Compliant vs Non-compliant Balloons

A Prospective Randomized Study

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SUMMARY

In this prospective randomized trial we explored the possibility of different procedural outcomes with regard to compliant (polyolefin copolymer (POC)), and non-compliant (polyethylene terephthalate (PET)) balloon materials commonly used during percutaneous transluminal coronary angioplasty (PTCA).

For this purpose, 51 female and 149 male (total 200) patients were randomized to 100 compliant and 100 non-compliant balloons. Only single lesions were included in the study and patients who had PTCA for more than one lesion in different segments at different sessions were each entered separately (there were actually 49 female and 143 male patients). PTCA procedures were performed in conjunction with quantitative coronary angiographic techniques and the films were reviewed by two investigators in a blinded fashion. Statistical analysis for various procedural end-points were performed by non-paired Student t test with statistical significance being $p < 0.05$.

There were no differences in demographic and clinical characteristics between groups. Lesion characteristics of both groups were exactly matching for vessel size, balloon size, balloon vessel ratio, minimal luminal diameter and percent stenosis of the index lesion.

Similarly, minimal residual diameter, percent residual stenosis, net gain, densitometric net area gain, and maximum pressure (2.2 ± 5 mm vs 2.1 ± 0.6 mm, $18 \pm 17\%$ vs $23 \pm 15\%$, 0.8 ± 0.5 mm vs 0.8 ± 0.6 mm, $48 \pm 25\%$ vs $48 \pm 26\%$, 7.3 ± 2 atm. vs 6.8 ± 3 atm., respectively) values were not statistically different between compliant and non-compliant balloon groups.

Major in-hospital complications, dissections caused by the study balloon (mostly type A and B), crossover and bail-out procedures (5 vs 3, 34 vs 32, 4 vs 3, 13 vs 14, respectively) were similar for both compliant and non-compliant balloon groups. Study balloon success rate (defined as $< 50\%$ residual stenosis or $> 20\%$ net gain in the absence of major in-hospital complications, crossovers

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and bail-outs) and overall procedural success rate (80% vs 74%, 90% vs 85%) were not statistically different for compliant and non-compliant balloons.

In conclusion, we did not observe any statistically significant difference between compliant and non-compliant balloons in terms of immediate procedural results. (Jpn Heart J 1998; 39: 45-54)

Key words: Percutaneous transluminal coronary angioplasty, Compliant balloon material, Non-compliant balloon material

PERCUTANEOUS transluminal coronary angioplasty (PTCA) has become a well established procedure for the treatment of symptomatic ischemic coronary heart disease since AR Gruentzig first performed this procedure in 1977.¹⁾ Although PTCA is a quite safe and highly successful procedure it still has some major and minor complications which may result in morbidity and mortality.²⁻⁶⁾ Several coronary morphologic and clinical determinants of outcome with angioplasty are well documented.⁷⁾ However, there may also be some other factors which have an impact on the outcome such as the balloon material used for PTCA.⁸⁾

PTCA balloons are made of several types of materials. These are the non-compliant PET (polyethylene teraphthelate) (< 3% from 6 to 10 atm), low-compliant elastomer (PM 300), intermediately compliant (PE 600), and highly compliant polyolefin copolymer (POC) (14% from 6 to 10 atm) balloons. Compliance is defined as the degree of increase in balloon diameter as the inflation pressure increases. The compliant balloons can increase their diameter 10-15% above their nominals when the inflation pressure reaches bursting pressure (which is usually low), while the non-compliant balloons can only reach less than 5% above their nominal sizes at their burst pressure (which is usually high).⁹⁾

In this prospective study we randomized 200 lesions in 192 patients (100 POC and 100 PET) to assess the impact of balloon material on the immediate outcome of PTCA.

