

# Quantitative measurements of balloon-to-artery ratios in coronary angioplasty

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## Summary

To determine the optimal balloon-to-artery ratio in percutaneous transluminal coronary angioplasty (PTCA), the effects of balloon size on the extent of residual stenosis, the incidence of coronary dissection, and the percentage of cases requiring repeat PTCA for restenosis were examined retrospectively. Fifty consecutive patients who underwent elective PTCA for simple and discrete lesion localized in the left anterior descending coronary artery were selected for this study. To measure the absolute cross-sectional area of the adjacent control segment of the artery, we developed a new method of quantitative coronary angiography, a hybrid of cinevideodensitometry and the edge detection method. The balloon-to-artery ratio was calculated as the cross-sectional area ratio between the control segment adjacent to the stenosis and the balloon which was visually selected by the operator during PTCA. Residual stenosis was determined as the percent area of stenosis by our hybrid method using cinevideodensitometry. The balloon-to-artery ratio ranged from 0.4 to 2.4, and a weak but significant inverse correlation ( $r = -0.51$ ) was observed between the balloon-to-artery ratio and the extent of residual stenosis. In 23 patients whose balloon-to-artery ratios were less than 1.0, residual stenosis was greater ( $59.9 \pm 11.9\%$  vs  $46.0 \pm 19.6\%$ ,  $p < 0.05$ ), and the percentage of repeat PTCA was higher

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(26% vs 4%,  $p < 0.05$ ) than in the group of 27 patients whose balloon-to-artery ratios were higher than 1.0. The incidence of coronary dissection was similar in the 2 groups (9% vs 15%, ns). The percent area of stenosis before PTCA, the number of inflations, the inflation pressures, and the inflation times were also similar between these 2 groups.

We concluded that the optimal balloon size is slightly more than the control segment dimensions of simple and discrete isolated stenoses of the left anterior descending artery treated at lower inflation pressures, and that an accurate measurement method of the coronary arterial dimensions is necessary to determine this optimal balloon size.

#### Key words

Balloon size      Coronary angioplasty      Restenosis      Coronary dissection      Quantitative coronary arteriography

### Introduction

Computer assisted quantitative measurement methods for relative coronary arterial stenosis in coronary arteriography have recently been adopted by several investigators<sup>1-3)</sup>, and the value of these methods has been recognized for clinical and research use<sup>4-7)</sup>. However, there still remain 2 major problems in measurement of the absolute dimensions of the coronary arteries and the measurement of regions of stenosis with complex geometry. The edge detection method with correction of pin-cushion distortion and magnification error can provide the absolute coronary arterial diameter calibrated by a catheter, but it cannot measure stenosis with complex geometry. On the other hand, densitometry can measure the relative cross-sectional area ratio independent of geometrical assumptions, but it cannot provide an absolute value alone. These 2 measurements are especially important in evaluating residual stenosis and in determining balloon size in percutaneous transluminal coronary angioplasty (PTCA). Pathological and angiographic investigations performed immediately after PTCA have shown that the geometry of the dilated arterial segment was asymmetrical and its internal surface was irregular<sup>8-11)</sup>. Thus, in order to measure the residual stenosis immediately after PTCA, a method of evaluating the severity of stenosis independent of geometric assumptions is necessary. The importance of using balloons of the optimal sizes

during coronary angioplasty has been underscored by several investigators<sup>12-15)</sup>. In practice, the balloon size is generally determined by the operator based on his/her visual assessments of the diameter of the adjacent normal coronary segment. Quantitative measurements of absolute coronary arterial dimensions are necessary to determine balloon sizes more accurately.

In this report, we propose a method which can facilitate measurements of the absolute coronary arterial dimensions independent of geometric assumptions with regard to the shape of the arterial stenosis. Using this method, we retrospectively evaluated the balloon-to-artery ratios in patients who had undergone PTCA. The aim of this study is to clarify the relationships between angioplasty balloon sizes and the residual stenoses, the incidence of coronary dissections and the incidence of restenoses.

### Patients and methods

**Patient population:** A series of 50 consecutive patients who underwent elective PTCA in our Department and fulfilled the following criteria were studied. Each patient had single and discrete stenotic lesions without calcification in the left anterior descending artery; no visible collaterals; no clinical evidence of coronary artery spasm; follow-up angiography 3-6 months after angioplasty; and diagnostic arteriograms for quantitative analysis. Patients who had total occlusions or stenoses in bifurcations of the coronary artery were excluded from the analysis.

