Safety and Acceptable Initial Outcomes of Reused Balloon Catheters for Percutaneous Transluminal Coronary Angioplasty

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Abstract

Objectives : This study was conducted to compare the safety and initial outcomes applying reused balloon (RB) catheters with those of attained new balloon (NB) catheters when performing percutaneous transluminal coronary angioplasty.

Background : Recently, PTCA procedures have been used increasingly for the treatment of patients with coronary heart disease. In the era of national economic constraint, reused balloon catheters will reduce the cost of expensive, imported coronary angioplasty devices. Hence, data concerning the safety and success rate of RB catheters compared with NB catheters are urgently required.

Methods : Prospective comparative study between reused and new balloon catheters for coronary angioplasty. Data forms were completed after each procedure and before the patient was discharged after an 18-month period.

Results : From July 1996 to December 1997, 221 cases (121-RB, 100-NB) were enrolled. Mean age, ejection fraction, diseased vessel and lesion characteristics were similar in both groups. The number of lesions was much higher performed in the RB than in the NB group(1.7 ± 0.9 *vs* 1.4 ± 0.8, $p = 0.02$). The RB group had more cases of acute myocardial infarction than the NB group (7.4% *vs* 1%, $p = 0.003$), however, the angiographic and case success rate were the same (99.5% *vs* 97.9% and 98.3% *vs* 97% respectively). Major adverse cardiac events in RB amounted to 1.7 per cent and for NB to 1.0 per cent (p = ns). The total amount of balloons used in RB was much higher than in the NB group (1.5 ± 0.6 *vs* 1.1 ± 0.3, $p = <0.0001$). There were neither infection nor positive blood cultures in either group.

Conclusions : Reused balloon catheters can be safely used for percutaneous transluminal coronary angioplasty with a high success rate. The total cost of angioplasty can be reduced without a decline in efficacy.

Key word : Reused Balloon, Percutaneous Transluminal Coronary Angioplasty

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In 1977, A.Gruentzig[1] introduced the first percutaneous transluminal coronary angioplasty (PTCA), and by now it has become the most common form of myocardial revascularization[2,3]. In 1994, about 420,000 PTCA procedures were performed in the United States at an average charge of $16,000 per intervention. In Thailand, about 1,500 cases were performed in 1998 and there is a tendency toward increase every year. The average charge of simple balloon angioplasty per procedure is 100,000 Baht (2,500 $). It is not inexpensive especially for the Asian countries that are facing an economic recession. Strategies to reduce procedural costs while still maintaining acceptable results, are desperately needed. Using reused balloon catheters implies infections and mechanical risks detected in experimental studies[4], as well as increased complications and procedural time[5], however, a few recent reports[6-10] showed safe, cost-saving and acceptable outcomes.

In the midst of serious economic constraints, most of the catheterization laboratories in Thailand as well as some other countries in Asia have policies to reuse balloon catheters for PTCA procedures. This study was conducted to compare the initial outcomes and complications of new balloon (NB) *versus* reused balloon (RB) catheters for performing coronary angioplasty procedures.

METHOD

Patient population

Patients, who underwent PTCA from July 1996 to December 1997 in King Chulalongkorn Memorial Hospital, were enrolled. The patients who received both new and reused balloon catheters were excluded. Medical history, angiographic information, procedural data and complications were recorded prospectively after each procedure and before discharge. Balloons were selected according to the patient's financial status classified by hospital policy. The most regular patients would receive RB catheters. Those patients who could be reimbursed for their medical expenses would likely receive NB catheters. The availability of the balloon stocked in the catheterization laboratory will also influence balloon selection. Coronary stent was used if clinically indicated. Two samples of blood culture were collected by separate venous sticks by a standard sterile technique immediately after the procedure and routine post-PTCA management was implemented. Anti-HIV antibody is routinely checked in our laboratory before starting the procedure, if the result is positive, the patient will be managed with medical treatment for coronary artery disease.

