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Svelte Integrated Delivery System Performance Examined Through Diagnostic Catheter Delivery: The SPEED Registry

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Aims: The multi-center SPEED registry evaluated the procedural success and in-hospital clinical outcomes of direct stenting with the Svelte 'all-in-one' coronary stent Integrated Delivery System (IDS) through diagnostic catheters to identify the clinical indications for which this approach is appropriately suited. Methods & results: Forty-eight (48) patients with 54 lesions of lengths ≤20 mm and RVD 2.5–3.5 mm were targeted for direct stenting through diagnostic catheters (4–6F) via radial or femoral approach. Procedural characteristics early in an investigator's experience (28 lesions) were compared with outcomes following experience (26 lesions). Procedure, device and strategy success were realized in 54 (100%), 50 (93%) and 46 (85%) lesions, respectively, with strategy success significantly related to RVD ($P = 0.05$), lesion location ($P = 0.01$), and diagnostic catheter size ($P = 0.05$). Significant improvement in crossing and intervention time and trends toward improvement in device and strategy success, reductions in procedure and radiation time and contrast use were observed. Conclusions: Direct stenting through diagnostic catheters via radial or femoral approach using the Svelte IDS is feasible and associated with good in-hospital outcomes. This approach offers the attractive option of assessing lesions via diagnostic catheter and, depending upon vessel anatomy and lesion morphology, continuing with ad-hoc interventional treatment using the same diagnostic catheter. Improvements in strategy success and procedural efficiencies, based on operator experience, facilitate catheter downsizing and reduce intervention time, ancillary product use and overall procedure costs.

Key words: coronary artery disease; diagnostic cardiac catheterization; direct stenting; percutaneous coronary intervention

INTRODUCTION

Percutaneous coronary intervention (PCI) through diagnostic catheters was first attempted shortly after the advent of coronary stents and largely abandoned due to technological limitations confounding the feasibility of this approach [1,2]. However, an ever-increasing interest in downsizing in interventional cardiology, supported by dedicated technological advances and reports of improved outcomes associated with smaller access sites, has made exploration of PCI through diagnostic catheters relevant again [3,4]. Procedure time and cost may be reduced if the need to insert a guiding catheter (and requisite additional manipulation to re-engage the vessel) can be avoided by performing PCI directly through the diagnostic

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catheter. Whether using the trans-femoral or trans-radial approach, reducing catheter size results in earlier ambulation and enhanced patient comfort, less access site complications and reduced contrast use/risk of contrast-induced nephropathy (CIN) [5,6].

Direct stenting is employed in approximately 30–40% of PCI procedures [7,8]. In selected lesions (lesser degrees of calcification, moderate vessel tortuosity), the procedural benefits of direct stenting compared with conventional pre-dilatation stenting have been previously shown: high technical and procedural success [8,9] with significant reductions in procedure and fluoroscopy times, contrast use and procedural cost [10–12]. Direct stenting may also be associated with improved clinical outcomes: shorter ischemic times, reduced vessel trauma and containment of thrombus and friable plaque are postulated to mitigate myocardial cell injury (as reflected in reduced post-procedural troponin levels) [13,14] while major adverse cardiac events are reduced [12,15,16].

The Svelte (Svelte Medical Systems, New Providence, New Jersey, USA) coronary stent Integrated Delivery System (IDS) is an ultra-low profile, bare-metal cobalt–chromium stent mounted on an integrated wire delivery platform specifically designed to downsize access sites and facilitate use of the radial approach. Indicated for direct stenting, the Svelte IDS was previously evaluated against matched historical controls in a single-center, single-operator pilot study examining the feasibility of direct stenting *de novo* lesions through 5F diagnostic catheters [17]. The multi-center SPEED registry seeks to expand upon this initial positive experience, examining the procedural success and in-hospital outcomes across various patient subsets to better determine the clinical indications in which direct stenting through diagnostic catheters is ideally suited.

METHODS

Device Description

The Svelte IDS is comprised of an uncoated balloon expandable L-605 cobalt–chromium stent (strut thickness 8 μm) pre-mounted on a single lumen integrated (fixed) wire delivery catheter (Fig. 1). The hybrid stent design is highly flexible with a crimped cross-sectional area one-half that of currently available commercial stents and is available in diameters 2.5–3.5 mm and lengths 13, 18, and 23 mm. The IDS is characterized by low lesion entry (0.012″, 0.305 mm or 0.014″, 0.356 mm, depending on wire tip configuration) and crimped stent (as low as 0.029″, 0.737 mm) profiles.

Two wire tip configurations of platinum–iridium flexible coil construction are available with the IDS: 0.012″ diameter with 22 mm length (Acrobat™) and 0.014″ diameter with 30 mm length (Acrobat FT™, Fig. 2). The wire tip is manually shaped in conventional fashion, with catheter navigation facilitated by an integrated torquing device located on the proximal shaft of the delivery system.