MATERIALS AND METHODS

Study patients: 126 patients (60 compliant and 66 non-compliant) treated at Millard Fillmore Hospital during the interval November 1993 — June 1995 and 74 patients (40 compliant and 34 non-compliant) at the teaching and research hospital of Dokuz Eylül University Medical Faculty during the interval August 1995 - October 1996 who underwent PTCA were randomized in this study. All patients who were initially treated with coronary balloon angioplasty were randomized in a double blind fashion after review of their coronary angiographies by their attending interventional cardiologists. The films were reviewed by two of

the researchers who were blinded against the type of balloon used and did not take part in the interventional procedure in a given patient. An informed consent designed by the researchers and approved by the Institutional Committee on Human Research of both Millard Fillmore Hospital and the Research Hospital of Dokuz Eylül University, was obtained from each patient following a detailed explanation of both the procedure and nature of the research.

Patients with only a single lesion in each segment of their coronaries were included and each lesion was randomized separately. Multiple lesions treated at different sessions were randomized separately.

All patients who were initially treated with DCA, rotablator and stenting and patients who underwent primary PTCA for acute myocardial infarction or rescue PTCA were excluded. Patients with graft lesions, ostial lesions, or lesions at major branching sites were also excluded.

Angiography and angiographic analysis: Quantitative measurements were performed by both automated quantitative coronary angiography (QCA) program of the angiography system (Siemens and Toshiba) and by using hand calipers. At least two orthogonal (right and left) views of the angiographic films were obtained during PTCA following the intracoronary injection of 100 micrograms of nitroglycerin. The films included a sizeable segment of the guiding catheter filled with dye to compare the measurements before and after the procedure.

Clinical and procedural variables: Clinical and procedural variables were collected by reviewing the patient hospital charts and angiography files including the procedure reports and nurse records during the procedure. Coronary angioplasty report sheets of the New York State Department of Health State Cardiac Advisory Committee and the patient office charts which included the stress testing, nuclear testing, echocardiography, angiography and angioplasty reports were also reviewed in the process of data collection.

Clinical and angiographic definitions: Procedural success was defined as < 50% residual stenosis or > 20% net gain without major ischemic complications or the need for surgical revascularization.

Coronary dissections were categorized using the National Heart, Lung, and Blood Institute classification system for intimal tears, developed by the coronary angioplasty registry.¹⁰⁾

Acute occlusion was defined as angiographic coronary occlusion at the site of dilatation with loss of antegrade distal coronary opacification in the catheterization laboratory or within 24 hours after PTCA.

Myocardial infarction was defined as the appearance of new electrocardiographic Q Waves compared with baseline in association with a transient increase in serum creatine phosphokinase level by standard laboratory criteria.

Intra-coronary clotting was considered present if a compatible angiographic

intraluminal filling defect with contrast on 3 sides was visualized.

ECABG was defined as sending the patient to operating room from cath lab or from his or her bed within 24 hours after the procedure due to the presence of a major complication or imminent major complication.

Statistics: All data are expressed as mean $\pm$ 1 standard deviation (SD). Chi square analysis was used to test differences in variables and unpaired Student's *t* tests were used to assess differences in continuous variables. Differences were considered statistically significant at $p < 0.05$. Values are presented as mean $\pm$ 1 SD, unless otherwise indicated.

RESULTS

Table I shows the clinical and demographic characteristics of the study population. Both groups are almost entirely matching in terms of all parameters other than the history of previous myocardial infarction which was significantly more common in the non-compliant balloon group.

Table II shows the distribution of the lesion types among the balloon groups. Type B lesions were the majority of the lesions in both groups while type C lesions were the least common lesions. The mean lesion length was 8.19 ± 4.57 mm (7.82 ± 0.24 mm vs 8.55 ± 0.85 mm) and there were no differences between

Table I. Demographic and Clinical Characteristics of the Study Population

	All patients	Compliant	Non-compliant	P value
Age (years)	58 $\pm$ 12	56 $\pm$ 13	61 $\pm$ 11	ns*
BSA (m ²)	1.93 $\pm$ 0.21	1.94 $\pm$ 0.19	1.92 $\pm$ 0.23	ns
LVEF (%)	61 $\pm$ 10	60.9 $\pm$ 9	62 $\pm$ 11	ns
CCS angina class	3.33 $\pm$.71	3.41 $\pm$.64	3.26 $\pm$.76	ns
Total cholesterol	213 $\pm$ 42	213 $\pm$ 45	213 $\pm$ 39	ns
Hx hyperlipidemia	76%	77%	63%	ns
Hx MI	43%	28%	60%	$p < 0.05$
FHx/CAD	31%	28%	35%	ns
Hx hypertension	53%	51%	55%	ns
Hx D.M.	18%	18%	18%	ns
Hx smoking	52%	44%	61%	ns

ns* = non-significant.

