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Angiographic long-term results after implantation of the paclitaxel-eluting coronary stent „coroflex please“: Data under real-world conditions

U. Gerk[1], B. Leithäuser[2], U. Schäfer[3], F. Jung[4], J.-W. Park[2]

[1]Municipal Hospital Dresden-Friedrichstadt, 2nd Medical Department, Cardiology, Dresden, Germany; [2]Asklepios Klinik Harburg, 1st Medical Department, Cardiology, Hamburg, Germany; [3]medical practice for cardiology, Hoyerswerda, Germany; [4]Center for Biomaterial Development and Berlin-Brandenburg Center for Regenerative Therapies (BCRT), Helmholtz-Zentrum Geesthacht, Centre for Materials and Costal Research, Teltow, Germany

Introduction

Most results in re-stenoses after implantation of a paclitaxel-eluting coronary stent are derived from clinical trials with tight defined inclusion criteria. Though the effectiveness of paclitaxel in prevention of re-stenosis by reducing proliferation of smooth muscle cells could be demonstrated. The clinical and angiographic outcome after deployment of stents coated with paclitaxel into de novo coronary lesions [1, 2] and into in-stent restenoses [3] was significantly superior in comparison to bare metal stents in reducing neointimal hyperplasia, late luminal loss, and angiographic re-stenosis leading to decreased target lesion revascularisation.

Long-term results under conditions as to be seen in clinical routine in the cath-lab – e.g. in patients with unstable angina or acute myocardial infarction or in patients with complex lesions in multi-vessel disease – are very few.

Therefore all patients receiving a stent of the type „Coroflex Please“ (B.Braun, Melsungen, Germany) in our cath-lab were followed in order to collect the rate of patency and the rate of re-stenosis of this type of stent respectively.

Material and methods

Registry

In order to gather quality of the results of coronary interventions in the cath-lab, all patients receiving a coronary stent in the period of january 2001 until beginning of 2008 were followed up. This means an analysis under conditions of real-world.

Included were a total of 1,388 patients, 148 of them received a „Coroflex Please“ stent. 99 of those 148 patients underwent a second angiography in the cath-lab in Hoyerswerda, that means a rate of 66.9%.

Collected were the indication for the implantation of the stent, demographic data of the patients, cardiovascular diseases in the history (myocardial infarction, CABG, stent implantation, angina pectoris), the angiographic result before implantation of the stent, the amount of implanted stents, characteristics of the implanted stents (diameter, length, implantation pressure) and the patency in the stent in the following months.

The „Coroflex please“ stent

The following table shows the technical data of the investigated Coroflex Please stent [4].

material	stainless steel 316 L
design	multi cellular
diameter	2.5 - 4.0 mm
lengths	8 - 32 mm
diameter of cells	bis zu 1,2 mm
radial stability	0,8 atm
coating matrix:	polysulfon
thickness of matrix luminal:	7 µm
thickness of matrix abluminal:	4 µm
medication:	paclitaxel
application rate:	1 µg/mm^2
manufacturer:	B. Braun AG

Table 1: Technical data of the "Coroflex Please" stent

Results

Registry population

The mean age of the patients (male: 100 / female: 48) was 66.5 ±10.1 years with a height of 168.9 ± 9.0 cm and a body weight of 82.9 ± 14.4 kg. The patients showed a cardiovascular risk profile quite typical for patients with coronary artery disease. Over 90% of the patients suffered arterial hypertension, more than 35% diabetes mellitus and nearly 80% had a lipidemic disorder. The angiographic results are shown in table 2.

The indication for coronary angiography or stent implantation respectively is shown in table 3.

All implanted „Coroflex Please" stents have been included and evaluated.

The 148 patients received a total of 312 stents, 247 of them have been „Coroflex Please" stents, meeting a stent rate of 2.1 stents per patient (see table 4).

An overview over the included and followed patients is given in table 5.

A re-angiography could be performed in 99 of the 148 patients, representing an angio-

1 - vessel disease	32 (21.6%)
2 - vessel disease	43 (29.1%)
3 - vessel disease	73 (49.3%)
former myocardial infarction	68 (45.9 %)
former CABG	10 (6.8%)
former PCI	89 (60.1%)

Table 2: Angiographic results and coronary heart disease

indication	**n**
stable angina pectoris (or equivalent)	88
unstable angina pectoris	60
acute myocardial infarction	37
evidence of myocardial ischemia	5
total	148

Table 3: Indication for stent implantation

	total	"Coroflex Please"
1 stent	63	87
2 stents	38	33
3 stents	30	18
4 stents	10	10
5 stents	4	
6 stents	-	
7 stents	1	

Table 4: Frequency of stents per implantation

Table 5: Synoptical table

Patients	Re-angiography (169.6±92.1 days)	Number of implanted stents	Number of implanted "Coroflex Please" stents
148	99	312	247

graphic follow-up in 66.9 %. The follow-up was performed after a mean of 169.6 ± 92.1 days.

Follow-up

Table 6 shows the degree of re-stenosis of all implanted „Coroflex Please" stents in % after 169.6 ± 92.1 days. Narrowing in the implanted stents of more than 50% is considered as re-stenosis.

Additional re-stenoses of at least 70% were listed, because they are suggested to be hemodynamically relevant. In 99 patients the process of re-stenosis of 149 implanted stents could be controlled.

A target-lesion-revascularisation was performed in 13 of 149 implanted stents (8.7%). This affected 11 of the 99 patients (11.1%).

