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Comparison of the Sheath Delivery System Versus Bare Stenting for Coronary Stent Implantation

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Outside the United States, Palmaz-Schatz coronary stents are implanted by hand-crimping the stent to a high pressure balloon without the use of a protective sheath. This lowers the delivery profile, increases the ease of deployment, and ensures that the postdilatation balloon is centered on the stent. To assess this bare stenting technique, 209 patients were retrospectively analyzed: 92 patients (107 lesions) with the sheath protected stent delivery system (SDS) and 117 patients (150 lesions) with the bare stent approach. The number of balloons used per lesion in the bare stent group was significantly less than in the SDS group (1.9 ± 0.6 vs. 3.8 ± 1.2, $P < 0.0001$). In addition, the procedure time in the bare stent group was significantly shorter than in the SDS group (106 ± 55 vs. 134 ± 60 min, $P = 0.001$). There was no difference in frequency of adverse events or stent displacement during the procedure. The bare stenting technique decreases the procedure time, reduces the number of balloons used, and is as safe as the SDS approach. *Cathet. Cardiovasc. Diagn. 43:386–394, 1998.*

Key words: coronary stents; stent delivery system; bare stenting

INTRODUCTION

In recent years, a variety of intracoronary stents has been developed that offer a valuable nonsurgical approach to the management of acute complications of failed angioplasty and to reduce restenosis compared with percutaneous transluminal coronary angioplasty [1,2]. The most commonly used stent system in the United States is the Palmaz-Schatz coronary stent (Cordis, a Johnson & Johnson Company, Miami Lake, FL). This stent has two slotted tubular segments joined by a single filament and is delivered with a sheath-protected stent delivery system [2]. Despite its successful clinical use, the Palmaz-Schatz stent is relatively bulky and inflexible, and is difficult to place in tortuous vessels. Outside the United States, to overcome these drawbacks, the majority of Palmaz-Schatz stents are implanted by hand-crimping the stent to a high pressure balloon without the use of a protective sheath [3,4]. This lowers the delivery profile, increases the ease of deployment, and ensures that the postdilatation balloon is centered on the stent. The purpose of the present study was to retrospectively evaluate the benefit and safety of the bare stenting technique as practiced in one center in the United States.

METHODS

Patients

From March 1995 through February 1997, 226 consecutive patients with 291 lesions were treated with intracoronary stents by two operators. The stent delivery system (SDS) was used until October 1996; after this period, all patients received stents that were removed from the SDS and hand-crimped to a high pressure balloon. We retrospectively analyzed 209 patients with 257 lesions that were treated with Palmaz-Schatz stents. The other 17 patients were excluded because they received Gianturco-Roubin stents (Cook Inc., Bloomington, IN). Patients were classified into two groups: 117 patients (150 lesions) with the bare stent technique (bare stent group) and 92 patients (107 lesions) with the sheath-protected stent delivery system (SDS group). The clinical characteristics of study patients are shown in Table I.

Stent Implantation Procedure

In the SDS group, Palmaz-Schatz stents were delivered with a sheath-protected stent delivery system according

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TABLE I. Clinical Characteristics of Study Patients*

	Bare Stent Group	SDS Group	*P* Value
Number of patients	117	92	
Number of lesions	150	107	
Number of stents used	192	151	
Age, year	66 ± 11	65 ± 12	0.30
Male	93 (79%)	69 (75%)	0.44
Indication for stenting			
Stable angina	33 (28%)	31 (34%)	0.39
Unstable angina	55 (47%)	49 (53%)	0.37
Acute MI	29 (25%)	12 (13%)	0.03
Lesion site			
LAD	70 (47%)	45 (42%)	0.46
LCX	27 (18%)	23 (22%)	0.49
RCA	41 (27%)	30 (28%)	0.90
LM	1 (1%)	0	0.99
CABG	11 (7%)	9 (8)	0.75
Number of treated lesions per patient			
1 lesion	82 (70%)	71 (77%)	0.25
2 lesions	31 (27%)	19 (21%)	0.33
3 lesions	4 (3%)	2 (2%)	0.59

*CABG = Coronary artery bypass graft, LAD = left anterior descending coronary artery, LCX = left circumflex coronary artery, LM = left main coronary artery, MI = myocardial infarction, RCA = right coronary artery.

