Original Studies

New Approach to Direct Stenting Using a Novel "All-In-One" Coronary Stent System Via 5 French Diagnostic Catheters: A Pilot Study

Ahmed A. Khattab,* MD, Crochan J. O'Sullivan, MB, BCh, Giulio G. Stefanini, MD, Lorenz Räber, MD, Mark Paquin, BS, Stephan Windecker, MD, and Bernhard Meier, MD

Objectives: We sought to evaluate the strategy success and short term clinical outcomes of direct stenting via 5 French (F) diagnostic catheters using a novel bare metal stent with integrated delivery system (IDS) (Svelte Medical Systems, New Providence, NJ) and compare the results to a conventionally treated matched group. Methods: Fifteen consecutive patients with lesions deemed suitable for direct stenting using a bare metal stent were included. The primary endpoint was the strategy success defined as the ability to successfully treat a target lesion via a 5 F diagnostic catheter with a good angiographic result (TIMI III flow, residual stenosis $\leq$20%). Procedure and fluoroscopy times, contrast agent use, cost, and short-term clinical outcomes were compared to a matched group treated via conventional stenting. Results: The primary endpoint was reached in 14/15 patients (93%). There were no significant differences in procedural (58.6 min $\pm$ 12.7 vs. 57.4 min $\pm$ 14.2) or fluoroscopy times (10.0 min $\pm$ 4.3 vs.10.1 min $\pm$ 3.9) or contrast agent use (193.7 ml $\pm$ 54.8 vs. 181.4 ml $\pm$ 35.6). However, there were significant reductions in materials used in the study group compared to the control group equating to cost savings of almost US $600 per case (US $212.44 $\pm$ 258.09 vs. US $804.69 $\pm$ 468.11; $P = 0.001$). Conclusions: Direct stenting using a novel bare metal stent with an IDS via 5 F diagnostic catheters is a viable alternative to conventional stenting in selected patients and is associated with significant cost savings. © 2013 Wiley Periodicals, Inc.

Key words: coronary artery disease; direct stenting; stents

INTRODUCTION

Percutaneous coronary intervention (PCI) through diagnostic catheters had been introduced in the nineties [1–3] but was later abandoned because of the difficulty in using stents.

In Europe, direct stenting is employed in approximately 30% of PCI [4] and has been favorably compared in certain lesion subsets to conventional stenting with predilatation in numerous observational studies [5,6], randomized controlled clinical trials [7–17], and meta-analyses [18,19] using both bare metal stents [7–15] and drug eluting stents [16,17]. In selected lesions (lesser degrees of lesion calcification and moderate vessel tortuosity), high rates of technical and procedural success have been observed [7–17]. In addition, significant reductions in procedural and fluoroscopy times, as well as contrast agent use and overall cost have been reported [18,20].

Department of Cardiology, Bern University Hospital, Bern, Switzerland

Conflict of interest: Nothing to report.

Disclosure: AAK and BM are consultants for SVELTE.

*Correspondence to: Ahmed A. Khattab, Department of Cardiology, Bern University Hospital, 3010 Bern, Switzerland.
E-mail: ahmed.khattab@insel.ch

Received 1 November 2012; Revision accepted 27 January 2013

DOI: 10.1002/ccd.24860
Published online in Wiley Online Library (wileyonlinelibrary.com).

The Svelte™ Medical Systems coronary stent Integrated Delivery System (IDS) comprises a bare metal, thin-strut, ultra flexible cobalt chromium stent mounted on a fixed-wire platform. The system received Conformité Européenne (CE) Mark certification in August 2010, is indicated for direct stenting through 5 French (F) or larger catheters and is currently the lowest profile commercially available coronary stent system [21], enabling its implantation even via 4 F and 5 F diagnostic catheters as previously described in individual case reports [22,23].

The aim of this pilot study was to evaluate the strategy success and short-term clinical outcome of the Svelte IDS in direct stenting de novo lesions in native coronary arteries via 5 F diagnostic catheters and compare the findings to a control group of matched conventional PCI cases.

METHODS

This prospective, nonrandomized, pilot study was performed at the Bern University Hospital, Bern, Switzerland. Informed patient consent was obtained prior to intervention for data acquisition and analysis, and the same operator (AAK) performed all diagnostic and therapeutic procedures in both the study and control groups. Coronary angiography and left ventriculography were performed using standard 5 F diagnostic catheter sets (Judkins Left 4 [JL4], Judkins Right 4 [JR4], and pigtail catheters [Cordis, Johnson & Johnson, Miami Lakes]) via the femoral artery, immediately followed by PCI in all cases in both groups. All stent implantations were performed after administration of a weight adjusted IV heparin bolus. Patients were prescribed dual anti-platelet therapy for at least 1 month (for bare metal stents) or 12 months (for drug eluting stents) and lifelong acetylsalicylic acid was recommended afterwards.

