European Heart Journal (1998) **19,** 1224–1231
Article No. hj981028

Treatment of calcified coronary lesions with Palmaz–Schatz stents

An intravascular ultrasound study

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Aims To evaluate the result of coronary stenting in calcified lesions and to find morphological and procedural factors influencing the final result.

Methods and Results Three hundred and twenty three native coronary artery lesions in 303 patients (197 men, mean age 63·9 ± 11·5 years) treated with Palmaz–Schatz stents were differentiated into four groups depending on their degree of circumferential calcification as defined by intravascular ultrasound [0–90° (n = 120), 91–180° (n = 58, 181–270$ (n = 71) and 271–360° (n = 74)]. In 117 lesions rotational atherectomy was used prior to stent placement. Intravascular ultrasound and quantitative angiography were performed prior to treatment and after stent placement to measure minimal and maximal lumen diameter and lumen cross-sectional area at the lesion site and the reference segments. Acute lumen gain and eccentricity index were calculated. Although higher balloon pressures were used than in the minimally calcified lesions, the final angiographic minimal lumen diameter decreased with increasing arc of calcification (3·01 ± 0·47, 3·04 ± 0·43, 2·85 ± 0·53, 2·83 ± 0·40 mm, respectively, P = 0·0320) resulting in a decrease in acute diameter gain with increasing arc of calcification (2·06 ± 0·51, 1·91 ± 0·46, 1·81 ± 0·56, 1·78 ± 0·51 mm, respectively, P = 0·0067). Adjunctive rotational atherectomy prior to stent placement resulted in a greater acute diameter and a greater lumen cross-sectional area gain, coupled with less final residual stenosis than pre-treatment with balloon angioplasty.

Conclusion Implantation of stents in calcified lesions results in less optimal stent expansion, especially in lesions with thick, eccentric calcific plaque layers. Use of adjunctive rotational atherectomy before stent placement may improve the procedural result.
(Eur Heart J 1998; 19: 1224–1231)

Key Words: Calcified coronary lesions, intracoronary stents, intravascular ultrasound, rotational atherectomy.

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Introduction

Heavily calcified coronary stenoses have been classified as complex lesions requiring percutaneous transluminal coronary balloon angioplasty because of decreased success and an increased complication rate[1–4]. Complications are primarily the result of severe dissections, with dissection planes frequently occurring at the transition between the calcified plaque and 'normal' vessel wall[5]. Other interventional treatment devices, such as rotational atherectomy and excimer laser coronary angioplasty have been evaluated to see if they can improve the success rate. Rotational atherectomy, in its ability to ablade calcified plaque selectively, is particularly useful in calcified lesions[6–7]. Excimer laser angioplasty is useful in moderately calcified lesions[8]. However, both techniques normally require further therapy[9–11]. Although stent placement has been found to result in larger acute lumen gain than balloon angioplasty[12–15] its use has initially been confined to non-calcified lesions. This is because stent delivery into calcified lesions may be difficult and stent expansion inadequate due to the resistance of the calcified plaque. The aim of this study was (1) to evaluate the results of coronary stenting as the severity of lesion calcification increases, (2) to study

Revision submitted 5 February 1998, and accepted 25 February 1998.

This study was supported in part by the Cardiology Research Foundation Washington, DC, U.S.A.

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***Table 1** Clinical and procedural data for four groups with different degrees of circumferential calcification by intravascular ultrasound*

	Arc of Ca^{2+} 0–90° (n=120)	Arc of Ca^{2+} 91–180° (n=58)	Arc of Ca^{2+} 181–270° (n=71)	Arc of Ca^{2+} 271–360° (n=74)	*P*
Age (years)	61·2 ± 12·5	63·4 ± 11·1	65·7 ± 9·9	66·9 ± 10·9	0·0051
Arc of calcium (°)	20 ± 30	127 ± 30	217 ± 27	322 ± 36	<0·0001
Arc of superficial calcium (°)	8 ± 20	84 ± 64	200 ± 54	311 ± 61	<0·0001
CK max (U . l^{-1})	113 ± 129	153 ± 248	160 ± 177	144 ± 138	0·2997
CK-MB (U . l^{-1}))	5 ± 16	8 ± 16	7 ± 12	11 ± 23	0·2544
Maximal balloon pressure (atm)	14·2 ± 3·9	14·8 ± 3·7	16·7 ± 3·0	16·3 ± 3·1	<0·0001
Maximal balloon size (mm)	3·52 ± 0·47	3·54 ± 0·52	3·67 ± 0·42	3·65 ± 0·45	0·1322
Use of rotational atherectomy	0 (0%)	12 (21%)	49 (69%)	56 (76%)	<0·0001