Low-compliant balloon material and proprietary elastic Balloon Control Bands (BCBs) located on the proximal and distal balloon shoulders focus pressure inside the stent, providing controlled balloon expansion with minimal balloon-vessel contact beyond the stent edges (Fig. 3). The stent delivery balloon increases in diameter by approximately 0.25 mm at the balloon rated burst pressure (NOM: 11 ATM; RBP: 18ATM; MBP: 26ATM), allowing high-pressure postdilata-

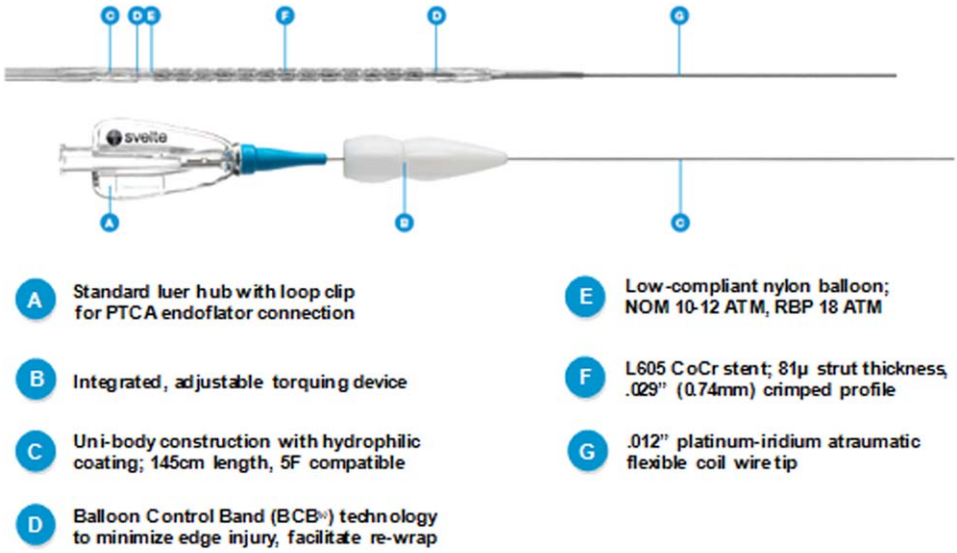

Fig. 1. The Svelte coronary stent integrated delivery system (IDS).

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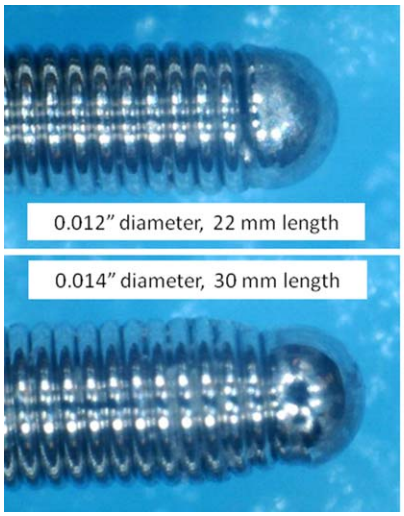

Fig. 2. Detail of the Svelte Acrobat™ and Acrobat FT™ wire tip configurations.

tion(s) with the delivery system and often obviating the need for a separate non-compliant balloon.

Study Overview and Patient Population

SPEED was a prospective, open-label, multi-center registry designed to confirm the results of the previously published single-center, single-operator evaluation of direct stenting with the Svelte IDS through 5F diagnostic catheters [17] and further assess procedural success and in-hospital outcomes across various patient subsets to better determine the clinical indications for which this approach is ideally suited. Inclusion of 'real-world' clinical presentations were encouraged: patients with acute coronary syndromes (ACS), complex and bifurcation lesions, a wide distribution of coronary vessels (as defined by the CASS system) and use of any size diagnostic catheter, including 4F, were permitted. Patients aged >18 years with symptomatic ischemic heart disease due to a single *de novo* stenotic lesion within a native coronary artery or saphenous vein graft (SVG) were eligible for inclusion in the study. Lesion length was <20 mm with vessel reference diameter (RVD) between 2.5 and 3.5 mm.

Patients with angiographic evidence of thrombus, total occlusions (TIMI 0/1 flow), unprotected left main disease, severe vessel tortuosity, significant calcification contra-indicating direct stenting or lesions clearly indicated for treatment with drug-eluting stents were excluded from the study. Other exclusion criteria included known hypersensitivity or contraindication to aceltyl salcilic acid (ASA), heparin or bivalirudin, clopidogrel, ticlopidine, or contrast media.

Fig. 3. Detail of Svelte balloon control band (BCB) technology.

The registry adhered to the principles of good clinical practice and the Declaration of Helsinki. All patients provided informed consent prior to the intervention for data acquisition and analysis.