Reused balloon catheter preparation

Immediately after completion of the PT CA procedure, the balloon catheter was inspected for deformity of the shaft and the balloon portion. If the catheter was without visible abnormality, the outer surface was cleaned with tap water to remove blood clots and the wire entry lumen was flushed to ensure that nothing would obstruct the lumen. For the balloon portion, the mixture of contrast media was removed by multiple application of negative pressure generated by pulling back from a 50-ml plastic syringe and replaced with tap water at least 3 times to ensure that contrast media was completely removed. Then the balloon was emptied with negative pressure and dried for 24 hours at room temperature (about 25-30°C). Before packing, a wire stylet was introduced into the wire lumen of the balloon with a plastic sleeve covering the balloon portion to maintain a low profile balloon and to avoid a balloon-wing pattern. The balloon catheter was sent for gas sterilization with 30 per cent ethylene oxide for 4 hours. Before the next use, the operator would carefully inspect the shaft and the outer surface. The wire-lumen was flushed and the balloon was inflated with low pressure to ensure that it worked properly without leaking. Then the balloon was deflated and the plastic sleeve was used to re-cover the balloon portion for 1 minute before the balloon was inserted into the coronary artery.

Definition of success

An angiographic success was defined as a residual diameter of stenosis below 50 per cent. Case success was defined as patients with angiographic success and without major adverse cardiac events (myocardial infarction (MI), emergency coronary artery bypass graft (CABG), urgent re-PTCA and deaths) during hospitalization.

Statistical analysis

The continuous variables are expressed as mean ± SD. For the analysis of continuous data,

two-tailed student *t*-test was used to assess differences between the two groups. The nominal variables were expressed as counts and percentages. Statistical significance was expressed by the chi-square test. All tests were considered statistically significant when the P value was below 0.05.

RESULTS

From July 1996 to December 1997, 282 procedures of PTCA were performed in King Chulalongkorn Memorial Hospital. Fifty-five cases were excluded due to both reused and new balloon catheters used during angioplasty and another 6 cases could not be studied because the guidewire could not cross the stenotic lesion. Therefore, 221 patients were analyzed. 121 cases were enrolled in the RB group and 100 cases were in the NB group. Table 1 shows baseline characteristics of the patients. There were no significant differences in mean age (60.4 ± 10.6 *vs* 61.2 ± 10.8 yrs), coronary risk factors except that the RB group had a higher percentage of smoking than the NB group (43.1% *vs* 26.9%, p = 0.009), previous MI (39.7% *vs* 34.0%), previous CABG (2.5% *vs* 3.0%), left ventricle ejection fraction (47.4 ± 13.6 *vs* 53.4 ± 14.3) for RB and NB, respectively. Regarding indication for PTCA, there was a statistically significant difference between both groups. RB had a higher percentage of patients who underwent PTCA because of acute MI than the NB group (7.4% *vs* 1.0%, p = 0.02). However, lesion type, diseased vessel involvement and vessel size attempted were similar. Approximately 50 per cent of the cases were processed after diagnostic coronary angiography in both groups.

Table 2 shows the results of PTCA. The RB group had a higher number of lesions per case than the NB group (1.7 ± 0.9 *vs* 1.4 ± 0.8, p = 0.02) which correlated with a higher total amount of balloons used (1.5 ± 0.6 *vs* 1.1 ± 0.3, p = <0.0001). Nevertheless, the fluoroscopy time (16.9 ± 13.8, 16.5 ± 10.7 minutes, p = ns) and procedure time (67.2 ± 23.3 *vs* 64.7 ± 27.5 minutes, p = ns) were similar in both groups. There were no significant differences in visual estimation of stenosis pre (87.0 ± 13.7 *vs* 87.5 ± 8.6) *versus* post procedure (17.0 ± 13.8 *vs* 16.6 ± 16.4), maximal pressure dilatation (8.7 ± 3.6 *vs* 8.9 ± 3.0), percentage of stent implantation (40.5% *vs* 46.0%) between RB and the NB group, respectively. Zero point eight of balloons used in the RN group were ruptured during inflation but none in the NB group. Regarding complications of PTCA (Table 3), there were no significant differences in abrupt closure rate, Q-wave MI, emergency CABG and in-hospital death. Overall major adverse cardiac events occurring in the hospital were the same in both groups. The case success rate was 98.3 per cent in the RB group compared with 97.0 per cent in the NB group. None of the patients had a positive blood culture for microorganisms.

DISCUSSION

The health care expense, particularly for coronary angioplasty, has become an increasingly important issue worldwide. Asian countries, especially Thailand, now facing economic recession, have a limited budget for the coronary angioplasty program. Since the Baht was devalued by about 50 per cent against the US dollar the cost of the devices dramatically increased. Reusing balloon catheters is one way to reduce the cost of the procedure, however, there was widespread concern about the outcomes being jeopardized. Many experimental and clinical data have suggested that reused equipment may be safe and cost saving[6-17]. It is difficult to design a randomization in this situation because the patients who were to be enrolled in the reused balloon group would not accept it.

