Treatment of saphenous vein graft lesions with paclitaxel- and sirolimus-eluting stents: comparison of short- and long-term clinical outcomes

Safen ven greft lezyonlarının paklitaksel ve sirolimus salınımlı stentler ile tedavisi: Kısa ve uzun dönem klinik sonuçların karşılaştırılması

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ABSTRACT

Objective: The purpose of this study was to compare treatment of saphenous vein graft (SVG) lesions with paclitaxel-eluting (PES) and sirolimus-eluting stents (SES) in daily practice with regard to short- and long-term clinical outcomes.
Methods: Between August 2002 and September 2006, a total of 71 patients with SVG lesions who were implanted PES or SES with percutaneous coronary intervention in our center were evaluated retrospectively. Forty-six patients with PES (PES group) were compared to twenty-five patients treated with SES (SES group) in terms of in-hospital, 30-day, six-months and 1-year clinical outcomes. Statistical analyses were performed using Chi-Square statistics or Fisher's exact and independent sample t test. Survival analysis was done using Kaplan-Meier method and log-rank test.
Results: Baseline clinical characteristics were similar in both groups except for a tendency toward a lower age in the SES group. No statistically significant difference was found between two groups by means of lesion and procedural characteristics. All clinical outcomes at 30-day, 6-month and 1-year after the interventions were similar in both groups. Early stent thrombosis was detected in one patient (2.2%) of PES group (p=0.65). Late stent thrombosis was not observed in both groups. The rate of major adverse cardiac events at 1-year was 8.7% in the PES group and 16% in the SES group (p=0.44).
Conclusion: Short- and long-term clinical outcomes of PES and SES in the treatment of SVG lesions are similar. The results of our study showed that both drug-eluting stents are effective and safe in real-world patient with diseased SVGs. *(Anadolu Kardiyol Derg 2008; 8: 431-6)*
Key words: Drug-eluting stents, saphenous vein, angioplasty, outcomes, survival analysis

ÖZET

Amaç: Bu çalışmada amacımız günlük pratikte paklitaksel salınımlı (PSS) ve sirolimus salınımlı (SSS) stentler ile tedavi edilen safen ven greft (SVG) lezyonlu hastaları kısa ve uzun dönem klinik sonuçlar açısından karşılaştırmaktır.
Yöntemler: Merkezimizde Ağustos 2002 ile Eylül 2006 tarihleri arasında SVG lezyonu için perkütan koroner girişim ile PSS veya SSS uygulanmış olan toplam 71 hasta retrospektif olarak değerlendirildi. Hastane içi, 30. gün, 6. ay ve 1. yıl klinik sonuçları açısından PSS uygulanan 46 hasta (PSS grubu), SSS uygulanan 25 hasta (SSS grubu) ile karşılaştırıldı. İstatistiksel değerlendirmede Ki-Kare, "Fisher exact" ve bağımsız örneklem t testleri kullanıldı. Sağkalım analizi Kaplan-Meier yöntemi ve log-rank testi ile yapıldı.
Bulgular: Temel klinik özellikler her iki grupta da SSS grubundaki hastaların yaş ortalamasının daha düşük olması dışında benzerdi. Lezyon ve işlem özellikleri açısından her iki grup arasında istatistiksel olarak anlamlı bir fark bulunmadı. Girişim sonrası 30. gün, 6. ay ve 1. yılda tüm klinik sonuçlar her iki grupta da benzerdi. Erken stent trombozu PSS grubundaki 1 hastada (%2.2) saptandı (p=0.65). Geç stent trombozu her iki grupta da görülmedi. Birinci yılda majör istenmeyen kardiyak olay oranı PSS grubunda %8.7, SSS grubunda %16 idi (p=0.44).
Sonuç: Safen ven greft lezyonlarının tedavisinde paklitaksel ve sirolimus salınımlı stentlerin kısa ve uzun dönem klinik sonuçları birbirlerine benzerdir. Çalışmamızda elde ettiğimiz bulgular, her iki ilaç salınımlı stentin de SVG lezyonu bulunan hastaların tedavisinde etkin ve güvenli olduğunu göstermektedir. *(Anadolu Kardiyol Derg 2008; 8: 431-6)*
Anahtar kelimeler: İlaç salınımlı stent, safen ven, anjiyoplasti, sonuçlar, sağkalım analizi