to standard guidelines [2]. In the bare stent group, the stent was removed from the delivery system and manually mounted on a low profile balloon catheter according to the method of Colombo [3, personal communication]. Because unmounted stents are not available in the United States, the factory premounted and sheathed Palmaz-Schatz stents were delivered to the table. The delivery sheath was retracted from the stent. The stent was removed from the balloon catheter by applying steady traction and gently rotating it from side to side. The stent was then placed onto a 16 gauge angiocath plastic sheath. The tapering surface of the angiocath needle facilitated the stent transfer, although this can also be accomplished over a straight wire mandril. The angiocath, loaded with the stent, was advanced over the balloon catheter and the stent was placed proximal to the uninflated balloon. A low profile, high pressure, noncompliant balloon catheter was most commonly used (NC Bandit™, SCIMED/Boston Scientific Corp, Maple Grove, MN). The balloon was inflated to 4 atm and the surface was wiped with an alcohol swab to remove the hydrophilic coating with the expectation that this would enhance the stability of the stent on the balloon. The balloon was prepped with 20 cc negative suction to ensure minimum profile. The stent was positioned between the balloon markers and the negative pressure was released from the balloon. The stent was manually squeezed in a circumferential fashion until it was tightly mounted on the balloon. A short segment wire was advanced into the distal end on the balloon catheter to stiffen the catheter and to prevent collapse of the inner lumen when the stent was crimped. The balloon catheter was then advanced over the guidewire and a final crimping was performed prior to insertion into an 8F guiding catheter. Examples of a hand-crimped bare stent or a preloaded SDS are shown in Figure 1. The diameter of a crimped bare stent on an NC Bandit™ 3.5 mm balloon or an SDS with a 3.0 mm balloon were measured by a micrometer five times and averaged. The mean diameter of the hand-crimped bare stent was 0.5 mm smaller than the SDS (1.3 mm vs. 1.8 mm).

A single stent was defined as one full-stent or one half-stent implantation. The number of balloons per lesion was defined as the sum of dilatation balloons used to predilate, deliver the stent, or postdilate the stent. The number of balloons per stent was calculated as the number of balloons per lesion divided by the number of stents per lesion. In the bare stent group, the stents were delivered with one of the dilatation balloons and frequently the same balloon was used to predilate, deliver the stent, and then expand it at high pressures. Procedure time was defined as the period that the patient entered and exited the catheterization laboratory.

The dictated procedure notes were reviewed retrospectively to determine the incidence of difficult stent deliveries. This was defined as significant resistance in getting the stent to the lesion which required extra time, a different guidewire or special manipulation.

Adverse events were defined as intraprocedural complications during the coronary intervention, including stent displacement. Stent displacement was defined as stent dislodgement from the balloon catheter in an unexpected place.

Statistical Analysis

Statistical analysis was performed on a Power Macintosh 8500 with a commercially available software program (Statview 4.5, Abacus Concept Inc., Berkeley, CA). Values were expressed as mean ± standard deviation (SD). Differences between groups were evaluated by chi-square analysis (two-way table or multiple proportions test) or Fisher exact test for categoric variables and by *t*-test for continuous variables. P values <0.05 were considered significant.

RESULTS

Clinical Characteristics

There were no differences in mean age, gender, lesion site, or the number of treated lesions per patient in the two groups. However, PTCA for acute myocardial infarction was more frequent in the bare stent group than in the SDS group (25% vs. 13%, $P < 0.05$).

