implantation is a safe and effective method of coronary revascularization with a low in-hospital morbidity and mortality even in diabetics, multivessel disease and in patients with acute coronary syndrome. Our data shows direct stenting is a preferable method in majority of cases with high primary success and low complication rate in the hands of experts.

INTRODUCTION

Coronary artery stenting has gained such a wide popularity that a large variety of stent makes are now available for use. Over the last one-decade stenting has almost replaced the conventional Balloon PTCA as our data also show that 94% of the PTCA procedures are now utilizing the coronary stents (Fig 1). Use of coronary stents have made the job of the interventionists and the lives of the cardiac patients easier and many cases that were previously thought to be surgical, are now being handled increasingly by the cardiologists on account of high primary success rate of stenting procedures¹⁻⁷. However on the other hand in-stent restenosis has emerged as a challenging problem that is yet to be solved⁸⁻¹⁶. Therefore, there is always a need to improve the skills and technology to

get the best possible procedural outcomes for the safety and care of the patients. Medical audit of such procedures is an important step towards innovation and hence we have designed our coronary stent database to analyse the outcomes of the stents procedure performed in our institute during the last year. Currently we have the data to show only the early outcomes and clinical events of the stents procedures performed over that period.

Fig 1. Yearly Incidence of PTCA and Stent procedures at AFIC Rawalpindi



* Armed Forces Institute of Cardiology and National Institute of Heart Diseases Rawalpindi

PATIENTS AND METHODS

Armed Forces Institute of Cardiology coronary stents database was used to analyse retrospectively the procedural results in 715 consecutive patients who underwent coronary artery stenting during August 2002 - July 2003. Patient characteristics are shown in table 1. Majority of the patients were males (87%). 25 % of patients were smoker, about a third had a positive family history and about the same number were hypercholesterolaemic. 16% patients were hypertensives and 7% were diabetics. 28% patients had previous MI, 6% previous PTCA and 2 % had CABG in the past.

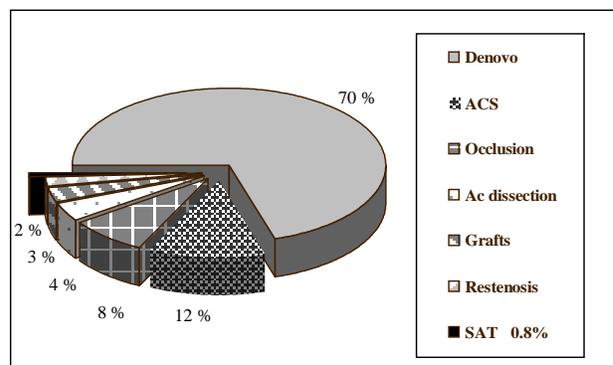
Table 1 Patients Characteristic

Age: 55+7 yrs	
Sex:	n (%)
Males	622(87)
Females	93(13)
Risk Factors:	
Hypercholesterolaemia	236(33)
Hypertension	114(16)
Smoking	179(25)
Family history	215(30)
Diabetes Mellitus	50(7)

RESULTS AND DISCUSSION

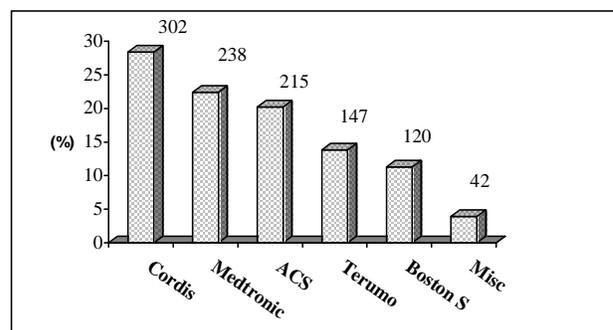
797 stents procedures were performed in 715 patients through right femoral approach using 6F angioplasty guiding system in majority of the patients. A total of 1064 stents were deployed during the procedures. The main indication was elective, utilizing 745(70%) stents in denovo lesions, 128(12 %) stents were deployed either in the setting of unstable angina or acute myocardial infarction, 85(8%) stents in total occlusions and 43(4%) stents were deployed to cover acute dissections. 32(3 %) stents were used in venous grafts and 22(2 %) stents were implanted to treat restenosis at the sites of previous stent or PTCA. 9(0.8 %) stents were deployed to treat SAT (Fig 2.)

