Present Status and Perspective of Percutaneous Transluminal Coronary Angioplasty from the Viewpoint of Short and Long Term Results: Comparative Study of the Results of PTCA and CABG Procedure

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Balloon technology has advanced to incorporate the skills of angioplasters while efforts to enhance their skills continue. These factors have contributed to the expansion of percutaneous transluminal coronary angioplasty (PTCA) indications.

We have analyzed the comparison of short and long term results between PTCA and CABG revascularization procedures.

In the development of revascularization procedures, one graft surgery has significantly declined in use since 1983 (2 years after the start of PTCA) while there has been an increase of multi graft surgery (more than 2 grafts).

On the other hand, PTCA has showed a linear increase since 1982 and reached 160 cases in 1985. The growth of complex angioplasty other than PTCA for single discrete lesions is parallel to that of PTCA and has been used in 44% of overall cases. The growth curve of angioplasty crossed over that of revascularization surgery in 1983.

PTCA was successful in 246 patients out of 300 overall cases representing 88% success rate and in 340 lesions representing an 81% success.

For CABG the patency rate was 89.5% which means a out of 638 grafts were successful. PTCA was conducted in 137 cases with multiple lesion. That data could be interpreted as mean patient success of 120/137, lesion success was 196/265 with a success rate of 88% and 73%, respectively. Primary results in 284 multi CABG cases were good with a patency rate of 91% (487 patent grafts out of 536 anastomoses).

However, in-hospital deaths were 3.5% higher (10 cases with CABG group). The effective dilatation of high-grade organic lesion was found to be closely related to the improvement of clinical symptoms and a marked decrease in incidence of ergonovine induced spasms at the angioplasty site in patients with vasospastic angina (VSA). Thus PTCA can be accepted as an alternative therapy to CABG in VSA.

In the long term follow up, work load response parameters such as exercise time, % predicted HR, PRP, Mets and the modified treadmill exercise scores improved significantly after the successful PTCA.

Key words:

Percutaneous transluminal coronary angioplasty
(PTCA)
Coronary artery bypass grafting (CABG)
Complex angioplasty

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The cumulative survival rate of 5 years was 94.7% for PTCA and 90.7% for CABG (N.S.).

In conclusion, as the selection of management for angina caused by multi-vessel disease the background of each individual case and evaluate the risk/benefit ratio of the palliative therapy of PTCA and CABG in the total clinical course of the patients.

WITH the clinical application of the double lumen balloon dilatation catheter, developed by Gruntzig¹ in 1977, to the cleaning of coronary atherosclerosis, Percutaneous Transluminal Coronary Angioplasty (PTCA) with balloon dilatation has suddenly attracted attention as the non-surgical revascularization procedure for angina.

Along with that, the balloon technology itself has advanced to incorporate such features as low profile, trackability, pushability and strength and efforts have been made to further enhance the skills of angioplasters. These factors have contributed to the expansion of indications for PTCA.²

However, reports which compare the short and long term results of PTCA for expanded indications with those of revascularization surgery are so far limited in number. There is no unified view on the basic issue of indications for PTCA and CABG and the relationship between the two. We have studied these issues at our institution based on our own experiences.

SUBJECTS AND METHOD

Subjects were 300 patients (male 257 and female 43) who received PTCA at the Cardiovascular Diagnostic Laboratory Center, Toho University School of Medicine from September 1981 to March 1986. Age varied from 32 to 81 years old with the average of 57.1 ± 9.4 . Total number of lesions was 420. On the average, each patient had 1.3 lesions. 64 patients among the 420 lesions (21%) were aged patients more than 65 years old. The 420 lesions can be broken down to 133 single lesion PTCA cases (44%) and 329 cases of complex angioplasty (64%). This 64% can be farther broken down to 137 cases (45%) of multi-lesion PTCA, 3.0% (10 cases) of PTCA after CABG and 12% (38 cases) of AMI or chronic complete obstruction. As control, we have employed 366 patients or 368 grafts with CABG which had been performed at the First Department of Surgery, Toho University.

The trans-femoral approach was used for elective PTCA and the trans-brachial method was mainly used for emergency PTCA. The kissing

Fig.1. Growth of revascularization procedure.