Interventional Procedure

All patients received ASA (minimum 75 mg daily, commencing at least 24-h prior to the procedure and continuing indefinitely) and clopidogrel (300–600 mg loading dose within 24-h prior to the procedure and then 75 mg daily for a minimum of 30-days) or otherwise per institutional practice. Choice of vascular access (i.e., radial or femoral) was left to operator discretion. Coronary angiography and left ventriculography were performed using standard 4F or 5F diagnostic catheter sets. During the procedure heparin was administered per institutional practice; monitoring of activated coagulation time (ACT) was not mandatory.

Baseline coronary angiography was performed in at least two orthogonal views free of vessel overlap or foreshortening following 100–200 mcg of intracoronary nitroglycerine. Lesions judged suitable for treatment by direct stenting using a bare-metal stent were included. The study protocol mandated a first attempt at treating the target lesion using the initial diagnostic catheter set (Judkins left and right configuration catheters). If necessary, subsequent attempts were made by selecting another diagnostic catheter shape or, as a last resort, switching to a guiding catheter.

Study Endpoints and Definitions

The primary study endpoint was procedural success, defined as attainment of <20% final residual stenosis of the target lesion and no in-hospital MACE, calculated on a per-patient basis. Secondary endpoints included strategy, device and lesion success and an assessment of procedural efficiencies which included crossing, procedure, intervention and radiation time as well as contrast and adjunctive product use. Procedural characteristics early in an operator's experience were compared with those after experience was gained to account for operator variability and increased proficiency through greater use of diagnostic catheters for interventional applications. An operator was considered

'experienced' with the use of diagnostic catheters for interventional applications after completing four interventions, a definition created post-hoc. An exploratory univariate analysis was performed to evaluate associations between patient baseline characteristics and device and strategy success.

Strategy success was defined as attainment of <20% final residual stenosis of the target lesion using only the Svelte IDS, with no pre-dilatation and delivery only through a diagnostic catheter, calculated on a per-lesion basis. Device success was defined as attainment of <20% final residual stenosis of the target lesion using the Svelte IDS and any other non-stent therapy, delivered via any catheter (diagnostic or guiding), calculated on a per-lesion basis. Lesion success was defined as attainment of <20% final residual stenosis of the target lesion using any stent or adjunctive devices, calculated on a per-lesion basis.

Crossing time was the time from when the wire tip of the Svelte IDS exited the first diagnostic catheter used in the coronary intervention until stent deployment. If another stent system was used, the crossing time continued running until the alternative stent was deployed. Procedure time was the time from insertion of the first diagnostic catheter into the introducer sheath until removal of the catheter from the sheath. Intervention time was the time of heparin administration intended for the PCI until removal of the catheter from the introducer sheath. Radiation exposure was measured in total minutes and contrast was measured in total milliliters across the entire procedure time.

In-hospital MACE was defined as a hierarchical composition of all-cause mortality, myocardial infarction (MI) or repeat revascularization until discharge from the hospital for the index procedure. All deaths were considered cardiac unless an unequivocal non-cardiac cause was established. MI was defined as: (a) Q-wave MI—chest pain or other acute symptoms consistent with myocardial ischemia *and/or* elevation of post-procedure CK-MB $\geq 5\times$ the upper limit of normal (ULN) *and* new pathological Q-waves in two or more contiguous ECG leads (in the absence of timely cardiac enzyme data), or new pathologic Q-waves in two or more contiguous ECG leads and elevation of cardiac enzymes above normal; (b) non-Q-Wave MI (NQWMI)—chest pain or other acute symptoms consistent with myocardial ischemia *and* elevation of post-procedure CK-MB $\geq 5\times$ ULN [18].

Cost Savings

To assess potential cost savings associated with direct stenting the Svelte IDS through diagnostic catheters, hypothetical costs were calculated for conventional direct stenting in the SPEED population. Based on cross-over rates reported in previous randomized trials designed to evaluate direct stenting, a success rate of conventional direct stenting was estimated at 90% [10,12], with post-dilatation rates the same as reported in the current study (26%). The assumption was made that diagnostic catheters were used only for diagnostic purposes and not to perform PCI with conventional stenting. Material prices and product usage rates, regarded as representative of European cath labs, were provided by the cath lab purchasing manager at one of the participating centers.

Sample Size and Statistical Analysis

The SPEED registry was designed to provide informational data about the performance, feasibility and safety of direct stenting using the Svelte IDS via diagnostic catheters while providing guidance for the clinical indications in which this approach can be recommended.

All data were analyzed using IBM SPSS Statistics software version 20 (IBM Corp., Armonk, NY). Results for continuous variables were presented as means $\pm$ standard deviation or medians [interquartile range], as considered appropriate. Categorical variables were reported as counts and percentages. Comparison of continuous variables was performed using the Student's *t*-test or Mann–Whitney *U* test, depending on data distribution and group size. Categorical variables were analyzed using Chi-square or Fisher's exact test. A two-sided *P*-value ≤ 0.05 was regarded statistically significant. Associations between variables were expressed in odds ratios (OR).