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Introduction

Treatment of stenotic lesions of saphenous vein grafts (SVGs) remains one of the challenging issues of cardiovascular medicine. Effective and satisfactory therapies are still lacking. Almost half of all SVGs are totally occluded and up to 40% of patent SVGs are severely diseased within a decade following coronary bypass surgery due to a tendency of degenerative process in vessel wall (1, 2). As repeat coronary artery bypass grafting was shown to be associated with a high morbidity and mortality, percutaneous coronary interventions (PCI) have become the preferred revascularization procedure for SVG lesions (3, 4). However, balloon angioplasty in degenerated soft and friable SVG lesions is associated with a high complication rate and a high incidence of restenosis (5-7). Bare-metal stents (BMS) deployment in SVG lesions has been shown to improve procedural and clinical outcomes when compared with balloon angioplasty (8-9). However, the results of BMS in diseased SVGs are less favorable than those in de novo coronary lesions due to high restenosis rates (10, 11). Drug-eluting stents (DES) have reduced the rate of restenosis and repeat revascularization with respect to BMS in de novo native coronary artery lesions in selected patient population (12-14). Some studies have proposed superiority of DES in SVG lesions when compared to BMS in short and mid-term follow-up (15-23). A recent trial, however, reported unfavorable clinical outcomes with DES compared to BMS in long-term (>3 years) follow-up (24). Since the clinical trials comparing different DES to treat diseased SVGs are currently limited, we performed this retrospective study to evaluate short-and long-term clinical outcomes with sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES).

Methods

This was a retrospective study, which analyzes the PCI database of our institute. We identified a total of 77 consecutive patients who underwent percutaneous revascularization for SVG lesions which were treated with PES (Taxus™, Boston Scientific Corp., Natick, Massachusetts) or SES (Cypher™, Cordis Corp., Miami, Florida) between August 2002 and September 2006. Six patients were excluded from the analysis due to lack of proper office-visit records and contact information. The remaining 71 patients with 88 lesions in 80 SVGs were included in the study. The PES group included forty-six patients with 59 SVG lesions and SES group included twenty-five patients with 29 SVG lesions. Out of 101 stents deployed totally, 68 were PES and 33 were SES. The data about patients and procedural characteristics were collected from hospital records. All patients were clinically followed-up by hospital visits at 30-day, 6-month and 1-year. Both groups were compared with regard to their baseline clinical, procedural and lesion characteristics and in-hospital, 30-day, 6-month and 1-year clinical outcomes. The PCI procedures were performed by standard percutaneous techniques using the femoral approach and standard stent applications as described previously (25). All patients underwent 12-lead electrocardiography pre- and post interventions. Creatine kinase-MB (CKMB) enzymes were also routinely collected before the PCI and at 6 and 24 hours after intervention. Platelet glycoprotein IIb/IIIa receptor inhibitors and distal protection devices as AngioGuard ™ (Cordis Corp., Miami, Florida) and Filterwire EX™ (Boston Scientific Corp. Natick, Massachusetts) were used at the discretion of each operator. Written informed consent for a routine procedure was taken from all patients before the procedure. Patients were treated with lifelong aspirin and clopidogrel for at least six months after DES implantation. Digital coronary angiograms were analyzed offline by an expert operator blinded to the procedure using Philips QCA-DCI software. Minimal lumen diameter (MLD), reference vessel diameter (RVD) and percent diameter stenosis at baseline and post-procedure were measured, respectively.

Definitions and clinical end-points. Target vessel revascularization (TVR) was defined as all ischemia-driven PCI or coronary bypass surgery. ST-elevation myocardial infarction (MI) was defined as presence of new pathological Q waves in the electrocardiogram associated with an elevation of CKMB ≥3 x the upper limit of the normal value. A non-ST elevation MI was defined as creatine kinase-MB enzyme elevation ≥3 x the upper limit of the normal value. Major adverse cardiac events (MACE) were defined as death, non-fatal MI (ST-elevation or non-ST elevation) and TVR. All deaths were considered as cardiac unless otherwise recorded. Clinical outcomes of all patients were obtained from previous clinical visit records and telephone contacts, which were conducted by trained cardiologists. Stent thrombosis was classified as definite, probable, or possible in accordance with criteria developed in 2006 by the Academic Research Consortium. Early stent thrombosis included all events occurring within 30 days of PCI, late stent thrombosis included those occurring between 31 to 360 days after PCI (26). Procedural success was defined as successful stent deployment and residual stenosis <30% assessed by quantitative analysis, without MACE during the hospital stay.