TABLE I RESULTS (From the View Point of Types in MVD)

Type	Patient Success	Lesion Success
I	28/33 (85%)	45/51 (82%)
II	9/9 (100%)	17/18 (94%)
III	38/49 (78%)	60/81 (78%)
IV	5/5 (100%)	5/5 (100%)
V	5/5 (100%)	7/8 (88%)
I + III	35/36 (97%)	65/94 (69%)
II + III	1/2 (50%)	5/8 (62%)
Total	120/137 (88%)	196/265 (73%)

Target lesions per patient : 2.0

Type I : High grade stenosis in two or three major vessels.

Type II : One high grade stenosis and non-high grade stenosis. ($\geq 50\% < 70\%$ stenosis) in other vessel.

Type III: Bifurcated stenoses or tandem stenoses.

Type IV: Graft failure after CABG.

Type V: Native coronary artery disease (high grade stenosis) with closed graft or native new coronary lesion on non-grafted vessel.

balloon technique was used for bifurcated lesions when necessary. For the first 30 cases, the Gruentzig balloon dilatation catheter (fixed guide wire) was used in the dilatation procedure. For the remaining cases (at a later stage), the movable steerable guide wire system was used.

The dilatation effect was confirmed angiographically by a double injection through the guiding catheter and balloon catheter tips (the balloon catheter was pulled back to the guiding catheter). At the same time, the digital imaging system was used to automatically analyse the dilatation effect on the target lesion on a real time basis.³ The criteria for PTCA success were; 1) reduction or stenosis by more than 20% (% diameter stenosis with less than 50% stenosis of luminal diameter).

RESULTS

1) Primary success

The primary success of overall PTCA was 246 patients representing an 88% success rate and 340 lesions representing an 81% success rate. Among 230 patients or 322 lesions or successful PTCA, 130 cases or 166 lesions were followed from 3 months to one year. Angiographical re-

TABLE II RESULTS (Primary Success in Various Lesion Numbers)

Target Lesion Number	Primary Success	
	Patients Success	Lesion Success
2 lesions/patient	64/69 (92.7%)	106/134 (79.0%)
3 lesions/patient	22/23 (95.6%)	49/69 (71%)
4 lesions/patient	2/2 (100%)	6/8 (75%)
5 lesions/patient	2/2 (100%)	7/10 (70%)
6 lesions/patient	1/1 (100%)	6/6 (100%)
	91/97 (94%)	174/227 (77%)

stenosis was observed in 46 lesions among those 166. The restenosis rate was 29% (restenosis rate by lesion was 28%).

For CABG, the patency rate was 89.5% which means a 571 graft success out of 638 grafts.

2) Growth of revascularization procedure (Fig. 1)

The chronological changes of PTCA and CABG (revascularization surgery), show that single graft surgery has been declining since 1983 (two years after the start of PTCA) while multi grafts surgery (more than 2 grafts) has increased although these also have declining since 1983.

On the other hand, PTCA has shown a linear increase since 1982 and reaching 160 cases in 1985. The growth of complex angioplasty other than PTCA for single discrete lesions is parallel to that of PTCA and has a share of 44 to 50% in overall cases. The growth curve of angioplasty crossed over that of revascularization surgery in 1983. This may be a world wide trend.

3) Effect of dilatation in terms of involved vessels

Lesion success by target vessel was; 182 out of 201 for LAD (Left Descending Coronary Artery) with a success rate of 91% and a dilatation rate of 49.6%, 45 cases out of 56 for LCX (Left Circumflex Coronary Artery) with an 80% success rate and 51.2% dilatation rate, 64 lesions out of 78 for RCA (Right Coronary Artery) with a success rate of 82% and a dilatation rate of 48.8% and 10 out of ten for vein graft with 100% success rate. There is no major difference between success rate and dilatation results by lesion. The results were quite favourable.