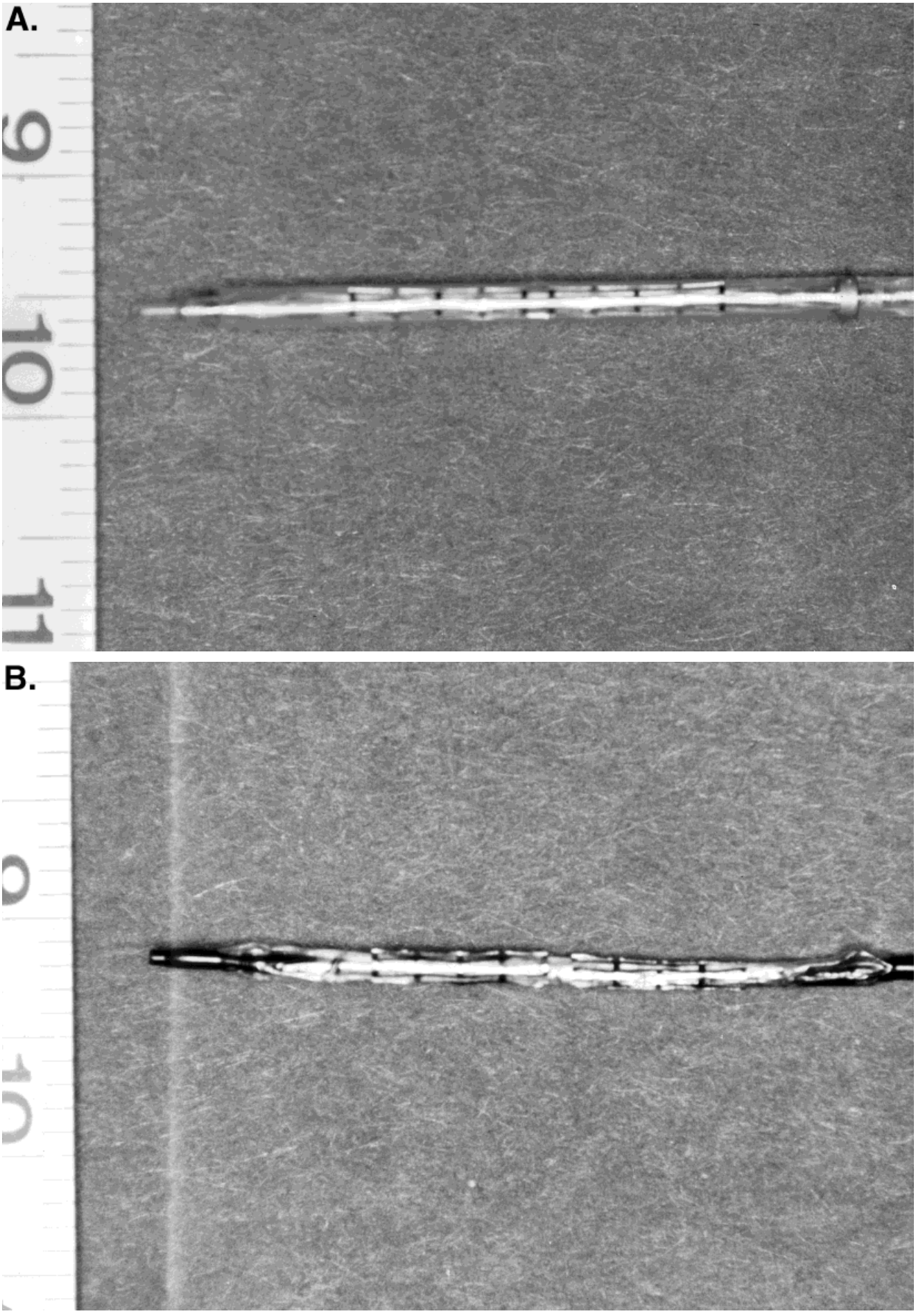

Figure 1.

Procedural Characteristics

There were 192 stents successfully deployed in the bare stent group, and 151 stents in the SDS group. As shown in Table II, there were no significant differences in the number of stents used per lesion or the frequency of lesions treated with a Rotablator™ (SCIMED, Boston Scientific Corp., Maple Grove, MN) prior to stent placement. A half-stent was used in six lesions (4%) in the bare stent group and three lesions (3%) in the SDS group ($P = 0.45$). In the SDS group, the half-stents were remounted on the stent delivery system after cutting the stent at the articulation. A single stent was used in 109 lesions (73%) in the bare stent group and in 69 lesions (66%) in the SDS group ($P = 0.24$). However, the mean number of balloons used per lesion in the bare stent group was significantly less than in the SDS group (1.9 ± 0.6 vs. 3.8 ± 1.2, $P < 0.0001$). Even if the balloon used with the SDS is discounted, the mean number of balloons used per lesion in the bare stent group was significantly less than in the SDS group (1.9 ± 0.6 vs. 2.4 ± 0.7, $P < 0.0001$). If the number of balloons is counted per stent instead of per lesion, the mean number of balloons used per stent in the bare stent group was significantly less than in the SDS group (1.6 ± 0.6 vs. 2.8 ± 0.7, $P < 0.0001$). If the balloon used with the SDS is discounted, the mean number of balloons used per stent in the bare stent group was still significantly less than in the SDS group (1.6 ± 0.6 vs. 1.9 ± 0.7, $P < 0.01$). The incidence of using only a single balloon was 25% per lesion or 44% per stent in the bare stent group. The maximal balloon size in the SDS group was significantly larger than in the bare stent group (3.5 ± 0.4 vs. 3.3 ± 0.4 mm, $P < 0.0001$). There was no difference in the frequency of high pressure (≥16 atm) inflations in the two groups. Intravascular ultrasound (IVUS) guidance for stent deployment was used in 20% of the patients in the bare stent group versus 70% in the SDS group ($P < 0.0001$). The procedure time in the bare stent group was significantly shorter than in the SDS group (106 ± 55 vs. 134 ± 60 min, $P = 0.001$). In addition, fluoroscopy time in the bare stent group was 29% shorter than in the SDS group (29 ± 17 vs. 41 ± 22 min, $P < 0.0001$). There was no difference in total contrast volume used in the two groups.