All patient procedural data was collected via dedicated clinical report forms and submitted for analysis and summary to the R&D core-lab at the University Medical Center Utrecht (Utrecht, The Netherlands).

RESULTS

Forty-eight (48) patients were enrolled at four clinical sites in Switzerland, The Netherlands, Germany and France between March 2012 and April 2013. Patients were aged 67.8 ± 11.0 years and 18 (38%) were female, with 13 (27%) exhibiting ACS and 18 (38%) undergoing PCI via trans-radial approach. A total of 54 lesions with mean diameter stenosis of $79.8 \pm 11.9\%$ and even distribution across the left and right coronary trees were treated with 57 stents. Investigator-assessed mean reference vessel diameter was 3.09 ± 0.36 mm and median stented length was 18 mm [13–19] (Tables I and II).

Procedural success was achieved in 48 patients (100%) and lesion success was achieved in 54 lesions (100%). Device success was achieved in 50 lesions

TABLE I. Baseline Patient and Lesion Characteristics

Patients	$N = 48$
Age (years)	67.8 ± 11.0
Female (*n*, %)	18 (38)
Smoking (*n*, %)	8 (17)
Hypertension (*n*, %)	27 (56)
Diabetes mellitus (*n*, %)	6 (13)
Dyslipidemia (*n*, %)	17 (32)
Renal impairment (*n*, %)	2 (4)
Indication for percutaneous coronary intervention	
NSTEMI (*n*, %)	7 (15)
Unstable angina pectoris (*n*, %)	6 (12)
Stable angina pectoris (*n*, %)	35 (73)
Number of lesions	
1 (*n*, %)	43 (90)
2 (*n*, %)	4 (8)
3 (*n*, %)	1 (2)
Lesions	$N = 54$
Target vessel	
RCA (*n*, %)	26 (48)
LAD (*n*, %)	20 (37)
RCX (*n*, %)	8 (15)
Lesion type (AHA)	
A (*n*, %)	17 (32)
B1 (*n*, %)	33 (61)
B2 (*n*, %)	4 (7)
Lesion length	
<10 mm (*n*, %)	25 (46)
10–20 mm (*n*, %)	26 (48)
>20 mm (*n*, %)	3 (6)
Bifurcation lesion (*n*, %)	1 (2)
Diameter stenosis (%)[a]	79.8 ± 11.9
Reference vessel diameter (mm)*	3.09 ± 0.36

NSTEMI, non-ST-elevation myocardial infarction; AHA, American Heart Association.
[a]Visually estimated by the operator.

TABLE II. Procedural Data (Per-lesion Analysis)

Variable	$N = 54$
Approach	
Femoral (*n*, %)	33 (61)
Radial (*n*, %)	21 (39)
Diagnostic catheter size	
4F (*n*, %)	10 (19)
5F (*n*, %)	20 (37)
6F (*n*, %)	24 (44)
More than one stent implanted	
Per patient (*n*, %)	7 (15)
Per lesion (*n*, %)	3 (6)
Stented length	
Per patient (mm)	18 [13–18]
Per lesion (mm)	18 [13–19]
Direct stenting (*n*, %)	50 (93)
Svelte IDS delivered through diagnostic catheter (*n*, %)	46 (83)
Other stent than Svelte IDS implanted (*n*, %)	4 (7)
Svelte IDS delivery failure (*n*, %)	2 (4)
Postdilatation (*n*, %)	14 (26)
Non-Svelte IDS postdilatation (*n*, %)	8 (15)
Maximum applied pressure(atm)	16.4 ± 3.4
Crossing time (min)	1.4 [0.5–4.2]
Intervention time (min)	10.3 [5.1–18.7]
Procedural time (min)	41.7±20.4
Radiation time (min)	9.9 [4.9–12.1]
Contrast used (ml)	120 [100–156]
Procedural success (*n*, %)	48 (100)
Lesion success (*n*, %)	54 (100)
Device success (*n*, %)	50 (93)
Strategy success (*n*, %)	46 (85)
Freedom from procedural complications (*n*, %)	46 (96)
Coronary artery dissection (*n*, %)	2 (4)
In-hospital MACE (*n*, %)	0

IDS, integrated delivery system; ATM, atmosphere.

(93%), while strategy success was realized in 46 lesions (85%). A total of 50 lesions (93%) were successfully treated with direct stenting, while 30 lesions (56%) were treated via 4F or 5F diagnostic catheter delivery, with an average 1.0 ± 0.2 diagnostic catheters used per patient. Freedom from procedural complications was 96%, with two procedural dissections noted: the first, a small Type-A distal dissection which resolved without need for placement of an additional stent, and the second, proximal and distal dissections attributed by the investigator to overestimating the vessel diameter, necessitating placement of two additional smaller stents (Table II). No patients experienced in-hospital MACE.