Study Group

Fifteen consecutive patients with lesions judged to be suitable for treatment by direct stenting using a bare metal stent were included in the study group. The study protocol mandated a first attempt at treating the target lesion using the initial standard 5 F diagnostic catheter set (JL4 and JR4 catheters). If necessary, subsequent attempts were to be made by selecting another diagnostic catheter shape or, as a last resort, switching to a guiding catheter. In all cases, the Svelte IDS was to be used in the study group.

Study Device

The Svelte IDS comprises a balloon expandable bare metal, L-605 cobalt chromium stent (strut thickness 81 μm) premounted on a single lumen fixed-wire delivery catheter. Stents are available in 2.5 through 3.5-mm diameters and 13-, 18-, and 23-mm lengths. The stent is highly flexible, with a crimped cross-sectional area half that of currently available commercial stents. The Svelte IDS delivery catheter has a working length of 145 cm and includes two proximal shaft markers at 90 and 100 cm. Proximal and distal radiopaque markers mounted under the balloon indicate both the working length of the balloon and stent under fluoroscopy. Low-compliant balloon material and Balloon Control Bands (BCBs) superimposed on the tips of the balloon are designed to control expansion and limit vessel contact with multiple inflations, while facilitating balloon re-wrapping after stent deployment. An integrated torquing device located on the proximal shaft of the delivery system beneath the inflation connector port can be loosened and positioned along the proximal shaft to facilitate steerability. Alternatively, the catheter can be rotated with the help of the connector wings. Two wire tip configurations are available: 0.012″ with 22-mm length (Acrobat™) and 0.014″ with a flexible, middle-weight 30 mm length (Acrobat FT™) (Fig. 1).

Primary and Secondary Endpoints

The primary endpoint was strategy success. This was defined as the ability to successfully treat a target lesion via a diagnostic catheter using the Acrobat stent with a good angiographic result (TIMI III flow, <20% in-stent stenosis).

Secondary endpoints were in-hospital major adverse cardiovascular and cerebrovascular events, which included death, myocardial infarction, target vessel revascularization (TVR) and cerebrovascular accidents prior to hospital discharge.

Control Group

Study group cases were matched to conventional stenting cases (using a guiding catheter and 0.014″ guidewire, with or without balloon predilation) considering target vessel, vessel segment (i.e., proximal, mid, or distal segment) and lesion type (i.e., AHA/ACC type A, B1, B2, or C lesions) in patients treated contemporarily by the same operator (AAK). After matching, the two groups were analyzed for differences in procedural and fluoroscopy times, contrast volume and cost.

Statistical analysis was done using a Microsoft Office Excel 2007 version 12.0 (Microsoft Corp., Redmond, WA) software. Absolute numbers and percentages were computed to describe the patient population. Categorical values were compared between groups using Chi-square test. For direct comparison between the two treatment groups two-sample *t*-tests assuming unequal variances was used. Differences

