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Influence of Stent Length on the Outcomes of Coronary Stent Implantations

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ÖZET

KORONER STENT İMPLANTASYONLARINDA STENT UZUNLUĞUNUN SONUÇLARA ETKİSİ

Çalışmanın amacı stent uzunluğunun koroner stent işlemlerinin üzerine etkisini araştırmaktı. Altıncı ayda kontrol koroner anjiografisi yapılan AVE-GFX stentleri bire bir eşleştirme tekniği ile "kısa stent" (KS grubu, (18 mm, 53 stent, 51 hasta) ve "uzun stent" (US grubu, (18 mm, 47 stent, 44 hasta) olmak üzere iki grupta toplanmıştır. Çalışma grupları koroner stentlerin kötü sonucuna işaret edebilecek olası faktörler açısından, lezyon uzunluğu hariç benzerdir. Sonuçlar: KS ve US gruplarına erken sonuçlar, sırasıyla: Akut Q-dalgalı, MI 1 ve 2 hastada; acil KABG gereksinmesi, her iki grupta 1 hastada; stent trombusu, 1 ve 2 hastada görülmüştür (tüm karşılaştırmalarda, P>0.05). Takip sırasında ölüm olmamıştır. Altıncı ay koroner anjiografide binary restenoz (≥%50) oranı US grubunda anlamlı olarak fazla olmuştur (KS grubunda %13, US grubunda %34, P<0.05). Altıncı ayda hedef lezyonda yüzde daralma oranı gruplar arasında anlamlı olarak farklı bulunmuştur (KS grubunda %23 ± 27, US grubunda %44 ± 28, P<0.01). Hedef lezyonda revaskülarizasyon US grubunda daha sık gerekmiştir (US grubunda 12 hastada, KS grubunda 5 hastada, P<0.05). Yorumlar: Stent uzunluğu, uzun dönemde koroner stent işlemlerinin sonucunu kötü yönde etkilemekte ve daha sık revaskülarizasyon gereksinmesine yol açmaktadır. Kısa dönemde stent uzunluğu sonuçları etkilememiştir.

Coronary stenting has been a widely accepted method to improve immediate and long-term outcomes of coronary angioplasty [1-3] and to overcome acute complications such as coronary dissections and abrupt vessel closure. [4] Despite a lot of achievements in the outcomes since the commencement of coronary stenting in 1986, there still remains a lot to be clarified. Effect of stent length on the immediate and late outcomes has been one of the unsettled issues. Therefore, objective of our study was to find whether the stent length affects the outcomes after coronary stenting.

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METHODS

Study groups: Our study was a retrospective case-control study. In order to eliminate the impact of different type of stents to the outcomes we have included only a single type of stent (GFX stents, Arterial Vascular Engineering, Santa Clara, CA) in our study. One hundred and fifty-seven GFX stents were implanted in our clinic between June 1995 and December 1997 into the coronaries of 131 patients. All patients (n=131) had a significant angiographic stenosis (≥50% diameter stenosis) associated with clinical and/or objective evidence of myocardial ischemia before coronary stenting. After the stent implantation all patients were asked to undergo a coronary angiography follow-up at 6 months (or earlier in case of symtoms).

Follow-up coronary angiography could not be performed to 21 patients and these patients were not included into the study. In the remaining 110 patients who were performed a control angiography at 6 months, 95 patients (79%) with 100 GFX stents and were matched into two groups of either short stent (SS) or long stent (LS) group. Matching of patients was made within groups and was blinded with respect to the patient's clinical information and outcome of coronary angiography. Stents were arbitrarily divided into two groups; LS group, which were consisted of stents with a length of 18 mm or longer, and SS group, which were consisted of stents with a length of 17 mm or shorter. In regard to the other factors which may be a predictive for the adverse outcome our study groups were comparable except lesion type according to modified AHA/ACC criteria (5) (table 1, table 2). In particular; prevalence of diabetes mellitus (16% in SS group vs 23% in LS group, P>0.05), unstable angina (35% in SS group vs 41% in LS group, P>0.05), percent diameter stenosis before stenting (74 ± 15 % in SS group vs 71 ± 11 % in LS group, P>0.05), percent diameter stenosis after stenting (9 ± 8 % in SS group vs 11 ± 8 % in LS group, P>0.05), reference vessel diameter (3.15 ± 0.44 mm in SS group vs 3.02 ± 0.51 mm in LS group, P>0.05), and maximal balloon inflation pressure (9.2 ± 3.1 atm in SS group vs 9.9 ± 3.7 atm in LS group, P>0.05) were comparable in the study groups. There were significant differences between the study groups in regard to the lesion length (8.6 ± 2.9 mm vs 16.3 ± 5.5 mm, P<0.001).