Fig 2 Indications for Stent Implantation (n=1064)



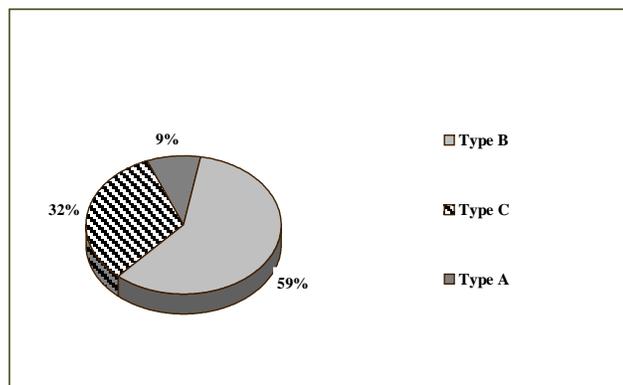
A total of 1064 stents were deployed in 797 coronary arteries. Various stents used are shown in Fig 3. Majority of the stents commonly used in our center were 302 (28.4%) Cordis (mainly Bx Velocity or Sonic), 238 (22.4 %) Medtronic (mainly Be Stents or S7) and 215(20.2%) ACS (mainly Penta or Tetra). 147(14%) Tsunami and 120(11.3%) Boston Scientific (mainly Express or Nir) was the next in order. Other 42 (3.9%) stents used in smaller number include Bio Divisio, Jomed, Direct stent, R stent, Hele and Phytus. The use of Cypher and Taxus are now gaining popularity but have not been used in greater number during the last year when the evidence was still in progress to support their use.

Fig 3. Stent Makes Used in AFIC During Aug 2002-Jul 2003 (n=1064)



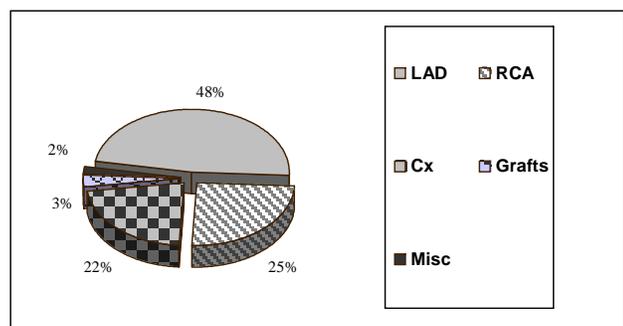
470(59%) lesions treated were Type B, 255(32%) Type C and 72(9%) lesions were Type A (Fig 4). Patients with single vessel coronary artery disease (SVCAD) were 314(44 %), double vessel coronary artery disease (DVCAD) 272(38 %) and triple vessel coronary artery disease (TVCAD) 129(18%).

Fig 4. Types of Target Lesions (n= 797)



382 (48%) lesions treated were located in LAD, 199(25%) in RCA, 175(22%) in Cx and 24(3%) in grafts. Sixteen (2%) lesions were located 5 in left main stem and 11 in major diagonal or trifurcation (Fig 5). Direct stenting was done in 734(69 %) of cases. 18% patients received Iib IIIa inhibitors especially those with acute coronary syndrome, small caliber /multivessel diabetics and those who had visible coronary thrombus during the procedure. Over all procedural success was obtained in 785 (98.6 %) cases. Unsuccessful procedures were mainly due to inability to cross the lesions (usually total occlusions).

Fig 5. Locations of Target Lesions (n= 797)



COMPLICATIONS

The patients case notes and the relevant documents were used to record procedural complications and major adverse cardiac events. In-hospital clinical events include 6(0.8 %) deaths, two of which were due to intracranial bleeding in patients on Iib IIIa receptor antagonists, three patients who died were already in cardiogenic shock after acute MI, and one patient died of extensive coronary dissection leading

to sudden cardiac arrest unresponsive to resuscitation. 12 (1.7%) patients developed non fatal MI (Q and non Q) post-procedure, 8(1.1 %) patients developed sub acute thrombosis six of which were successfully balloon dilated or restented. Two patients had major bleeding groin complications necessitating surgical intervention. 9 patients had bleeding complications requiring blood transfusions or conservative management. Two patients developed cardiac tamponad post procedure possibly as a result of coronary artery perforation but were successfully managed by prompt pericardiocentesis. Both of them were receiving Iib IIIa inhibitors. Two cases were recorded to have stents dislodged one of which was retrieved and the other got lost in the circulation with out a recognized clinical event.

CONCLUSIONS AND RECOMMENDATIONS

In our series of about eight hundred procedures, stent implantation is a safe and effective method of coronary revascularization. Our data show a low in-hospital morbidity and mortality in terms of early procedural outcomes and clinical events.

Our data show that primary success rate is higher even in diabetics, multivessel disease, type C lesions and in patients with acute coronary syndrome. Although use of Iib IIIa inhibitors is helpful in these settings as the evidence also suggests¹⁷⁻²⁰ but is not without the risk of bleeding as we have lost two patients with intracranial bleed. We strongly recommend that prior to the administration of Iib IIIa inhibitors the ACT should be well below 200 and any underlying bleeding state or liver dysfunction be carefully excluded. It is also important that the dose of heparin should also be adjusted accordingly.

At the time when mega trials on surgery versus PTCA were conducted, the stent era had just started with 1st generations of stents. Now when drug eluting stents and better designs and makes are available with more track ability together with antiplatelet regimens the trend in medical versus surgical practice/indications is also changing. As our data also show the sizable number of patients with diabetes and multivessel disease have been treated with success. Hence there is a need that we have our own trials to compare the long-term results of PTCA/Stents versus CABG in such groups of patients.