CK=creatinine kinase.

whether rotational atherectomy prior to stent placement improves the result after stent replacement and (3) to define lesion characteristics by intravascular ultrasound for prediction of non-optimal stent expansion.

Methods

Patients and lesions

Three hundred and twenty three native coronary artery lesions in 303 patients (197 men and 106 women, mean age 63·9 ± 11·5 years) were the primary study cohort. The lesions were a consecutive series evaluated by intravascular ultrasound. At the Washington Hospital Center, intravascular ultrasound imaging is part of the routine interventional procedure in all lesions in which intravascular ultrasound imaging seems to be possible. Coronary lesions were separated into four groups, according to the different degrees of lesion calcification. The arc of circumferential calcification identified by intravascular ultrasound was used as the marker of calcification severity, with the four groups being 0–90° (n=120), 91–180° (n=58), 181–270° (n=71) and 271–360° (n=74). One hundred and thirty four lesions were in the left anterior descending artery, 58 in the circumflex artery and 131 in the right coronary artery. Twenty six lesions were treated with articulated ‘biliary’ stents (PS204) and 297 with ‘coronary’ stents. Of those lesions treated with coronary stents, 103 received 3·0 mm diameter stents, 118 3·5 mm stents and 76 4·0 mm stents. In 117 lesions, rotational atherectomy was used prior to stent placement. The burr size was 1·5 burr in 14 cases, 1·75 burr in 36 cases, 2·0 burr in 36 cases, 2·15 burr in 10 cases, 2·25 burr in 16 cases and 2·5 burr in five cases. Lesion and treatment characteristics in each of the four groups are given in Table 1.

Maximal creatinine kinase and maximal creatinine-MB release were measured (normal maximal creatinine kinase up to 100 U . l^{-1}). The occurrence of death, Q wave and non-Q wave myocardial infarction, abrupt target vessel closure and urgent and emergency CABG after the interventional procedure were determined. Maximal balloon pressure and maximal balloon size for stent placement were recorded. Lesions were evaluated by intravascular ultrasound and quantitative angiography before and after stent placement.

Palmaz–Schatz stents were implanted according to standard protocols, the ‘coronary’ stent being delivered with the sheath-based stent delivery system and the ‘biliary’ stent being hand crimped on a conventional coronary or peripheral angioplasty balloon. Operators were not blinded to the intravascular ultrasound findings during stent implantation. Intravascular ultrasound revealed that the targeted stent expansion was a minimum stent cross-sectional area ≥80% of the average of the proximal and distal reference lumen cross-sectional areas, as well as complete stent–vessel wall apposition.

Intravascular ultrasound imaging protocol

Studies were performed using one of three commercially available systems. The first system (CVIS/InterTherapy Inc., Sunnyvale, CA, U.S.A.) incorporated a single element 25 MHz transducer and an angled mirror mounted on the tip of a flexible shaft. This was rotated at 1800 rpm within a 3·9 F short monorail polyethylene imaging sheet, to form planar cross-sectional images in real time. The second system (Cardiovascular Imaging Systems, Inc., Sunnyvale, CA, U.S.A.) used a 30 MHz single element bevelled transducer, mounted on the end of a flexible shaft. This was rotated at 1800 rpm within either a 2·9 F long monorail/common distal lumen imaging sheath or within a 3·2 F short monorail imaging sheath. With both systems, the transducer was withdrawn within the stationary imaging sheath at a speed of 0·5 mm . s^{-1} using a motorized transducer pull-back device. The third system (Hewlett-Packard, Andover, MA and Boston Scientific Corporation, Watertown, MA, U.S.A.) incorporated a single element 30 MHz transducer bevelled transducer, mounted on the end of a flexible shaft. This rotated at 1800 rpm within a 3·5 F short monorail lumen imaging sheath; with this system the transducer was withdrawn manually with fluoroscopic guidance.