In our study, we enrolled all the patients who had undergone PTCA from July 1996 to December 1997. The baseline characteristics of the patients were almost similar in both groups except that the RB group had more cases of a cute MI, a higher number of lesions attempted and a higher amount of total balloons used. The results didn't have any statistically significant difference between both groups. The previous report from Plante S, et al[6] showed that the RB catheter had a higher incidence of late closure, urgent CABG and longer hospitalization. The amount of contrast media used and procedural time was also high in the reused balloon group. However, these results could be explained by the

Table 1. Baseline characteristics of patients.

Character	Reused	New	P value
No.of cases	121	100	
Age (yr)	60.4 ± 10.6	61.2 ± 10.8	NS
Gender: Male (%)	75.2	67.0	NS
Smoking (%)	43.1	26.9	0.009
Hypertension (%)	39.7	44.1	NS
Dyslipidemia (%)	32.8	38.7	NS
Diabetes (%)	32.8	36.6	NS
Previous MI (%)	39.7	34.0	NS
Previous CABG (%)	2.5	3.0	NS
Ejection fraction	47.4 ± 13.6	53.4 ± 14.3	NS
Indication for PTCA			0.02
Stable angina (%)	39.7	50.0	
Unstable angina (%)	24.8	24.0	
Acute MI (%)	7.4*	1.0	
Post MI angina (%)	28.1	25.0	
Vessel diameter (mm)	2.76 ± 0.52	2.83 ± 0.53	NS
Diseased vessel			NS
LAD (%)	71.1	70.0	
LCX (%)	38.0	36.0	
RCA (%)	49.6	41.0	
Graft (%)	1.7	1.0	
Type of lesion			NS
A (%)	20.6	26.7	
B (%)	43.1	43.2	
C (%)	36.3	30.1	
Ad hoc PTCA (%)	48.8	52.0	NS

* p = 0.003

MI – myocardial infarction; CABG – coronary artery bypass graft; PTCA – percutaneous transluminal coronary angioplasty; LAD – left anterior descending artery; LCX – left circumflex artery; RCA – right coronary artery.

Table 2. Result of angioplasty.

	Reused	New	P value
No.of cases*	121	100	
No.of lesion per case	1.7 ± 0.9	1.4 ± 0.8	0.02
Stenosis (%) - pre PTCA	87.0 ± 13.7	8.75 ± 8.6	NS
Stenosis (%) - post PTCA	17.0 ± 13.8	16.6 ± 16.4	NS
Maximal pressure inflation (atm)	8.7 ± 3.6	8.9 ± 3.0	NS
Stent implantation (%)	40.5	46.0	NS
Fluoroscopy time (min)	16.9 ± 13.8	16.5 ± 10.7	NS
Procedure time (min)	67.2 ± 23.3	64.7 ± 27.5	NS
Total balloon used	1.5 ± 0.6	1.1 ± 0.3	<0.0001
Balloon rupture (%)	0.8	0	NS

PTCA – percutaneous transluminal coronary angioplasty;
CABG – coronary artery bypass graft.
* 6 cases were excluded since the wire couldn't cross the lesion.

patients not being matched. The reused balloon group had a higher number of unstable angina patients. In addition, at that time, a stent was not commonly used and Reopro was not available which has been proven to reduce the major adverse cardiac events[17,18]. In our study, the reused balloon group had a higher number of cases with acute MI. The mortality rate was also slightly higher but there was no statistical significance and no effect on the overall results.

Table 3. Adverse outcomes of angioplasty.

	Reused (%)	New (%)	P value
Abrupt closure	2.5	0	NS
Q-wave myocardial infarction	1.7	0	NS
CABG	1.7	1.0	NS
Death			
During PTCA	0	0	NS
In hospital after PTCA	1.7	0	NS
Major cardiac events (MACE)	1.7	1	NS
Angiographic success	99.5	97.9	NS
Case success	98.3	97.0	NS

PTCA – percutaneous transluminal coronary angioplasty;
CABG – coronary artery bypass graft.

