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Evaluating long-term outcomes of coronary angioplasty with or without post-dilatation

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ABSTRACT

Introduction: Post-dilatation is associated with a simultaneous expansion of the stents that enhances the angioplasty outcomes. However, increased risk of mortality and morbidity has been reported in patients with acute myocardial infarction (AMI) which has provoked considerable controversies concerning its efficiency.

Materials and Methods: During a two-year period, all patients underwent angioplasty with or without post-dilatation procedure, due to clinical features of the acute coronary syndrome (ACS), including unstable angina, non-ST-elevated myocardial infarction, and AMI, were included. The patients underwent 12 months of follow-ups after the angioplasty with or without post-dilatation. The primary endpoint was the TIMI flow of coronary artery after intervention. However, mortality, readmission due to ACS, need for revascularization, and incidence of AMI during 12 months, were secondary endpoints.

Results: No significant difference was observed in terms of demographic data between the groups with and without post-dilatation. Comparing mortality rate, the prevalence of AMI, intervention for revascularization and incidence of major adverse cardiac events (MACE) during the follow-up period showed no significant difference between the study groups.

Conclusion: Based on the findings of the present study, balloon post-dilation was not associated with a reduction in MACE incidence. However, post-dilation may improve the TIMI flow in these patients.

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Introduction

Percutaneous coronary intervention (PCI) which was introduced in the last decades primarily included fluid-filled balloon inflation via the incompressible fluid. It has developed to stent implementation which enhances the accuracy and efficacy of stenosis resolving (1, 2). However, several post-procedural complications, such as medial injury and arterial dissection were

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probable, as well as mal apposition and under expansion after an increase in luminal diameter during the balloon angioplasty or stent implementation (3-5). Furthermore, using intravascular ultrasonography (IVUS) revealed that higher stent inflation pressure might contribute to the optimal stent expansion and prevent stent thrombosis and stenosis (6-8). It has been suggested that post-dilatation with a non-compliant (NC) balloon is associated with a humdrum and symmetric expansion of the stents[5].

Further findings estimated that stent balloons provide more identical stent expansion in comparison to the NC balloons. However, it has been shown in the literature that in patients with the acute coronary syndrome (ACS) who underwent early angioplasty, the incidence of non-myocardial infarction, stent thrombosis, and need for revascularization reduced after the post-dilatation (9, 10) . Nevertheless, high-pressure post-dilatation may develop serious complications, such as reduced distal flow and coronary dissection, which promoted heated debates over its advantages. Recent studies reported that post-dilatation might increase the risk of mortality and morbidity in patients with acute myocardial infarction (AMI) and only patients who suffer from stable angina may benefit from this procedure (11, 12). Considering current controversies over the efficacy of the post-dilatation intervention, the present study aimed to evaluate the long-term outcomes of angioplasty with or without post-dilatation.

Materials and methods

The present study was retrospective cross sectional carried out between May 2014 and May 2016, in Shahid Madani and Aali Nasab heart centers, Tabriz University of Medical Sciences, Tabriz, Iran. The current study was approved by the Ethics Committee of the Vice-Chancellor of Research and Development, Tabriz University of Medical Sciences. All patients underwent angioplasty after clinical features of the ACS, including unstable angina, non-ST-elevated myocardial infarction, and acute myocardial infarction (AMI). Patients with desirable angiographic results were included in this study. We reviewed patients' angiography reports and also their film of angiography to see if post-dilatation was done or not. We followed these patients by telephone call and visits in clinic for 12 months to find out any complication or MACEs. When a patient had definite indication for post dilatation because of remained stent diameter stenosis more than 10% of the distal reference vessel, failure of stent inflation or need for a long stent patient excluded from study.

Furthermore, the inclusion criteria entailed: 1) patients with severe coronary arteries stenosis sought for angioplasty and 2) patients who underwent angioplasty with stent implementation.

The exclusion criteria entailed: 1) patients who needed urgent or elective coronary artery bypass surgery, 2) patients who died during angioplasty, 3) patients with cardiogenic shock during admission who underwent angioplasty for in-stent restenosis, and 4) patients with severe valvular diseases.

Patients' demographic data included age, gender, smoking, and history of chronic diseases, such as diabetes mellitus (DM) and hypertension (HTN). Pre-interventional and post-interventional thrombolysis in myocardial infarction (TIMI) flow scores were calculated in both groups and recorded for each participant. The culprit vessel occlusion resolved via stent implementation and PCI endpoints were considered successful reperfusion measured as ST-segment resolution and residual stenosis of less than 20%. Following the procedure, all patients received medications according to the guideline recommendations, including clopidogrel, aspirin, statins, nitrates, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and beta-blockers in case of no contraindications. In addition, the diameter and length of the used balloons and implemented stents during the angioplasty were recorded for all the patients. After angioplasty, ischemia type, number of culprit vessels, and stenosis severity were reported.