Univariate Analysis

Univariate analysis (Table III) revealed a statistically significant association between device success and lesion type, as well as lesion location ($P = 0.03$ and $P = 0.02$, respectively). Strategy success appeared significantly related to RVD ($P = 0.05$), target vessel ($P = 0.01$), lesion location ($P = 0.01$), and diagnostic catheter size ($P = 0.05$).

Post-hoc analysis (Table IV) demonstrated significantly greater device success in Type A/B1 lesions compared with Type B2 lesions (OR 15.7; 95% CI: 1.60–153) and in main-branches compared with side-branches (OR 24.0; 95% CI: 2.14–269). Significantly higher strategy success rates were realized in main-branch versus side-branch lesions (OR 45.0; 95% CI: 4.01–505), RCA/LAD versus LCX vessels (OR 10.5; 95% CI: 1.87–58.9), larger diameter (>2.5 mm) versus small diameter vessels (OR 8.20; 95% CI: 1.55–43.5) and smaller (<6F) versus larger caliber catheters (OR 11.9; 95% CI: 1.35–106). Multivariate analysis was not performed as sample sizes were deemed insufficient to generate robust univariate data.

TABLE III. Univariate Analysis for Predictors of Device Success and Strategy Success

Variable		Device success (*n*, %)	*P*-value	Strategy success (*n*, %)	*P*-value
Indication	Stable AP	37/40 (92)	0.46	6/40 (85)	0.21
	Unstable AP	5/6 (87)		2/6 (67)	
	NSTEMI	8/8 (0)		8/8 (100)	
Approach	Radial	18/21 (86)	0.30	4/21 (81)	0.70
	Femoral	32/33 (97)		4/33 (88)	
Catheter size	6F	21/24 (87)	0.52	17/24 (71)	0.05[a]
	5F	19/20 (95)		20/20 (100)	
	4F	10/10 (100)		9/10 (90)	
Target vessel	RCA	25/26 (96)	0.35	3/26 (89)	0.01[a]
	LAD	17/20 (85)		19/20 (95)	
	RCx	8/8 (100)		4/8 (50)	
Lesion location	Proximal	15/17 (88)	0.02[a]	17/17 (100)	0.01[a]
	Mid	26/26 (100)		3/26 (89)	
	Distal	6/6 (100)		6/6 (100)	
	Side-branch	3/5 (60)		1/5 (20)	
Lesion type	A	17/17 (100)	0.03[a]	3/17 (82)	0.27
	B1	31/33 (94)		29/33 (88)	
	B2	2/4 (50)		1/4 (75)	
Lesion length	≤10 mm	23/24 (96)	0.30	21/25 (84)	1.00
	10–20 mm	24/26 (92)		4/26 (85)	
	≥20 mm	2/3 (67)		3/3 (100)	
RVD	>3.0 mm	19/21 (90)	0.06	2/21 (91)	0.05[a]
	2.5–3.0 mm	24/24 (100)		2/22 (92)	
	≤2.5 mm	7/9 (78)		5/9 (56)	

AP, angina pectoris; NSTEMI, non-ST-elevation myocardial infarction; AHA, American Heart Association; RVD, reference vessel diameter.
[a]Statistically significant difference.

TABLE IV. Post-hoc Univariate Analysis for Predictors of Device Success and Strategy Success

Variable		Device success ($n = 50$) (*n*, %)	*P*-value	OR	95% CI
Lesion location	Main-branch	48/50 (96)	0.02[a]	24.0	2.14–269
	Side-branch	2/4 (50)			
Lesion type	A/B1	47/49 (96)	0.04[a]	15.7	1.60–153
	B2	3/5 (60)			
Variable		Strategy success ($n = 46$) (*n*, %)	*P*-value	OR	95% CI
Lesion location	Main-branch	45/49 (98)	0.001[a]	45.0	4.01–505
	Side-branch	1/5 (20)			
Target vessel	RCA/LAD	42/46 (91)	0.01[a]	10.5	1.87–58.9
	RCX	4/8 (50)			
RVD	>2.5 mm	41/45 (91)	0.02[a]	8.20	1.55–43.5
	=2.5 mm	5/9 (56)			
Catheter size	4F/5F	29/30 (97)	0.02[a]	11.9	1.35–106
	6F	17/24 (71)			

RVD, reference vessel diameter.
[a]Statistically significant difference.

