The First 100 Cases of Intracoronary Stent Implantation in Cardiac Center, King Chulalongkorn Memorial Hospital

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Abstract

At King Chulalongkorn Memorial Hospital from July 1994 to December 1996, 123 stents were implanted in 75 males and 25 females. Average age of the patients was 61.3 ± 9.6 years. Fifty-five per cent of the cases were performed in stable angina, 26 per cent in post myocardial infarction angina, 17 per cent in unstable angina and 2 per cent in acute myocardial infarction. Seventy stents were implanted in the left anterior descending artery, 25 in the left circumflex artery, 27 in the right coronary artery and one stent in the left main. The indications for stent implantation were abrupt closure in thirteen sites, mild dissection in 58, suboptimal dilatation in 19, restenosis in 23 and de novo in 10. Mean size of the stents was 2.99 ± 0.49 mm and mean inflation pressure was 11.9 atmosphere. Palmaz-Schatz stent was the most commonly used (53.6%) followed by AVE Microstent II (42.3%). There were 3 stents loss in the right femoral artery without any complications. Two stents were misplaced, one stent dislodged in the left main and needed emergency coronary bypass graft surgery. Two patients developed acute stent thrombosis and were successfully reopened with intracoronary urokinase. No patient had major bleeding complication, subacute thrombosis, acute myocardial infarction or death.

Conclusion: Stent implantation can be performed rather safely with a high success rate and minimal complications.

Key word : Stent, Coronary Angioplasty, First 100 Cases at King Chulalongkorn Memorial Hospital

Intracoronary stents are increasingly used as an adjunctive to balloon angioplasty. Because of the high rate of restenosis of conventional percutaneous coronary angioplasty (PTCA)[1-4], many

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devices[5-8] are introduced to decrease the resteno-sis rate but only intracoronary stent is the promising device and has proved to reduce the restenosis rate from 30 - 50 per cent to 10 - 30 per cent in 6 months [9-12]. In 1993, Flex stent or Gianturco-Roubin I was approved by the Food and Drug Administration of the United States of America for treatment of abrupt or threatened closure, a serious complication during PTCA. Palmaz-Schatz stent was approved for use as an adjunctive in PTCA a year later.

In King Chulalongkorn Memorial Hos-pital, the first stent was deployed in 1994 and after that, the number of intracoronary stents has in-creased rapidly. Three intracoronary stents were deployed in 1994 (2.6% of the PTCA cases) up to 80 cases in 1996 (35.9% of the PTCA cases). This study was introduced to evaluate the indication, procedural success and complication rate in the first 100 cases of intracoronary implatation.

PATIENTS AND METHOD

All patients who had angioplasty with attempted intracoronary stent implantation at King Chulalongkorn Memorial Hospital from 1994 to 1996 were included in the study. History, indication for revasclarization, angiographic information, pro-cedural success and complications were recorded prospectively.

A successful case was defined as a patient who had less than 50 per cent post angioplasty resi-dual stenosis of the attempted lesion without major adverse events. The adverse events were recorded as acute myocardial infarction (MI), emergency coronary artery bypass graft (CABG) or death during the procedure or hospitalization.

Statistical analysis

For the analysis of consecutive data, stu-dent T-test was used to assess the differences between the two groups. The results were expressed as mean ± SD. Nominal variables were expressed as counts and percentages and were compared by the chi-square test. All results were considered sta-tistically significant when the p-value was less than 0.05.