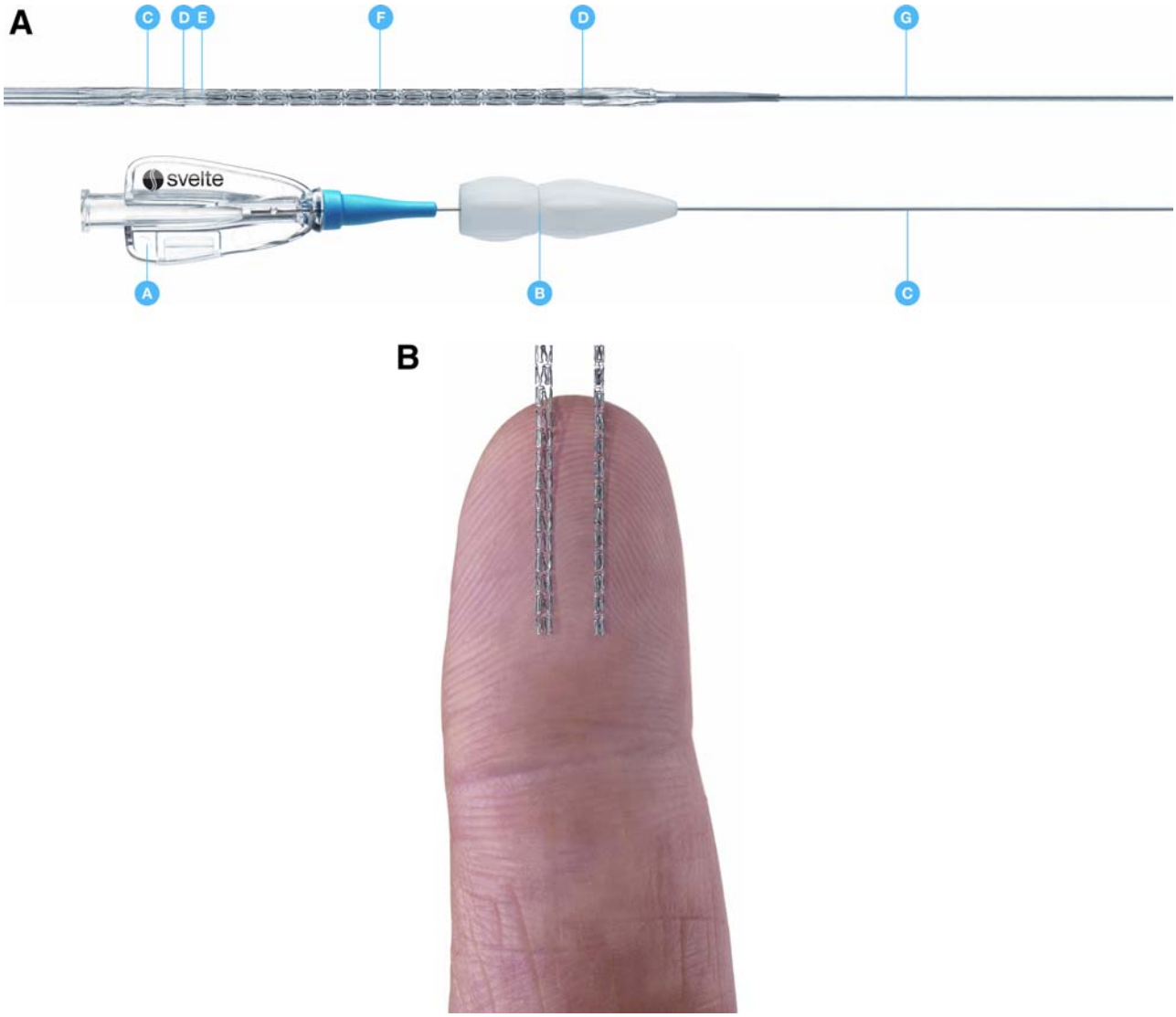

Fig. 1. (a and b) Specifications of The Svelte™ Medical Systems coronary stent IDS. A: Standard luer hub with loop clip for PTCA indeflator connection. B: Integrated, adjustable torque device. C: Uni-body construction with hydrophilic coating; 145-mm length, 5 F compatible. D: BCB technology to minimize edge delivery, facilitate rewrap. E: Low-compliant nylon balloon; Nominal pressure 10–12 Atmospheres, Rated Burst Pressure 18 Atmospheres. F: L605 Cobalt Chromium Stent: 81 μm strut thickness. 0.029 inch (0.74 mm) crimped profile. G: 0.012 inch platinum-iridium atraumatic flexible coil wire tip.

were considered statistically significant at a *P*-value < 0.05. All p-values are results of two-tailed tests. Data, unless otherwise specified, are presented as mean $\pm$ standard deviation.

RESULTS

Fifteen patients with 18 lesions were deemed suitable by the operator and enrolled into the study group. Tables I and II present the baseline demographic and lesion characteristics of the patients treated in both groups. The study group comprised only patients with stable coronary artery disease, whereas over a third of patients in the control group presented with an acute coronary syndrome (all non-ST segment elevation myocardial infarctions). The target vessels treated in the control group were more evenly distributed compared to the study group, where almost 60% of the treated lesions were located in the right coronary artery. Vessel segments treated were essentially equivalent across both groups, as were lesion characteristics as defined by the ACC-AHA Lesion Classification System. Most of the lesions were readily accessible, with the target vessel take-off angle at the origin less

TABLE I. Patient Demographics

	Study group ($N = 14$)	Control group ($N = 14$)	P value
Age (years)	64.2 ± 5.2	71.6 ± 8.0	–
Male gender (n, %)	11 (78.6)	7 (50.0)	0.1
Diabetes mellitus (n, %)	3 (21.4)	1 (7.1)	0.2
Hypertension (n, %)	10 (71.4)	11 (78.6)	0.8
Dyslipidemia (n, %)	6 (42.9)	10 (71.4)	0.1
Family History of IHD (n, %)	2 (14.3)	4 (28.6)	0.3
Prior myocardial infarction (n, %)	8 (57.1)	2 (14.3)	0.02
ACS at presentation (n, %)	0 (0)	5 (35.7)	0.01

ACS: Acute Coronary Syndrome; IHD: Ischemic Heart Disease.