The stent-related rate of re-stenosis for stenoses of at least 70%, therefore nessitating a revascularisation, was 8.7% under real-world conditions. Table 7 shows the late-lumen-loss, thus the narrowing after stent implantation in the long-term. Here is to be considered that the diameters of the vessels have not been calculated with quantitative coronary analysis system (QCA) but by estimation of two independent interventional cardiologists.

Table 6: Angiographic results in the area of the implanted "Coroflex Please" stents during follow-up

without pathological findings	re-stenosis ≥ 30%	re-stenosis ≥ 50%	re-stenosis ≥ 70%	re-stenosis = 100%
70	79	21	13	9

Table 7: Late-lumen-loss of the "Coroflex Please" stent

Implanted	Angiography	Diameter of vessel	Late-lumen-loss
247	149	2.86 ± 0.33	0.64 ± 0.76

Table 8: Other drug-eluting stents

Stent	Implanted	Re-stenosis	Late-lumen-loss
Taxus	37	5.41 %	0.34 ± 0.81
Cypher	91	4.39 %	0.27 ± 0.69
Dexamet	8	62.5 %	1.92 ± 1.22
CoStar	56	12.5 %	0.63 ± 1.01

The stent-related rate of re-stenosis as well as the late-lumen-loss reached dimensions that have been noticed for other drug-eluting stents investigated in this registry (see table 8).

Association between rate of re-stenosis and type of angina pectoris

It also seems to be of some interest, whether there is a difference in the rate of re-stenosis in patients undergoing a planned coronary intervention, patients with stable angina or evidence of myocardial ischemia and those with an emergency indication for revascularisation as unstable angina or myocardial infarction respectively.

myocardial infarction vs. unstable angina: p=0.1404

myocardial infarction vs. stable angina: p=0.6722

stable angina vs. unstable angina: p=0.0961

There is no difference in the rate of re-stenosis in these three groups (ANOVA: p=0.2459)

Diameter of treated coronary artery and rate of re-stenosis

It is remarkable that in the group of patients treated with a „Coroflex Please" stent the amount of small vessels is rather high (34.4%). In two patients stents have been implanted in vessels not larger than 2 mm. Therefore the relationship between vessel diameter and rate of re-stenosis was investigated.

There is no significant association between the diameter of the target vessel and the diameter in the stent at follow-up (ANOVA: p=0.501). The data are shown in table 10.

Rate of re-stenosis after revascularisation of in-stent-re-stenoses

Initially revascularisations have been performed by implantation of "Coroflex Please"

Table 9: Diameter of coronary artery and rate of re-stenosis

Diameter	n	re-stenosis ≥ 50%	re-stenosis ≥ 70%
2.5 mm	48	10 (20.8%)	4 (8.3%)
3.0 mm	87	18 (20.7 %)	9 (10.3%)
3.5 mm	11	1 (9.1 %)	0 (0%)
4.0 mm	2	0 (0%)	0 (0%)

Table 10: Diameter of coronary artery and degree of re-stenosis at follow-up

Diameter	Follow-up (days)	Stenosis in stent [%]
2.5 mm	166.7±84.6	25.8±29.6
3.0 mm	171.1±96.2	21.9±25.9
3.5 mm	146.3±96.8	19.1±20.2
4.0 mm	258.0±21.2	0±0

stent in a total of 24 in-stent re-stenoses after a mean of 155 ± 86 days.

In 4 stents (16.7%) a further stenosis > 50%, and in 2 stents (8.3%) another re-stenosis > 70% was found. The rate of re-stenosis was not different to those of the remaining patients (p=0.390).

Discussion

The included patients showed a cardiovascular risk profile that was typical for coronary heart disease. More than 90% of the patients suffered from arterial hypertension, more than 35% from diabetes mellitus and nearly 80% from a hyperlipidemic disorder. The patients were in an advanced stage of their atherosclerotic disease: 49.3% had a coronary three-vessel disease, 45.9% had a myocardial infarction in their history. 60.1% of the patients had already at least one implanted stent and 6.8% had a CABG in their history.

Until now 99 (66.9%) of the 148 patients that have received a „Coroflex Please" stent could be followed. The stent-related rate of re-stenosis, for stenoses of at least 70%, therefore requiring treatment, was – under „real-world conditions" in patients with advanced atherosclerosis and a distinct cardiovascular risk profile – only 8.7% after almost half a year (169.6 ± 92.1 days). In 14% of those patients a re-stenosis of more than 50% was to be found. The results of the registry are in line with the data of a recently published multi-center study with the same stent and a binary re-stenosis rate of 13.3% [5, 6] and a study with the "TAXUS Express" stent and a binary re-stenosis of 8.7% [7].

The rate of re-stenosis after treatment of in-stent re-stenoses was not different from the results after implantation of a „Coroflex Please" stent in a native coronary artery. As well there was no significant association between the diameter of the target vessel and the re-stenosis rate in the follow-up, although the data seem to indicate a trend to higher re-stenosis rates and higher stenoses in smaller vessels.

In summary it can be stated that the rate of re-stenoses after „Coroflex Please" stent implantation in this registry under real world conditions in patients with advanced atherosclerosis was well in line with other clinical studies with the same stent as well as with other paclitaxel eluting stents.

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Correspondance address:
Ulrich Gerk, M.D.
II. Medizinische Klinik
Krankenhaus Dresden-Friedrichstadt
Friedrichstr. 41
01067 Dresden
Germany