

ROLE OF BARE-METAL STENTS IN TREATMENT OF UNCOMPLICATED LESIONS IN SMALL CORONARY ARTERIES (LESS THAN 3.0 MM).

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Perkütan koroner girişimlerin (PKG) %30 dan fazlası, küçük damarlara uygulanmıştır. Koroner arter hastalığı (KAH) bulunan 426 hastada yapılmış bu randomize çalışmanın amacı, küçük koroner arterlerde (2,2-3,0 mm) restenozu önlemede, sadece perkütan transluminal koroner anjiyoplasti (PTKA) yapılanlarla kıyaslandığında çıplak-metal stentler (BMS) etkinliğini tayin etmek idi. Hastalar, PTKA veya stentte kateter laboratuvarında randomize edildi. Randomizasyon sonrası, 214 hasta PTKA ya alındı, 212 hastaya BMS implante edildi. Hastaların yaş ortalaması 58+11 yıl idi ve %16 si kadindi. Ortalama total kolesterol düzeyi 211mg/dl ve hastaların %8 i diyabetikti. Ortalama arteriyel damar çapı PTKA grubunda 2.45±0,25 mm ve BMS grubunda 2.43±0,27 idi. Tüm hastalar, girişimden sonra en az 3 ay klopidogrel aldı. Aspirin sürekli verildi.

Anjiyografik işlem başarıları PTKA hastalarında %85.5, BMS hastalarında %96.2 idi (p<0,001).

INTRODUCTION

During the last decade numerous coronary interventional trials have shown a reverse relationship between the size of dilated vessel and rate of restenosis and major adverse cardiac events (MACE) after percutaneous coronary interventions (PCI)¹. This is primarily due to substantial limitation of the capacity to adaptation after the dilation⁴⁵.

After the introduction into the praxis of drug-eluting stents with antiproliferative agents (sirolimus, paclitaxel, everolimus, dexamethason)⁶⁷⁸ it looked as if the use of bare-metal stents (BMS) and/or percutaneous transluminal coronary angioplasty (PTCA) alone belongs to history. The advantage of using stents with antiprolife-

Pespese PKG (PTKA veya stent) yapılanlarda anjiyografik işlem başarıları her 2 grupta da %100 idi. Hastanede majör kardiyak olay hızı PTKA grubunda %3.7 ve BMS grubunda %2.8 idi (anlamli değil). Altı aylık takipte restenoz hızı ve hedef damara tekrarlanan revaskülarizasyon (HDR) PTKA grubunda %24.3 ve BMS grubunda (%15.6) idi (p=0,034). Takip sırasında toplam komplikasyon hızı, hedef damar başarısızlığı ile ilgili, PTKA grubunda %36.9 ve BMS grubunda %26.9 idi.

Sonuç olarak, küçük damarlarda, PTKA ile kıyaslandığında, koroner stentingin daha düşük restenoz ve daha iyi akut ve uzun dönem sonuçlarına sahip olduğu görülmüştür.

Anahtar kelimeler: Küçük damar koroner arter hastalığı, Stent, PTKA, Restenoz, Perkütan koroner girişim, Majör kardiyak olay

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native agents was maximal in the vessels with diameter less than 3.0 mm⁹, whereas after the implantation of BMS in the vessels of small size resulted in more frequent occurrence of restenosis and a higher MACE rate⁷⁸.

Interventions on small coronary vessels are carried out in 30-50% of all PCI¹⁰¹¹⁻¹², so PTCA and stenting in small coronary arteries (CA) are applied in 600,000-1,000,000 patients annually. However expenses for DES are not covered by insurance companies in many European and Asian countries because of their expensive cost. Therefore, the use of BMS remains to be a relevant issue even in the interventions on small CA¹³. Retrospective analysis showed that BMS could be superior to PTCA alone in the interventions on small vessels¹⁴. Larger expenses of stenting compared to PTCA¹⁵ were compensated by the lower need of repeat PCI, making stenting more cost effective in the long-term follow-up¹⁶¹⁷. However, all stents tried in 90's are

no more produced⁸¹². And the data on long-term results of BMS, especially in small CA, is scarce. Therefore we tried to evaluate the utility of presently available bare-metal stents^{1819,20} in interventions on coronary arteries with diameter less than 3.0 mm.