TABLE II. Lesion Characteristics

	Study group (lesions = 17)	Control group (lesions = 17)
Target vessel		
Left anterior descending (n, %)	3 (17.6)	6 (35.3)
Left circumflex (n, %)	2 (11.8)	6 (35.3)
Right coronary artery (n, %)	10 (58.8)	5 (29.4)
Other[a] (n, %)	2 (11.8)	0 (0)
Lesion location		
Proximal (n, %)	7 (41.2)	8 (47.1)
Mid (n, %)	6 (35.3)	7 (41.2)
Distal (n, %)	4 (23.6)	2 (11.8)
ACC/AHA classification		
Type A (n, %)	3 (17.6)	3 (17.6)
Type B1 (n, %)	8 (47.1)	7 (41.2)
Type C (n, %)	0 (0)	0 (0)
Delivery route characteristics	(Target vessels = 17)	(Target vessels = 16)[b]
Take-off angle proximal to target lesion		
<45 (n, %)	11 (64.7)	10 (62.5)
45–90 (n, %)	6 (35.3)	7 (43.8)
>90 (n, %)	0 (0)	0 (0)
Vessel tortuosity		
Mild tortuosity (n, %)	12 (70.6)	12 (75)
Moderate tortuosity (n, %)	5 (29.4)	4 (25)
Severe tortuosity (n, %)	0.0%	0.0%
Degree of calcification		
None to mild (n, %)	17 (100)	9 (56.3)
Moderate (n, %)	0 (0)	7 (43.8)
Severe (n, %)	0 (0)	0 (0)

[a]One Acrobat stent implanted in a second and in a third obtuse marginal branch of the left circumflex coronary artery (one stent in each).
[b]Includes one case where two lesions treated in same vessel.

than 45°. Nearly half of the control group lesions were located in vessels that had moderate calcification, whereas all study group lesions were located in vessels that had mild to no calcification. Baseline reference vessel diameter was about the same for both groups, while the control group had longer lesions. All other angiographic variables were almost identical for both groups (Table III).

TABLE III. Quantitative Coronary Angiography

	Study group (lesions = 17)	Control group (lesions = 17)	P value
Baseline RVD (mm)	3.01 ± 0.37	3.10 ± 0.40	0.5
Lesion length (mm)	11.78 ± 2.39	17.10 ± 6.70	0.0006
MLD-Pre (mm)	0.69 ± 0.06	0.66 ± 0.05	0.1
MLD-Post (mm)	3.32 ± 0.41	3.40 ± 0.45	0.5
Acute gain (mm)	2.63	2.74	N/A
% Diameter Stenosis	77.11 ± 15.29	78.69 ± 11.79	0.7
% Residual Stenosis	20.79	19.42	N/A

RVD: Reference vessel diameter; MLD: Minimum lumen diameter.

TABLE IV. Primary and Secondary Endpoints of the Study (Study group)

Endpoints	$N = 15$	Lesions = 18
Strategy Success[a] (n, %)	14 (93.3)	17 (94.4)
Device Success[b] (n, %)	14 (93.3)	17 (94.4)
Lesion Success[c] (n, %)	15 (100)	18 (100)
1st diagnostic catheter success (n, %)	12 (80)	N/A
2nd diagnostic catheter success (n, %)	2 (13.3)	N/A
Conversion to conventional PCI (n, %)	1 (6.7)	1 (5.6)
TIMI 3 Flow (n, %)	15 (100)	18 (100)
≤ 20% residual stenosis (n, %)	15 (100)	18 (100)

[a]Strategy success: Direct Acrobat stent deployment using a diagnostic catheter resulting in TIMI flow 3, and ≤20% residual stenosis with freedom of MACCE.
[b]Device success was defined as the ability to deliver the Acrobat DS stent to the lesion and deploy it.
[c]Lesion success, TIMI flow 3, ≤ 20% residual stenosis with the freedom of MACCE with any stent.

The primary endpoint of strategy success was achieved in 14 (93.3%) out of 15 patients in whom PCI was performed using a diagnostic catheter to successfully treat 17 out of 18 (94.4%) lesions (Table IV). Two patients required a change from the standard diagnostic catheter to another shape during the procedure due to a lack of catheter support. In both cases a JR4 was replaced with an Amplatz Left diagnostic catheter to treat lesions in the right coronary artery. There was one patient (6.7%) who mandated conversion to conventional stenting (guiding catheter, guidewire, balloon, and drug-eluting stent). This occurred after a failed attempt with a second diagnostic catheter in a distal, type B2 lesion in a moderately tortuous LAD with a >45° take-off angle. In this case, the diagnostic catheters provided inadequate support to allow the Svelte IDS to reach the lesion, which was then successfully treated with a drug-eluting stent using conventional methods. This patient was excluded from the analysis. All 14 patients in the control group were treated using drug-eluting stents, as per hospital protocol. Seven of these patients were treated by direct stenting and seven with balloon predilatation followed by stenting (due to moderate lesion calcification).