RESULTS

One hundred patients had 123 intracoro-nary stents implantation from 1994 to 1996. The data were analyzed by comparing then with conven-tional PTCA. Fig. 1 shows the number of cases of
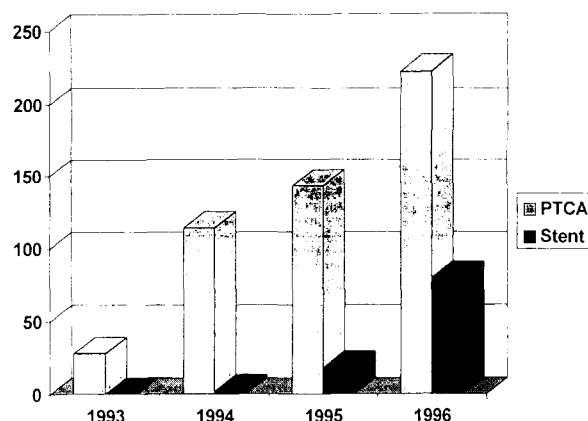

Fig. 1. **Number of percutaneous coronary angio-plasty (PTCA) and intracoronary stent im-plantation in King Chulalongkorn Memo-rial Hospital from 1993 - 1996.**

PTCA and intracoronary stent implantation from 1993 to 1996. There was a rapid increase of use of intracoronary stent from 3 cases in 1994 to 17 cases in 1995 and up to 80 cases in 1996. The ratio of intracoronary stent implantation to conventional PTCA increased from 2.6 per cent in 1994 to 11.7 per cent in 1995 and 35.9 per cent in 1996 respec-tively. The baseline characteristics of the patients are shown in Table 1. There was no statistically sig-nificant difference in age, sex, smoking, hyperten-sion, diabetes, previous PTCA, previous CABG, previous MI and left ventricular ejection fraction except for the lesser cases of dyslipidemia in the stent group compared to the conventional group. Stable angina pectoris was the most common indi-cation for PTCA in both groups followed by post MI angina, unstable angina and acute MI (Table 2). Most of the cases had single vessel disease and the most common target vessel for PTCA was left ante-rior descending artery in over 50 per cent (Table 3). Table 4 demonstrates the indications for stent deployment. Minimal dissection without flow dis-turbance was the most common indication for stent-ing. Type of stent used is shown in Table 5 and size and length of stent are shown in Table 6. Palmaz-Schatz stent with 3.00 mm diameter was the most frequenctly used. Median length of stent was 18 mm. Overall results are shown in Table 7. The stent group, maximal pressure dilatation was higher than

Table 1. Baseline characteristics of patients in PTCA group compared with the stent group.

	PTCA	Stent
No. of patients	361	100
Age (years)	61.0 ± 9.6	61.3 ± 9.6
Sex ; M : F	2.1: 1	3 : 1
Smoking (%)	39.9	43.0
Hypertension (%)	45.5	50.5
Diabetes Mellitus (%)	35.9	36.2
Dyslipidemia (%)	60.1*	39.5
Previous PTCA (%)	31.8	35.0
Previous CABG (%)	3.6	2.0
Previous myocardial infarction (%)	34.7	33.0
LVEF (%)	59.5 ± 17.5	54.5 ± 19.5

PTCA - percutaneous transluminal coronary angioplasty
CABG - coronary artery bypass graft
LVEF - left ventricular ejection fraction
* P < 0.05

Table 2. Indications for coronary angioplasty and stenting.

	PTCA (%)	Stent (%)
Stable angina	52.4	55.0
Unstable angina	17.4	17.0
Acute myocardial infarction	3.3	2.0
Post infarction angina	26.9	26.0

Table 3. Number of vessel and vessel distribution for coronary angioplasty and stenting.

	PTCA (%)	Stent (%)
1 - vessel disease	54.6	53.0
2 - vessel disease	31.2	38.0
3 - vessel disease	14.2	9.0
Left main	1.1	1.0
Saphenous vein graft	0.3	0
Left anterior descending a.	70.5	70.3
Left circumflex a.	42.6	42.6
Right coronary a.	45.7	45.7

Table 4. Indications for stent deployed.