Statistical analysis

Statistical analysis was performed using SPSS statistical software package (version 15.0 for Windows, SPSS Inc. Chicago, Illinois). Categorical variables were expressed as frequencies and continuous variables as mean±1 standard deviation. Continuous variables were compared using independent sample t test. Categorical variables were compared with Chi-Square statistics or Fisher's exact test. Survival free of MACE was estimated using the Kaplan-Meier method and the differences between the two survival curves were compared with the log-rank test. A p value <0.05 was considered statistically significant, and all reported p values are two-sided.

Results

Clinical characteristics at baseline were similar in both groups except for a lower age in the SES group (67.02±8.26 versus 61.92±8.59, p=0.017 (Table 1). The frequency of male gender was 89% and the percentage of patients with diabetes was 46.5% in our study population. Mean SVG age in PES and SES groups was 12.15±4.64 years and 10.92±4.67 years, respectively (p=0.29). Procedural and lesion characteristics are shown in Table 2. There was no statistically significant

Table 1. Baseline clinical characteristics in PES and SES groups

Parameters	PES group (n=46)	SES group (n=25)	p*
Age, yrs	67.02±8.26	61.92± 8.59	0.017
Male, n (%)	43 (93.5)	20 (80)	0.12
Family history of CAD, n (%)	13(28.3)	11(44)	0.18
Hypercholesterolemia, n (%)	38 (82.6)	21 (84)	0.88
Smoking, n (%)	12 (26.1)	10 (40)	0.22
Hypertension, n (%)	35 (76.1)	19 (76)	0.99
Diabetes mellitus, n (%)	18 (39.1)	15 (60)	0.09
Prior PCI, n (%)	18 (39.1)	9 (36)	0.79
Prior MI, n (%)	24(52.2)	14 (56)	0.75
Unstable angina, n (%)	19 (41.3)	12 (48)	0.58
Mean SVG age, years	12.15±4.64	10.92±4.67	0.29
LVEF <40, %	6 (13)	4 (16)	0.73

Categorical variables are expressed as numbers (%) and continuous variables as mean±1 standard deviation. *- independent samples t test, Chi-Square statistics and Fisher's exact tests. CAD - coronary artery disease, LVEF - left ventricular ejection fraction, MI - myocardial infarction, PCI - percutaneous coronary interventions,PES - paclitaxel-eluting stent, SES - sirolimus-eluting stent, SVG - saphenous vein graft

difference between two groups by means of lesion and procedure characteristics. Procedural success was 97.8% in PES group and 92% in SES group (p=0.24). The frequency of glycoprotein IIb/IIIa inhibitor and distal embolic protection device usage in SES and PES groups was 13% vs. 8% (p=0.70) and 6.5% vs. 16% (p=0.23), respectively.

In-hospital results and clinical follow-up outcomes

During the in-hospital period non-fatal MI was observed in 1 (2.2%) patient of PES and in 2 (8%) patients of SES (p=0.28) group while there was no death and TVR. One patient died in PES group within the first month after discharge. There was no statistically significant difference between two groups in terms of clinical outcomes at 30-day, six month and 1-year (Table 3). The rates of MACE at 30-days and six months were 4.3% and 6.5% for the PES group and, 8% and 16% for the SES group. At the end of six months after index procedure, there was no additional death recorded in both groups while only one TVR was performed in SES group. In the PES and SES groups, MACE rates at 1-year were 8.7% and 16%, respectively (p=0.44). The rate of MACE-free survival was 91.3% in the PES group and 84% in the SES group (p=0.33) (Fig. 1). One patient (2.2%) was regarded as having early stent thrombosis in the PES group, whereas there was no early stent thrombosis in SES group (p=0.65). Late stent thrombosis was not observed in each group. Nine patients had undergone coronary angiography due to ischemic symptoms and/or a positive functional ischemia study at the end of one-year. As routine angiographic follow-up was not the planned end-point; the results of the angiographic examinations during the follow-up period were not analyzed in the study.