Fig. 1. A: Palmaz-Schatz stent with a sheath delivery system. The measured diameter of this stent delivery system with a 3.0 mm balloon was 1.8 mm. B: Palmaz-Schatz stent manually mounted on an NC Bandit™ 3.5 mm balloon ("bare stent"). The diameter of this mounted bare stent was 1.3 mm.

TABLE II. Comparison of Procedural Characteristics*

	Bare Stent Group	SDS Group	*P* Value
Number of stents per lesion			
Mean ± SD	1.3 ± 0.5	1.4 ± 0.7	0.21
1 half	4 (3%)	1 (1%)	0.32
1 full	105 (70%)	68 (65%)	0.39
1 full + 1 half	2 (1%)	2 (2%)	0.54
2 full	35 (24%)	22 (21%)	0.66
3 full	3 (2%)	10 (10%)	0.01
4 full	0	1 (1%)	0.41
Number of balloons per lesion			
Mean ± SD	1.9 ± 0.6	3.8 ± 1.2	<0.0001
1	37 (25%)	0	<0.0001
2	94 (63%)	7 (7%)	<0.0001
3	18 (12%)	46 (44%)	<0.0001
≥4	0	51 (49%)	<0.0001
Number of balloons per stent			
Mean ± SD	1.6 ± 0.6	2.8 ± 0.7	<0.0001
1	65 (44%)	0	<0.0001
2	76 (51%)	37 (36%)	0.015
3	8 (5%)	49 (47%)	<0.0001
≥4	0	18 (17%)	<0.0001
Maximal balloon size (mm)	3.3 ± 0.4	3.5 ± 0.4	<0.0001
Maximal inflation pressure			
<16 atm	20 (13%)	9 (10%)	0.42
≥16 atm	129 (87%)	91 (90%)	0.42
IVUS guidance	23 (20%)	64 (70%)	<0.0001
Rotablator used	33 (28%)	21 (23%)	0.43
Procedure time (min)	106 ± 55	134 ± 60	0.001
Fluoroscopy time (min)	29 ± 17	41 ± 22	<0.0001
Total contrast used (ml)	373 ± 198	385 ± 179	0.67

*IVUS = Intravascular ultrasound.

Single Stent Placement

Table III shows the procedural characteristics in the patients who were treated with a single stent in only one lesion. The mean number of balloons used in the bare stent group was significantly less than in the SDS group (1.9 ± 0.5 vs. 3.2 ± 0.7, $P < 0.0001$). Even if the balloon used with the SDS is discounted, the mean number of balloons used per lesion in the bare stent group was significantly less than in the SDS group (1.9 ± 0.5 vs. 2.2 ± 0.7, $P < 0.05$). The procedure time in the bare stent group was significantly shorter than in the SDS group (85 ± 49 vs. 108 ± 56 min, $P < 0.05$). In addition, the fluoroscopy time in the bare stent group was 33% shorter than in the SDS group (24 ± 16 vs. 32 ± 22 min, $P < 0.05$). There was no difference in total contrast volume used in the two groups.

Difficulty of Stent Delivery

As shown in Table IV, it was difficult to deliver nine of 192 stents (4.7%) in the bare stent group, which included

TABLE III. Procedural Characteristics in the Patients Treated With a Single Stent*

	Bare Stent Group	SDS Group	*P* Value
Number of patients	56 (48%)	45 (49%)	
Number of balloons			
Mean ± SD	1.9 ± 0.5	3.2 ± 0.7	<0.0001
1	10 (18%)	0	0.002
2	40 (71%)	6 (13%)	<0.0001
3	6 (11%)	26 (58%)	<0.0001
≥4	0	13 (29%)	<0.0001
Procedure time (min)	85 ± 49	108 ± 56	0.04
Fluoroscopy time (min)	24 ± 16	32 ± 22	0.03
Total contrast used (ml)	342 ± 211	304 ± 149	0.33
IVUS guidance	12 (21%)	34 (75%)	<0.0001

*IVUS = Intravascular ultrasound.