Learning Curve Analysis

When sub-grouping patients treated by operators 'inexperienced' (24 patients with 28 lesions) and 'experienced' (24 patients with 26 lesions) with diagnostic catheter delivery, significant improvements in crossing time (2.5 [1.0–4.9] vs. 0.8 [0.3–3.0] min, $P = 0.01$) and intervention time (16.0 [9.8–36.0] vs. 6.8 [4.8–10.9] min, $P < 0.01$), as well as trends toward improvement in device and strategy success and reductions in procedure time, were observed. Small decreases in radiation time and contrast were also noted (Table V).

Product Utilization and Cost Savings

An average of 1.04 ± 0.19 diagnostic catheters were used per lesion, while the number of guiding catheters, guidewires and PTCA balloons ranged from 0.2 to 0.3 per patient and per lesion, indicative of the success in

TABLE V. Learning Curve Analysis

Variable	Learning curve ($n = 28$)	Continued experience ($n = 26$)	P-value
Device success (n, %)	25 (89)	25 (96)	0.61
Strategy success (n, %)	22 (79)	24 (92)	0.25
>1 Diagnostic catheter used (n, %)	1 (4)	1 (4)	1.00
Crossing time (min)	2.5 [1.0–4.9]	0.8 [0.3–3.0]	0.01*
Intervention time (min)	16.0 [9.8–36.0]	6.8 [4.8–10.9]	<0.01*
Procedural time (min)	44.5 ± 21.6	38.4 ± 18.8	0.31
Contrast used (ml)	122 [97–164]	120 [100–148]	0.66
Radiation time (min)	9.4 [5.4–12.1]	7.9 [4.5–12.6]	0.93

TABLE VI. Resource Utilization

Variable	Dx catheters	Guiding catheters	Guidewires	PTCA balloons
Total quantity (n)	56	15	12	14
>1 used per lesion (n, %)	2 (4)	1 (2)	2 (4)	2 (4)
>1 used per patient (n, %)	3 (6)	1 (2)	2 (4)	2 (4)
Average per lesion (n)	1.04 ± 0.19	0.31 ± 0.51	0.25 ± 0.53	0.29 ± 0.62
Average per patient (n)	1.08 ± 0.35	0.28 ± 0.49	0.22 ± 0.50	0.26 ± 0.59
No. of lesions material used in (n, %)	–	14 (26)	10 (19)	11 (20)
No. of patients material used in (n, %)	–	14 (29)	10 (21)	11 (23)

delivering the Svelte IDS through diagnostic catheters (Table VI). Though no matched controls were provided, material usage appears from previous experience to be considerably lower than would be expected with conventional stenting [17].

Material usage and cost estimates are provided in Table VII. Median material costs (excluding the stent system) were 0.00 [0.00–119.44] USD in the study population versus 119.40 [119.40–358.33] USD in the hypothetical conventional stenting group ($P < 0.0001$), representing per-patient potential cost savings of 119.40 [63.19–119.44] USD. Savings were primarily driven by differences in guiding catheter, guide wire and postdilatation balloon catheter use. In addition to savings derived from reductions in material costs, benefits may result from decreases in procedure time and contrast media used, which seems reasonable once experience is gained using this approach.

DISCUSSION

Use of 6F diagnostic catheters for interventional procedures has been achieved, as previously reported [19]. However, this experience is of diminishing relevance as emphasis is continually placed on downsizing, with 4F and 5F catheters increasingly used. This is particularly true in light of the recent global shift from the femoral to radial approach [20], based upon reports of reduced procedural complications, overall mortality and hospital costs with increased patient comfort [21]. Reduced profiles remain at a premium given the difficulties of catheter manipulation and increased incidence of radial artery occlusion when the ratio between the radial artery's inner diameter and the catheter's outer diameter is less than 1 [22].

This study is the first to assess delivery of the Svelte IDS through diagnostic catheters as small as 4F across a broad patient population and across multiple clinical sites. Only 50 patients were targeted for the study, as the Svelte IDS is available solely as a bare-metal stent platform at present and the 4 participating clinical sites are tertiary centers primarily engaged in complex procedures indicated for drug-eluting stent use. Despite the challenges of stenting through diagnostic catheters (less robust catheter construction, back-up support and catheter shape configurations compared with standard interventional guiding catheters), the high procedural, device and strategy success rates experienced in this study support the feasibility of this approach in the conventional cath lab setting. From an operator's perspective, the Svelte IDS provides strong back-up support through its proximal shaft and can be methodically advanced beyond tight stenoses. Its low profile allows adequate contrast injection and vessel visualization during stent positioning and implantation despite the reduced lumen diameters of diagnostic catheters. Occasional dampening of pressure tracing recordings across the diagnostic catheter (prior to delivery and while the Svelte IDS was in the diagnostic catheter) were observed, however this had no clinical relevance or impact on product performance. Average contrast use per procedure (120 ml, range 100–148 ml) appeared less than that typically observed with conventional stenting procedures, which is of obvious benefit