Table II. Lesion Characteristics of the Study Population

	All patients	Compliant	Non-compliant	Statistics
Type A lesion	22%	24%	20%	ns*
Type B lesion	64%	62%	66%	ns
Type C lesion	14%	14%	14%	ns
QCA lesion length (mm)	8.19 $\pm$ 4.57	7.82 $\pm$ 4.24	8.55 $\pm$ 4.85	ns
Caliper lesion length (mm)	7.59 $\pm$ 3.72	8.02 $\pm$ 4.26	7.2 $\pm$ 3.11	ns

ns* = non-significant.

the compliant and non-compliant balloon groups.

Table III shows the QCA measurements before and after the procedures. Mean reference diameter (MRD) (2.78 ± 0.54 mm), balloon size (BS) (2.79 ± 0.47 mm, QCA; 2.75 ± 0.54 mm, hand caliper) balloon/vessel ratio (B/V R) (0.99 ± 0.13 , QCA; 1.01 ± 0.11 hand caliper), minimal luminal diameter (MLD) (1.39 ± 0.44 mm), % stenosis (49 ± 17), minimal residual luminal diameter (MRLD) (2.18 ± 0.57 mm), % residual stenosis (21 ± 16), net gain (0.8 ± 0.6 mm) and % net gain (28 ± 19) were all completely matching in both the compliant and non-compliant balloon groups.

Table IV shows hand caliper measurements before and after the procedures. The MRD (2.8 ± 0.6 mm vs 2.7 ± 0.6 mm), MLD (0.6 ± 0.4 mm vs 0.7 ± 0.5 mm), % stenosis (77 ± 15 vs 73 ± 19), MRLD (2.1 ± 0.5 mm vs 2 ± 0.6 mm), % residual stenosis (24 ± 16 vs 26 ± 16), net gain (1.5 ± 0.7 mm vs 1.3 ± 0.8 mm) and % net gain (53 ± 20 vs 48 ± 25) were all similar in both the compliant and non-compliant balloon groups. Preprocedural variables measured by hand caliper were significantly greater than QCAQ measurements while post-proce-

Table III. QCA Measurements before and after Procedure

	All patients	Compliant	Non-compliant	P value
Vessel size (mm)	$2.78 \pm .54$	$2.79 \pm .52$	$2.78 \pm .55$	ns*
Balloon size ¹ (mm)	2.79 ± 0.47	2.81 ± 0.45	2.77 ± 0.49	ns
Balloon size ² (mm)	2.75 ± 0.54	2.81 ± 0.49	2.7 ± 0.57	ns
B/V Ratio ³	0.99 ± 0.13	1.02 ± 0.13	0.97 ± 0.12	ns
B/V Ratio ⁴	1.01 ± 0.12	1.02 ± 0.11	1.01 ± 0.12	ns
MLD ⁵ (mm)	1.39 ± 0.44	1.42 ± 0.33	1.36 ± 0.52	ns
Stenosis	$49 \pm 17\%$	$48 \pm 15\%$	$51 \pm 19\%$	ns
MRLD ⁶ (mm)	2.18 ± 0.57	2.25 ± 0.52	2.12 ± 0.61	ns
Res sten	$21 \pm 16\%$	$18 \pm 17\%$	$23 \pm 15\%$	ns
Net gain (mm)	0.8 ± 0.6	0.8 ± 0.5	0.8 ± 0.6	ns
Net gain	$28 \pm 19\%$	$29 \pm 16\%$	$27 \pm 21\%$	ns

¹QCA measured inflated balloon size; ²QCA Measured inflated balloon size at optimum pressure; ³Manufacturer indicated balloon / QCA measured vessel ratio; ⁴QCA measured balloon / QCA measured vessel ratio; ⁵Minimal luminal diameter; ⁶Minimal residual diameter; ns* = non-significant.