TABLE III COMPARISON OF EACH PARAMETER PRE-PTCA, SHORT TERM AND LONG TERM OF POST-PTCA (TREADMILL EXERCISE TESTING)

	Pre-PTCA <i>n</i> = 12	Post-PTCA		
		Short Term	Long Term	
		< 7 days <i>n</i> = 127	< 6 months 2.9 ± 3.2M <i>n</i> = 59	6 months ≤ 9.5 ± 3.1M <i>n</i> = 24
Exercise Time (min)	7.09 ± 2.74	9.19 ± 2.29	9.94 ± 2.72	9.98 ± 2.47
		$p < 0.001$	$p < 0.001$	$p < 0.001$
Maximal Heart Rate (beat/min)	137.3 ± 23.1	159.4 ± 17.2	161.9 ± 18.7	155.0 ± 18.9
		$p < 0.001$	$p < 0.001$	$p < 0.001$
% maximal Predicted Heart Rate (%)	90.7 ± 14.4	105.3 ± 10.0	105.6 ± 11.0	105.0 ± 9.9
		$p < 0.001$	$p < 0.001$	$p < 0.001$
PRP	24640 ± 6480	30520 ± 6140	31960 ± 6120	30740 ± 6070
		$p < 0.001$	$p < 0.001$	$p < 0.001$
Mets	6.20 ± 1.85	6.87 ± 1.79	7.57 ± 2.25	7.65 ± 2.01
		$p < 0.01$	$p < 0.05$	$p < 0.001$
$\dot{V}O_2$ (ml/kg/min)	21.6 ± 6.5	24.1 ± 6.3	26.5 ± 7.9	26.6 ± 7.0
		$p < 0.01$	$p < 0.05$	$p < 0.01$
M-T.E.S.	-1.59 ± 1.46	-0.94 ± 0.78	-1.06 ± 0.90	-1.21 ± 1.20
		$p < 0.001$	$p < 0.002$	

4) Incidence of complications

The major complications during or after the procedures were: 1) 13 cases of emergency CABG (4.3%), 2) 7 cases of acute myocardial infarction (2.3%) and one attributable death (0.3%). Major complications for CABG were 13 cases of perioperative myocardial infarction (3.4%), 5 cases of low output syndrome (1.3%) and 10 cases of hospital death (2.6%).

5) Follow up study

The results of an average 13.3-month-follow-up of 245 cases showed: 36 cases of 2nd PTCA (11%), 4 cases of late cardiac death. Elective CABG was conducted in 15 cases (5.0%) because of the failure of PTCA in 10 cases (67%), isolated restenosis in 3 cases (20%) and restenosis with new lesion in 2 cases (13%). On the other hand, mortality of 386 CABG cases during the follow

Fig. 2. Comparison of five years survival between PTCA and CABG group.

up period of more than 6 months was 3.4% or 13 cases.

6) Multi lesion PTCA (Table I, II)

As there are variations in this type of disease, for example, some lesions may be located on multivessels or multiple lesions may be located on the same branch including the major one, guidelines for the definition were prepared⁴

PTCA was conducted in 137 cases with multiple lesions. The average number of lesions per case was 2.0. The results were: Type I success was 28/33 with a success rate of 85% and patient and lesion success for Type III (which include bifurcated stenosis and sequential or tandem stenosis of the same branch) were 78% and 74%, respectively. Patient and lesion success of Type IV (post CABG graft failure) were both 100%. These results were quite favourable. Primary success in Types I and III tended to be low in comparison with other types, but these data could be interpreted as acceptable since mean patient success was 120/137, lesion success was 196/265 with a success rate of 88 and 73% respectively. Primary results in 284 multi CABG cases (multiple graft surgery) were good with a patency rate of 91% (487 patent grafts out of 536 anastomoses). However, in-hospital deaths were a rather high 3.5% (10 cases).

7) PTCA for vasospastic angina

PTCA was performed on 67 organic high-grade stenoses of 56 vasospastic angina patients which

had been confirmed to be total spasm by ergonovine maleate. Restenosis rate was 24%, but PTCA was successful for all these cases. Interesting changes were observed for ergonovine sensitivity derived from ergonovine provocation test. Those cases with more than 99% spasm showed the reduction to 20% after PTCA for initial angioplasty site. The effective dilatation of high-grade organic lesion was found to be closely related to the improvement of clinical symptoms

On the other hand, the patency rate of CABG on 48 vasospastic angina cases was a rather low 84%. There was 10% PMI and 2.4% mortality. The authors are concerned with this high rate of peri operative complications in this procedure.