**Angioplasty procedure:** Percutaneous transluminal coronary angioplasty was performed using a standard guide wire system. The balloon catheters used in this study were SRB (ACS Inc) or Proact (Mansfield). The sizes of the balloon catheters were determined by the operators based on their visual assessments of the control arterial diameter. The inflation pressure, inflation time, and the number of times of balloons inflated were also determined by the operators.

**Quantitative angiographic measurements:** Coronary arteriograms were obtained immediately before and after coronary angioplasty. Films were made at 30 frames/sec using an image intensifier of a 7-inch field size. Suitable frames of the R wave of the electrocardiogram were selected for analysis and were digitized with an image analyzer (Kontron, Mipron 1). To measure the absolute coronary arterial diameter and the cross-sectional area independent of geometrical assumptions, we developed a new method from the edge detection method and cinevideodensitometry. Details concerning the radiographic equipment used, the film development method, the criteria for frame selection, and the accuracy and reproducibility of these 2 methods have been described previously<sup>11</sup>. This new hybrid method encompassed the following steps: 1) Measurement of the diameter of the control arterial segment adjacent to the stenotic segment using the edge detection method. This step involved correction of pin-cushion distortion and magnification error to provide the absolute coronary arterial diameter and the guiding catheter which was used as a scale device. We calculated the cross-sectional area of the normal segment, assuming it had cylindrical geometry. 2) Measurement of the cross-sectional area ratio of the normal and stenotic segments was made by cinevideodensitometry. 3) The cross-sectional area of the stenotic segment was calculated from the results of the first and second steps.

The guiding catheter which functioned as a scale was usually positioned at a corner of the frame of the coronary arteriogram. Since

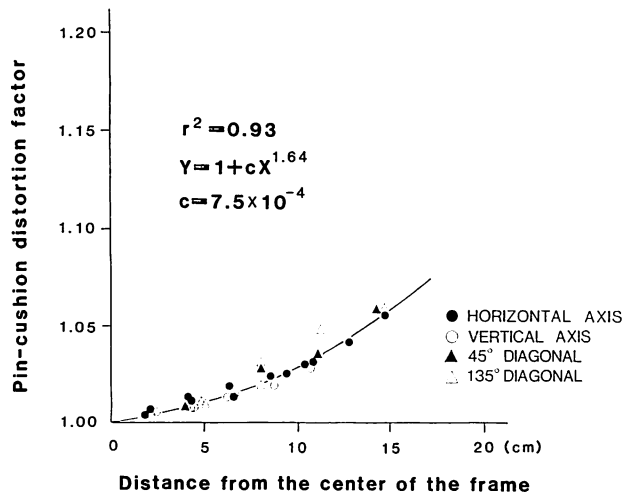
the catheter images were distorted severely, its correction was essential for the measurement of absolute diameter. We attempted to determine a factor distorting these images using a one cm rectilinear grid, and found that the pin-cushion distortion can be corrected by an empirical formula,  $1+cX^{1.64}$ , in which  $c$  is a constant and  $X$  is the distance from the center of the frame (Fig. 1).

In many cases, the catheter and the coronary artery to be measured were magnified independently on the films. To correct for differences in magnification, we measured the distance between the catheter and the artery along the axis of the X-ray beam from the orthogonal view, then calculated a correction factor,  $1+d/D$ , in which  $d$  is the distance between the catheter and the artery, and  $D$  is the distance between the X-ray tube and the film. We confirmed that this method allowed appropriate correction of the magnification factor using the one cm rectilinear grid (Fig. 2).

To test the overall accuracy and reproducibility of our hybrid method, the following experiment was performed. Seven cylindrical holes with diameters ranging from 0.6 mm to 6.0 mm were drilled in lucite blocks, and were filled with contrast medium. These blocks were then positioned at various sites in the arteriographic frame. Films were made in the same manner with normal coronary arteriography, and the cross-sectional area of each of the cylindrical holes was measured by 5 independent operators using the hybrid method after correcting pin-cushion distortion and magnification. The measured and the actual cross-sectional areas were then compared.