Our experience and data also show that direct stenting saves the cost and time of the procedure and perhaps also reduces trauma. We recommend that direct stenting should be attempted in most of the cases where coaxiality and support of the guiding catheter is stronger and the lesion is at a favorable location, not diffusely stenosed in a long segment. However the skill, expertise and the operator's confidence has also a strong bearing on the decision.

Unfortunately due to lack of research awareness and lack of cooperation from the patients, the follow-ups are very poor and difficult in our set up. Currently we do not have the complete data on long-term results in terms of MACE events and restenosis in our stents procedures. We are therefore revising and improving our database by encouraging and motivating the patients and our health services to provide assistance and cooperation to facilitate the follow-up record. In our next attempts we hope to provide more data and our original experience in the fields of interventions that remain and need to be explored.

REFERENCES

1. Serruys PW, de Jaegere P, Kieemeneij F, et al: A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. *N Eng J Med* 1994 331 :489-95
2. Fischman DL, Leon MB, Bairn DS, et al: A randomised comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. *N Engl J Med* 1994 331 :496-501.
3. Klugherz BD; DeAngelo DL, Kim BK, et al: Three-year clinical follow-up after Palmaz-Schatz stenting. *J Am Coll Cardiol* 1996 27:1185-91.
4. Kimura T, Yokoi H, Nakagawa Y, et al. Three-year follow-up after implantation of metallic coronary-artery stents. *N Engl J Med* 1996 334:561-66.
5. Macaya C, Serruys PW, Ruygrok P, et al.: Continued benefit of coronary stenting versus balloon angioplasty: one-year clinical follow-up of Benestent trial. Benestent Study Group. *J Am Coll Cardiol* 1996 27:255-61
6. Serruys PW, Emanuelsson H, Van der Giessen W, et al.: Heparin coated Palmaz-Schatz stents in human coronary arteries. Early outcome of the Benestent-II Pilot Study. *Circulation*
7. Sawada Y, Nosaka H, Kimura T, Nobuyoshi N: Initial and six months outcome of Palmaz-Schatz stent implantation: STRESS/Benestent equivalent Vs non-equivalent lesions (abstract). *J Am Coll Cardiol* 1996 27:252A
8. Illegass WB, Ohman EM, Califf RM: Restenosis: the clinical issues. In: Topol EJ editor. *Textbook of Interventional Cardiology*, 2nd. ed. Philadelphia: WB Saunders, 1994:15-35.
9. Dussaillant GR, Mintz GS, Pichard AD, et al.: Small stent size and intimal hyperplasia contribute to restenosis: a volumetric intravascular ultrasound analysis. *J Am Coll Cardiol* 1995 26:720-4.
10. Ikara Y, Hara K, Tamura T, et al.: Luminal loss and site of restenosis after Palmaz-Schatz coronary stent implantation. *Am J Cardiol* 1995 76: 117-20.
11. Gordon PC, Gibson CM, Cohen DJ, et al.: Mechanisms of restenosis and redilatation within coronary stents - quantitative angiographic assessment. *J Am Coll Cardiol* 1993 21: 1166-74.
12. Dangas G, Fuster V: Management of restenosis after coronary intervention. *Am Heart J* 1996 132:428-36.
13. Bairn DS, Levine MJ, Leon ME, et al.: Management of restenosis within the Palmaz-Schatz coronary stent (the US multicenter experience). *Am J Cardiol* 1993 71:364-6.

14. Tan R-C, Sketch MRJr, Tan ME, et al.: Is there an optimal treatment strategy for stent restenosis? (abstract) *Circulation* 199694:1-91.
15. Sridhar K, Teefy PJ, Almond DG, et al.: Long-term clinical outcome of patients with in-stent restenosis (abstract) *Circulation* 199694:1-454.
16. Dangas G, Fuster V: Management of restenosis after coronary intervention. *Amer Heart J* 1996 132:428-36.
17. A. Michael Lincoff, M.D., Robert M. Califf, M.D. et al ; Complementary Clinical Benefits of Coronary-Artery Stenting and Blockade of Platelet Glycoprotein IIb/IIIa Receptors *New England Journal of Medicine* July 1999: 341:319-327
18. L'Allier PL, Lincoff AM. Platelet glycoprotein iiB/iiiA inhibitors combined with fibrinolytic agents to treat acute myocardial infarction. *J Thromb Thrombolysis* 2001 Feb;11(1):83-91
19. Collet JP, Montalescot G, Lesty C, Mishal Z, Soria J, Choussat R, Drobinski G, Soria C, Pinton P, Barragan P, Thomas D. Effects of abciximab on the architecture of platelet-rich clots in patients with acute myocardial infarction undergoing primary coronary intervention. *Circulation* 2001 May 15;103(19):2328-31
20. Slovenia et al: Administration of abciximab before primary angioplasty in patients with elevated ST-segment myocardial infarction (MI): *American Journal of Cardiology* 2002; 90:533-535.