Length of GFX stents in the study were; 8 mm (12 stents), 12 mm (41 stents), 18 mm (33 stents), 24 mm (10 stents), 30 mm (2 stents), 40 mm (2 stents) mm, and sizes were; 2.5 mm (4 stents), 3 mm (45 stents), 3.5 mm (37 stents), 4 mm (14 stents).

Stent implantation procedure: Stents were implanted according to the standart protocols. After the placement of an 8F femoral arterial sheath 15.000 IU of heparin was gi-

Table 1. Baseline clinical characteristics of the study population (All P>0.05)

	Short Stent Group (<18 mm) (n=51)	Long Stent Group (≥18 mm) (n=44)
Stent (n)	53	47
Male (n)	42	37
Age (year)	56.6 ± 8.9	54.4 ± 8.9
LV ejection fraction (echo.) (%)	52 ± 9	54 ± 11
Previous myocardial infarction (n)	10	12
Clinical presentation (n)		
Stable angina pektoris	33	26
Unstable angina	18	18
Risk factors for coronary artery dis.		
Diabetes mellitus	8 (16%)	10 (23%)
Smoking ((10 cigarettes/day)	18 (35%)	16 (36%)
Hypercholesterolemia ((240 mg/dL)	7 (14%)	11 (25%)
Family history	10 (20%)	9 (20%)
Obesity	5 (10%)	6 (14%)
Indication for stenting (n)		
Elective	13	8
Chronic occlusion	3	4
Restenosis	6	4
Suboptimal	16	15
Bail out	15	17
IVUS Performed during stenting (n)	5	3

ven to all patients. Predilation with a 2,5 mm balloon was performed in those who had very tight stenosis. After stent implantation, angiographic optimization was performed to achieve a good angiographic result with <20% residual stenosis. Intravascular ultrasonography study was performed only in doubtful cases (in 5 and 3 patients in SS and LS group, respectively). High pressure balloon inflations (≥14 atm) were used only in minority of cases (in 5 and 7 patients in SS and LS group, respectively). If there was an evidence of an incomplete deployment a second inflation either with a slightly larger size of balloon or with a higher inflation pressure was performed. After the deployment all patients received aspirin 300 mg/day indefinetely and ticlopidine 500 mg/day for the first month. Patients did not receive dextran or dipyridamole before, during or following the stent procedure and anticoagulation with coumadin was not used in any of the patients. Angiographic follow-up was performed at a mean of 5.9 ± 1.1 months after stenting.

Angiographic analysis: Angiographic analysis were obtained in multiple projections at baseline, immediately after stenting and at six-month follow-up. Measurements were made from magnified cine-frames. The external diameter of the contrast-filled catheter was used as the calibration method. Using these methods, the diameter of the proximal and distal reference segments were averaged to yield the mean reference vessel diameter, and the per cent diameter stenosis.

Statistical analysis: Continuous variables are presented as mean ± SD. Subgroups comparisons were made by chi-square analysis and, when needed, by Fisher exact chi-square analysis for categorical variables and by the Student t test for continuous variables. Mann Whitney test was used if the continous variables were not normally distrubuted. Multivariate logistic analysis was used to determine the best predictors of angiographic stent restenosis (≥50%) for the whole study population. For the multivariate regression analysis only univariate predictors of angiographic restenosis with a p value of <0.05 entered into the analysis. A p value less than 0.05 was considered statistically significant.