Matched Analysis of Cost and Resources

Seventeen lesions were available for comparison in each group. Procedural and materials data are presented in Tables V and VI. Overall, there were no significant differences in either procedure (study group: 58.6 min ± 12.7 vs. control group: 57.4 min ± 14.2) or fluoroscopy time (study group: 10.0 min ± 4.3 vs. control group: 10.1 min ± 3.9), or contrast agent use (study group: 193.7 ml ± 54.8 vs. control group: 181.4 ml ± 35.6). However, there was a significant reduction in materials used and respective cost between study and control groups of nearly US $600 per case (US $212.44 ± 258.09 vs. US $804.69 ± 468.11; $P = 0.001$), excluding the individual stent costs.

Subanalysis of Single Lesion Direct Stenting Cases

A sub-analysis (Table VI) comparing patients undergoing direct stenting of single lesions in both groups confirmed the significant material and costs savings seen in the overall study population (study group: US $75.00 ± 44.59 vs. control group: US $418.11 ± 48.43; $P < 0.0001$). Differences in procedural and fluoroscopy times, contrast use favoring the study group (49.9 min ± 7.7 vs. 59.4 min ± 9.6; 7.5 min ± 2.4 vs. 9.3 min ± 3.5; 163 ml ± 32.8 vs. 174.1 ml ± 24.8) but were not statistically significant.

Table VII presents PCI material usage by case. The study group used significantly fewer guidewires, guiding catheters and balloon catheters per case. Guidewires and balloon catheters were required in two cases in the study group in which (1) conventional PCI was performed on a separate lesion following diagnostic catheter PCI in the same patient and (2) during the case when conventional PCI was performed after a second attempt at PCI via diagnostic catheter was unsuccessful. Otherwise, diagnostic catheters were used without the need for additional guidewires, guiding catheters and pre or post dilation balloon catheters.

DISCUSSION

With the overall improvement in stent designs, including lower profiles and greater flexibility and deliverability, stenting through diagnostic catheters has become possible. The deployment of stents without balloon predilation has gained widespread acceptance in certain lesion subsets in both stable coronary disease [4–17] and acute coronary syndromes [13,24]. This is the result of several observational studies [5,8] and

TABLE VII. PCI Material Usage

	Study ($N = 15$)	Devices/case	Control ($N = 15$)	Devices/case
Guidewires[a]	2	0.1	18	1.3
Diagnotic catheters[b]	20	1.3	0	---
Guiding catheters	2	0.1	15	1.0
Balloon catheters (predilation and postdilation)[a]	2	0.1	10	0.7

[a]Started out as an intent to treat by Acrobat DS/DS only procedure.
[b]Diagnostic catheters were used in performing PCI in study group.
[c]Including the need to change catheter shape and including multivessel PCI.

TABLE V. Overall Cost and Resource Savings[a]

	Study group ($N = 14$)	Control group ($N = 14$)	P value
Mean procedural time (min.)[b]	58.6 ± 15.6	54.7 ± 17.2	0.5
Mean contrast use (ml)[b]	193.7 ± 54.8	181.4 ± 35.6	0.4
Mean fluoroscopy time (min.)[b]	10.0 ± 4.3	10.1 ± 3.9	0.9
Mean materials cost[c]	187.67 CHF ± 227.96	710.73 CHF ± 413.45	0.001
	212.44 USD ± 258.09	804.69 USD ± 468.11	0.001

[a]Including multivessel and multilesion cases.
[b]Includes both diagnostic and therapeutic parts of the procedure.
[c]Excluding individual stent costs.

TABLE VI. Subanalysis Cost and Resource Savings Single Lesion Direct Stenting

	Study group ($N = 8$)	Control group ($N = 7$)	P value
Mean procedural time (min.)[a]	49.9 ± 7.7	59.4 ± 9.6	0.06
Mean contrast use (ml)[a]	163.0 ± 32.8	174.1 ± 24.8	0.4
Mean fluoroscopy time (min.)[a]	7.5 ± 2.4	9.3 ± 3.5	0.2
Mean materials cost[b]	66.25 CHF ± 39.38	369.29 CHF ± 42.78	<0.0001
	75.00 USD ± 44.59	418.11 USD ± 48.43	<0.0001

[a]Includes both diagnostic and therapeutic parts of the procedure.
[b]Excluding individual stent costs.