In all studies intravascular ultrasound was performed after administration of 0·2 mg intracoronary nitroglycerin. To perform the imaging sequence, the transducer was positioned approximately 10 mm beyond the coronary lesion prior to intervention and 10 mm distal to the distal edge of the stent after intervention. The motorized transducer pull-back device was activated, and imaging continued until the transducer reached the aorto-ostial junction. Ultrasound studies were recorded on half-inch high resolution S-VHS video tape for off-line analysis. Patients were studied only after giving written, informed consent; all intravascular ultrasound studies have the ongoing approval of the Washington Hospital Institutional Review Board.

Quantitative intravascular ultrasound analysis

Before stent placement, the smallest segment was searched for, and defined as the segment with the smallest cross-sectional area. Computerized planimetry was used to trace the smallest area two to four times and to determine the smallest and largest lumen diameter. The arcs of total and superficial calcification were measured. If the intravascular ultrasound catheter could encompass the intravascular ultrasound catheter or if the intravascular ultrasound catheter could not cross the lesion, a lumen diameter of 1·0 mm diameter was assumed.

For the proximal and distal reference segment, lumen areas and lumen diameters were measured in a similar way. Reference segments were defined as the most normal-looking cross-sections within a 10 mm segment distal or proximal to the lesion, but approximate to any major side branch. Validation by intravascular ultrasound of cross-sectional area measurements of stents and lumen have been reported[16–18].

Lesions with an arc of circumferential calcification more than 180° were divided into two morphological groups, depending on their circumferential distribution of calcification:

(1) Concentric calcification = single arc of calcium > 300° or multiple arcs distributed uniformly around the vessel circumference Fig. 1a.
(2) Eccentric calcification = eccentric calcium with either a normal vessel or non-echogenic plaque opposite the calcium Fig. 1b.

After stent placement, lumen cross-sectional areas as well as minimal and maximal lumen diameters were measured for the smallest area within the stent.

The following calculations were then made from the measurements of lumen diameters and areas before and after stent placement:

(1) Acute diameter gain (mm) = Δ(post-intervention minus pre-intervention) lumen diameter

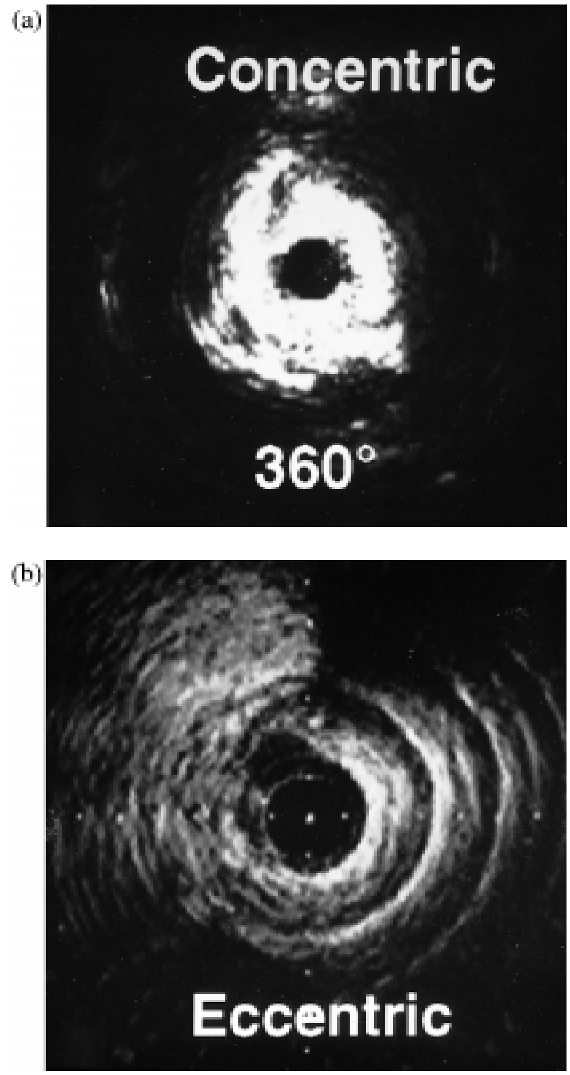

Figure 1 **(a) Example of a lesion with concentric calcification and a 360° thick calcific layer, resulting in total shadow behind the calcified layer. (b) Example of a lesion with 185° of eccentric superficial calcification. There is reverberation behind the superficial calcification. The vessel wall opposite the calcified vessel wall is non-calcified.**