RESULTS

Early outcomes: Results are provided in table 3. Stent deployment was considered to be optimal in 52 stents (52/53, 98%) in SS group and 44 stents (44/47, 94%) in LS group (p>0.05). The reason for suboptimal deployment was the inability to cover whole length of target lesion in all of these patients, leaving a small portion of uncovered lesion either proximal or distally.

Major complications (myocardial infarction [MI], coronary artery bypass grafting [CABG], death) within the first month occurred in 2 patients in SS group and 3 patients in LS group: Acute Q-wave MI was seen in 1 patient in SS group and in 2 patients in LS group, a CABG was required in 1 patient in both study groups. Stent thrombosis occurred in 1 patient in SS group and in 2 patients in LS group. There were no deaths within the first month. There were no significant differences in regard to these early angiographic endpoints between the study groups (P>0.05 for all).

Table 2. Baseline coronary angiographic characteristics (* P<0.001, P for all others >0.05)

	Short Stent Group (<18 mm) (n=51)	Long Stent Group (≥18 mm) (n=44)
Stent (n)	53	47
Lesion stented (n)	53	48
Location of lesion (n)		
LAD	21	14
Diagonal	2	1
LCX	12	10
RCA	18	23
Portion of artery stented (n)		
Proximal	19	16
Mid segment	23	20
Distal	11	12
Modified AHA/ACC lesion type (n)		
Type A	39	0
Type B1	11	4
Type B2	3	12
Type C	0	32
Stent length (mm)*	11.1 ± 1.7	20.7 ± 5.3
Lesion length (mm)*	8,6 ± 2,9	16,3 ± 5,5
Reference vessel diameter (mm)	3,15 ± 0,44	3,02 ± 0,51
Preprocedural		
Diameter stenosis (%)	74 ± 15	71 ± 11
Postprocedural		
Diameter stenosis (%)	9 ± 8	11 ± 8
Max. Deployment pressure (atm)	9.2 ± 3.1	9.9 ± 3.7

Table 3. Results

	Short Stent Group (<18 mm)	Long Stent Group (≥18 mm)	p
Early outcome (< 1 month) (n)			
Acute myocardial infarction	1	2	NS
Coronary artery bypass graft	1	1	NS
Death	0	0	NS
Stent thrombosis	1	2	NS
Late Outcome ((6 month)			
Binary restenosis ((50%) (%)	7 (13%)	14 (34%)	<0.05
Per cent diameter stenosis (%)	23 ± 27	44 ± 28	<0.01
Target vessel re-intervention n (%)	5 (10%)	12 (27%)	<0.05

NS: Not significant

Late outcomes: (Table 3 and figure 1) At 6th month follow-up coronary angiography there was a significant difference between the restenosis rates. After excluding patients with in-stent thrombosis, which occurred in 1 patient in SS group and 2 patients in LS group, restenosis occurred in 7 patients (7/52, 13%) in SS group and 14 patients (14/45, 31%) in LS group (p<0.05). Per cent diameter stenosis was 23 ± 27 in SS group and 44 ± 28 in LS group (p<0.01). Target vessel re-intervention was required in 5 patients (10%) in SS group and 12 patients (27%) in LS group (p<0.05). There were no deaths within the six month.

Predictors of angiographic restenosis: Univariate predictors of angiographic restenosis in the whole study population were; *post procedural diameter stenosis* (14.2% ± 10.6% in those with restenosis and 8.1% ± 7.1% in those without restenosis, P<0.05, OR:2.7, 95% CI:1.2-8.4), *reference vessel diameter* (2.63 ± 0.57 mm in those with restenosis and 3.21 ± 0.41 mm in those without restenosis, P<0.001, OR:0.39, 95% CI: 0.23-0.68), *lesion length* (18 ± 6.3 mm in those with restenosis and 5.7 ± 2.1 mm in those without restenosis, P<0.0001, OR:11,2, 95% CI:6.2-27.2), *stent length* (22.2 ± 7.5 mm in those with restenosis and 9.2 ± 1.7 mm, P<0.0001, OR: 8.2, 95% CI:4.7-14.5), and presence of diabetes mellitus (44% in those with restenosis and 11% in those without restenosis, P<0.05, OR:6.22, 95% CI:2.0-19.8). In multivariate logistic regression model; lesion length (P<0.0001, OR:4.7, 95% CI:1.4-7.6), stent length (P<0.0001, OR:7.2,