TABLE IV. Frequency of Difficult Stent Delivery

	Bare Stent Group (n = 192)	SDS Group (n = 151)	*P* Value
Total number of difficult stent deployments	9 (4.7%)	11 (7.3%)	0.32
Unsuccessful deployment	1 (0.5%)	3 (2.0%)	0.32
I) Stent delivered through a non-stented artery			
Number of difficult stent deployments	5 (2.6%)	9 (6.0%)	0.12
Successful deployment	5 (2.6%)	8 (5.3%)	0.20
Unsuccessful deployment	0	1 (0.7%)	0.44
II) Stent delivered through a deployed stent to a distal site			
Number of difficult stent deployments	4 (2.1%)	2 (1.3%)	0.59
Successful deployment	3 (1.6%)	0	0.26
Unsuccessful deployment	1 (0.5%)	2 (1.3%)	0.59

five stents delivered through a nonstented but tortuous artery and four stents delivered through a prior proximal stented lesion. Only one of these stents could not be deployed successfully. In the SDS group, it was difficult to deliver 11 of 151 stents (7.3%, $P = 0.32$), which included eight stents delivered through a nonstented artery. If the SDS catheter could not be advanced to the lesion, the sheath was withdrawn to reduce the profile and the stent was readvanced. In eight of the nine cases, this resulted in successful deployment. The SDS system was also attempted in two cases to pass through a stent that had just been deployed at a proximal site. This was unsuccessful in both cases, despite attempts to withdraw the sheath. A representative example where the bare stent approach was used after the SDS failed is shown in Figure 2.

Adverse Events

Adverse events during the procedure occurred in four patients in the bare stent group and in six patients in the SDS group (3.4% vs. 6.5%, $P = 0.30$). There was no difference in the incidence of acute occlusion, coronary dissection, coronary perforation, or stent displacement, as shown in Table V. In the bare stent group, two of three displaced stents were successfully retrieved, however, one stent was deployed proximal to the target lesion because it was not able to be retrieved, and then bypass surgery was performed. In the SDS group, one stent was dislodged after the sleeve was withdrawn and was deployed proximal to the target lesion. There was no case of stent embolization to the systemic circulation in either group.

Subset Analysis of Cases Without IVUS Guidance

Table VI shows the procedural characteristics in the cases where IVUS guidance was not used. The mean number of balloons used per lesion in the bare stent group was significantly less than in the SDS group (1.9 ± 0.6 vs. 3.6 ± 0.9, $P < 0.0001$). The mean number of balloons used per stent in the bare stent group was significantly less than in the SDS group (1.6 ± 0.6 vs. 2.6 ± 0.5, $P < 0.0001$). There was no significant difference in the procedure time in the two groups, however, the fluoroscopy time in the bare stent group was significantly shorter than in the SDS group (27 ± 17 vs. 37 ± 24 min, $P < 0.05$).

DISCUSSION

Although Palmaz-Schatz stents are beneficial in treating coronary artery lesions, the ease of deployment with the current system is less than optimal. Schatz et al. [5] reported that failed delivery occurred with 22 of the 321 stents (six of 30 prototype rigid stents and 16 of 291 articulated stents) without a protective sheath delivery system. Of these stents, 11 were successfully withdrawn, three were deployed proximal to the target lesion, and eight embolized systemically during attempted withdrawal into the femoral sheath without clinical sequelae. Because of concern over stent dislodgement from the balloon and stent embolization, a sheathed delivery system was developed to protect the stent until it was positioned at the intended site [6].

Despite their utility, the stents currently available in the United States have many limitations associated with their length and rigidity, making deployment in calcified or tortuous vessels difficult. Although clinical studies have demonstrated that the procedural success rate of Palmaz-Schatz coronary stent placement was significantly higher than balloon angioplasty [1,2], the Benestent and STRESS

trials showed that stent placement failed in 10 of 259 patients (3.9%) and three of 205 patients (1.5%), respectively, because of an inability to cross the lesion. To facilitate stent delivery in difficult cases, several reports describe that cutting the Palmaz-Schatz stent in half has several advantages [4,7–9]. The half-stent can be remounted on the stent delivery system to increase the SDS flexibility and still maintain the safety of the delivery sheath [10,11].

In an attempt to address the problem of difficult stent delivery, investigators outside the United States can purchase Palmaz-Schatz stents without the sheathed stent delivery system [3]. The stents are then hand-crimped to a low profile, high pressure balloon which facilitates passing the stent through tortuous arterial segments. Alternatively, the stent can be cut in half and the 7 mm long section is crimped to the balloon to improve delivery through a tortuous segment or to a distal lesion through a previously deployed stent. The potential problem with this bare stenting approach is that the unprotected stent could slide off the balloon and remain in the coronary artery proximal to the intended lesion or embolize during attempted retrieval. Colombo et al. [3] reported that embolization of a stent occurred in four of 100 patients (two in a coronary artery, two in a peripheral artery) during bare stent implantation. However, the incidence of major problems encountered during stent implantation tends to decrease with operator experience [3,5]. Recently, Levine et al. [12] reported that the bare stent method was successful in 15 of 18 attempts after an SDS approach failed to deliver the stent to the lesion. An accompanying editorial cautioned that ''bare stenting cannot be . . . openly endorsed as a replacement for the standard stent delivery system. . . .'' Our study suggests that from a technical standpoint, bare stenting is as safe as the SDS technique and has definite advantages in ease of delivery, use of fewer balloons, and less fluoroscopy time.