(2) Acute cross-sectional area gain (mm^2) = Δ(post intervention minus pre-intervention) cross-sectional area
(3) Eccentricity index = maximal lumen diameter/minimal lumen diameter

Quantitative angiographic analysis

Quantitative coronary angiography was performed by an independent core angiographic laboratory which was blinded to the results of the ultrasound analysis. Quantitative coronary angiography was performed using a computer-assisted, automated edge-detection algorithm (ImageComm)[19]. The external diameter of the contrast-filled catheter was used as the calibration standard. The minimal lumen diameter and reference

***Table 2** Comparison of angiographic and intravascular ultrasound data for four groups with different degrees of circumferential calcification by intravascular ultrasound*

	Arc of Ca^{2+} 0–90°	Arc of Ca^{2+} 91–180°	Arc of Ca^{2+} 181–270°	Arc of Ca^{2+} 271–360°	*P*
Quantitative angiography					
Calcification by angiography (%)	21	40	71	78	<0·0001
Reference diameter (mm)	2·99 ± 0·55	3·09 ± 0·48	2·83 ± 0·48	2·97 ± 0·48	0·1085
Minimal lumen diameter pre (mm)	0·95 ± 0·45	1·13 ± 0·34	1·04 ± 0·37	1·04 ± 0·38	0·0681
Minimal lumen diameter final (mm)	3·01 ± 0·47	3·04 ± 0·43	2·85 ± 0·53	2·83 ± 0·40	0·0320
Acute diameter gain (mm)	2·06 ± 0·51	1·91 ± 0·46	1·81 ± 0·56	1·78 ± 0·51	0·0067
Diameter stenosis final (%)	2 ± 9	2 ± 10	4 ± 13	9 ± 10	0·0005
Intravascular ultrasound					
Reference diameter (mm)	3·07 ± 0·52	3·16 ± 0·59	3·07 ± 0·55	3·16 ± 0·59	0·6294
Reference CSA (mm^2)	9·20 ± 2·99	9·88 ± 3·85	9·47 ± 3·16	9·85 ± 3·69	0·5341
Minimal lumen diameter pre (mm)	1·46 ± 0·39	1·50 ± 0·32	1·51 ± 0·26	1·46 ± 0·26	0·7662
Minimal lumen diameter final (mm)	2·80 ± 0·45	2·81 ± 0·44	2·54 ± 0·35	2·65 ± 0·42	0·0013
Lumen CSA pre (mm^2)	2·3 ± 1·5	2·6 ± 1·2	2·6 ± 0·9	2·4 ± 0·9	0·3658
Lumen CSA final (mm^2)	7·7 ± 2·4	7·7 ± 2·3	7·0 ± 1·6	7·2 ± 2·0	0·1616
Acute diameter gain (mm)	1·35 ± 0·43	1·34 ± 0·47	1·02 ± 0·47	1·19 ± 0·50	0·0006
Acute CSA gain (mm^2)	5·4 ± 2·0	5·1 ± 2·3	4·4 ± 1·9	4·8 ± 2·0	0·0411
Diameter stenosis final (%)	7 ± 14	9 ± 12	16 ± 11	15 ± 12	<0·0001
CSA stenosis final (%)	12 ± 23	17 ± 21	23 ± 18	20 ± 19	0·0150
Stent eccentricity final	1·20 ± 0·10	1·19 ± 0·08	1·31 ± 0·13	1·33 ± 0·23	<0·0001

CSA = cross sectional area; final = post-intervention; pre = pre-intervention.

lumen diameter at end diastole were measured from multiple projections of the lesion before treatment. A user-defined reference segment was selected as a mean of 10 mm smooth vessel segment proximal and distal to the lesion. A similar analysis was performed after stent placement, with the reference segments being within 10 mm of the proximal and distal stent margin. The results from the 'worst' view were recorded. Acute lumen gain was calculated for the angiographic data according to the description for intravascular ultrasound.