Perhaps, the number of acute MI patients being in the minority could explain this. The angiographic and case success rates were high in our study due to exclusion of uncrossed guidewire cases from data analysis. Additionally, the new generation balloons had a lower profile and could tolerate higher pressure than the old-fashioned ones. Perhaps, these balloons' properties could explain why there were no statistically significant differences in fluoroscopy and procedure time in our study and of course, a high success rate to cross the lesion. Nevertheless, these properties of the balloon varied from manufacturer to manufacturer, and even when of identical manufacture but of different type. It is unknown how many cycles of reuse a balloon catheter can tolerate. If one balloon can be used 2 times, 3 times or 4 times the cost of balloon will be reduced by 40-45 per cent, 60-65 per cent or 65-70 per cent, respectively. The average cost of one balloon in Thailand is 20,000 Baht (500 $), and thus, the balloon's cost may be reduced to 6,000 Baht (150 $) by using the balloon catheter 4 times. Apart from the cost reduction, the safety of the patient has to be considered. In our study, the rate of balloon rupture was not increased when compared with new balloons. In addition, there was no evidence of catheter-related bacterial infection in any of the patients. The overall success rate was also high and similar to that of the NB catheters.

Limitations of study

This has not been a randomized study and a selection bias may occur. Most of the patients in the new balloon group could afford the cost of angioplasty or could have their expenses reimbursed by government or state enterprises. The variety of the balloon models available also could affect the results. The number of patients was not large enough to detect small differences between the two groups.

SUMMARY

Reused balloon catheters can be safely used for coronary angioplasty with a high success-rate. The preparation and sterilization techniques for reused balloon catheters are essential. Standardization of the technique should be considered. The operator needs to know the balloon's properties very well and properly select the balloon for each lesion, as well as carefully inspect and test the balloons before using them. This strategy, once standardized and tested in a larger, randomized trial, could reduce the cost of this expensive procedure and make it increasingly available to more patients in developing countries.

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REFERENCES

1. Gruentzig A. Transluminal dilatation of coronary artery stenosis. Lancet 1978; 1: 263.
2. Weintraub WS, Jones EL, King SP III, et al. Changing use of coronary angioplasty and coronary bypass surgery in the treatment of chronic artery disease. Am J Cardiol 1990; 65: 183-8.
3. Topol EJ, Ellis SG, Cosgrove DM, et al. Analysis of coronary angioplasty practice in the United State with an insurance-claims database. Circulation 1993; 87: 1489-97.
4. Grimandi G, Sellal O, Grimandi F. Risks of reusing coronary angioplasty catheters: results of an experimental study. Cathet Cardiovasc Diagn 1996; 38: 131-4.
5. Mak KH, Eisenberg M, Eccleston DS, Brown KJ, Ellis SG, Topol EJ. Cost-efficacy modeling of catheter reuse for percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1996; 28: 106-11.
6. Plante S, Strass BH, Goulet G, Watson RK, Chisholm RJ. Reuse of balloon catheters for coronary angioplasty: a potential cose-saving strategy? J Am Coll Cardiol 1994; 24: 1475-81.
7. Mak KH, Eisenberg MJ, Plante S, Strauss BH, Arheart KL, Topol EJ. Absence of increased in-hospital complications with reused balloon catheters. Am J Cardiol 1996; 78: 717-9.
8. Browne KF, Maldonado R, Telatnik M, Vlietstra RE, Brenner AS. Initial experience with reuse of coronary angioplasty catheters in the United States. J Am Coll Cardiol 1997; 30: 1735-40.
9. Vaitkus P. Patient acceptance of reused angioplasty equipment. Am J Heart 1997; 134: 127-30.
10. Mahanonda N, Tresukosol D, Chaithiraphan S, et al. Angiographic outcomes of reused percutaneous transluminal coronary angioplasty (PTCA) balloon catheters. Asean Heart J 1997; 5: 46-9.
11. Bentolila P, Jacob R, Roberge F. Effects of re-use on the physical characteristics of angiographic catheters. J Med Eng Technol 1990; 14: 254-9.
12. Bourassa MG, Cantin M, Sanborn EB, Pederson E. Scanning electron microscopy of surface irregularities and thrombogenesis of polyurethane and polyethylene coronary catheters. Circulation 1976; 53: 992-6.
13. Sande MA, Levinson ME, Lukas DS, Kaye D. Bacteremia associated with cardiac catheterization. N Engl J Med 1969; 281: 1104-6.
14. Ravin CE, Koehler PR. Reuse of disposable catheters and guide wires. Radiology 1977; 122: 577-9.
15. Frank U, Herz L, Daschner FD. Infection risk for cardiac catheterization and arterial angiography with single and multiple use disposable catheters. Clin Cardiol 1988; 11: 785-7.
16. Jacobson JA, Schwartz CE, Marshall HW, Conti M, Burke JP. Fever, chills and hypotension following cardiac catheterization with single and multiple use disposable catheters. Cathet Cardiovasc Diagn 1983; 9: 93-6.
17. Jordy A, Hedstuck W, Reinisch S, Residues and reaction products of devices sterilized with ethylenoxide. Hyg Med 1984; 11: 247-9.
18. The EPIC Investigators. Use of a monoclonal antibody directed against the platelet glycoprotein IIb/IIIa receptor in high-risk coronary angioplasty. N Engl J Med 1994; 330: 956-61.
19. The EPILOG Investigators. Platelet glycoprotein IIb/IIIa receptor blockade and low-dose heparin during perctaneous coronary revascularization. N Engl J Med 1997; 336: 1689-96.