8) Physical work capacity after PTCA (Table III)

We examined the effect of dilatation of the organic coronary artery on the improvement in ischemic disease and on work capacity. Quantitative analysis was conducted on 127 cases by treadmill exercise testing as shown in Table III

Work load response parameters improved significantly. Physical work capacity was clearly improved even at a later stage after successful PTCA.

A questionnaire survey was conducted with regard to the late stage quality of life and the results between PTCA and CABG groups were compared. Subjects of the questionnaire were 202 PTCA patients with more than 24 months follow up period and 190 CABG cases with more than a

Fig.3

6-month follow-up period. The response rate was 85%. There is no significant difference between the two groups in terms of the ordinary life level. Percentage of full time labor is 61% for PTCA and 55% for CABG.

12% of PTCA patients had work loads higher than the ordinary level and 14% had increased work intensity. These results were significantly higher than those of CABG ($p < 0.05$). Average time required to return to the job was 7.5 days for PTCA and 78 days for CABG. The above figure indicates the advantage of PTCA.

9) 5 year survival (Fig. 2)

The cumulative survival rate of 5 years was 94.7% for PTCA and 90.8% for CABG. There was no significant difference between the two (N.S.). The results were favourable for both groups. Non-cardiac death was included in PTCA group.

DISCUSSION

1) Ultimate objectives of PTCA

They are; a) minimum complication with maximum results, b) PTCA results should be equivalent to surgical intervention, c) improved angioplasty skills, d) development of better catheter systems and e) the expansion of indications.

Maximum results means not only an angina

free condition but also an improvement in exercise capacity and quality of life. The development of better catheter systems includes softer guiding catheters, lower profiles, more trackability, more pushability, stronger balloon dilatation catheters and the development of more flexible and steerable guide wires⁵.

These required features already have been taken into account and improved features have become a reality in certain areas. For example, other than the classical indications of proximal single discrete lesion, advocated by Gruentzig,¹ the indications for PTCA expanded to include more complicated lesions for single vessel disease (calcified lesions, diffuse eccentric lesion, ulcerative plaque etc.), multi-vessel disease, chronic total occluded lesions, graft stenosis after CABG or native artery lesions. Current clinical indications can include stable effort angina, unstable angina, emergency PTCA for acute myocardial infarction and angioplasty procedure for vasospastic angina. In terms of clinical and anatomical features, this procedure was evaluated as alternative palliative treatment for surgical intervention. When confronted with angina, the anatomical characteristics of each case were considered, and the procedure to be employed was decided upon. In this process, it is essential to take into account the relative advantages and disadvantages of both procedures. Judgement

Restenosis rate and possible risk factors

Fig.4

should be based on ample experience and literature.

2) Primary results

Primary success includes both patient and lesion success. Stable results mean less discrepancy between patient success and lesion success. Success also depends on the technique, in other words, learning curve of angioplasters. The primary success of leading institutions in the U.S., European countries and Japan should exceed 80%.

Patient success and lesion success of the 300 cases were reported here at 88 and 81%, respectively. These are acceptable results. According to King⁶ whose experience exceeds 7000

cases, the present success rate is 89% and for the time being, the success rate will hover around 90%. This is because of an increase in challenging cases with the expansion of indications. Some of the major complications are unavoidable as is the case in surgical interventions. Emergency CABG was 4.3%, acute myocardial infarction was 2.3% and attributable death was 0.3%.

These features are lower than those of NHLBI registry⁷ where emergency CABG is 6.6%, AMI was 5.5% and death 1%. Our figures are more or less the same as those of Emory University⁸ which is the leading institution of PTCA where the percentages are 2.7%, 5.6% and 0.1%, respectively. The frequency of emergency CABG is higher in our institution compared with that of

Emory. This is because in cases of acute coronary occlusion, together with prolonged chest pains and ST elevations, it is our policy to move to emergency CABG as swiftly as possible, as our first priority is the salvage of myocardium in the perfused area. This policy was established after discussions with cardiac surgeons.⁹ We do not insist on repeated PTCA for acute coronary occlusion.