Discussion

The results of our study showed that short- and long-term clinical outcomes of PES versus SES in the treatment of SVG lesions are similar and both drug-eluting stents seem to be effective and safe in real world patients with diseased SVG's.

In most centers, PCI for SVG lesions accounts for 10% to 15% of all coronary interventions (27). Intervention for SVG lesions is associated with a higher risk of peri-procedural complications and late cardiac events when compared with the native coronary PCI (5-9). In general, patients with diseased SVGs tend to be older and likely to have co morbidities, which may reflect relatively high-risk population. Moreover, the tendency for distal atheroembolization of friable and soft plaque results in peri-procedural no-reflow and myocardial infarction in SVG interventions (5). High late cardiac adverse event risk is related to increased restenosis rate at the target site and progression of disease at other sites of SVG's (8).

Several devices and drugs have been tested in SVG lesions to reduce these adverse cardiac outcomes. In two randomized

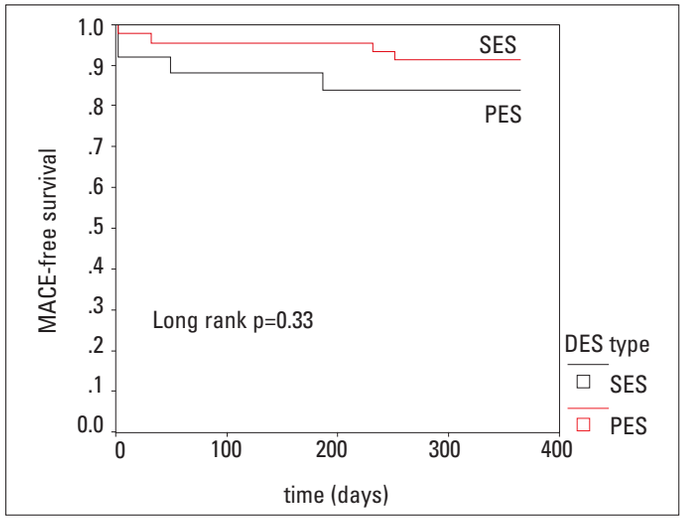

Figure 1. Kaplan-Meier event free survival curve of both study groups
DES - drug-eluting stent, MACE - major adverse composite events, PES - paclitaxel-eluting stent, SES - sirolimus-eluting stent

Table 2. Lesion and procedure characteristics of the study populations

Variables	PES group	SES group	p
Lesion characteristics	(n=59)	(n=29)	
Lesion localization, n (%)			0.29
Ostial	17 (28.9)	4 (13.8)	
Shaft	39 (66.1)	21 (72.4)	
Distal and anastomosis	3 (5.0)	4 (13.8)	
Thrombus	5 (10.9)	2 (8.0)	0.69
In-stent restenosis	8 (13.5)	2 (6.8)	0.50
Procedural characteristics	(n=46)	(n=25)	
Number of stents per patient	1.48±0,66	1.32±0.63	0.33
Reference vessel diameter, mm	3.12±0.32	3.09±0.31	0.69
Pre-intervention			
Diameter stenosis, %	82.2±13.17	80.4±11.72	0.55
Minimal lumen diameter, mm	0.55±0.40	0.61±0.37	0.52
Post-intervention			
Diameter stenosis, %	5.67±2.54	6.24±2.26	0.35
Minimal lumen diameter, mm	3.13±0.27	3.11±0.32	0.70
Stent diameter, mm	3.25±0.26	3.23±0.33	0.78
Lesion length, mm	22.45±6.01	21.64±6.96	0.60
Stent length, mm	25.52±6.27	24.64±7.37	0.60
Maximum balloon pressure, atm	14.59±4.13	16.24±4.67	0.13
Usage of GPIIb/IIIa receptor inhibitors	6 (13.0)	2 (8.0)	0.70
Distal embolic protection device	3 (6.5)	4 (16.0)	0.23
No-reflow	3 (6.5)	3 (12.0)	0.66
Overlapping stent	14(30.4)	5 (20.0)	0.34
Procedural success	45 (97.8)	23 (92)	0.24