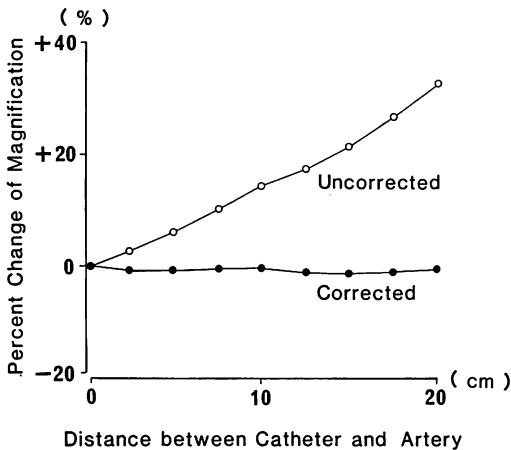
**Data analysis and definition:** To verify the importance of correcting pin-cushion distortion and magnification error, we compared the coronary arterial diameters of the control segments between 2 orthogonal views, with and without corrections, before angioplasty.

The balloon-to-artery ratio was calculated as the cross-sectional area ratio between the inflated balloon and the proximal control segment adjacent to the stenosis. The relationship be-



**Fig. 1. Pin-cushion distortion of a rectilinear grid.**

The relative distortion could be characterized by the function  $1 + cX^{1.64}$  according to our laboratory study, where  $c$  is a constant and  $X$  is the distance from the center of the frame. Similar results observed along different axes demonstrate radial symmetry of the distortion. Using this formula, we corrected pin-cushion distortion in the clinical study.



**Fig. 2. The results of magnification correction.**

The correction formula was  $1 + d/D$ , where  $d$  is the distance between the catheter and the artery and  $D$  is the distance between the X-ray tube and the film.  $D$  was set at 90 cm in our laboratory. This correction was necessary because the catheter which was used as a scale device provided magnification different from the artery.

tween this ratio and the residual stenosis was then investigated. The patients were categorized into 2 groups; namely, the undersized balloon group whose balloon-to-artery ratios were less than 1.0, and the oversized balloon group whose balloon-to-artery ratios were greater than 1.0. The incidence of coronary dissection, the incidence of repeat PTCA due to restenosis, the percent area of stenosis before PTCA, and the residual stenosis were compared between these 2 groups.

Balloon size was defined as the maximum balloon size used during angioplasty, and the diameter at each inflation pressure was derived from the manufacturer's specifications. Residual stenosis was defined as the percent area of stenosis determined by cinevideodensitometry immediately after PTCA. Coronary dissection was defined as the angiographic appearance of an intraluminal filling defect, extravasation of contrast medium, or luminal staining extending beyond the length of the lesion before angioplasty.

**Statistical analysis:** The accuracy of our

system was evaluated by the least squares linear regression analysis using phantom models. The pin-cushion distortion factor was determined by the nonlinear regression analysis. The statistical significance of the mean values was determined using the Student's t-test and differences between proportions were tested by the chi-square test in comparisons between the undersized and oversized balloon groups.

### Results

**Phantom study:** There was a strong linear correlation ( $r=0.99$ ) between the measured and the actual cross-sectional areas of the cylindrical phantoms (Fig. 3). Its regression equation was  $y=1.03x-0.09$ .

**Importance of correcting pin-cushion distortion and magnification error:** The control segment diameters of the coronary arteries measured using the right anterior oblique (RAO) view and the left anterior oblique (LAO) view are plotted in Fig. 4. The difference in diameter between the RAO and LAO views before correction (left panel) was  $0.30 \pm 0.19$  mm

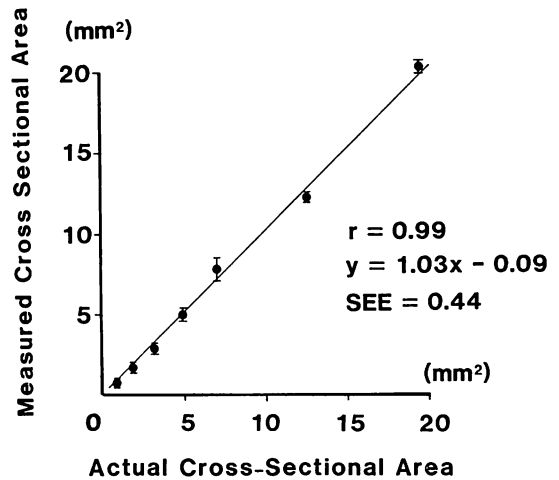


Fig. 3. Correlation between measured and actual cross-sectional areas.