Benefit and Safety of Bare Stent

In the present study, there were significant differences between the bare stent group and the SDS group in the number of balloons used per lesion or per stent. In addition, the frequency of using only a single balloon to predilate the lesion, deliver the stent, and expand it at high pressure in the bare stent group was significantly higher than the SDS group (25% vs. 0%, $P < 0.0001$). Even if the balloon that comes with the stent delivery system is discounted, the number of balloons used per lesion was significantly less in the bare stent group than in the SDS group (1.9 ± 0.6 vs. 2.4 ± 0.7, $P < 0.0001$). These results suggest that the bare stent technique may reduce the cost of intracoronary stent implantation.

Another method to decrease the number of balloons is to use IVUS imaging before an intervention to choose the appropriate size balloon to predilate and postdilate the stent [14,15]. On the other hand, IVUS guidance may account for an increase in the number of balloons used after deployment in an attempt to optimize stent expansion. To account for the effects of performing IVUS studies, a subset analysis was performed (Table VI). Although limited by a smaller sample size, this analysis of the cases without IVUS guidance demonstrates that there was still a significant difference in the number of balloons used in the two groups.

Although using a bare stent approach requires extra time to mount and crimp a stent on a balloon, the total procedure and fluoroscopy time were less in the Bare stent group. One explanation for this is the ease of delivery and positioning of the balloon and stent which required less exchanges for different balloons or less manipulation than is required with the SDS method. Knowing that the balloon is centered on these nonradiopaque stents, provides confidence for the operator to immediately deploy the stent at high pressures. The use of IVUS imaging could have increased the procedure time in the SDS group where IVUS was used more frequently. The subset analysis of the cases without IVUS guidance (Table VI) indicates that the procedure time in the bare stent group was slightly shorter than in the SDS group, but was not statistically significant for this smaller cohort. Fluoroscopy time was still significantly shorter in the Bare stent group without IVUS imaging.

In the present study, stent displacement in the bare stent group occurred in three of 117 patients (2.6%), however, there was no difference compared with the SDS group (one of 92 patients, 1.1%). In addition, there was no case of stent embolization to the systemic circulation in the bare stent group. The incidence of major problems encountered during stent implantation tend to decrease with operator experience. These results suggest that the bare stent technique is as safe as the approach with a sheath-protected stent delivery system.

Difficulty of Stent Delivery

Although there was no significant difference between the two groups in the incidence of difficult stent delivery, there was a tendency for more difficult delivery in the SDS group than in the bare stent group for stents deployed through nonstented tortuous arteries (6.0% vs. 2.7%, $P = 0.12$). The number of cases where it was attempted to pass a stent through a previously stented site was limited, however this was successful in three of the four cases with the bare stent approach, but was unsuccessful in the two cases with the SDS method. After a failed attempt to advance the stent into a coronary artery, the