Statistics

Statistical analysis was performed using Statview 4.02. (Abacus Concepts, Berkley, CA, U.S.A.). Quantitative data were presented as mean ± 1 standard deviation. Comparisons between groups were performed using paired and unpaired t-tests for continuous variables or factorial analysis of variance. The level of significance was a P value $\leq 0{\cdot}05$.

Results

Clinical data

The release of maximal creatine kinase and creatine kinase-MB in patients with a stent in a heavily calcified lesion (arc of calcium above 180°) was similar to that in patients with a stent in a minimally calcified lesion (Table 1). There was a trend towards higher creatine kinase (159 ± 186 U . l^{-1} vs 126 ± 160 U . l^{-1}, $P = 0{\cdot}1256$) and creatine kinase-MB release (9 ± 15 U . l^{-1} vs 6 ± 18 U . l^{-1}, $P = 0{\cdot}1381$) following treatment of heavily calcified lesions with rotational atherectomy prior to stent placement vs treatment using only balloon angioplasty before stent placement. Clinical events for the lesion groups with an arc of calcification of more than 180° consisted of three non-Q wave myocardial infarctions, one Q wave myocardial infarction and two deaths. In the minimally calcified lesion group, one Q wave myocardial infarction, three non-Q wave myocardial infarctions and two urgent or emergence coronary artery bypass surgeries occurred. Average maximal balloon pressure applied for stent expansion increased with increasing arc of calcification, being 14·2 ± 3·9, 14·8 ± 3·7, 16·7 ± 3·0 and 16·3 ± 3·1 atm, respectively ($P < 0{\cdot}0001$). There was no significant difference in the maximal balloon size to reference vessel diameter ratio between the different lesion groups, (Table 1). Lesions with a higher degree of calcification were found in older patients.

Angiographic and intravascular ultrasound measurements for coronary lesions with increasing severity of calcification

There were no significant differences in lesion and reference vessel dimensions before interventional therapy between the different lesion groups, as measured by intravascular ultrasound (Table 2). After stent placement, angiography revealed that the minimal lumen diameter was progressively smaller for the lesion groups with an increasing arc of calcification prior to intervention (Table 2). This resulted, with an increasing

***Table 3** Comparison of lesion characteristics and acute interventional results for heavily calcified lesions (more than 180° circumferential calcification) treated with stents alone vs rotational atherectomy (RA)+stent*

	Stent alone (n=40)	RA+stent (n=105)	*P*
Maximal balloon pressure (atm)	16·0 ± 4·2	16·6 ± 2·5	0·3293
Quantitative angiography			
Acute diameter gain (mm)	1·72 ± 0·57	1·94 ± 0·48	0·0237
Diameter stenosis final (%)	9 ± 11	4 ± 12	0·0444
Intravascular ultrasound			
Arc of calcification (°)	254 ± 54	276 ± 63	0·0488
Arc of superficial calcification (°)	225 ± 82	269 ± 77	0·0032
Length of calcification (mm)	10·0 ± 4·7	11·6 ± 6·5	0·1750
Reference CSA (mm^2)	9·89 ± 3·24	9·03 ± 3·44	0·1710
Acute diameter gain (mm)	1·02 ± 0·46	1·35 ± 0·48	0·0003
Acute CSA gain (mm^2)	4·57 ± 1·97	5·41 ± 1·99	0·0242
Diameter stenosis final (%)	17 ± 9	12 ± 15	0·0287
CSA stenosis final (%)	23 ± 15	16 ± 24	0·0773
Stent eccentricity index	1·36 ± 0·17	1·28 ± 0·19	0·0644

CSA=cross sectional area.

arc of calcification, in a decreasing acute diameter gain and a higher final diameter stenosis. Measurements by intravascular ultrasound confirmed the smaller acute diameter gain as well as a smaller cross-sectional area gain, resulting in an increasing final diameter stenosis and cross-sectional area stenosis for lesions with an increasing arc of calcification (Table 2).