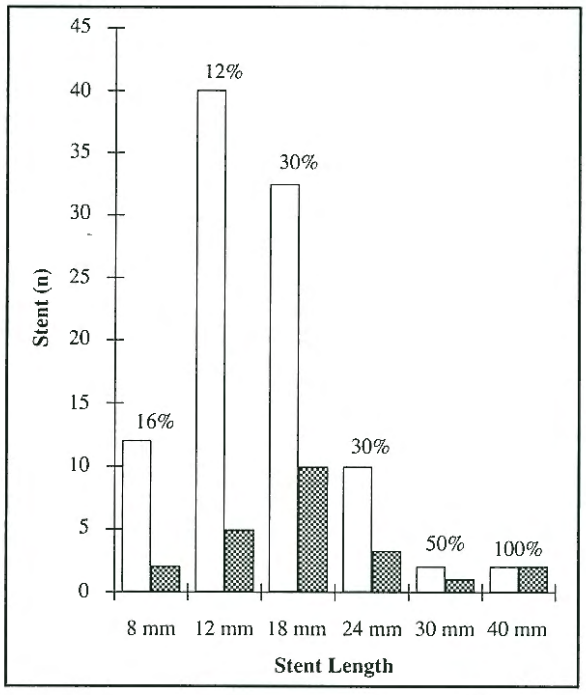

Figure 1. Coronary stents used in the study. Open bars represent number of stents in different lenghts and filled bars represent number of stents with restenosis. Percentages above bars represent percentage of restenosis of the related stent length.

95% CI:2.2-15.7), reference vessel diameter (P<0.001, OR:0.27, 95% CI:0.12-0.72) remained as significant predictors of angiographic stent restenosis.

DISCUSSION

The use of coronary stenting has increased dramatically in the last years. Although coronary stenting reduces the risk of in-stent restenosis rate it does not completely prevent its occurence. There have been numerous studies to clarify the mechanism and predictors of in-stent restenosis. Serial intravascular ultrasonography studies showed that in-stent restenosis is mostly due to neointimal hyperplasia [6,7].

Although there were conflicting data regarding which factors were predictors for in-stent restenosis most of the studies reported that post-procedural MLD and/or implantation of multiple stents were predictors in multivariate models [8-12]. Lesion length was also reported to be a predictor in some of the previous studies. [13,14] In our study stent length, lesion length and reference vessel diameter were multivariate predictors of angiographic restenosis. Presence of diabetes mellitus was a predictor in univariete analysis but lost its significance in the multivariate model. This was probably due to the fact that patients with diabetes mellitus had longer lesions and were implanted longer stents. We could not test implantation of multiple stents since only few patients were implanted multiple stents in our study.

To our knowledge there was no published article which sought the influence of stent length on the outcomes of coronary stenting comparing only one type of stent. There were some observational reports in abstract format [15,16]. None of these were a controlled study. Chevalier and colleagues compared long (≥25 mm) and short (<25 mm) coronary stents and found that stent length did not affect short-term outcomes but induced a higher rate of re-intervention (16.3% vs 8.7%, p<0.05) [15]. This finding was comparable to our results. Hamasaki and colleagues studied influence of lesion length on late outcome after coronary stenting and reported that restenosis rate was significantly higher in long lesions [16]. Restenosis rate in their study was 31% for lesions longer than ≥15 mm, 20% for intermediate- length lesions, and 15% for lesions shorter than 7.5 mm. Influence of the use of multiple overlapping stents were studied by several authors [17-19]. In all of these studies restenosis rate and need for target vessel revascularization was at least twice that of single stents. But, it should be noted that the situation is not similar in multiple overlapping stents to that of a single long stent with the same length. Plaque protrusion between stents may disturb rheology of blood flow and may be a responsible factor for more restenosis.