TABLE VII. Cost Savings

	Study population ($n=48$)		Conventional direct stenting ($n=48$)	
	n	Per patient	*n*	Per patient
Diagnostic catheters	56	1.17	34	0.71
Guiding catheters	15	0.31	50	1.04
Guidewires	12	0.25	51	1.06
Balloon catheters	14	0.29	21	0.44
Median material costs[a]	0.00 EUR [0.00–86.00] 0.00 USD [0.00–119.44]		86.00 EUR [86.00–258.00][b] 119.40 USD [119.40–358.33][b]	

[a]Excluding individual stent costs.
[b]*P*-value <0.0001 for comparison SPEED vs. conventional direct stenting material costs (Wilcoxon signed ranks test).

to patients with impaired renal function, however this is merely an anecdotal observation of this registry.

Given the device success rates experienced in our study, use of the Svelte IDS offers the attractive option of assessing lesions via diagnostic catheter and, depending upon vessel anatomy and lesion morphology, continuing with ad-hoc interventional treatment using the same diagnostic catheter. For modestly experienced operators, so doing in appropriate lesions reduces intervention and overall procedure time, as well as ancillary product use and overall procedural costs, while enhancing patients comfort [17].

Device success was achieved in 93% of lesions, with strategy success realized in 85%. Of the eight lesions in which strategy success was not achieved (i.e., failure to deliver the Svelte IDS via diagnostic catheter without pre-dilatation), five required pre-dilatation and three required greater trackability and/or back-up support. All patients experienced procedural success. There did not appear to be a difference in device or strategy success based on radial versus femoral approach.

A higher probability for strategy success was identified in Type A and/or Type B1, non-RCX main-branch lesion subsets. Interestingly, device and strategy success were most frequently encountered with the use of 4F and 5F catheters, though this may be explained by more complex interventions being attempted through 6F diagnostic catheters. Strategy success with B2 lesions (50%) appeared to be influenced by degree of experience using the Svelte IDS with diagnostic catheters: two of the four B2 lesions were treated by 'inexperienced' operators, which may account for lower success rates, as well as a tendency to avoid B2 lesions later in the study. No correlation between strategy success and patient status (stable AP, unstable AP, NSTEMI) was apparent, though direct stenting of side-branches via diagnostic catheters appeared to be a significant detriment to strategy success.

Most ACS patients experienced device and strategy success (93% and 79%, respectively), a potentially important finding in our study given the HORIZONS-AMI study demonstrated direct stenting to be associated with lower rates of all-cause death compared with conventional pre-dilatation stenting (1.6% vs. 3.8%, $P=0.01$) and stroke (0.3% vs. 1.1%, $P=0.049$) at 1-year [16]. The postulated mechanism of these improved outcomes is reduced distal embolization, microcirculatory dysfunction and slow or no-reflow by avoiding pre-dilatation. As a fixed-wire delivery system indicated for direct stenting, the Svelte IDS may prove especially useful in an ACS setting where minimal manipulation and reduced intervention time and are high priorities.

In the 54 lesions treated in this study, 56 diagnostic catheters, 15 guiding catheters, 14 PTCA balloons, and 12 guidewires were used, a considerable reduction in material use and associated cost compared with conventional PCI. Increased experience with the Svelte IDS resulted in significant reductions in lesion crossing and overall intervention time. Direct stenting Type A and B1 lesions located in the proximal-mid portion of vessels $\geq$2.5 mm in diameter through 4F–6F diagnostic catheters, via radial or femoral approach, is especially viable in our experience.

Finally, not infrequently a guiding catheter will fail to engage a coronary ostium despite earlier cannulation with a diagnostic catheter. Whether this is due to slight differences in catheter tip shape or design or simply difficulty in re-accessing a unique take-off, continuing to a therapeutic approach via diagnostic catheter may simplify certain procedures.

Study Limitations

This was a small, non-randomized study intended to provide insights into the safety and efficacy of the Svelte IDS delivered primarily through diagnostic catheters. The univariate analysis to identify factors related to device and strategy failure must be regarded as exploratory and hypothesis generating. More patients with longer follow-up in a randomized setting are required to provide conclusive assessments regarding long-term clinical outcomes in specified clinical indications. Availability of the Svelte IDS in a drug-eluting version (currently in clinical trials) would allow for assessment across wider patient and lesion sub-groups. Finally any cost savings analysis is hypothetical, intending only to explore the potential financial advantages of direct stenting the Svelte IDS through

diagnostic catheters, a more rigorous, and ideally randomized study, is necessary to determine true economic benefit.

CONCLUSION

Direct stenting through diagnostic catheters via radial or femoral approach using the Svelte IDS is feasible and associated with good short-term clinical outcomes. This approach offers the attractive option of assessing lesions via diagnostic catheter and, depending upon vessel anatomy and lesion morphology, continuing with ad-hoc interventional treatment using the same diagnostic catheter. Improvements in strategy success and procedural efficiencies, based on operator experience, facilitate catheter downsizing, and reduce intervention time, ancillary product use and overall procedure costs in selected patients.