Table IV. Hand Caliper Measurements of Pre and Post Procedural Variables

	All patients	Compliant	Non-compliant	P value
Vessel size (mm)	2.75 ± 0.58	2.83 ± 0.6	2.68 ± 0.56	ns
MLD (mm)	0.66 ± 0.47	0.62 ± 0.41	0.7 ± 0.52	ns
Stenosis	$75 \pm 18\%$	$77 \pm 15\%$	$73 \pm 19\%$	ns
MRLD (mm)	2.06 ± 0.6	2.12 ± 0.55	2 ± 0.63	ns
Residual stenosis	$25 \pm 16\%$	$24 \pm 16\%$	$26 \pm 16\%$	ns
Net gain (mm)	1.4 ± 0.71	1.5 ± 0.65	1.3 ± 0.75	ns
Net gain	$50 \pm 23\%$	$53 \pm 20\%$	$48 \pm 25\%$	ns

dural variables were completely matching.

Table V shows QCA measured densitometric area occlusion and visually estimated diameter occlusion parameters. The average densitometric area occlusion (DAO) ($83 \pm 13\%$ vs $84 \pm 15\%$), residual densitometric area occlusion (RDAO) ($34 \pm 19\%$ vs $37 \pm 20\%$), densitometric net area gain (DNAG) ($48 \pm 25\%$ vs $48 \pm 26\%$), visual diameter occlusion (VDO) ($91 \pm 7\%$ vs $87 \pm 10\%$), visual residual stenosis (VRS) ($17 \pm 15\%$ vs $18 \pm 13\%$) and visual net area gain (VNAG) ($74 \pm 16\%$ vs $68 \pm 19\%$) were all matching in both compliant and non-compliant balloon groups. Both QCA measured densitometric area occlusion and visually estimated area occlusion parameters were completely matching and these figures were considerably better than QCA measured and hand caliper measured diametric parameters.

Table VI shows some procedural variables which demonstrated some differences which might have an impact for the physician preference of either type of balloons in a given lesion. Average number of balloon inflations was significantly higher in the compliant balloon group (3.9 ± 3.2 vs 3.1 ± 1.6 $p < .05$). However the average longest duration of inflation (189 ± 100 second vs 230 ± 194 second), total inflation time (489 ± 326 second vs 505 ± 337 second) average inflation time (137 ± 60 second vs 164 ± 117 second) and average maximum pressure (7.4 ± 2.3 atm. vs 6.7 ± 3.1 atm.) were not different between the compliant and non-compliant balloon groups.

Table V. Pre and Post Procedural QCA Measured Densitometric Area Occlusion and Visually Estimated Diameter Occlusion Parameters

	All patients	Compliant	Non-compliant	P value
Densitometric area occlusion	$83 \pm 14\%$	$83 \pm 13\%$	$84 \pm 15\%$	ns*
Residual dens. area occlusion	$36 \pm 20\%$	$34 \pm 19\%$	$37 \pm 20\%$	ns
Dens. net area Gain	$48 \pm 25\%$	$48 \pm 25\%$	$48 \pm 26\%$	ns
Visual diameter occlusion	$89 \pm 9\%$	$91 \pm 7\%$	$87 \pm 10\%$	ns
Residual visual stenosis	$17 \pm 14\%$	$17 \pm 15\%$	$18 \pm 13\%$	ns
Visual net gain	$71 \pm 18\%$	$74 \pm 16\%$	$68 \pm 19\%$	ns

ns* = non-significant.