MATERIAL AND METHODS

Patients selection criteria: Patients with angina pectoris or stress-induced ischemia were included into the study. All patients had hemodynamically significant stenoses (more than 50%) in native CA with diameter > 2.2 mm and < 3.0 mm. **Exclusion criteria** were as follows: Any prior target vessel revascularization (TVR: PCI or coronary artery bypass graft (CABG) surgery), first seven days after Q-wave acute myocardial infarction (MI). Patients with aspirin or clopidogrel resistance, haemorrhagic stroke or gastrointestinal bleeding within last 6 months were also excluded from the study. **Angiographic exclusion criteria** were: Existing left main coronary artery lesion, three-vessel disease, bifurcation lesion, ostial left anterior descending (LAD), left circumflex (LCx) or right CA (RCA) lesion, reference diameter (RD) of target lesion larger than 3.0 mm, angular lesion with the angle more than 60 degrees, and angiographic signs of acute intracoronary thrombosis of target vessel. The present study was randomized: According to the ethic protocol, all patients, included into the study provided informed consent before intervention. After guiding catheter placement and successful introduction of intracoronary guide wire distal to the target lesion the patients were randomized to PTCA alone or BMS stent implantation.

Envelopes with computer predetermined therapy method directions were opened to carry out the respective procedure.

Totally, in the period from 2002 till 2003 four hundred twenty six patients were included into the study. Among them 212 patients underwent bare-metal coronary stenting, and 214 - PTCA alone. **Pharmacological support of intervention:** All patients received regularly aspirin 100-325 mg daily starting after admission to the hospital. Clopidogrel (Plavix) was administered one day prior to intervention in dose of 75 mg, or - if it was given 6 hours before intervention - the loading dose was 300 mg. After PCI Clopidogrel was administered in dose 75 mg daily and the patients took it for at least 3 months. At beginning of intervention unfractionated heparin was injected to all patients as a bolus 70 U/kg (up to 5000 U) through catheter into the aorta and then each hour 35U/kg (up to 5000 U) until the end of intervention. Heparin efficacy was evaluated by acti-

vated clotting time (ACT) which was prolonged more than 300 sec. Intracoronary nitroglycerin was made in dose of 200 mkg directly before balloon dilation, stent deployment and in the end of PCI.

Angiographic analysis was made by determining lesion morphology according to the American College of Cardiology and American Heart Association (ACC/AHA) classification²¹. Quantitative coronary analysis (QCA)²² was made by means of Quantcor QCA (Siemens, Germany) and QCA-Plus (Sunders Systems, USA), quantitative analysis comprised of minimal luminal diameter (MLD) before PCI, RD, stenosis percentage (MLD to RD relation), stenosis length. MLD changes were determined after balloon predilation, at the end of PCI (PTCA or stenting), and after 6 months follow-up. MLD Acute Gain (Acute Gain = MLD after PCI minus MLD before PCI); MLD Late Loss (MLD after PCI minus MLD after 6 months); final MLD (MLD after 6 months minus MLD before PCI) and Late Loss index (Late Loss / Acute Gain).

Stent characteristics: Balloon expandable bare-metal stents "BiodivYsio" (Biocompatibles Ltd, United Kingdom), "Ephesos" (Nemed Ltd Turkey), "Tais" (Nemed Ltd, Turkey), "Biodiamond" (Plasmachem GmbH, Germany), were used in the present study. Nominal diameter of the used stents was 2.0-3.0 mm.

Stenting techniques: Stents were implanted by a single dilation in 20-30 sec with nominal pressure applied (6-8 atm). If direct stenting was available, balloon predilation was not performed. Stent and arterial wall congruency were reached by subsequent dilations with pressure 9-14 atm. **Definition of procedural success:** According to generally accepted definitions¹²²¹. PCI was considered successful if final stenosis was less than 30% diameter, and TIMI 3 flow was achieved. In PTCA group urgent stenting was performed in case of significant residual dissection (more than 5 mm) or TIMI flow after PTCA less than 3.