Categorical variables are expressed as numbers (%) and continuous variables as mean±1 standard deviation. * - independent samples t test, Chi-Square statistics and Fisher's exact tests.
GP - glycoprotein, PES - paclitaxel-eluting stent, SES - sirolimus-eluting stent

trials, a significant reduction in periprocedural complications and 30-day adverse events has been demonstrated with distal embolic protection devices in SVG interventions (28-29). Thrombectomy catheters may be useful to prevent distal thromboembolism if large luminal thrombi are present (30). However, the use of membrane-covered stents or platelet glycoprotein IIb/IIIa inhibitors has shown no benefit in this lesion subset (31-36). Although, stenting of SVG lesions with BMS reduces acute complications of PCI, the incidence of restenosis and repeat revascularization is still high. There are several studies suggesting favorable outcomes with DES compared to BMS in the treatment of SVG lesions in short- and mid-term follow-up (15-23). Ge et al. (17) reported significantly lower cumulative MACE at six months in DES group compared to BMS group (11.5% vs 28.1%, p=0.02). Lee et al. (18) also demonstrated reduced composite MACE rates with DES in 9.1±2.1 months follow-up (10% in DES vs 37% in BMS, p=0.035). In a randomized trial, Vermeersch et al. showed that SES significantly reduced restenosis rate and repeat revascularization procedures in de novo SVG lesions with respect to BMS at six month (22). On the other hand, in the current literature number of the studies comparing SES with PES in SVG interventions is limited. In a prospective and non-randomized study, comparing SES with PES to treat SVG lesions Chu et al. showed that PES and SES have similar efficacy and clinical outcomes at the end of a six-month follow-up (37). Their six-month MACE rate was 10.5% in the PES group and 8.5% in the SES group (p=0.75). Consistent with this finding, the six-month MACE rate in our study also has not shown a significant difference between two groups (6.5 % in PES group and 16 % in SES group, p=0.23). We have also found non-significant relationship between both groups regarding 1-year clinical outcomes. In addition, when compared with previous studies on SVG interventions with DES, our study population have considerably more diabetic patients (39% in PES group and 60% in SES group, p=0.09) which probably reflect a higher risk profile (15-23, 37).

In the present study, there was only one case of stent thrombosis during the 1-year follow-up. A patient from the PES

Table 3. Short- and mid-term clinical outcomes of PES and SES groups

	PES group (n=46)	SES group (n=25)	p
In-hospital follow-up			
MACE, n(%)	1 (2.2)	2 (8.0)	0.28
Death, n(%)	0 (0)	0 (0)	-
Non-fatal MI, n(%)	1 (2.2)	2 (8.0)	0.28
TVR, n(%)	0 (0)	0 (0)	-
30-day follow-up			
MACE, n(%)	2 (4.3)	2 (8.0)	0.60
Death, n(%)	1 (2.2)	0 (0)	0.65
Non-fatal MI, n(%)	1 (2.2)	2 (8.0)	0.28
TVR, n(%)	0 (0)	0 (0)	-
6-month follow-up			
MACE, n(%)	3 (6.5)	4 (16.0)	0.23
Death, n(%)	1 (2.2)	0 (0)	0.65
Non-fatal MI, n(%)	2 (4.3)	3 (12.0)	0.33
TVR, n(%)	0 (0)	1 (4)	0.35
1-year follow-up			
MACE, n(%)	4 (8.7)	4 (16.0)	0.44
Death, n(%)	1 (2.2)	0 (0)	0.65
Non-fatal MI, n (%)	2 (4.3)	3 (12.0)	0.33
TVR, n(%)	1 (2.2)	1 (4.0)	0.58
Early stent thrombosis, n(%)	1 (2.2)	0 (0)	0.65
Late stent thrombosis, n(%)	0 (0)	0 (0)	-