Management of long lesions has been a challenging situation since optimal therapy has not been determined yet. It has been shown that outcome of coronary angioplasty in long lesions was worse than that of discrete ones [20,21]. Rotational atherectomy, [22-23] directional atherectomy [24] and excimer laser angioplasty [23,25] were not superior to balloon angioplasty in this regard, as well. Therefore outcome of coronary stenting in long lesions has gained much attention.

Our study showed that, although short-term outcomes of our study groups were comparable, restenosis rate at 6th month was significantly higher in patients

with longer GFX stents (≥18 mm) than those with shorter GFX stents (<18 mm). Target vessel revascularization was also more frequently performed in LS group. Since our study groups were comparable in regard to the factors that had been found to be associated with restenosis, we think stent length (or lesion length) should be responsible factor for the increased incidence of restenosis. We should emphasize that our study was not powered to detect whether stent length or lesion length was the responsible factor for the worse outcome in LS group.

The reason for increased incidence of restenosis in LS group of our study could be due to stent-related or lesion-related factors: The stimulus for intimal proliferation in longer stents, acting as a foreign body or due to their scaffolding properties, might have been more. Also, some inherent drawbacks of long lesions such as increased chance of having an adverse morphology like bifurcation points and angulations, or more uneven opening after dilatation might have affected the outcomes. Since we did not perform intravascular ultrasonographic investigation in most of our patients we could not exclude possibility of more uneven opening in LS group of our study definitely.

GFX stent is a ring stent which is composed of 2 mm length segments with 6 crowns. Segments are fully connected at each junctions with laser fusion technology. It is premounted on a balloon. Metallic surface area of the stent is relatively high (20% in expanded state of a 3.5-mm stent). To date there has been no article showing outcomes of GFX coronary stents. Our study also demostrated that they may be at least equally effective when used in discrete lesions. We did not experienced any procedural failure due to inability to cross the lesion and this may be due to better flexibility of the stent. Although metal surface of the stent is high, incidence of in-stent thrombosis was acceptable (3%) in our study.

Our experience suggest that other approaches are necessary for the management of long lesions. Idea of 'spot' stenting, whereby only areas of suboptimal result after balloon angioplasty are stented, may be a reasonable solution in these situations. But superiority of this approach, as well as the use of long coronary stents in long lesions should be tested with large randomized trials.

Limitations of the study

There were several limitations in this study. The most important one was small sample size of our study groups. Unfortunately we could not enroll more patients into the study since we wanted to study only a single type of stent. We think feasibility of coronary stenting in long lesions should be studied further in large randomized or in prospective and controlled-cohort studies.

Thirty-six (21%) of patients with GFX stents at the time of study design were not included into the study and this was another limitation of our study. Stents shorter than 18 mm length were implanted to 24 of these patients and remaining 12 patients had longer stents. Twenty-one of patients who were not included into the study could not be performed a control angiography. Medical history of patients who could not be performed a control angiography were provided with a telephone interview and frequency of symptom of angina pectoris was not different from those who were enrolled into our study. Another group of 15 patients were excluded for a better matching between study groups. Nine of these patients were in SS group and 6 were in LS group. Restenosis was present at control angiography in 2 (22%) of them in SS group and in 3 (50%) of them in LS group.

Intravascular ultrasonographic investigation was not performed in most of the patients. It could have provided more detailed information about lesion morphology before and after coronary stenting and led more insights about the adverse outcomes in long stenting.

Although study groups were matched according to most of the possible risk factors for restenosis, lesion types according to modified AHA/ACC criteria were not comparable. Lesion type of the study patients was affected mainly by lesion length since we usually avoid coronary stenting to complex lesions such as lesions with major angle (≥45 degrees) or at bifurcation sites according to our institutional policy. Also, study groups were not compared as a whole including all possible risk factors for adverse outcomes after coronary stenting. This may represent another limitation for our study since cumulative effects of risk factors which may be associated with worse outcomes may be significantly higher in LS group.

Conclusion

Both early and long term outcomes of short GFX stents were excellent. Long term outcomes of long GFX stents were significantly worse than that of short GFX stents. The stent length did not affect the short term results but induced a higher rate of re-intervention later.

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