Evaluation of direct, in-hospital and long-term results: In all patients demographic data were collected, to include angina pectoris anamnesis, prior MI and presence of atherosclerosis risk factors. By non-invasive investigation angina functional class, and clinical meaning of coronary lesions were assessed. At the diagnostic coronary angiography quantity and location of coronary lesions and QCA were performed.

The results of PCI were assessed by 3 end-points: Primary end-point - event free survival at the 6 months follow-up which was assessed by the occurrence of the determined MACE (overall mortality, frequency of MI, repeated PCI at the target ves-

Table 1: Basic clinical characteristics

	PTCAgroup(n=214)	BMS group (n=212)	
Age (yrs), range	57±11;	59*11; 31-72	ns
Females (%)	17	15	ns
Diabetes melitus (%)	7	8	ns
Smokers (%)	22	29	ns
Hypercholesterolemia	35	34	ns
Cholesterol level	212±	209±46	ns
Blood pressure (mm)			
Systolic	145±	147±27	ns
Diastolic	76±	72±12	ns
Prior MI (%)	30	29	ns

PTCA - balloon angioplasty, BMS - bare-metal stents, MI - myocardial infarction, ns - nonsignificant (difference)

Table 2: Baseline angiographic parameters

	PTCA group (n=214)	BMS group (n=212)	P
Left ventricular ejection fraction (%)	59±15	61±14	ns
Quantity of vessels involved (%)			
Single-vessel disease	73	71	ns
Two-vessel disease	25	26	ns
Three-vessel disease	2	3	ns
Target vessel (%)	248	265	-
Left anterior descending CA	58.0	54.9	ns
Left circumflex CA	19.9	18.1	ns
Right CA	22.1	27.0	ns
Lesion type according ABC AHA/ACC classification (%)			
Lesion A-B1 (%)	60.1	49.1	0.02
Lesion B2 (%)	33.8	41.1	ns
Lesion C (%)	6.1	9.7	ns
VILD (mm)	0.59±0.38	0.53±0.33	ns
RD (mm)	2,45±0,25	2,43±0,27	ns
Stenosis diameter (%)	76±14	78±16	ns
Lesion length (mm)	11.8*7.1	12.5±6.9	ns

CA-coronary artery, MLD-minimal luminal diameter, RD -reference diameter, AHA/ACC-American Heart Association/American College of Cardiology,

el and rescue CABG surgery). All patients after discharge were contacted by telephone to identify occurrence of long-term adverse events (death, non-fatal MI, recurrent angina and TVR). In case of recurrent angina all patients underwent coronary angiography.

Secondary end-point was event in-hospital outcomes, included direct angiographic results and event-free survival before hospital discharge. In-hospital MACE were determined by overall mortality, frequency of non-fatal MI, repeated PCI at the target vessel and rescue CABG surgery.

Subacute complications were determined as events at the first 30 days after intervention. Subacute occlusion was determined as a total occlusion of target vessel outside catheter laboratory at first 30 days after intervention. Early restenosis was defined

if it occurred at first 30 days after PCI if stenosis was more than 50%.

Third end-point - angiographic results in 6 month after PCI, which were evaluated by the frequency of binary hemodynamically significant restenosis (re-narrowing for more than 50%) of the target lesion. QCA was done in 120 patients in PTCA group and in 125 BMS patients, in whom coronary angiography was repeated albeit clinical signs of restenosis were absent.

Statistical analysis: All data is presented as mean ± Standard deviation. In evaluation of qualitative data the "Chi-square" test or Fisher's exact test were used. The parameters were matched by z-test with Yates correction Fisher's exact test. End-points analysis was made by unpaired binary Student's t-test. Kaplan-Meier curve was obtained for survival