randomized controlled trials [7–17] performed since the mid 1990s comparing direct stenting with stenting after balloon predilatation, which have affirmed the comparable, and in some cases, superior, short- and long-term clinical outcomes of direct stenting in certain lesion subsets. Much of the early enthusiasm for direct stenting stemmed from initial experimental data suggesting there would be more endothelial preservation and less vascular inflammatory response associated with direct stenting, leading to lower restenosis rates [25]. However, with one notable exception [26], no trial has demonstrated a significant benefit in patients treated with direct stenting in terms of reduction in TVR. Nevertheless, a recently published meta-analysis of 24 randomized controlled trials comparing direct stenting with stenting after balloon predilation showed that direct stenting in selected coronary lesions improves 6-month clinical outcomes in patients undergoing PCI, primarily by reducing the incidence of myocardial infarction [19]. Moreover, a recent analysis of the multicenter, randomized Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial showed that at 1-year follow-up, direct stenting compared to stenting after balloon predilation was associated with a significantly lower rate of all-cause death (1.6% vs. 3.8%, $P = 0.01$) and stroke (0.3% vs. 1.1%, $P = 0.049$) [24]. The postulated mechanism of this improved outcome is a reduction in distal embolization with reduced microcirculatory dysfunction and no-reflow [24]. In addition, less vessel dissections with direct stenting due to the elimination of balloon predilation leads to the use of fewer and shorter stents [20,24].

In this small single center, single operator pilot study, we found that direct stenting using a novel bare metal stent IDS specifically designed for direct stenting, when implanted via 5 F diagnostic catheters was both safe and technically feasible, significantly reducing overall procedural cost when compared to conventional PCI. No adverse clinical events occurred neither during the procedure nor through hospital discharge. The financial savings were considerable and were mainly due to the Svelte IDS obviating the need for guidewires, predilation balloons and guiding catheters. Interestingly, a subanalysis of single lesion direct stenting only cases, revealed material and cost savings in the study group beyond the savings resulting from direct stenting alone compared to stenting after balloon predilation in the control group.

Direct stenting using the Svelte IDS has also been reported through 4 F diagnostic catheters owing to its extremely low profile [23]. Despite the limited back-up support of diagnostic catheters, the Svelte IDS provides strong back-up support through its proximal shaft and can be methodically advanced through tight stenoses with proper technique. For instance, it can be continuously screwed through a tight lesion in contrast to a conventional stent-balloon device [23]. The narrow lumen of diagnostic catheters still allows adequate contrast dye injection and vessel visualization during stent positioning and implantation with the Svelte IDS [22]. Direct stenting using the Svelte IDS via a diagnostic catheter is an attractive option in select lesions for several reasons. First, significant financial savings can be made given the need for guiding catheters and guidewires is obviated unless a bailout situation arises or subsequent lesions require treatment using a conventional approach. In this small pilot study a significant cost reduction of almost US $600 per case (excluding individual stent costs) was realized. Second, in cases where PCI is performed via a femoral approach, the use of smaller femoral sheaths is associated with a significant reduction in incidence of major bleeding complications [27] and less radial artery spasm and occlusion, when using the radial approach [28]. Finally, the often-encountered challenge of engaging a guiding catheter in the ostium of the coronary artery after a diagnostic catheter was perfectly engaged beforehand is avoided.

Theoretically, one would assume that procedural and fluoroscopy times, as well as contrast use, would be significantly reduced along with overall procedure cost with the use of the Svelte IDS via 5 F diagnostic catheters owing to the fact that no time is wasted in changing sheaths, catheters, and loading stents onto guidewires. Analysis of all patients in our study did not demonstrate significant differences in procedure or fluoroscopy times, nor contrast use, between the study group and the control group. However, this is likely due to the fact that following the treatment of a target lesion using the study device, additional lesions deemed not suitable for direct stenting or requiring use of a drug eluting stent (as opposed to a bare metal stent) in the same patient were treated using conventional PCI, adding time to the procedure and contrast use. When only single lesion direct stenting cases of the study group ($n = 7$, 50%) were compared to matched single lesion direct stenting cases of the control group, differences in procedural and fluoroscopy times, and contrast use were indeed observed, although they did not reach statistical significance probably because of the small sample size.

The main limitations of this study are the small sample size, short duration of clinical follow-up, use of only bare metal stents in the study group and nonrandomization. However the same operator treated all patients in the study and control groups, reducing bias. A longer follow-up is needed to assess the rate of TVR

in these patients treated with bare metal stents. However, we first wanted to perform a pilot study focusing on procedural success and demonstrate the technical feasibility of performing direct stenting via 5 French diagnostic catheters using the IDS. Further randomized studies with larger numbers of patients are needed to assess for TVR. In addition, it must be emphasized that the IDS is readily usable via the radial approach, as was demonstrated in individual cases. However, for the purposes of this study the right femoral artery was the access site of choice for all patients. Three patients in the study group had diabetes mellitus and the diameters of the stents deployed were 3.0, 3.0, and 3.5 mm in each patient, respectively. We would caution against using a 2.5-mm diameter bare metal stent in diabetic patients.