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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 Feb;25(2):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 Sep;30(1):22–26.
3. Meier B, Binder RK, Vogel R. Coronary stenting through 4 French diagnostic catheter. Catheter Cardiovasc Interv 2012 Jan; 79(1):122–124.
4. Khattab A, Shrestha NR, Meier B. Double-vessel coronary stenting via 5 French diagnostic catheteters. Catheter Cardiovasc Interv 2012 Oct;80(4):630–633.
5. Grossman PM, Gurm HS, McNamara R, Lalonde T, Changezi H, Share D, Smith DE, Chetcuti SJ, Moscucci M, Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2). Percutaneous coronary intervention complications and guide catheter size: bigger is not better. JACC Cardiovasc Interv 2009;2:636–644.
6. 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 lonmg-term survival among 17,901 patients treated at the Mayo Clinic from 1994 to 2005. JACC Cardiovasc Interv 2008;1:202–209.
7. Beohar N, Davidson CJ, Kip KE, Goodreau L, Vlachos HA, Meyers SN, Benzuly KH, Flaherty JD, Riccardi MJ, Bennett CL, Williams DO. Outcomes and complications associated with off-label and untested use of drug-eluting stents. JAMA 2007; 297(18):1992–2000.
8. Ormiston JA, Mahmud E, Turco MA, Popma JJ, Weissman N, Cannon LA, Mann T, Lucca MJ, Lim ST, Hall JJ, McClean D, Dobies D, Mandinov L, Baim DS. Direct stenting with the TAXUS Liberte drug-eluting stent. J Am Coll Cardiol Intv 2008;1(2):150–160.
9. Moses JW, Weisz G, Mishkel G, Caputo R, O'shaughnessey C, Wong SC, Fischell TA, Mooney M, Williams DO, Popma JJ, Fitzgerald P, Smith S, Kuntz RE, Collins M, Cohen SA, Leon MB. The SIRIUS-DIRECT trial: a multi-center study of direct stenting using the sirolimus-eluting stent in patietns with de novo native coronary artery lesions. Catheter Cardiovasc Interv 2007 Oct 1;70(4):505–512.
10. 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.
11. Barbato E, Marco J, Wijns W. Direct stenting. Eur Heart J 2003;24:394–403.
12. Piscone 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 percutaneous coronary intervention? Results from a meta-analysis of 24 randomised controlled trials. Heart 2010;96:588–594.
13. Atmaca Y, Ertas F, Gülec S, Dincer I, Oral D. Effect of direct stent implantation on minor myocardial injury. J Invasive Cardiol 2002 Aug; 14(8):443–446.
14. Nageh T, Thomas MR, Sherwood RA, Harris BM, Jewitt DE, Wainwright RJ. Direct stenting may limit myocardial injury during percutaneous coronary intervention. J Invasive Cardiol 2003 May; 15(3):115–118.
15. 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.
16. 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.
17. Khattab A, O'Sullivan C, Stefanini G, Räber L, Paquin M, Windecker S, Meier B. New approach to direct stenting using a novel 'all-in-one' coronary stent system via 5 French diagnostic catheters: a pilot study. Catheter Cardiovasc Interv 2013 Oct;82(4):E403–E410.
18. Thygesen K, Alpert J, White H, et al. Third universal definition of myocardial infarction. Eur Heart J 2012;33:2551–2567.
19. Resar JR, Prewitt KC, Wolff MR, Blumenthal R, Raqueno JV, Brinker JA. Percutaneous transluminal coronary angioplasty through 6F diagnostic catheters. Am Heart J 1993; 125:1591–1596.
20. Feldman DN, Swaminathan RV, Kaltenbach LA, Baklanov DV, Kim LK, Wong SC, Minutello RM, Messenger JC, Moussa I, Garratt KN, Piana RN, Hillegass WB, Cohen MG, Gilchrist IC, Rao SV. Adoption of radial access and comparison of outcomes to femoral access in percutaneous coronary intervention: an updated report from the national cardiovascular data registry (2007–2012). Circulation 2013;127:2295–2306.
21. Jolly SS, Yusuf S, Cairns J, Niemelä K, Xavier D, Widimsky P, Budaj A, Niemelä M, Valentin V, Lewis BS, Avezum A, Steg PG, Rao SV, Gao P, Afzai R, Joyner CD, Chrolavicius S, Mehta SR. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. Lancet 2011;377:1409–1420.
22. Saito S, Ikei H, Hosokawa G, Tanaka S. Influence of the ratio between radial artery inner diameter and sheath outer diameter on radial artery flow after transradial coronary intervention. Catheter Cardiovasc Interv 1999 Feb; 46(2): 173–178.