Table 3: Direct results of interventio

	PTCA group	BMS group	F
Procedural success	85.5	96.2	0.001
Urgent additional	14.5	0.5	0.001
Overall success (%)	100	100	ns
Total number of	24(1.16)	265(1.25)	0.05
Final flow			
TIMI - III (%)	95.5	98.6	ns
TIMI-II (%)	4.7	1.4	ns
PCI in one	84.1	75.0	0.05
Stents quantity per	0.15	1.25	0.001
Ballon/vessel	1.06±0.12	1.13±0.12	0.001
RD after intervention	2.51±0.27	2.49±0.29	ns
MLD after	2.03±0.45	2.37±0.49	0.001
Resulting stenosis	19.1±11.5	4.8±4.5	0.001
Acute gain (mm)	1.44±0.55	1.84±0.64	0.001

PTCA - balloon angioplasty, BMS - bare-metal stents, CA - coronary artery, MLD - minimal luminal diameter, RD - reference diameter, AHA/ACC - American Heart Association/American College of Cardiology, TIMI - classification of flow restoration after revascularization, ns- nonsignificant (difference)

Table 4: In-hospital results

	PTCA group	BMS group	F
Death (%)	0	0	ns
Non-fatal MI (%)	1.9	0.9	ns
Repeated PCI of target vessel (%)	1.9	0.9	ns
Urgent CABG (%)	0.5	0.5	ns
Profound haemorrhage(%)	0.9	1.4	ns
Overall complications rate (%)	3.7	2.8	ns

PTCA - balloon angioplasty, PCI - percutaneous coronary interventions, BMS - bare-metal stents, MI - myocardial infarction, CABG - coronary artery bypass grafting, ns- nonsignificant (difference)

analysis. Group differences in patients without MACE were assessed by Cox F-test. Representativity assessment of the obtained results was made for all kinds of analysis. Significance level was considered if $p < 0.05$. Statistic software "Statistica for Windows Release 6.0" (USA) was used for analysis.

RESULTS

Among 426 patients, included into the study, there were 358 males (84%) and 68 females (16%). The groups were rather homogenous regarding clinical characteristics. Basic clinical parameters are presented at the Table 1.

Basal angiographic characteristics were very similar in both groups (Table 2), except for slightly greater proportion of uncomplicated lesions (type A -B1) in PTCA group in comparison with BMS group ($p = 0.016$); and a trend for relatively smaller MLD in stenting group

Direct results: Direct results of PCI are presented in the Table 3. Among patients, in whom coronary

stenting had been initially intended, in eight patients stent deployment was unsuccessful (3.8%) and they underwent PTCA alone. On the other side, in 31 patients, randomised to PTCA (14.5%), at least 1 stent was implanted due to development of complications or suboptimal PTCA results. Stent length in BMS group was 14.2 ± 6.4 mm. Thus, intended type of PCI yielded markedly better direct results in BMS group. All patients survived in both groups and at the end PCI were done with 100% success. In-hospital results

In-hospital outcomes are presented in the Table 4. There was no hospital lethality in either group. Nonfatal acute MI occurred in 4 patients in PTCA group (1.9%) and in 2 patients in BMS group (0.9%) - difference is not statistically significant ($p = 0.69$). In all patients with acute MI further cardiac catheterization was performed with PCI on infarct-related artery and infusion of glycoprotein IIb/IIIa inhibitors. Apart from that repeated PCI was performed in 1 patient with recurrent angina in PTCA

Table 5: Clinical results at 6 months follow-up

	PTCA group	BMS group	P
Death (%)	1.9	1.4	ns
Nonfatal MI (%)	5.1	3.8	ns
Restenosis and repeated PCI in target vessel rate (%)	24.3	15.6	0.034
CABG surgery (%)	5.6	6.1	ns
Total rate of repeated TVR (%)	29.9	21.7	0.068
Recurrent angina due to changes innontarget vessel/lesion (%)	15.0	12.7	ns
Total rate of MACE due to changes on target lesion (%)	36.9	26.9	0.035

PTCA - balloon angioplasty, PCI's - percutaneous coronary interventions, BMS- bare metal stents, MI - myocardial infarction, TLR - target vessel revascularization, CABG - coronary artery bypass grafting, MACE - major adverse cardiac events, ns - nonsignificant (difference)

