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Comparison of Rewiring (Fluoroscopy Time and Contrast Volume) Between Two Commercial Stents in Bifurcation Lesion

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ABSTRACT

We conducted this study to Comparison rewiring of side branch though onyx versus XIENCE stents and evaluated the correlation of their structural design (cell size and thickness) with time of fluoroscopy and the amount of Dye. Material and Method: 85 CAD patients referred to Modarres Hospital from May 2016 to May 2017 with bifurcation lesion after angiography, were divided randomly into two groups after recording the demographic characteristics and also data about the involved arteries and in each group separate commercial stents including xeince and onyx stents were used for rewiring. Both groups were rewired by a technician and the amount of consumed dye, time of fluoroscopy and the stent properties including length and diameter were separately recorded. No significant correlation was seen between the length and diameter of xience and onyx stents with Dye and time of fluoroscopy. There was significant negative correlation between branch size with Dye and time of fluoroscopy. In onyx group, there was a negative significant correlation between Dye and time of fluoroscopy with angle branch and severity of ostium (stenosis), in xeince group, there was a negative significant correlation between Dye and time of fluoroscopy with branch angle. Although in the present study there was no significant differences between the two groups for evaluated indices, but it seems that follow-up of patients for mortality rate, heart attack re-requirement to angiography and surgery in different periods of time, can be helpful in order to assessment of more appropriate stent.

Key words: Rewiring, Stent, Fluoroscopy time, Dye

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INTRODUCTION

Coronary bifurcations stay one of the vitally interesting and also challenging lesion subsets in interventional cardiology, with lesser procedural success rate, risk of plaque disruption, periprocedural complications and also enhanced prices of long-term unfavorable cardiac occasions. Coronary bifurcation lesions are popular accounting for 20% of percutaneous coronary interventions performed [1, 2]. A coronary bifurcation lesion occurs at or near a division of a major coronary artery. Diseased coronary bifurcations are mainly managed by percutaneous coronary interventions as well as in these types of complicated lesions the adoption of the most appropriate treatment approach and the choice of the most advantageous coronary stent are of primary emphasis. Clinical evidence implies that drug-eluting stent (DES) implantation utilizing a provisional strategy is the gold standard for unselected bifurcated lesions [2-4].

Side branch failure is one of the most common observed complications after stenting. The main branch is at bifurcations site which occurs in 7 to 20 percent of cases, agents such as Severity and length of SB ostial stenosis, plaque burden in ostial SB, narrow bifurcation angle, size and/or pressure of MV stent are known as its risk factors. Safe

guidewire placement in the main vessel (MV) and in the side branch (SB) does establish the main purpose for effective percutaneous coronary interventions in bifurcated lesions. If the angiographic results in the main vessel and in the SB are satisfactory with normal flow and with residual diameter stenosis less than 50% to 75%, the jailed SB wire is removed and the procedure is completed. If the result at the side branch ostium is not satisfactory or if the operator determines that there is a need for final kissing balloon inflation, then the side branch should be rewired. Side branch rewiring can be performed by using the main branch wire by pulling it back slowly from the main vessel or by using a third wire, and pointing the tip toward the side branch ostium with the intention to cross into the side branch through the distal strut closest to the tip of the flow divider[5, 6]

Fluoroscopy is now used as a supplementary technique for angiography and side branch rewiring. However, previous studies have shown that time of fluoroscopy from one way increases the mortality rate and on the other hand decreases the technician accuracy. furthermore, studies have shown that radiation exposure during fluoroscopy is correlated with incidence of malignancies, thyroid disorders, cataract and liver and kidney disorders as the repulsive organs of these materials [7], therefore, detecting novel methods in order to decreasing of fluoroscopy time and the amount of Dye can be helpful in improvement of this method and decreasing of its side effects, so the present study, we conducted this study to Comparison rewiring of side branch though onyx versus XIENCE stents and evaluated the correlation of their structural design (cell size and thickness) with time of fluoroscopy and the amount of Dye.

MATERIALS AND METHODS

In the present study, 85 CAD patients referred to Modarres Hospital from May 2016 to May 2017 with bifurcation lesion after angiography, were divided randomly into two groups after recording the demographic characteristics and also data about the involved arteries and in each group separate commercial stents including xeince and onyx stents were used for rewiring. In order to reducing the error caused by skill, both groups were rewired by a technician and the amount of consumed dye, time of fluoroscopy and the stent properties including length and diameter were separately recorded.

Ethics Committee Approval

This study protocol was approved by Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Statistical analysis

SPSS software version 22 was used in order to statistical analysis. T test was applied for comparison of both groups, the correlation between quantitative data was evaluated using pierson test and spearman test was applied for evaluation of correlation between qualitative data.

RESULTS

Demographic characteristics

In the present study, 85 patients were divided randomly into two groups of xience (45 patients) and onyx (40 patients). The average age of patients in xience group was 58.71±10.28 years and 57/38±8.32 years in onyx group, which there was no significant difference between the two groups from this aspect (P>0.05). Onyx group included 32 women (80%) and 8 men (20%), also, the xience group included 30 women (66.7%) and 15 men (33.3%), there was no significant difference observed between two groups for gender (P>0.05).

Background diseases

The results showed that DLP and FH were respectively the most and least frequent background diseases in both groups, but there was no significant differences between two groups for background diseases.