There was a linear correlation between the actual cross-sectional area ( $r=0.99$ ) and the measured cross-sectional area. Its regression line ( $y=1.03x-0.09$ ) was similar to the identical line ( $y=x$ ). The horizontal bars indicate the standard deviation of the measurements made by 5 independent operators. It shows that our hybrid method is accurate and sufficiently reproducible in clinical use.

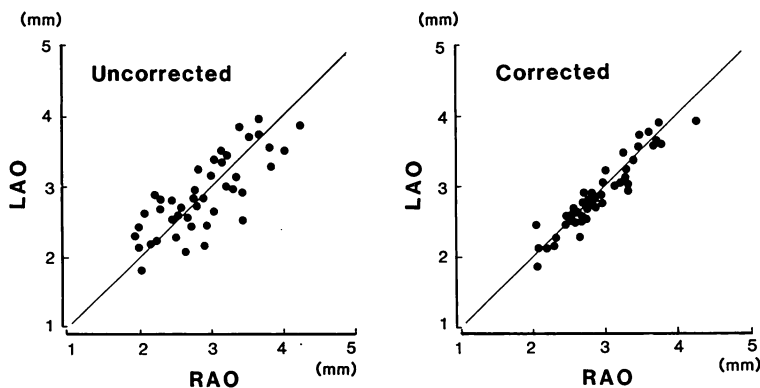


Fig. 4. Demonstration of importance of the correction of pin-cushion distortion and magnification.

Left panel: Significant discrepancies are observed between the control segment diameter measured from the right anterior oblique (RAO) and left anterior oblique (LAO) views before the corrections. The mean difference between the RAO and LAO views was  $0.30 \pm 0.19$  mm, sufficient to affect the calculation of the balloon-to-artery ratio. Right panel: After the corrections, the mean difference was reduced to  $0.11 \pm 0.07$  mm.

(mean ±SD). The maximum difference between these 50 patients was 0.78 mm, which was 29% of the corrected diameter in this case. After correction (right panel), the mean difference was reduced to 0.11±0.07 mm and the maximum difference was only 0.20 mm.

**Measured balloon-to-artery ratio:** The values were scattered widely from 0.4 to 2.4 (mean ±SD=1.1±0.5), corresponding to the diameter ratios of 0.6 and 1.5, respectively. The relationship between the diameter ratio and the residual stenosis is presented in Fig. 5. A relatively poor, nevertheless significant inverse correlation ( $r = -0.51$ ) was observed.

**Comparison between the undersized and oversized balloon groups:** The residual stenosis of the undersized balloon group was 59.9 ±11.9%, which was significantly greater than that of the oversized balloon group which was 46.0±19.6% (Table 1). However, the percent area of stenosis before PTCA was similar in both groups, being 91.4±5.1% and 89.2±6.2%, respectively. The percentage of patients requiring repeat PTCA due to restenosis in the undersized balloon group (26%, 6 of 23 patients) was significantly higher than that in

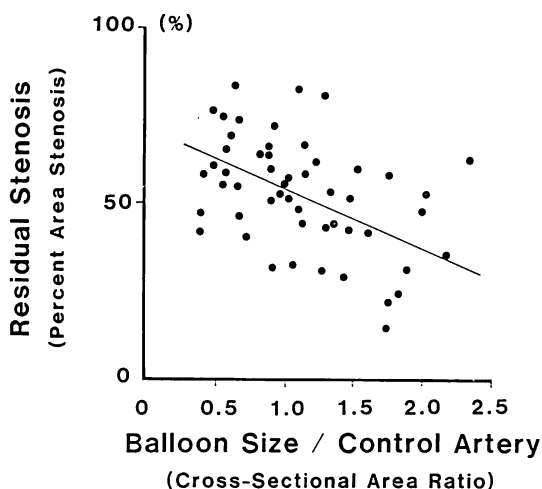


Fig. 5. Correlation between percent area stenosis and cross-sectional area ratio.

The balloon-to-artery ratio measured quantitatively was widely distributed from 0.4 to 2.4. This suggested that the operators' selection of balloon size based on visual estimation of the control segment diameter was occasionally inappropriate. The residual stenosis (percent area of stenosis) of 50 patients immediately after PTCA correlated inversely ( $r = -0.51$ ,  $y = 73.4 - 18.9x$ ) with the balloon-to-artery ratio (cross-sectional area ratio).