Table 6: Angiographic control at 6 months

	PTCA group	BMS group	P
Quantity of patients	172	158	-
Quantity of segments	199	197	-
Impaired target segment	60	41	-
Unimpaired target segment	139	156	-
Frequency of repeat target lesions in subgroup of patients, undergone control angiography	30.2%	20.8%	0.044
Quantitative coronary analysis:		2.48±0.27	ns
RD (mm)	2.46±0.28		
MLD (mm)	1.41±0.47	1.78±0.53	0.001
Late loss (MM)	0.62±0.40	0.59±0.38	ns
Final vessel diameter (mm)	0.82±0.58	1.25±0.73	0.001
Late loss index	0.43±0.26	0.32±0.21	0.001

PTCA - balloon angioplasty, BMS bare metal stents, MLD - minimal luminal diameter, RD - reference diameter, ns - nonsignificant (difference)

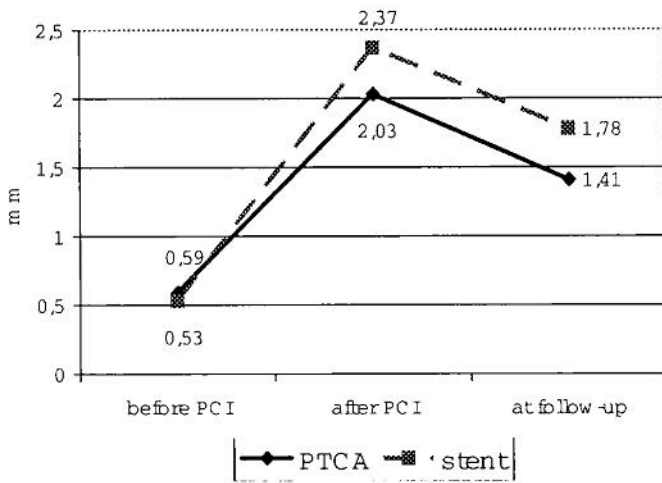
group (0.5%). Rescue CABG surgery was required in 1 patient in BMS (0.5%) and in 1 patient in PTCA group (0.5%), difference nonsignificant). Profound haemorrhages, which required haemotransfusion, occurred in 3 patients in BMS (1.4%) and in 2 patients in PTCA group (0.9%). Thus, overall in-hospital event free survival in PTCA group was 96.3% and in BMS group 97.2% (difference nonsignificant, p=0.80).

6 months follow-up: Long-term follow-up was carried out until MACE (death, MI, repeated revascularizations) or until 6 months (Table 5). During follow-up 4 patients in PTCA (1.9%) and 3 patients in BMS (1.4%) group died (nonsignificant, p=0.98). Non-fatal MI occurred in 11 patients in PTCA (5.1%) and in 8 patients in BMS (3.8%) group (nonsignificant, p=0.678). Angiographically proven binary restenosis developed in 52 PTCA patients (24.3%), which was significantly more frequent than in BMS patients (33, 15.6%; p=0.034). Clinical features of restenosis comprised of recurrent angina and/or nonfatal MI. All patients with restenosis at the target segment were

revascularized again. Due to inavailability of data on target vessel in dead patients, it was not included in restenosis analysis. Apart from that, in 12 PTCA patients (5.6%) and in 13 BMS patients (6.1%) CABG was carried out (nonsignificant, p=0.989). Thus, total MACE at the 6 months follow-up occurred in 79 patients in PTCA group (36.9%), which was significantly more frequent, than in BMS group (57 patients, 26.9%, p=0.035). Apart from events, related to target lesion, in 32 PTCA (15.0%) and in 27 BMS patients (12.7%) recurrent angina occurred, which was due to atherosclerosis in other, non-target vessel segment as it was revealed by repeated coronary angiography.