On the other hand, primary results of CABG indicate a graft patency rate of 89.5% among 389 CABG procedures. Primary success of PTCA is equivalent to that. We also have to consider the risk/benefit ratio of CABG. There are problems such as hospital mortality, perioperative mortality (PMI), low output syndrome (LOS), post-cardiotomy syndrome, wound infection, hepatitis and progression after CABG which cannot be neglected.

Our data on CABG shows a 2.2% hospital mortality, 3.4% PMI and 1.3% LOS. Although, there are differences in morphology and the number of lesions, mortality and morbidity are lower for PTCA. It should be emphasized that PTCA can be performed more safely than CABG on selected patients if there is ample experience in angioplasty and a full stand-by of cardiac surgeons.

3) *Expansion of indications*

i) Multi lesion PTCA

Multi lesion PTCA is a typical example of the expanded indications. The authors classified the disease into 5 types as a guideline for the determination of adequate indications and analysed the results by type.⁴ Type I, which has more than two targets on different major arteries, and Type II, which includes bifurcated lesions, show a lower success rate than other types.⁴ The results of this type correlate with the number of targets. The anatomy of target lesions tends to be more complicated than discrete lesions. In the case of Type III, the risk of side branch occlusions by PTCA is a rather high 16.7% when side branch stenosis originates within the lesion of the major artery¹⁰ as shown Fig. 3. Because of this risk factor, it is necessary to select a safer procedure adequate for the anatomical properties of each lesion. Procedures such as the following should be seriously considered: the use of staged PTCA for multiple-lesions with more than three targets, intentional incomplete revascularization to concentrate the CABG procedure on major ischemic lesions and the use of dual wire or kiss-

ing balloon techniques by dual balloon catheter systems to avoid the risk of side branch occlusion¹¹ as shown Fig. 3.

PTCA for post CABG graft failure, in other words graft stenosis (Type III), for native coronary artery disease after graft closure or for native new lesions (Type V) are quite effective (with 100% patient and lesion success).¹² Clinical manifestation of these kinds of complications often takes the form of unstable angina. It is reported that the possibility of reoperation because of the disease progression after CABG is about 3%. As there are technical difficulties for CABG such as the identification of previous saphenous veins, preparation of pericardium or others and as morbidity and mortality are rather high, PTCA can be considered as the alternative procedure.¹³ PTCA, however, also presents problems. PTCA should be used for graft stenosis originating from intimal hyperplasia. Old graft failure is undesirable because of flyable plaque fragmentation.¹⁴ On the other hand, most of the 284 CABG cases possessed features of multi vessel disease including LMT lesion which made PTCA undesirable. Patency rate was a high 91% but hospital mortality rate was 3.5% (10 cases). The authors are concerned by this fact.

Hartzler,¹⁵ who is the leading proponent of multi vessel PTCA in the U.S., stated the following with regard to the above mentioned issue:

1) Multiple vessel dilatation can be performed safely and effectively in a majority of well selected patients.

2) Multiple vessel dilatation can be performed with mortality equivalent to that reported for bypass surgery in similar population.

3) The advantages of angioplasty are obvious—fewer patient morbidity, more rapid recovery with an early return to full activity.

4) In most circumstances, failed multi vessel angioplasty will not preclude the subsequent elective CABG.

ii) Vasospastic angina

High grade organic stenosis and coronary artery spasm often co-exist in many clinical cases which are so-called vasospastic angina. These conditions tend to be unstable and if organic stenosis exceeds 90%, it is not possible to achieve improvement in physical capability with medical treatment alone. Because of these factors, PTCA was applied to these cases and primary results and studies of the changes of spasm before and after PTCA were analyzed. Primary patient and lesion success were 91 and 93%. Dilatation was