ความปลอดภัยและผลเบื้องต้นของการใช้สายบอลลูนเก่าซ้ำอีกในการทำการขยายบอลลูนหลอดเลือดหัวใจ

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วัตถุประสงค์ : เป็นการศึกษาความปลอดภัยและผลเบื้องต้นของการทำบอลลูนขยายหลอดเลือดหัวใจโดยใช้สายบอลลูนเก่าเปรียบเทียบกับบอลลูนใหม่

ภูมิหลัง : เนื่องจากภาวะวิกฤติทางเศรษฐกิจทำให้งบประมาณในการทำบอลลูนขยายหลอดเลือดหัวใจซึ่งเป็นหัตถการที่มีค่าใช้จ่ายสูงมีจำกัด การใช้สายบอลลูนเก่าจึงเป็นหนทางหนึ่งในการลดต้นทุนค่าใช้จ่าย แต่จำเป็นต้องมีการพิจารณาถึงความปลอดภัยและผลการรักษาโดยใช้สายบอลลูนเก่า

วิธีการ : เป็นการศึกษาเปรียบเทียบไปข้างหน้า โดยการใช้สายบอลลูนเก่าเทียบกับบอลลูนใหม่

ผลการศึกษา : รวบรวมผู้ป่วย 221 ราย (121-บอลลูนเก่า, 100-บอลลูนใหม่) จากเดือนกรกฎาคม 2539 ถึงเดือนธันวาคม 2540 อายุเฉลี่ย, ความสามารถในการบีบตัวของหัวใจ, เส้นเลือดหัวใจที่มีพยาธิสภาพ และลักษณะพยาธิสภาพของบริเวณที่จะทำการขยายหลอดเลือด ไม่มีความแตกต่างกันในผู้ป่วยทั้งสองกลุ่ม จำนวนพยาธิสภาพที่ทำการขยายหลอดเลือดในกลุ่มบอลลูนเก่ามีมากกว่า (1.7 $\pm$ 0.9 กับ 1.4 $\pm$ 0.8, p=0.02) และมีสัดส่วนของผู้ป่วยที่มีกล้ามเนื้อหัวใจตายเฉียบพลันมากกว่า (7.4% กับ 1.0%, p=0.003) ในกลุ่มบอลลูนใหม่ แต่อย่างไรก็ตามผลการรักษาไม่มีความแตกต่างกันอย่างมีนัยสำคัญ ภาวะอันไม่พึงประสงค์ทางหัวใจเกิดขึ้น 1.7% ในกลุ่มบอลลูนเก่าและ 1.0% ในกลุ่มบอลลูนใหม่ ในกลุ่มบอลลูนเก่ามีการใช้จำนวนบอลลูนมากกว่าในกลุ่มบอลลูนใหม่อย่างมีนัยสำคัญ (1.5 $\pm$ 0.6 กับ 1.1 $\pm$ 0.3, p=<0.0001) ไม่พบภาวะการติดเชื้อในกระแสโลหิตซึ่งเกิดจากการใช้บอลลูนเก่า

บทสรุป : บอลลูนเก่าสามารถใช้ในการทำบอลลูนขยายหลอดเลือดหัวใจได้เป็นอย่างดีและมีความปลอดภัยสูง ซึ่งจะเป็นการช่วยลดค่าใช้จ่ายในการทำหัตถการได้

คำสำคัญ : บอลลูนเก่า, การทำบอลลูนขยายหลอดเลือดหัวใจ

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