Long-term angiographic analysis: Repeat angiography was made in all patients, in whom recurrent angina or nonfatal MI developed. Apart from that in 120 patients in PTCA group and in 125 BMS patients coronary angiography was repeated despite the absence of clinical signs of coronary insufficiency. Thus, repeated coronary angiography was performed in 172 PTCA patients (80.4%) and in 158 BMS

Figure 1: Changes of minimal lumen diameter in target lesion



patients (74.5%, difference nonsignificant). The number of segments with binary hemodynamically significant restenosis (50%) was 30.2% in PTCA and in 20.8% in BMS group ($p=0.044$; analysis in subgroups with control coronary angiography). At the QCA all patients showed significant Late Loss in MLD. However, MLD of target vessel segment was significantly smaller in PTCA group than after stenting (1.41 ± 0.47 mm vs 1.78 ± 0.53 mm respectively, $p=0.001$). Late Loss were similar in both groups (0.62 ± 0.40 mm and 0.59 ± 0.38 mm respectively). Final Diameter of target vessel was significantly higher in BMS than PTCA patients (1.25 ± 0.73 mm vs 0.82 ± 0.21 mm respectively, $p=0.001$). The results of control coronary angiography are shown at the Table 6 and Figure 1.

DISCUSSION

The idea of using coronary stents was intended in order to prevent and treat abrupt vessel closure after PTCA^{23,24}. However, since the initial stent implantations, the indications for stenting have markedly broadened²⁵. It has been found out, that coronary stents can be an efficient tool in the restenosis prophylaxis, given the fact, that restenosis has been the major limitation of PTCA⁷.

More than 10 years ago the efficacy of coronary stenting in reduction of restenosis rate has been proven by numerous controlled randomized trials²⁶. However, the majority conclusions have been made on prevention of restenosis in discrete short lesions in vessels with luminal diameter more than 3.0 mm^{4,5,26}. Other studies demonstrated the utility of stents in various anatomical conditions and they showed relatively modest results in comparison with PTCA^{7,25}. Regarding coronary arteries of small calibre, the increased risk of thrombosis and uncer-

tainty of the investigators towards long-term outcomes in such arteries resulted in exclusion of PCI on small arteries from randomized clinical trials. Only in late 90-s rare studies in Europe, America and Japan dealt with PCI on small arteries^{27,28,29}.

Nevertheless, the interventions on small CA (less than 3 mm) account for 30-60% of the whole number of PCI^{13,30}. small CA can be found most frequently in females, suffering from diabetes mellitus, in patients with small body surface index. As is known, the two most strong predictors of restenosis are lesion length and vessel diameter^{31,32}. Probability of restenosis development was often calculated based upon only these two parameters¹⁰. Using restenosis model based on Late Loss Index (Late Loss Index = Late Loss/Acute Gain) some investigators suggested modest advantages of coronary stenting in small CA¹².

Elezi et al² analyzed 2602 patients after successful Palmaz-Schatz stenting in 3 relatively equal groups according to stented vessel size. Proportion of patients without cardiovascular complications in 1 year follow-up was as follows: if diameter of stented vessel was less than 2.8 mm it was 69.5%, in the group of patients with stented vessels from 2.8 till 3.2 mm event free survival was 77.5% and if more than 3.2 mm it was 81% (difference significant between each group, $p<0.001$). Late loss was similar in all three groups, restenosis rate was significantly higher in small arteries group (38.6%, 28.4% and 20.4% respectively, $p<0.001$). If patients divided into subgroups according to diabetes mellitus or complex lesions (B2-C) there was more pronounced differences in restenosis rate between patients with and without diabetes, between patients with complex or simple lesions. Investigators concluded, that if the lesion in small CA is of simple type (A-B1) and was not associated with negative clinical conditions, stenting could be safely performed with relatively slight risk of restenosis. Noteworthy is that Palmaz-Schatz stents are not designed to treat stenoses in small arteries.

Miketic et al³³ at the 6 months follow-up assessed safety and efficacy of NIR stents in 67 patients with complex lesions in arteries less than 3.0 mm. Stenting was successful in 98.2% of cases, without acute and subacute thrombosis, and restenosis at the six months follow-up occurred in 21 patients (36.2%). In the study of Akiyama et al³ subacute in-stent thrombosis developed in 1.5% of 602 patients, whom various stents were implanted in vessels smaller than 3 mm. Restenosis was revealed in 32.6% patients. Interesting data was obtained in the study of Kawagishi et al²⁸. In 33 patients with lesions in arteries less than 2.5 mm stents were implanted following subop-

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