Table 1. Patient characteristics and procedural details in the undersized and oversized balloon groups

	Undersized balloon group	Oversized balloon group	
Range of balloon-to-artery ratio	<1.0	>1.0	
Mean ratio	0.7±0.2	1.5±0.4	
Number of patients	23	27	
Age (yrs)	62±6	58±8	NS
Sex (male : female)	20 : 3	24 : 3	NS
Pre-PTCA stenosis (% area stenosis)	91.4±5.1	89.2±6.2	NS
Residual stenosis (% area stenosis)	59.9±11.9	46.0±19.6	p<0.01
Number of inflations	3.8±0.9	3.6±0.8	NS
Inflation time (sec)	62.0±9.4	69.4±15.0	NS
Inflation pressure (PSI)	98.3±8.3	93.7±15.1	NS
Number of dissections	2 (9%)	4 (15%)	NS
Number of patients who required repeat PTCA	6 (26%)	1 (4%)	p<0.05

The balloon-to-artery ratio was expressed as a cross-sectional area ratio. PSI=pounds per square inch; NS=not significant.

the oversized balloon group (4%, one of 27 patients) ( $p < 0.05$ ). In the undersized balloon group, 2 (9%) patients developed coronary dissections; compared to 4 (15%) in the oversized balloon group. (The difference was not statistically significant). Inflation pressure, inflation time, and the number of inflations were similar in these 2 groups (Table 1).

### Discussion

**Measurement of coronary arterial dimensions:** Our system for the quantitative analysis of coronary angiograms is a hybrid of the edge-detection and densitometric methods with correction function for pin-cushion distortion and magnification error. This hybrid method was developed to measure the absolute value of the minimal cross-sectional area of coronary arterial stenosis independent of the stenosis geometry. We previously reported that many cases of coronary arterial stenoses immediately after PTCA have a complex geometry<sup>11</sup>. Although densitometry was thought to be most suitable for evaluating the severity of residual stenosis in these cases, it could not provide the absolute value when used alone. The edge detection method could provide an absolute value for the stenoses with cylindrical geometry only by catheter calibration. Our method is a combination of these 2 methods, which provides a means of measuring the absolute cross-sectional area before and immediately after PTCA.

Corrections of the pin-cushion distortion and the magnification error were also essential for obtaining accurate measurements of the absolute coronary arterial dimensions. These corrections significantly reduce the difference in the measurements of the control segment diameters of the coronary artery obtained from the RAO and LAO radiographs. The maximum difference in the diameters between the 2 orthogonal views was 0.78 mm, which was about 30% of the corrected diameter, a difference which must affect the evaluation of the balloon-to-artery ratio.

**Visual vs quantitative measurement of the**

**balloon-to-artery ratio:** The balloon-to-artery ratio was measured retrospectively after PTCA and ranged from 0.4 to 2.4 cross-sectional area ratio. This suggests that visual estimation of the balloon size may be considerably inaccurate. To minimize such inaccuracy while achieving the maximum effect of angioplasty without increasing its risk, the operator must measure the diameter of the control segment and select the right balloon. Our hybrid method is accurate enough for this purpose.

**Optimal balloon size:** Reportedly, the balloon size may affect the residual stenosis, the incidence of acute complications, and the restenosis rate<sup>12-15</sup>. Results of the present study indicated that an oversized balloon may reduce the residual stenosis and the incidence of restenosis without increasing the risk of acute complications significantly. Roubin et al<sup>14</sup> have recommended that an undersized balloon is used because of the low incidence of acute complications and a similar initial success rate, the residual stenosis, and the restenosis rate compared with larger balloons. However, the mean inflation pressure was nearly one atm higher in the undersized balloon group than in the oversized balloon group in their study. The size of residual stenosis was similar in both groups, suggesting that residual stenosis is one of the most reliable predictors of restenosis<sup>16-19</sup>. They also reported that the use of oversized balloons may increase the incidence of acute complications, such as coronary dissections and acute coronary occlusions, as opposed to the results in the present study. These discrepancies may be attributed to the differences in inflation pressures and the patient population. In the oversized balloon group, their inflation pressure was nearly one atm higher than that in the present study. Acute complications occurred frequently in patients with multivessel disease and complex lesion morphology in their series. In our study, all patients had simple and discrete lesions in the left anterior descending artery only. Of course, an extremely oversized balloon which might increase the risk of coronary artery dissection

should not be selected. Consequently, we believe that a balloon whose length slightly exceeds that of the control segment of the coronary artery adjacent to the stenosis should be selected. We also suggest that the optimal balloon-to-artery ratio is 1.4 as a cross-sectional area ratio or about 1.2 as a diameter ratio. This value was derived from the balloon-to-artery ratio with which the residual stenosis was 50% (cross-sectional area ratio) on the regression line of the correlation analysis between the balloon-to-artery ratio and residual stenosis (Fig. 5).