Use of rotational atherectomy prior to stent placement

In lesions with an initial arc of calcification of more than 180°, rotational atherectomy was used in lesions that tended to have longer calcified segments (11·6 ± 6·5 vs 10·0 ± 4·7 mm, P=0·1750), in lesions with a higher degree of calcification (arc of calcium: 276 ± 63 vs 254 ± 54°, P=0·0488; arc of superficial calcium: 269 ± 77 vs 225 ± 82°, P=0·0039) and in smaller lesions (Table 3). Despite these differences in initial lesion characteristics, there were no significant differences in the final measurements of lumen dimensions, between lesions treated with adjunct rotational atherectomy and those treated with stents alone. Intravascular ultrasound and quantitative angiography showed that acute diameter gain, acute cross-sectional area gain and final diameter stenosis were better in lesions treated with rotational atherectomy prior to stenting than those not treated in this manner (Table 3).

Stent eccentricity

Final stent eccentricity was significantly dependent on the degree of calcification prior to stent placement, being higher in heavily calcified lesions than in minimally calcified lesions (Table 4). The higher stent eccentricity indicated that stent expansion was restricted by calcified plaque elements.

For highly calcified lesions (arc of circumferential calcification >180°) morphological characteristics predicting a high final stent eccentricity could be identified (Fig. 2). For lesions which were classified as having an eccentric calcification pattern the stent eccentricity index was found to be 1·41 ± 0·17, significantly higher than for lesions with concentric calcification (1·26 ± 0·19, P<0·0001). The circumferential distribution of the calcified plaque also had an impact on the final minimal lumen diameter (Table 4).

Discussion

Background

Significant calcification of coronary artery stenosis has been identified as a strong predictor for decreased success and an increased complication rate in balloon angioplasty [1–4], the primary reason for complications being severe dissections with possible subsequent abrupt closure of the vessel. Fitzgerald *et al.*[5] reported the incidence of dissections after balloon angioplasty to be 53% for non-calcified lesions and 88% for calcified lesions. Balloon inflation pressures used in calcified lesions are often significantly higher than usual, resulting in an increased risk of vessel trauma. Due to the frequency of suboptimal results after treatment of calcified lesions with balloon angioplasty, other interventional devices have been researched. Rotational atherectomy has been found to have a high procedural success rate in calcified lesions [6,7], while excimer laser coronary angioplasty has been confined to treatment of, at most, moderately calcified lesions[8]. However, the

***Table 4** Comparison of intravascular ultrasound findings after stent placement in lesions with an arc of circumferential calcification more than 180 degrees and either (1) concentric calcification (single arc of calcium >300 degree or multiple arcs distributed uniformly around the vessel circumference) or (2) eccentric calcification (eccentric calcium with either a normal vessel wall or non-echogenic plaque opposite the calcium)*

	Concentric (n=73)	Eccentric (n=72)	*P*
Minimal lumen diameter final (mm)	$2{\cdot}64 \pm 0{\cdot}42$	$2{\cdot}47 \pm 0{\cdot}33$	0·0262
Acute diameter gain (mm)	$1{\cdot}01 \pm 0{\cdot}52$	$0{\cdot}77 \pm 0{\cdot}42$	0·0095
Lumen CSA gain (mm^2)	$4{\cdot}21 \pm 2{\cdot}26$	$3{\cdot}60 \pm 1{\cdot}94$	0·1282
Stent eccentricity index	$1{\cdot}26 \pm 0{\cdot}19$	$1{\cdot}41 \pm 0{\cdot}17$	<0·0001

CSA=cross-sectional area; eccentricity index=maximal lumen diameter/minimal lumen diameter.