Patients underwent 12 months of follow-up after the angioplasty with or without post-dilatation. The primary endpoint of the current research was the TIMI flow after intervention. However, mortality, readmission due to ACS, need for revascularization, and incidence of AMI

during 12 months, were secondary endpoints.

Statistical analysis

The Chi-squared test was used for comparing two qualitative variables and a student T-test was performed for comparing quantitative variables between groups. A p-value of less than 0.05 was considered statistically significant and all the results were expressed by frequency (percent) for qualitative variables and Mean±SE for quantitative variables.

Results

A total of 500 patients with MI underwent coronary intervention after the ACS diagnosis included in this study. They were assigned into two groups with attention to the administration of the post-dilatation procedure. Of these patients, 381 (76.2%) were male and 119 (23.8%) were female. The patients' demographic data, risk factors, and coronary intervention findings are presented in Table 1. According to risk factors of atherosclerosis, 158 (31.6%) patients had DM and 196 (39.2%) had HTN. Moreover, smoking was reported in 207 (41.4%) patients. However, there was no significant difference between patients with and without post-dilatation intervention regarding demographic data and risk factors. Comparing culprit vessel number and coronary arteries stenosis percentage between two study groups revealed no significant difference (Table 1). Subsequently, the mean TIMI flow score before the intervention was calculated at 2±1.27 and 1.89±1.26 in the patients who did not receive post-dilatation and patients who received post-dilatation, respectively, which revealed no statistically significant difference (P=0.35).

Data regarding interventional features of the patients are summarized in Table 2. Pre-dilatation was performed in 317 patients (144 received no post-dilatation and 173 patients received post-dilatation, P=0.13) and glycoprotein IIa/IIIb inhibitor was prescribed for 197 (77 did not undergo post-dilatation and 120 patients underwent post-dilatation; P=0.11).

Culprit's vessels were determined during angiography, which turned out to be descending and circumflex branches of the left anterior artery in 208 (41.6%) and 95 (19%) patients, respectively, and right coronary artery in 197 (39.4%) patients. Comparing the prevalence of coronary vessel impairment, no significant difference was observed between the study groups concerning the post-dilatation procedure (P=0.7).

Although there was a significant difference regarding the type of the stent implemented between patients with and without post-dilatation, no significant difference was detected while comparing stent and balloon characteristics, including length and diameter of the balloon and stent between the groups (Table 2).

Post-interventional TIMI scores were measured at 2.79±0.51 and 2.75±0.61 in patients who underwent post-dilatation and who did not, respectively (P=0.052). Mortality rate, the prevalence of AMI, intervention for revascularization, and incidence of major adverse cardiac events (MACE) during the one-year follow-up period in the participants are shown in Table 3 that showed no significant difference between the study groups.

Participants who underwent post-dilatation had a median survival time of 11.9 (95% CI, 11.8 to 12) months, which was not longer than the group which did not receive post-dilatation, which had an identical median survival of 11.9 (95% CI, 11.9 to 12) months. Post-interventional outcomes and complications according to post-dilatation administration is shown in (Table 3).

Discussion

There are major controversies surrounding stent post-dilatation in patients with ACS. Stent post-dilatation during angioplasty may increase the risk of suboptimal TIMI flow immediately following post-dilatation. Post-dilatation is essential to achieve optimal stent expansion and strut apposition for better long-term clinical outcomes (12, 14). Previous studies have associated postulation with an increased risk of death and MI in patients with AMI; however, this relationship has not been reported in patients with stable angina.

Table 1. Patients' characteristics according to post dilatation intervention

		Post dilatation			
		Performed	**Not performed**	**Total**	**P value**
Age		59.51±10.69	61.5±12.95	60.37±11.75	0.067*
Gender	Male	311 (62.2%)	70 (14%)	381 (76.2%)	0.57**
	Female	70 (14%)	49 (9.8%)	119 (23.8%)	
Diabetes		91 (18.2%)	67 (13.4%)	158 (31.6%)	0.76**
Hypertension		114 (22.8%)	82 (16.4%)	196 (39.2%)	0.31**
Smoking		115 (23%)	92 (18.4%)	207 (41.4%)	0.38**
Ischemia type	Acute MI	99 (19.8%)	78 (15.6%)	177 (35.4%)	0.25**
	NSTEMI	92 (18.4)	65 (13%)	157 (31.4%)	
	Stable angina	51 (10.2%)	30 (6%)	81 (16.2%)	
	Unstable angina	41 (8.2%)	44 (8.8%)	85 (17%)	
Culprit vessels	SVD	102 (20.4%)	64 (12.8%)	166 (33.2%)	0.068**
	2VD	104 (20.8%)	102 (20.4%)	206 (41.2%)	
	3VD	77 (15.4%)	51 (10.2%)	128 (25.6%)	
Stenosis percentage	<50%	24 (4.8%)	8 (1.6%)	32 (6.4%)	0.35**
	50%-70%	113 (22.6%)	91 (18.2%)	204 (40.8%)	
	70%-90%	84 (16.8%)	54 (10.8%)	138 (27.6%)	
	90%-100%	77 (15.4%)	49 (9.8%)	126 (25.2%)	
Primary TIMI		1.89±1.26	2±1.27	1.94±1.26	0.18*