Indication	Cases	%
Abrupt closure	13	10.6
Mild dissection	58	47.2
Sub-optimal result	19	15.4
Restenosis	23	18.7
De novo	10	8.1

the conventional PTCA group and residual stenosis was less than the conventional PTCA group. Overall success rate was over 90 per cent in both groups. There were 2 cases who developed acute stent thrombosis and were successfully opened with intracoronary thrombolytic agent and re-PTCA. Four stents were dislodged, 3 in the right femoral artery without any subsequent complication but 1 stent in the left main coronary artery needed emergency CABG. No patient in the stent group died. Table 8 shows the complications from the stent implantation.

Referring to the use of antithrombotic agents following stent implatation, nearly all patients

Table 5. Type of stent used.

Type	%
Palmaz-Schatz stent	53.6
: Bare stent	51.2
: Stent delivery system	2.4
AVE Micro stent II	42.3
Wall stent	1.7
Gianturco Roubin Stent I	2.4

Table 6. Size and length of stent used.

Size (mm)	Number	Length (mm)	Number
2.25	2	7	9
2.50	20	10	6
2.75	14	12	5
3.00	63	15	40
3.25	2	18	57
3.50	19	20	3
4.00	2	22	2
4.50	1	30	1

Table 7. Results of percutaneous coronary angioplasty (PTCA) compared with intracoronary stent.

	PTCA	Stent
Percent stenosis - Pre-angioplasty	91.5	90.0
Percent stenosis - Post-angioplasty	27.5	4.37*
Maximal inflation pressure used (atm)	8.2	11.9*
Average balloon or stent size (mm)	2.48	2.99*
Lesion success rate	95.5	94.3
Case success rate	91.0	94

* P value < 0.05

Table 8. Complications of intracoronary stent implantation

Complications	No. of cases
No. of patients	100
Acute stent thrombosis	2
Cardiac tamponade	1
Stent dislodged	4
: in right femoral artery	3
: in left main coronary a.	1
Improper placement	2
Toe gangrene	1
Groin hematoma	1
Guidewire broken	1
Can't pass stent across lesion	2

Table 9. Anti-platelet and anti-coagulant used post stent implantation.

	%
Aspirin	100
Ticlopidine	97
Heparin overnight	70
LMWH	35
Warfarin	3

LMWH - low molecular weight heparin

received aspirin combined with ticlopidine for one month. Over-night intravenous heparin was infused in 70 per cent of cases while another 35 per cent continued with subcutaneous low molecular weight heparin for 1 week. Only 3 cases in 1994 received warfarin. Table 9 shows the antithrombotic agents used after stent implantation.

Sixteen cases in the stent group were prospectively followed for evaluation of restenosis. Only 12.5 per cent had angina pain and 43.8 per cent had positive exercise stress test. Angiographic restenosis at 6 months follow-up was 25 per cent in this group of patients.

DISCUSSION

The number of intracoronary stent implantation has been increasingly used at an alarming rate during the past few years including in our center. Because of the high restenosis rate of conventional PTCA, stent was intended to be a new device to reduce restenosis. This study was not designed to detect restenosis rate but to evaluate the indication, immediate result, safety and efficacy of the stent implantation by comparing it with the conventional PTCA. There was no statistically significant difference in terms of success rate of stent implantation when compared with conventional PTCA but stent deployment can produce larger minimal luminal diameter and less residual stenosis with accepted complications. The serious complications were acute stent thrombosis and stent dislodgement especially in the coronary tree. Fortunately, no subacute stent thrombosis developed in this study probably because of the use of aspirin combined with ticlopidine, in almost all cases. Heparin and low molecular weight heparin were used in the cases of major dissection, threatened or abrupt closure and thrombus presenting before or during PTCA. No more warfarin is in use now. Overall success rate is over 90 per cent similar to conventional PTCA with no deaths.

There are several important points relevant to the use of stent. First, the indications for stenting; should include suitable vessels in every case or in some cases, minor dissection without flow disturbance, sub-optimal result of PTCA, restenosis lesion, calcified and long lesion. Secondly, how to deal with the vessel with a diameter less than 2.5 mm? Thirdly, which stents should be selected for which lesion. Fourthly, pre-mounted or bare stent, which one is better? And finally, the cost of the procedure, is it more cost-effective than the conventional PTCA, especially in developing countries.