Table VI. Procedural Variables

	All patients	Compliant	Non-compliant	P value
Number of inflations	3.5 ± 2.5	3.9 ± 3.2	3.1 ± 1.6	$p > 0.05$
Longest inflation (sec)	210 ± 157	189 ± 100	230 ± 194	ns*
Total inflation (sec)	497 ± 332	489 ± 326	505 ± 337	ns
Average inflation (sec)	151 ± 95	137 ± 60	164 ± 117	ns
Maximum pressure (bar)	7.02 ± 2.58	7.37 ± 2.25	6.74 ± 3.11	ns

ns* = non-significant

Table VII shows minor and major complications associated with the balloon procedures. There were equal numbers of minor (type A and B); (29 vs 26) and major (type C and D which required a bailout procedure); (5 vs 6) dissections in the compliant and non-compliant groups. Acute occlusion (1 vs 2), Re-do (1 vs 2), MI (0 vs 1), Arrhythmia (2 vs 1) intracoronary clotting (3 vs 1), emergency CABG (0 vs 1) non-emergency CABG (3 vs 1) were not different between the compliant and non-compliant groups. The percentage of patients with major

Table VII. Complications

	All patients	Compliant	Non-compliant	P value
Total dissections ¹	66	34	32	ns*
Minor dissections ²	55	29	26	ns
Major dissections ³	11	5	6	ns
Acute occlusion ⁴	3	1	2	ns
Re-do ⁵	3	1	2	ns
MI ⁶	1	0	1	ns
Arrhythmia ⁷	3	2	1	ns
Intracoronary clot ⁸	4	3	1	
ECABG ⁹	1	0	1	ns
CABG ¹⁰	3	3	0	
Others ¹¹	6	5	1	
Total number of complications	56	32	24	ns
Total number of Px with Cx ¹²	40	20	20	ns
Total major complications ¹³	8	5	3	ns
Total number of Px with major Cx ¹⁴	6 (3%)	4 (4%)	2 (2%)	ns

¹Type A, B, C and D; ²Type A and B; ³Type C and D; ⁴Case 73, 154, 178; ⁵Case 118, 154, 178; ⁶Case 73; ⁷Cases 73 and 116 (VF, VT); ⁸Cases 33, 47 and 73; ⁹Case 100; ¹⁰Cases 60, 73 and 74; ¹¹Cases 37, 68, 74 and 81 recathed and found to be normal, Cases 25 and 70, balloon bursted; ¹²All patients who had one or more complications at one session; ¹³Total number of major complications; ¹⁴All patients who had one or more major complications at one session; ns* = non-significant

Table VIII. Crossovers, Bail-out Procedures, Failures and Success Rate

	All patients	Compliant	Non-compliant	P value
Crossover ¹	7	4	3	ns*
Bail-out perfusion Balloon ²	9	4	5	ns
Bail-out DCA ³	13	7	6	ns
Bail-out stent ⁴	4	2	2	ns
Bail-out long balloon	1	0	1	ns
Sub-optimal results	19	6	13	ns
Total failures ⁵	46	20	26	ns
Study balloon success rate	72%	80%	74%	ns
Type A lesions	89%	92%	85%	ns
Type B lesions	78%	82%	74%	ns
Type C lesions	53%	50%	57%	ns
Overall procedural success rate	87.5%	90%	85%	ns

¹Cases 25, 30, 44, 101, 102; ²Cases 14, 33, 47, 58, 98, 109, 116; ³Cases 15, 16, 33, 43, 50, 54, 61, 77, 98, 116, 130; ⁴Cases 14, 82 and Cases 88, 126; ⁵Major complications, crossovers, bail-outs and sub-optimal results combined; ns* = non-significant

complications was the same in the two groups (4% vs 2%). There was no death or stroke associated with the procedure in this study population. No difference was noticed between the groups in the distribution of minor and major dissections during the procedure.

Table VIII shows crossovers, bail-outs, failures and success rates in both groups. Study balloon success rates (80% vs 74% overall, 92% vs 85% for type A lesions, 82% vs 74% for type B lesions and 50% vs 57% for type C lesions respectively) and overall procedural success rates (90% vs 85) were statistically similar for both the compliant and non-compliant balloon groups. There were equal numbers of perfusion balloon, DCA and stent bail-outs and crossovers between balloon types in each group.