*Independent t test
**chi-square test

Table 2. Patients' angioplasty findings according to post dilatation intervention

		Post dilatation		total	P- value
		performed	not-performed		
Predilatation		173 (34.6%)	144 (288%)	317 (63.4%)	0.13**
Iia/IIIb administration		120 (24%)	77 (15.4%)	197 (39.4%)	0.11**
Stented vessel	LAD	121 (24.2%)	87 (17.4%)	208 (41.6%)	0.71**
	LCX	55 (11%)	40 (8%)	95 (19%)	
	RCA	107 (21.4%)	90 (18%)	197 (39.4%)	
Stent type	BMS	35 (7%)	51 (10.2%)	86 (17.62%)	0.001**
	DES	248 (49.6%)	166 (33.2%)	414 (82.8%)	
Balloon length		10.29±8.47	10.97±8.35	10.58±8.42	0.37*
Balloon diameter		1.26±1.03	1.31±1	1.28±1.01	0.58*
Stent length		23.25±8.07	21.24±8.14	22.38±8.15	0.006*
Stent diameter		3.01±0.34	2.97±0.43	2.99±0.38	0.22*

*Independent t test
**chi-square test

Table 3. Post-interventional outcomes and complications according to post-dilatation administration.

	Post dilatation		total	P-value
	performed	not performed		
Post angio TIMI	2.79±0.51	2.65±0.61	2.78±0.56	0.049*
Death	4 (0.8%)	4 (0.8%)	8 (1.5%)	0.71**
Acute MI	7 (1.4%)	8 (1.6%)	15 (3%)	0.43**
Revascularization	13 (2.6%)	16 (3.2%)	39 (7.8%)	0.18**
MACE	18 (3.6%)	22 (4.4%)	40 (8%)	0.12**

*Independent t test
**chi-square test

Based on the clinical outcomes, no significant difference was observed between the post-dilatation and non-post-dilatation subgroups in terms of the MACE-free survival probability at the end of the follow-up period. Regarding angiographic outcomes, there was a major tendency toward better TI|MI flow in the post-dilation group. However, better clinical or angiographic outcomes of routine post-dilation are still under discussion. The findings of the current study confirmed that in the current era of angioplasty for ACS, stent post-dilatation is justifiable if angiographically indicated optimized stent deployment.

Nonetheless, the obtained results differed from those of an investigation conducted by Zhang et al. on the effects of post-dilatation in patients with and without AMI in the National Heart, Lung, and Blood Institute Dynamic Registry within 2001-2006 (15). The authors found that post-dilatation was associated with an increased risk of death and repeated MI in patients with AMI. However, in this study, the ACS cohort was not separated into ST-elevation myocardial infarction (STEMI) and non-STEMI patients.

Based on the findings of the present study, post-dilation was not associated with a reduction of MACEs during one year which could be attributed to the use of second-generation drug-eluting stents in our trials. This offers improved stent performance with different vascular healing and re-endothelialization properties.

Patients with ACS had more unstable plaques and a higher volume of the necrotic core according to virtual histology-IVUS, compared to those with stable angina (16). Post-intervention elevation of cardiac troponin levels was more frequently observed in lesions with a large necrotic core by ultrasound and in lipid-rich lesions detected by a near-infrared spectroscopy (17, 18). Distal embolization due to aggressive mechanical expansion from post-dilation might be a possible underlying mechanism.

There were some limitations regarding the present study. Firstly, the current research was a retrospective observational study rather than a randomized controlled study. The lack of randomization may have potentially led to bias in the treatment strategy chosen by the operators based on the patient's clinical status and angiographic findings. However, there was no significant difference in the baseline characteristics of the two subgroups. Secondly, our sampling and a one-year clinical follow-up period may not be sufficient for the assessment of clinical outcomes. Thirdly, post-dilation performance after stent deployment was determined by corresponding physicians. All the coronary angiogram images were evaluated by the same interventional cardiologist to minimize inter-observer bias. However, the assessor was not blinded to the procedure details, which may have resulted in observer bias. In addition, it was assumed that patients who had their initial PCI at our hospital would be returned to our hospital if they required further cardiac intervention.

This may not have been true for all the patients and may have led to the over-estimation of MACE-free survival rates. A study design involving the collection of follow-up data simultaneously from patients and their hospital medical records alone may lead to more comprehensive data collection. Finally, further studies are needed to be performed to evaluate whether our clinical outcomes remain true in a more substantial study population with a long-term follow-up period.

Conclusion

From the results presented in the current study, it can be concluded that balloon post-dilation was not associated with MACE reduction during one year among the patients with ACS requiring stent implantation. However, it was revealed that post-dilation may improve TIMI flow in these patients. Furthermore, stent post-dilatation demonstrated no deleterious effect on patients' long-term clinical outcomes.

Conflicts of Interest:

The authors declare that there is no conflict of interest.

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