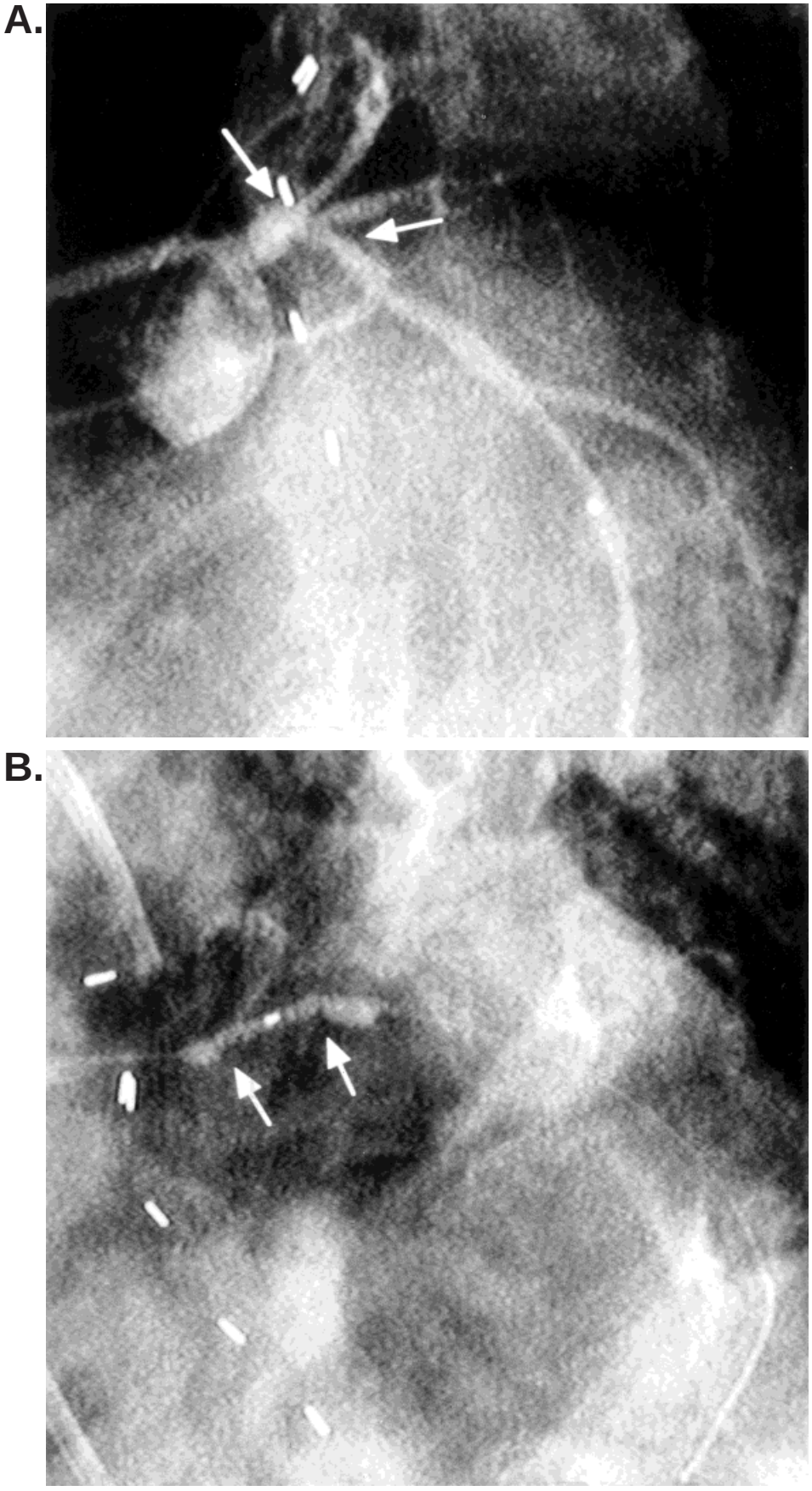

Figure 2.

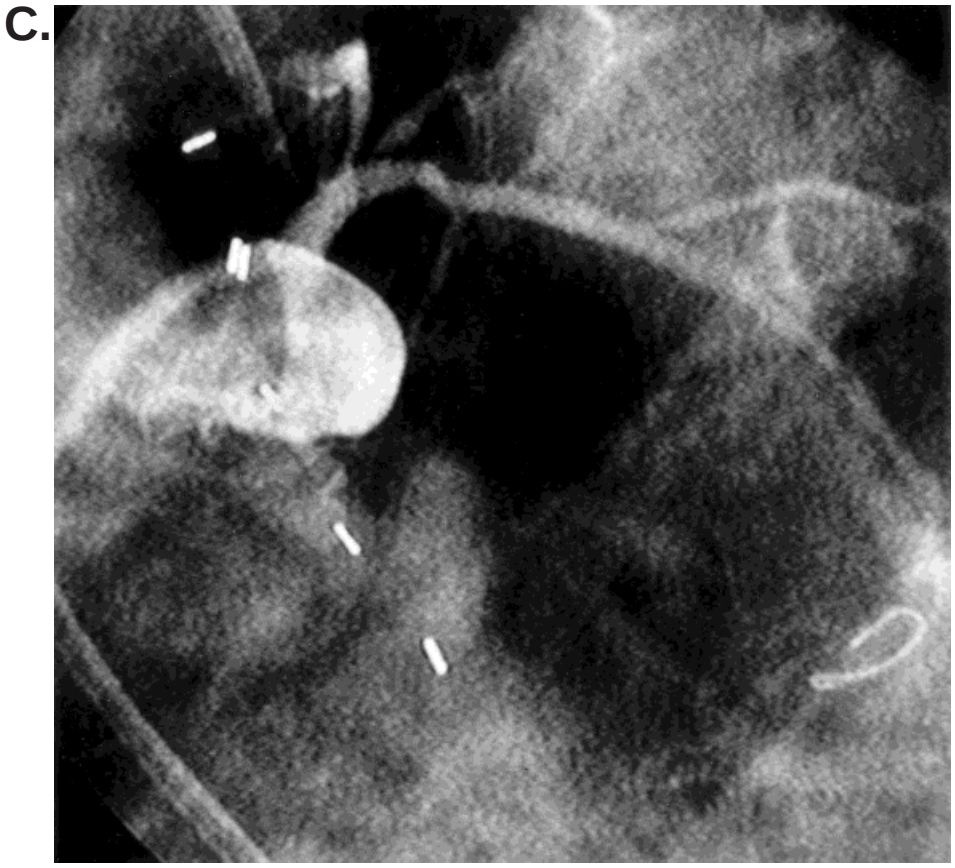

Figure 2. (Continued.)