DISCUSSION

Our data, comparing the immediate outcomes of PTCA performed with two different groups of balloons with two different compliance characteristics (compliant and non-compliant), show no difference in terms of immediate procedural success and both major and minor complications.

It has been suggested theoretically that overexpansion of compliant balloons may produce more intimal disruptions and coronary dissections and therefore cause more immediate and late complications as compared to non-compliant balloons.^{2,9,11} However the data presented by Raymenants E. *et al.*,⁸ Goel P. *et al.*,¹² Mooney M.R. *et al.*,¹³ and Bach R. *et al.*,¹¹ report no difference between compliant and non-compliant balloons in terms of immediate success and complications associated with the PTCA procedure. In addition the data presented by the Angioplasty Compliance Trial Study group are also in concordance with our results. The Angioplasty Compliance Trial is the only prospective data available in the literature and relate to 660 lesions in 490 patients.¹⁴ Although retrospective, both Mooney and Bach reviewed over a thousand cases each and suggested that operators should choose among the various balloon materials based on performance and preference factors as opposed to an intrinsic safety issue.

Our study, the second prospective trial in the literature, concurs with this suggestion.

One of our concerns when we first planned this study was whether the balloon sizing might be an issue in terms of matching the balloon size to vessel size. We thought that using compliant balloons might enable us to better match the vessel size as we could easily adjust balloon size with small increments of balloon pressure. However, there were no differences between the balloon types in terms of balloon/vessel ratio at the plaque disruption pressure which was similar for both balloon types.

The number of balloon inflations was statistically higher in the compliant balloon group. We think that this is due to the fact that the lesion resistance is difficult to overcome with compliant balloons because of less radiant force exerted by these balloons. The mean inflation pressure was also found to be slightly higher in this group without reaching any statistical significance. This observation supports the above mentioned thought.

The lower the amount of pressure required to disrupt the atherosclerotic lesion and the smaller increase in balloon diameter of non-compliant balloons reduce the “dog-bone” effect and result in less damage to the vessel wall.¹⁵⁾

It is widely believed that using compliant balloons reduces the number of balloons used for each procedure because of the ease of matching the balloon to the vessel size due to the availability of a large range of diameter variations with these types of balloons.¹⁶⁾ However, our data does not support this belief since we found no differences between the two groups in terms of balloon/vessel ratios indicating that there is no need to use less non-compliant balloons to match the vessel size.

Low pressure balloon inflation techniques are gaining popularity based on the assumption that lower inflation pressures cause fewer complications. Non-compliant balloons allow us to break the atherosclerotic plaque with low pressure inflations. In 3 of our 4 crossovers in the compliant balloon group the lesion did not break despite reaching the maximum pressure allowed by the manufacturer. The lesions were type C lesions in these patients.

The study balloon success rate tended to be higher with non-compliant balloons in type C lesions without reaching statistical significance (57% vs 40%, $p = ns$).

Based on the above observations we can speculate that non-compliant balloons give us a wider margin of safety by allowing us the ability to increase the pressure inside the balloon without dog boning, especially in heavily calcified type C lesions which are increasing as a percent of PTCA procedures despite the fact that the majority of lesion types were A and B in our study population.

Study limitations: One of the most important limitations of this study was the operator selection bias toward selecting small vessel lesions which were not targets for DCA, rotablator and stenting. Hence our data are valid only for mostly distal lesions in vessels smaller than 3 mm in diameter.

Most of the lesions in our study group were either type A or B lesions which require lower balloon pressures to break the plaque. However we know that the percentage of type C lesions which require higher balloon pressure are increasing in almost all labs. Compliant balloons inherently lack the ability to accommodate high balloon pressure and therefore using compliant balloons may result in lower success rates and higher complication rates in predominantly type C lesions. This

hypothesis needs to be investigated.

In conclusion, we suggest that both compliant and non-compliant balloons can safely be used in small vessel lesions with type A and B characteristics.

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