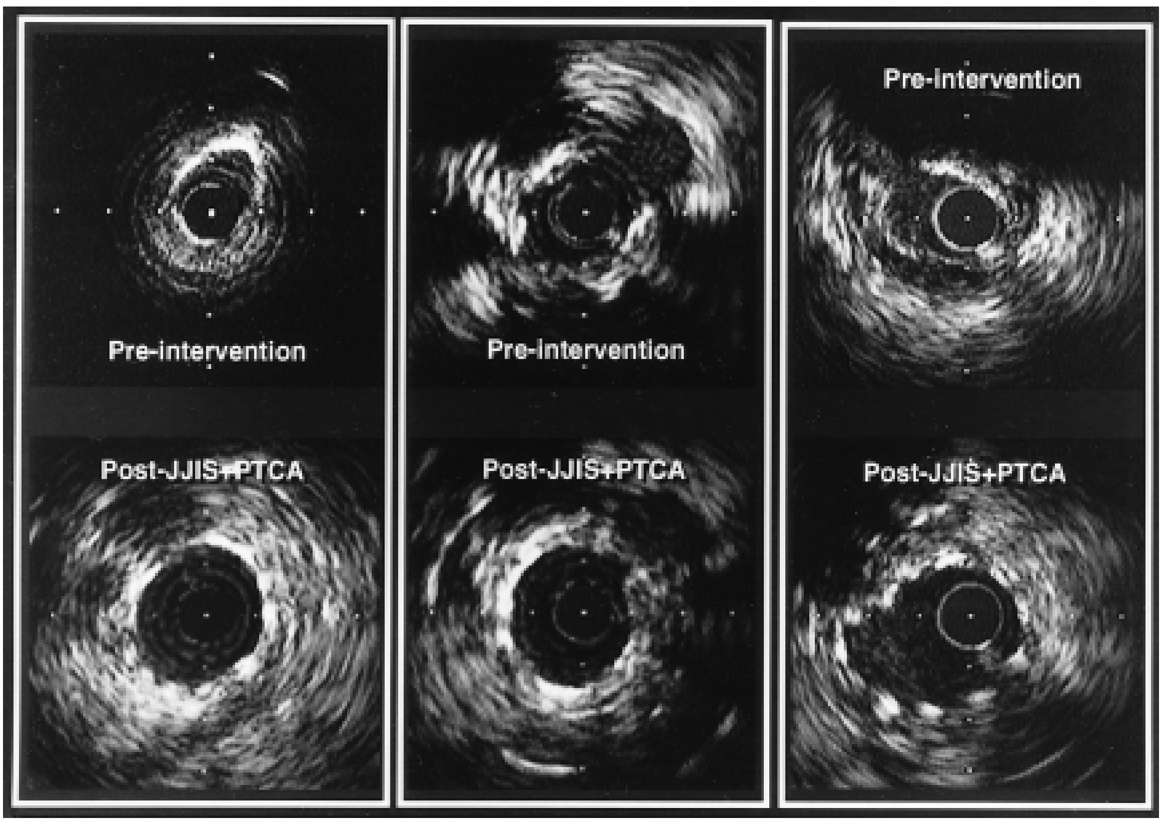

Figure 2 **Characterization of different calcification patterns for lesions with more than 180° of calcification (upper panel) and the corresponding findings after stent placement (lower panel). Left column: lesion with circumferential calcification resulting in concentric stent expansion. Middle column: Lesion with two separate areas of calcific plaque opposite to each other, resulting in concentric stent expansion. Right column: calcified plaque layer on one side with normal vessel wall opposite side resulting in eccentric stent expansion.**

result after rotational atherectomy for heavily calcified lesions normally requires further therapy. Balloon angioplasty has been used as the basic device for further increasing lumen dimensions[9]. Recently, the use of directional atherectomy and stent placement after rotational atherectomy has been reported to have promising results[20–22]. However, the results of stent placement in calcified lesions with and without adjunct rotational atherectomy have not been analysed in detail.

Stent placement in calcified lesions

The results of the study show that stent placement in calcified lesions is possible with a low rate of clinical events. However, the creatine kinase release tended to be higher with the additional use of rotational atherectomy. Final stent expansion in heavily calcified lesions resulted in a smaller minimal luminal diameter, a smaller minimal lumen cross-sectional area, a less acute diameter gain and less cross-sectional area gain, compared with stent expansion in minimally calcified lesions.

Albrecht *et al.*[23] reported on intravascular ultrasound findings of eight stents placed in calcified lesions. These showed significantly less relative lumen gain and significantly less symmetric stent expansion when compared with a control group of 17 stents placed in non-calcified lesions. This result was obtained although the mean arc of calcification for the group of calcified lesions was only $116 \pm 56°$.

It is noteworthy that higher final balloon pressures were used to expand the stent in heavily calcified lesions compared with only minimally calcified lesions. In this study, in which intravascular ultrasound guidance of stent placement was deployed, an optimal result was obtained. If stent deployment is performed without final intravascular ultrasound control, higher balloon pressures should be considered in more heavily calcified lesions than those in only minimally calcified lesions, to overcome the more rigid forces of the calcified lesion.