Another limitation is that the comparison with the nonrandomized control group is confounded by the small number of patients and by a matching process that only considers the vessel segment and lesion type (A,B,C classification) and ignores clinical variables, QCA values and presence of calcifications. In addition, the procedural time, cost and material usage was only given for the entire procedure and we did not stratify these variables according to number of segments treated. Seven patients in the control group underwent balloon predilatation and postdilatation. The additional cost of the balloons used for pre and postdilation and the price of the guidewires (which comprises part of the IDS but is included in the material costs of the control group) exaggerates the price difference between the two strategies. However, one of the advantages of the IDS is that the guidewire is included thereby reducing costs. A further limitation is the fact that the control group had patients presenting with non-ST segment elevation myocardial infarction and that group can have more significant and complex disease requiring more equipment and thus cost. In addition, the study is limited to type A and B1 lesions. The SPEED (Svelte "All-In-One" Stent System Performance Examined Through Diagnostic Catheter Delivery) multicenter, multioperator large registry is currently ongoing to confirm the results observed in our single-center experience. In this study, we will aim to include acute coronary syndromes, more complex lesions and a more even distribution of study group vessels. In addition, a drug eluting (sirolimus) stent utilizing a nonthrombogenic, fully bioabsorbable drug carrier on an IDS has been developed, with initial evaluation conducted in the DIRECT (Direct-on-a-wire Implantation of Rapamycin-eluting stent with bio-Eroding Carrier Technology) First-In-Man study. A larger multi-center study is planned this year in support of CE Mark certification of this new product.

CONCLUSIONS

Direct stenting using a novel bare metal stent with IDS via 5 F diagnostic catheters is associated with a high rate of technical success and significantly reduces procedural cost in properly selected lesions. The main advantages of this technique through diagnostic catheters over conventional PCI were observed in single AHA/ACC type A or B1 discrete lesions located in the proximal to mid segments of medium to large noncalcified epicardial arteries that were suitable for direct stenting in this study.

REFERENCES

1. Moles VP, Meier B, Urban P, de la Serna F, Pande AK. Percutaneous transluminal coronary angioplasty through 4 French diagnostic catheters. Cathet Cardiovasc Diagn 1992;25:98–100.
2. Mehan VK, Meier B, Urban P, Verine V, Haine E, Dorsaz PA. Coronary angioplasty through 4 French diagnostic catheters. Cathet Cardiovasc Diagn 1993;30:22–26.
3. Garachemani AR, Kaufmann U, Fleisch M, Meyer BJ, Luscher TF, MeiEr B. Percutaneous transluminal coronary angioplasty through 5 French diagnostic catheters. J Invasive Cardiol 1996;8:433–437.
4. Briguori C, Sheiban I, De Gregorio J, Anzuini A, Montorfano M, Pagnotta P, Marsico F, Leonardo F, Di Mario C, Colombo A. Direct coronary stenting without predilation. J Am Coll Cardiol 1999;34:1910–1915.
5. Pentousis D, Guerrin Y, Funck F, Zheng H, Toussaint M, Corcos T, Favereau X. Direct stent implantation without predilatation using the Multilink stent. Am J Cardiol 1998;82:1437–1440.
6. Wilson SH, Berger PB, Mathew V, Bell MR, Garratt KN, Rihal CS, Bresnahan JF, Grill DE, Melby S, Holmes DR. Immediate and late outcomes after direct stent implantation without balloon predilation. J Am Coll Cardiol 2000;35:937–943.
7. Ormiston JA, Webster MWI, Ruygrok PN, Elliot JM, Simmonds MB, Meredith IT, Devlin GP, Stewart JT, Dixon SR, Price S, Ellis CJ, West TM, on behalf of the NIR Future Trial Investigators. A randomized study of direct coronary stent delivery compared with stenting after predilatation: The NIR Future Trial. Catheter Cardiovasc Interv 2000;50:377–381.
8. Kovar LI, Monrad ES, Sherman W, Kunchithapatham S, Ravi KL, Gotsis W, Silverman G, Brown DL. A randomized trial of stenting with or without balloon predilatation for the treatment of coronary artery disease. Am Heart J 2001;142:E9.
9. Elbaz M, El Mokhtar E, Khalifè K, Citron B, Izaaz K, Hamon M, Juliard JM, Leclercq F, Fourcade J, Lipiecki J, Sabatier R, Boulet V, Rinaldi JP, Mourali S, Fatouch M, Asmar A, Steg PG, Puel J, Carriè D. Is direct coronary stenting the best strategy for long-term outcome? Results of the multicentric randomized benefit evaluation of direct coronary stenting (BET) study. Am Heart J 2002;144:e7.
10. Baim DS, Flatley M, Caputo R, O'Shaughnessy C, Low R, Fanelli C, Popma J, Fitzgerald P, Kuntz R. Comparison of Predilatation vs direct stenting in coronary treatment using the Medtronic AVE S670 coronary stent system (the PREDICT Trial). Am J Cardiol 2001;88:1364–1369.
11. Le Breton H, Boschat J, Commeau P, et al. Randomised comparison of coronary stenting with and without balloon predilatation in selected patients. Heart 2001;86:302–308.