Categorical variables are expressed as numbers (%). Chi - Square statistics and Fisher's exact tests
MACE - major adverse cardiac event, MI - myocardial infarction, PES - paclitaxel-eluting stent, SES - sirolimus-eluting stent, TVR - target vessel revascularization

group died suddenly within the first month after index PCI while taking dual anti-platelet treatment. Thus, it was categorized as a probable PES thrombosis. In recent years, some concerns were raised about higher rates of late adverse cardiac events after DES implantation because of several reports suggesting increased very late stent thrombosis with DES at long-term follow-up (38-40). In recently published randomized prospective RRISC trial comparing SES to BMS in patients with diseased SVGs, Vermeersch et al. reported a significant increase in total mortality at the end of three-year clinical follow-up and the reduced revascularization rates with SES proven at 6 months was no longer obtained at 3 years (24). This may be related to delayed endothelialization, increased late stent thrombosis risk or delayed restenosis due to reduced drug effectiveness of DES at late period. In our study, we have found no stent thrombosis in SES group while only one case in PES group developed stent thrombosis at the end of 1-year. As our study was limited to 1-year follow-up, no analyzes could be performed to evaluate very late (>1 year) stent thrombosis. In addition, because of the limited sample size, our study may have been underpowered to detect the rate of stent thrombosis.

Study limitations

This study has several limitations. First, it is a single center, retrospective and non-randomized observational study. Second, like similar studies related to SVG interventions, the sample size of our study was small too. Finally, the use of glycoprotein inhibitors and distal embolic protection devices were limited due to social insurance reimbursement problem and there was no routine angiographic follow-up. Despite limitations mentioned above, to the best of our knowledge, this study represents, the longest clinical follow-up of consecutive patients treated with SES versus PES for diseased SVGs.

Conclusions

Short and long-term clinical outcomes of paclitaxel- and sirolimus-eluting stents in the treatment of SVG lesions are similar. Findings of our study suggest that both drug-eluting stents seem to be effective and safe in real world patients with diseased SVGs. Further studies with larger patient groups are needed to clarify the effectiveness of different DESs on SVG lesions.

References

1. Fitzgibbon GM, Leach AJ, Kafka HP, Keon WJ. Coronary bypass graft fate: long-term angiographic study. J Am Coll Cardiol 1991; 17: 1975-80.
2. Fitzgibbon GM, Kafka HP, Leach AJ, Keon KW, Hooper GD, Burton JR. Coronary bypass graft fate and patients outcome: Angiographic follow-up of 5,065 grafts related to survival and reoperation in 1,388 patients during 25 years. J Am Coll Cardiol 1996; 28: 616-26.
3. Foster ED. Reoperation for coronary artery disease. Circulation 1985; 72 (6 Pt 2): V59-V64.
4. Weintraub WS, Jones EL, Morris DC, King SB 3rd, Guyton RA, Craver JM. Outcome of reoperative coronary bypass surgery versus coronary angioplasty after previous bypass surgery. Circulation 1997; 95: 868-77.
5. de Feyter PJ, van Suyken RJ, de Jaegere PP, Topol EJ, Serruys PW. Balloon angioplasty for the treatment of lesions in saphenous vein bypass grafts. J Am Coll Cardiol 1993; 21: 1539-49.
6. Morrison DA, Crowley ST, Veerakul G, Barbiere CC, Grover F, Sacks J. Percutaneous transluminal angioplasty of saphenous vein grafts for medically refractory unstable angina. J Am Coll Cardiol 1994; 23: 1066-70.
7. Webb JG, Carere RG, Virmani R, Baim D, Teirstein PS, Whitlow P, et al. Retrieval and analysis of particulate debris following saphenous vein graft intervention. J Am Coll Cardiol 1999; 34: 468-75.
8. Savage MP, Douglas JS Jr., Fischman DL, Pepine CJ, King SB 3d, Werner JA, et al. SAVED Investigators. Stent placement compared with balloon angioplasty for obstructed coronary bypass grafts. Saphenous Vein De Novo Trial Investigators. N Engl J Med 1997; 337: 740-7.
9. Hanekamp CE, Koolen JJ, Den Heijer P, Schalij MJ, Piek JJ, Bär FWHM, et al. Randomized study to compare balloon angioplasty and elective stent implantation in venous bypass grafts: the Venestent study. Catheter Cardiovasc Interv 2003; 60: 452-7.
10. Keeley E, Velez C, O'Neill W. W, Safian RD. Long-term clinical outcome and predictors of major adverse cardiac events after percutaneous interventions on saphenous vein grafts. J Am Coll Cardiol 2001; 38: 659-65.