Rotational atherectomy prior to stent placement

Rotational atherectomy prior to stent placement was used in a subset of lesions with a small minimal lumen diameter and a large arc of calcification. The use of this additional device was primarily based on the intravascular ultrasound findings before therapy. This resulted in the use of rotational atherectomy for more calcified and smaller lesions. Intravascular ultrasound imaging prior to therapy appears to be the appropriate imaging device to determine lesion calcification severity. Mintz *et al.*[24,25] demonstrated that intravascular ultrasound imaging is significantly more sensitive in the evaluation of lesion calcification. Adjunctive rotational atherectomy prior to stent placement resulted in a greater lumen gain and less residual diameter stenosis when compared to lesions treated with stents alone. Furthermore, there was a strong trend for a smaller stent eccentricity in lesions treated with rotational atherectomy prior to stent placement compared to lesions treated with stents alone. Thus, rotational atherectomy prior to stent placement results in more concentric stent expansion. This reflects the pronounced difference in acute diameter gain for lesions treated with rotational atherectomy plus stents compared with stents alone, while the acute cross-sectional area gain was less significantly different. The findings may be explained by easier stent expansion after ablation of the rigid calcified plaque, while stents implanted without prior rotational atherectomy are more likely to be restricted in their expansion pattern by calcium.

Lesion morphology prior to stent placement

Lesion morphology evaluated by intravascular ultrasound prior to stent placement identified lesions with a greater likelihood of final eccentric stent expansion. Unequal calcific plaque distribution, calcified plaque burden on one side and normal wall segments opposite this area, are prone to eccentric stent expansion. This is probably due to the restrictions of stent expansion by the calcified segment and the relative ease of expanding the stent in the other direction. This also results in a slightly smaller diameter gain, but due to the ease of stent expansion, in the other directions where there are similar lumen cross-sectional gains. In contrast, lesions with a concentric calcified plaque burden or several areas of calcification equally distributed around the circumference of the cross-section, tend to have less eccentric stent expansion.

Although more lumen eccentricity after stent placement has not been found to be a predictor of increased intimal hyperplasia in stents[26], increased eccentricity was considered to be a factor impairing coronary flow characteristics[27]. Further studies should evaluate whether repeated balloon angioplasty with higher balloon pressures increases the stent lumen area at the expense of significantly increased eccentricity of the stent.

Limitations of this study

In this study, the operator was not blinded to the results of the intravascular ultrasound studies prior to therapy and after stent placement. This resulted in more frequent application of rotational atherectomy before stent placement in smaller and more heavily calcified lesions, while less heavily calcified lesions were treated only with balloon angioplasty before stenting. This decision was the result of empirical knowledge that heavily calcified lesions should be treated by ablative therapy prior to stent placement. Thus, a direct comparison of therapeutic approaches was not possible in this study as lesion characteristics for the different device options differed. However, the initially significantly tighter and more calcified lesions treated with rotational atherectomy and the improved final result, as well as the higher acute luminal gain for lesions treated with rotational atherectomy indicate that rotational atherectomy should be used prior to stent placement in tight and heavily calcified lesions. Furthermore, even less optimal stent expansion with smaller final lumen diameters might have been found in the group with heavily calcified lesions, if intravascular ultrasound imaging after stent placement and first balloon angioplasty had not resulted in further balloon angioplasty with higher balloon pressures. This has equalized in part the differences between non-calcified and heavily calcified lesions.

This study describes only the acute procedural results of lesions with different degrees of calcification without follow-up data. However, the importance of these data is given by the known predictive value of the final lumen diameter and the final stent cross-sectional area for follow-up event and target lesion revascularization rates[28,29].

Conclusions

Stent placement in calcified lesions is associated with a low clinical event rate. The rigid calcified lesion results in small final lumen diameters and less acute lumen gain than stent placement in minimally calcified lesions in spite of higher balloon pressures used for stent expansion. Furthermore, the rigid calcified lesion causes more eccentric stent expansion. The use of adjunctive rotational atherectomy prior to stent placement in tight, easily calcified lesions should improve the result.

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