12. Brito FS, Caixeta AM, Perin MA, Rati M, Arruda A, Cantarelli M, Castello H, Machado BM, Silva LA, Ribeiro EE, da Luz PL. Comparison of direct stenting versus stenting with predilation for the treatment of selected coronary narrowings. Am J Cardiol 2002;89:115–120.
13. Loubeyre C, Morice MC, Lefèvre T, Pièchaud JF, Louvard Y, Dumas P. A randomized comparison of direct stenting with conventional stent implantation in selected patients with acute myocardial infarction. J Am Coll Cardiol 2002;39:15–21.
14. Martinez-Elbal L, Ruiz-Nodar JM, Zueco J, Lopez-Minguez JR, Moreu J, CAlvo I, Ramirez JA, Alonso M, Vazquez N, Lezaun R, Rodriguez C, for the DISCO Investigators. Direct coronary stenting versus stenting with balloon pre-dilation: Immediate and follow-up results of a multicentre, prospective, randomized study. The DISCO trial. Direct Stenting of Coronary Arteries. Eur Heart J 2002;23:633–640.
15. Mehilli J, Kastrati A, Dirschinger J, Etzel L, Bollwein H, Pache J, Schühlen H, von Beckerath N, Seyfarth M, Schmitt C, Schömig A. Intracoronary stenting and angiographic results: Restenosis after direct stenting versus stenting with predilation in patients with symptomatic coronary artery disease (ISAR-DIRECT Trial). Catheter Cardiovasc Interv 2004;61:190–195.
16. Ormiston JA, Mahmud E, Turco MA, et al. Direct stenting with the TAXUS Libertè Drug-Eluting Stent. JACC Cardiovasc Interv 2008;1:150–160.
17. Moses JW, Weisz G, Mishkel G, et al. The SIRIUS-DIRECT trial: A multi-center study of direct stenting using the sirolimus-eluting stent in patients with de novo native coronary artery lesions. Catheter Cardiovasc Interv 2007;70:505–512.
18. Burzotta F, Trani C, Prati F, Hamon M, Mazzari MA, Mongiardo R, Sabatier R, Boccanelli A, Schiavoni G, Crea F. Comparison of outcomes (early and six-month) of direct stenting with conventional stenting (a meta-analysis of ten randomized trials). Am J Cardiol 2003;91:790–796.
19. Piscione F, Piccolo R, Cassese S, Galasso G, D'Andrea C, De Rosa R, Chiariello M. Is direct stenting superior to stenting with predilation in patients treated with percuraneous coronary intervention? Results from a meta-analysis of 24 randomised controlled trials. Heart 2010;96:588–594.
20. Barbato E, Marco J, Wijns W. Direct stenting. Eur Heart J 2003;24:394–403.
21. Available at: http://www.sveltemedical.com/news.php?pid=39&article=69. Accessed on 21 July 2012.
22. Khattab AA, Shrestha NR, Meier B. Double-vessel coronary stenting via 5 French diagnostic catheters. Catheter Cardiovasc Interv 2012, epub ahead of print.
23. Meier B, Binder RK, Vogel R. Coronary stenting through 4 French diagnostic catheter. Catheter Cardiovasc Interv 2012;79:122–124.
24. Möckel M, Vollert J, Lansky AJ, Witzenbichler B, Guagliumi G, Peruga JZ, Brodie BR, Kornowski R, Dudek D, Farkouh ME, Parise H, Mehran R, Stone GW. Comparison of direct stenting with conventional stent implantation in acute myocardial infarction. Am J Cardiol 2011;108:1697–1703.
25. Rogers C, Parikh S, Seifert P, Edelman ER. Endogenous cell seeding. Remnant endothelium after stenting enhances vascular repair. Circulation 1996;94:2909–2014.
26. Brueck M, Scheinert D, Wortmann A, Bremer J, von Korn H, Klinghammer L, Kramer W, Flachskampf FA, Daniel WG, Ludwig J. Direct coronary stenting versus predilatation followed by stent placement. Am J Cardiol 2002;90:1187–1192.
27. Doyle BJ, Ting HH, Bell MR, Lennon RJ, Mathew V, Singh M, Holmes DR, Rihal CS. Major femoral bleeding complications after percutaneous coronary intervention. Incidence, predictors, and impact on long-term survival among 17,901 patients treated at the Mayo Clinic from 1994 to 2005. J Am Coll Cardiol Intv 2008;1:202–209.
28. Uhlemann M, Möbius-Winkler S, Mende M, Eitel I, Fuernau G, Sandri M, Adams V, Thiele H, Linke A, Schuler G, Gielen S. The Leipzig prospective vascular ultrasound registry in radial artery catheterization: impact of sheath size on vascular complications. JACC Cardiovasc Interv. 2012;5:36–43.