11. Silber S, Albertsson P, Aviles FF, Camici PG, Colombo A, Hamm C, et al. Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Guidelines for percutaneous coronary interventions: the task force for percutaneous coronary interventions of the European Society of Cardiology. Eur Heart J 2005; 26: 804-47.
12. Moses J, Leon M, Popma J, Fitzgerald PJ, Holmes DR, O'Shaughnessy C, et al. SIRIUS Investigators. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. N Engl J Med 2003; 349: 1315-23.
13. Morice MC, Serruys PW, Sousa JE, Fajadet J, Ban Hayashi E, Perin M, et al. RAVEL Study Group. Randomized study with the sirolimus-coated bx velocity balloon- expandable stent in the treatment of patients with de novo native coronary artery lesions. A randomized comparison of a sirolimus eluting stent with a standard stent for coronary revascularization. N Engl J Med 2002; 346: 1773-80.
14. Stone GW, Ellis SG, Cox DA, Hermiller J, O'Shaughnessy C, Mann JT, et al. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. N Engl J Med 2004; 350: 221-31.
15. Hoye A, Lemos PA, Arampatzis CA, Saia F, Tanabe K, Değertekin M, et al. Effectiveness of the sirolimus-eluting stent in the treatment of sphenous vein graft disease. J Inv Cardiol 2004; 16: 230-3.
16. Price M, Sawhney N, Kao JA, Madrid A, Schatz RA, Teirstein PS. Clinical outcomes after sirolimus-eluting stent implantation for de novo saphenous vein graft lesions. Catheter Cardiovasc Interv 2005; 65: 208-11.
17. Ge L, Iakovou I, Sangiorgi G, Chieffo A, Melzi G, Cosgrave J, et al. Treatment of saphenous vein graft lesions with drug eluting stents. J Am Coll Cardiol 2005; 45: 989-94.
18. Lee MS, Shah AP, Aragon J, Chieffo A, Melzi G, Cosgrave J, et al. Drug-eluting stenting is superior to bare metal stenting in saphenous vein grafts. Catheter Cardiovasc Interv 2005; 66: 507-11.
19. Sharma A, Minutello RM, Yang F, Wing E, Bhagan S, Chou ET. One-year clinical follow up of sirolimus-eluting stents in the treatment of saphenous vein graft disease. J Am Coll Cardiol 2005; 45 (3 Suppl 1): 25A.
20. Tsuchida K, Ong ATL, Aoki J, van Mieghem CA, Rodriguez-Granillo GA, Valgimigli M, et al. Immediate and one-year outcome of percutaneous intervention of saphenous vein graft disease with paclitaxel-eluting stents. Am J Cardiol 2005; 96: 395-8.
21. Chu WW, Rha SW, Kuchulakanti PK, Cheneau E, Torguson R, Pinnow E, et al. Efficacy of sirolimus-eluting stents compared with bare metal stents for saphenous vein graft intervention. Am J Cardiol 2006; 97: 34-7.
22. Vermeersch P, Agostoni P, Verheye S, Van den Heuvel P, Convens C, Bruining N, et. al. Randomized double-blind comparison of sirolimus-eluting stent versus bare-metal stent implantation in diseased saphenous vein grafts: six-month angiographic, intravascular ultrasound, and clinical follow-up of the RRISC Trial. J Am Coll Cardiol 2006; 19; 48: 2423-31.
23. Hoffmann R, Pohl T, Köster R, Blindt R, Boeckstegers P, Heitzer T. Implantation of paclitaxel-eluting stents in saphenous vein grafts: clinical and angiographic follow-up results from a multicentre study. Heart 2007; 93: 331-4.
24. Vermeersch P, Agostoni P, Verheye S, Van den Heuvel P, Convens C, Van den Branden F, et al. Increased late mortality after sirolimus-eluting stents versus bare-metal stents in diseased saphenous vein grafts results. From the randomized DELAYED RRISC Trial. J Am Coll Cardiol 2007; 50: 261-7.
25. Colombo A, Tobis J. Techniques in Coronary Artery Stenting. London: Martin Dunitz Publishers; 2000.
26. Mauri L, Hsieh WH, Massaro JM, Ho KK, D'Agostino R, Cutlip DE. Stent thrombosis in randomized clinical trials of drug-eluting stents. N Engl J Med 2007; 356: 1020-9.