stent should be deployed proximally or retrieved with care. Although no serious sequelae of stent embolization have been described, the potential remains for life-threatening complications, such as stent embolization to the cerebrovascular circulation with thrombosis. Kiemeneij et al. [16] recommended two strategies to prevent stent loss or embolization: one was to deploy the stent proximal to the target lesion, and the other was to withdraw the entire system (guiding catheter and stent-loaded balloon catheter) into the peripheral artery.

Fig. 2. Representative case. A: Cineangiogram in LAO caudal projection from a 54-year-old woman 5 years after coronary artery bypass surgery reveals a stenosis in the distal left main coronary artery extending into the origin of the circumflex artery (arrows). After predilatation with 3.0 mm diameter balloon, a Gianturuco-Roubin Flexstent™ was positioned in the proximal circumflex. Intravascular ultrasound imaging revealed that the distal left main stenosis was not covered by the stent. A Palmaz-Schatz stent delivery system was advanced into the left main, but could not extend around the sharp curve into the origin of the circumflex despite retraction of the sheath. B: The Palmaz-Schatz stent was removed from the stent delivery system catheter and hand crimped onto a 3.0 mm × 20 mm NC Shadow™ balloon. The catheter tip tracked easily over the guidewire into the circumflex artery. The Palmaz-Schatz stent was deployed at 16 atm in the distal left main artery (arrows). C: Final cineangiogram in LAO caudal projection after further dilatation with a Pinkerton™ 3.5 mm × 10 mm balloon.

TABLE V. Incidence of Adverse Events During the Procedure*

	Bare Stent Group (n = 117)	SDS Group (n = 92)	*P* Value
Total number of events	4 (3.4%)	6 (6.5%)	0.30
Acute occlusion	1 (0.9%)	3 (3.3%)	0.32
Dissection	0	1 (1.1%)[b]	0.44
Coronary perforation	0	1 (1.1%)	0.44
Stent displacement	3 (2.6%)	1 (1.1%)	0.63
Retrieved	2 (1.7%)	0	0.31
Deployed proximal	1 (0.9%)[a]	1 (1.1%)	0.69
Acute MI	0	0	
CABG	1 (0.9%)[a]	1 (1.1%)[b]	0.69
Death	0	0	

*CABG = Coronary artery bypass graft, MI = myocardial infarction.
[a]Same patient.
[b]Same patient.

Study Limitations

There are several limitations to the present study. This was a retrospective, nonrandomized study of two sequen-

TABLE VI. Procedural Characteristics in the Patients Without IVUS Guidance

	Bare Stent Group	SDS Group	*P* Value
Number of lesions	120	32	
Number of balloons per lesion			
Mean ± SD	1.9 ± 0.6	3.6 ± 0.9	<0.0001
Number of balloons per stent			
Mean ± SD	1.6 ± 0.6	2.6 ± 0.5	<0.0001
Procedure time (min)	99 ± 55	108 ± 58	0.53
Fluoroscopy time (min)	27 ± 17	37 ± 24	0.03

tial time periods and there were some baseline differences between the patients in the two groups. The use of bare stenting was started in May, 1996, and the majority of patients in the SDS group were treated before this time. This may explain the difference between the groups in the frequency of acute myocardial infarction (which was treated more frequently with stents in the latter period) or IVUS guidance (which was used more commonly in the initial period). In addition, the difficulty of stent delivery may depend on the subjectivity of each operator. We defined patients as having difficult stent delivery according to the dictated procedure report. The difference in the frequency of IVUS guidance between the two groups may partly explain the longer procedure time for the SDS group, but does not completely account for the observed difference.

CONCLUSIONS

The use of the bare stenting technique or sheathless method of deploying Palmaz-Schatz coronary stents decreases the procedure time, reduces the number of balloons used, and is as safe as the approach with a sheath-protected stent delivery system. The smaller diameter of the bare stent may permit the use of smaller guiding catheters such as 7F or 6F. Although low profile, sheathless systems are currently available outside the United States, it is uncertain when these stents will be permitted in this country. If the SDS approach is unsuccessful, this bare stenting technique may be a useful alternative until the newer stents are available.

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