**Limitations:** The optimal balloon size recommended in this study has some limitations. Although the correlation between the balloon-to-artery ratio and the extent of residual stenosis were significant, it was rather weak. This suggests that many other factors may influence this relationship, such as the patients' age, sex, history of angina or myocardial infarction, coronary risk factors, and the composition of the stenosis. Further investigation of patients with stenoses of other coronary arteries, multivessel disease, and complex types of stenosis is also needed.

The inflation pressure determined by the operators in this study was slightly lower than the optimal pressure offered by the manufacturers. Changes in actual balloon size at each inflation pressure<sup>20)</sup> were corrected in this study. However, the radial force required to dilate the stenosis in balloon angioplasty depends not only on the balloon diameter but also on the inflation pressure. The radial force is related to hoop stress, which is described by the following equation: hoop stress =  $P \times D$  ( $P$  is the inflation pressure and  $D$  is the diameter of the inflated balloon<sup>21)</sup>). Therefore, the hoop stress in this study was lower than that in the report by Roubin et al<sup>14)</sup> although the balloon-to-artery ratios were similar. This explains why coronary dissection did not increase in the oversized balloon group. Therefore, the optimal balloon-to-artery ratio derived from the results of the present study is limited to lower inflation pressure for

angioplasty.

## Conclusions

The present study indicates that the optimal balloon-to-artery ratio is slightly over 1.0. This ratio minimizes the extent of residual stenosis and thus reduces the need for repeated PTCA without increasing the risk of coronary dissection. An accurate measurement method of the coronary arterial dimensions before angioplasty, such as our hybrid method, is important in performing PTCA.

## 要 約

経皮的冠動脈形成術における balloon size の選択について：冠動脈造影の定量的評価法による検討

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経皮的冠動脈形成術 (PTCA) における使用バルーンサイズの適合性を検討するために、冠動脈造影から冠血管径あるいはその断面積を計測する方法を開発し、以下の検討を行なった。対象は PTCA を施行した左前下行枝一枝病変症例 50 例である。今回開発した冠動脈造影の定量的評価法は、まず edge detection 法により狭窄部近位側の対照血管径を pin-cushion distortion と拡大率を補正して計測し、次に densitometry 法により狭窄部位と対照部位の面積比を計測、両者より狭窄部の断面積を算出するもので、撮影方向や狭窄病変の形態にかかわらず、高い精度で冠動脈断面積の計測が可能であるという特徴を有する。本法により計測された対照血管と使用バルーン的面積比を適合性の指標とし、残存狭窄度との関係、再 PTCA や冠動脈解離の有無等と対比した。

結果は以下のごとくであった。



1. 使用バルーンと対照血管の断面積の比は 0.4 から 2.4 まで広く分布した。この比と残存狭窄度との間には、有意の逆相関関係 ( $r = -0.51$ ) を認めた。

2. この断面積比が 1.0 未満の小型バルーン使用例 23 例 (平均断面積比=0.7) では、1.0 以上の大型バルーン使用例 27 例 (同=1.5) に比し、残存狭窄度が大 ( $59.9 \pm 11.9\%$  vs  $46.0 \pm 19.6\%$ ) で、再狭窄により再 PTCA を必要とした症例数 (23 例中 6 例 (26%) vs 27 例中 1 例 (4%)) も多かった。一方、PTCA 前の狭窄度、冠動脈解離の出現率、拡張圧、拡張時間、拡張回数には差を認めなかった。

結論として、PTCA におけるバルーン径は残存狭窄や再狭窄等との関連で極めて重要であり、左前下行枝一枝病変症例を対象とする場合、対照血管断面積の約 1.4 倍 (内径比では約 1.2 倍) が適当と考えられる。そしてバルーンを選択には正確な冠動脈造影像の定量的評価法が必要である。

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