27. Baim D. Percutaneous treatment of saphenous vein graft disease: the ongoing challenge. J Am Coll Cardiol 2003; 42: 1370-2.
28. Baim DS, Wahr D, George B, Leon MB, Greenberg J, Cutlip DE, et al. On behalf of the Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) Trial Investigators. Randomized trial of a distal embolic protection device during percutaneous intervention of saphenous vein aorto-coronary bypass grafts. Circulation 2002; 105: 1285-90.
29. Stone GW, Rogers C, Hermiller J, Feldman R, Hall P, Haber R, et al. Randomized comparison of distal protection with a filter-based catheter and a balloon occlusion and aspiration system during percutaneous intervention of diseased saphenous vein aorto-coronary bypass grafts. Circulation 2003; 108: 548-53.
30. Stone GW, Cox DA, Babb J, Nukta D, Bilodeau L, Cannon L, et al. Prospective, randomized evaluation of thrombectomy prior to percutaneous intervention in diseased saphenous vein grafts and thrombus-containing coronary arteries. J Am Coll Cardiol 2003; 42: 2007-13.
31. Schachinger V, Hamm CW, Munzel T, Haude M, Baldus S, Grube E, et al. A randomized trial of polytetrafluoroethylene-membrane covered stents compared with conventional stents in aortocoronary saphenous vein grafts. J Am Coll Cardiol 2003; 42: 1360-9.
32. Stankovic G, Colombo A, Presbitero P, van den Branden F, Inglese L, Cernigliaro C, et al. Randomized evaluation of polytetrafluoroethylene-covered stent in saphenous vein grafts: the Randomized Evaluation of polytetrafluoroethylene COVERed stent in Saphenous vein grafts (RECOVERS) trial. Circulation 2003; 108: 37-42.
33. Schachinger V, Hamm CW, Munzel T, Haude M, Baldus S, Grube E, et al. STENTS (STents IN Grafts) Investigators. A randomized trial of polytetrafluoroethylene membrane-covered stents compared with conventional stents in aortocoronary saphenous vein grafts. J Am Coll Cardiol 2003; 42: 1360-9.
34. Ellis S, Linkoff A, Miller D, Tcheng JE, Kleiman NS, Kereiakes D, et al. Reduction in complications of angioplasty with abciximab occurs largely independently of baseline lesion morphology. J Am Coll Cardiol 1998; 32: 1619-23.
35. Roffi M, Mukherjee D, Chew DP, Bhatt DL, Cho L, Robbins MA, et al. Lack of benefit from intravenous platelet glycoprotein IIb/IIIa receptor inhibition as adjunctive treatment for percutaneous interventions of aortocoronary bypass grafts. A pooled analysis of five randomized clinical trials. Circulation 2002; 106: 3063-7.
36. Karha J, Gurm H, Rajagopal V, Fathi R, Bavry AA, Brener SJ, et al. Use of platelet glycoprotein IIb/IIIa inhibitors in saphenous vein graft percutaneous coronary intervention and clinical outcomes. Am J Cardiol 2006; 98: 906-10.
37. Chu WW, Kuchulakanti PK, Wang B, Clavijo LC, Suddath WO, Pichard AD, et al. Efficacy of sirolimus-eluting stents as compared to paclitaxel-eluting stents for saphenous vein graft intervention. J Interven Cardiol 2006; 19: 121-5.
38. McFadden EP, Stabile E, Regar E, Cheneau E, Ong AT, Kinnaird T, et al. Late thrombosis in drug-eluting coronary stents after discontinuation of antiplatelet therapy. Lancet 2004; 364: 1519-21.
39. Lakovou I, Schmidt T, Bonizzoni E, Ge L, Sangiorgi GM, Stankovic G, et al. Incidence, predictors, and outcome of thrombosis after successful implantation of drug-eluting stents. JAMA 2005; 293: 2126-30.
40. Pfisterer M, Brunner-La Rocca HP, Buser PT, Rickenbacher P, Hunziker P, Mueller C, et al. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents an observational study of drug-eluting versus bare-metal stents. J Am Coll Cardiol 2006; 48: 2584-91.