SUMMARY

Intracoronary stent implantation can be performed rather safely with a high success rate and minimal complications. Preliminary data suggests that the stent group has a lower restenosis rate than conventional PTCA group but there is a need for further case studies and a longer period of time to confirm the results.

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การใส่ขดลวดขยายเส้นเลือดหัวใจ 100 รายแรก ที่ศูนย์โรคหัวใจ โรงพยาบาลจุฬาลงกรณ์

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ระหว่างเดือนกรกฎาคม พ.ศ. 2537 ถึง ธันวาคม พ.ศ. 2539 ผู้ป่วย 100 รายได้รับการใส่ขดลวดขยายหลอดเลือดหัวใจจำนวน 123 ขดลวด อายุเฉลี่ยของผู้ป่วยเท่ากับ 61.3 ± 9.6 ปี ร้อยละ 55 ของผู้ป่วยอยู่ในภาวะ stable angina, ร้อยละ 26 เป็น post myocardial infarction angina, ร้อยละ 17 เป็น unstable angina และร้อยละ 2 เป็น acute myocardial infarction ขดลวด 70 ขดลวดถูกใส่ในเส้นเลือดแดง left anterior descending, 25 ขดลวดใส่ในเส้นเลือดแดง left circumflex, 27 ขดลวดในเส้นเลือดแดง right coronary และ 1 ขดลวดใส่ใน left main ข้อบ่งชี้ในการใส่ขดลวดขยายหลอดเลือดคือ เส้นเลือดอุดตันทันทีหลังทำบอลลูน (13 ขดลวด), เส้นเลือดปริแล็กน้อย (58 ขดลวด), ได้ผลไม่สมบูรณ์หลังจากทำบอลลูนอย่างเดียว (19 ขดลวด), เส้นเลือดมีการตีบซ้ำหลังจากที่เคยทำบอลลูนไปแล้ว (23 ขดลวด) และผู้ทำตั้งใจใส่ไว้ก่อนทำบอลลูน (de novo) (10 ขดลวด) ขนาดเฉลี่ยของขดลวดเท่ากับ 2.99 ± 0.49 มม. และความดันเฉลี่ยที่ใช้ในการขยายขดลวดเท่ากับ 11.9 atmosphere ขดลวดชนิด Palmaz–Schatz เป็นขดลวดที่ใช้บ่อยที่สุด (ร้อยละ 53.6) รองลงมาเป็น AVE Microstent II (ร้อยละ 42.3) ขดลวด 3 ขดลวดหลุดในเส้นเลือดแดง femoral โดยไม่มีภาวะแทรกซ้อนตามมา ขดลวด 2 ขดลวดใส่ในตำแหน่งที่ไม่เหมาะสม และมี 1 ขดลวดหลุดอยู่ใน left main ซึ่งจำเป็นต้องรับการผ่าตัดเส้นเลือดโดยรีบด่วน ผู้ป่วย 2 รายเกิดการอุดตันของขดลวดอย่างเฉียบพลันและสามารถแก้ไขด้วยการใช้ยา urokinase ร่วมกับการทำบอลลูนซ้ำ ไม่พบภาวะเลือดออกที่สำคัญ การเกิดขดลวดอุดตันในภายหลัง กล้ามเนื้อหัวใจตาย หรือผู้ป่วยเสียชีวิต

    บทสรุป : การใส่ขดลวดขยายเส้นเลือดหัวใจสามารถทำได้อย่างปลอดภัยโดยมีอัตราใส่สำเร็จค่อนข้างสูงและมีภาวะแทรกซ้อนเกิดขึ้นน้อย

คำสำคัญ : ขดลวดขยายหลอดเลือดหัวใจ, การทำบอลลูนขยายหลอดเลือดหัวใจ, ร้อยรายแรกที่โรงพยาบาลจุฬาลงกรณ์