effective. The 5-year cumulative survival rate was 100%. Treadmill exercise tests before and after PTCA for highgrade stenosis of more than 90% revealed that exercise time, maximum predicted heart rate, double products, $\dot{V}O_2$ and Mets had significantly improved after successful angioplasty with $p < 0.01$, $p < 0.001$, $p < 0.001$, $p < 0.05$ and $p < 0.05$, respectively.¹⁶ Physical work capacity was clearly improved. The higher the stenosis, the better the PTCA than medical or surgical treatments. The fact that spasm was reduced at the initial angioplasty site, shown by ergonovine test, contributed to the improvement of clinical symptoms. The mechanism for the reduction of spasm is not simple and several factors are involved which may be intermingled; there are some cases in which the coronary artery wall is sensitised by ergonovine maleate which may contribute to the stabilization. The geometrical theory can be applied when organic lesion is improved, circadian rhythm may be related and the vessel dilatation may result in the reduction of active vasoconstriction resulting from the damage of coronary vascular smooth muscle. These factors signify the importance of this procedure. When CABG is applied, PMI due to peri-operative spasm is rather high (10%) in comparison to other types. PTCA can be considered a more effective treatment procedure for vasospastic angina.

iii) Unstable angina

Possible underlying factors for unstable angina are: a subtotal occluded lesion, a superimposed spasm on organic lesion, a disruption of plaque, an ulcerative plaque or a thrombus formation based on complicated lesion which has been reported by Ambrose.¹⁷ For the unstable angina which can not be stabilized by vigorous medical treatment, emergency PTCA following emergency diagnostic CAG is quite effective.¹⁸ In cases of multi vessel disease especially, drastic improvement can be expected of dilatation is mainly concentrated on the "culprit lesion".¹⁹ In this case, PTCA is superior to CABG.

4) Long term results

Recurrence is an important factor in the discussion of long term results of PTCA. Restenosis is said to be the "Achilles' heel" of PTCA.¹⁴

To evaluate restenosis rate and risk factors for restenosis after successful coronary angioplasty (PTCA), we studied 196 patients (237 lesions) with pre-PTCA diameter stenosis greater than

60% who underwent elective successful PTCA. Restenosis was defined as a residual stenosis at the time of follow up angiography of more than 60% of luminal diameter.

Follow up angiogram was available in 138 patients (70%), 173 lesions (73%). Univariate analysis of various clinical, angiographic, and procedural factors revealed three factors significantly related to restenosis: duration of ischemic symptoms greater than 3 months compared with shorter duration (29% vs 47%, $p < 0.05$), bifurcation vs non-bifurcation lesion (43% vs 23%, $p < 0.05$), and stable vs unstable angina (30% vs 50%, $p < 0.05$). Further, restenosis rate also appeared to be higher in multi vessel disease, LAD lesion, more severe pre-PTCA percent stenosis, and long lesion.

Therefore, although recurrence has a multifactorial problem, the intrinsic atherogenesis due to an activity of target vessel wall, the complicated lesions more likely associated with unstable angina, and morphological characteristics such as bifurcation seemed to be an important factor for restenosis. (Fig. 4)

In order to evaluate the physical work capacity after successful angioplasty, the authors conducted treadmill exercise tests in 127 cases with a more than 6 month follow-up period. Protocol is the same as PTCA test (medication off for more than 12 hours, Bruce Protocol, symptoms limited). Pre PTCA and Post PTCA parameters were compared. Parameters for work load response such as exercise time, predicted HR, preoperative RPP and Mets showed significant improvement.²¹ The improvement of physical work capacity was clear. The data of exercise tests agreed with the improvement of long term clinical symptoms and the results of the questionnaire. It also supports the high 5-year survival rate. The fact that non-surgical revascularization procedure not only treats angina but also improves exercise capacity and the quality of life while the long-term survival rate is equivalent to that of revascularization surgery, should not be overlooked.

Here, the authors would like to state their basic strategy or attitude toward angioplasty; 1) attempt the most critical or highest risk stenosis first, 2) attempt total occlusion first if collateral can be supplied, 3) stop if unsuccessful in the major vessel, 4) stop if significant dissection occurs, 5) consider staging or kissing balloon angioplasty procedure if necessary, 6) do not attempt multi vessel angioplasty during AMI or

UAP, just dilate the "culprit lesion". On top of that, it should be emphasized that it is essential to make an unbiased judgement as to the selection of procedure—it is not good just to emphasize the good points of PTCA.

In summary, three options — medical treatment, PTCA and CABG — are now available for the treatment of angina. In order to select the most suitable treatment method, the background of each individual case and an evaluation of the risk benefit ratio of the three palliative treatments in the total clinical course of the patients should be done.

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