		Group onyx	Group xience
HTN	YES	11(27.5%)	16(36.6%)
	NO	29(72.5%)	29 (64.4%)
DM	YES	11(27.5%)	16 (28.89%)
	NO	29(72.5%)	32 (71.11%)
DLP	YES	14(35.0%)	16(36.6%)
	NO	26(65.0%)	29 (64.4%)
SM	YES	14(35.0%)	16(36.6%)
	NO	26(65.0%)	29 (64.4%)
FH	YES	1(2.5%)	2(4.44%)
	NO	39 (97.5%)	43(95.56%)

Patients' characteristics

Although the two groups differed considerably, but based on frequency, there was no significant differences for Admission reason, Culprit Vessel, Branch size, Angle of branch and main vessel, Severity of main vessel stenosis and severity of ostium stenosis between the two groups. As it is shown in table 2

		Group onyx	Group xience
Admission reason	DHF	1 (2.5%)	1 (2.22%)
	NSTEMI	5 (12.5%)	6 (13.33%)
	STEMI	1 (2.5%)	1 (2.22%)
	U/A	5 (12.5%)	5 (11.11%)
	U/S	28 (70%)	32 (71.11%)
Culprit Vessel	LM	1 (2.5%)	2 (4.44%)
	LAD	24 (60%)	21 (46.67%)
	LCX	9 (22.5%)	12 (26.67%)
	RCA	6 (15%)	10 (22.22%)
Branch size	1 mm	12 (30%)	14 (31.11%)
	1-1.5mm	8 (20%)	12 (26.67%)
	1.5-2mm	10 (25%)	11 (24.44%)
	>2mm	10 (25%)	8 (17.78%)
Angle of branch and main vessel	>90	1 (2.5%)	1 (2.22%)
	60-90	12 (30%)	8 (17.78%)
	30-60	22 (55%)	31 (68.89%)
	<30	5 (12.5%)	5 (11.11%)
Severity of main vessel stenosis	>90	19 (47.5%)	26 (57.78%)
	80-90	19 (47.5%)	18 (40%)
	70-80	2 (5%)	1 (2.22%)
severity of ostium stenosis	>90	3 (7.5%)	5 (11.11%)
	70-90	10 (25%)	8 (17.78%)
	50-70	13 (32.5%)	11(24.44%)
	<50	14 (35%)	21 (46.67%)

left anterior descending

Comparison

BMW was the most used wire in both group and two case were failed, additionally the length of onyx stent was significantly higher than xience, and also but the other characteristics did not show any significant difference. Fluoroscope time and dye in onyx group were higher than xience group, but these differences were not significant.

		Group onyx	Group xience
Wire	BMW	38 (95%)	39
	Pilot	1 (5%)	3 (6.67%)
	Whisper	1 (5%)	3 (6.67%)
	BMW+ Pilot+ whisper	1 (5%)	3 (6.67%)
	Failed	2 (5%)	3 (6.67%)
Stent	Length	28.45 ± 7.95	25.24 ± 6.95
	Diameter	2.78 ± 0.34	2.86 ± 0.38
	Dye	10.95 ± 6.39	9.98 ± 5.38
	Fluoroscope time	60.30 ± 58.05	54.40 ± 59.78

Correlation between

No significant correlation was seen between the length and diameter of xience and onyx stents with Dye and time of fluoroscopy. There was significant negative correlation between branch size with Dye and time of fluoroscopy. In onyx group, there was a negative significant correlation between Dye and time of fluoroscopy with angle branch and severity of ostium (stenosis), in xeince group, there was a negative significant correlation between Dye and time of fluoroscopy with branch angle, there was no significant correlation between Dye, time of fluoroscopy with other measured parameters.

DISCUSSION

A bifurcation lesion is a lesion happening at , or adjacent to , an important division of an important epicardial coronary artery. Nevertheless, bifurcations deviate not only in anatomy but in addition in the dynamic adjustments in anatomy that happen during the cardiac cycle as well as as a reaction to therapy consist of alternation in bifurcation angle during systole and diastole , plaque/carina shift following stenting .Around 15–20% of percutaneous coronary interventions (PCIs) are executed to treat coronary bifurcations . These types of procedures are prevalent for being technically challenging and generally are related to lower procedural success rates and also worse clinical results compared to non-bifurcation lesions [8, 9].

The optimal percutaneous treatment strategy for coronary bifurcation lesions remains a matter of debate. When atherosclerotic disease is limited to the main vessel (MV), there is a consensus that technical strategy should be kept as simple as possible, with single stenting of the MV, preferably with a drug-eluting stent (DES), with or without additional final (kissing) balloon dilatation of the side-branch (SB). However, when atherosclerotic disease involves the ostium of the SB, single vessel stenting of the MV may be insufficient, especially when the SB is large and the disease extends beyond the more proximal 2 or 3 mm of the SB or when blood flow in the SB becomes compromised [10, 11].

Until now, various studies have been conducted in order to discover the best treatment method for bifurcation lesion and side branch occlusion. Some of these studies have evaluated and compared various methods of stenting, while some others have compared various types of stents. Costa et al. (2014) compared two types of BioMatrix™ and Xience V™ stents and showed that the material of stent polymer can effect on treatment quality and long-term side effects by creating the minimum inflammation. The 5-years follow up of patients showed that the application of absorbable polymer leads less frequent occurring of heart accidents and decreasing of thrombosis rate during the first year after treatment. [12]. On the other hand, radioactive substances used in angiography, hurts the organs especially liver and kidneys, therefore,

the present study has evaluated the two types of stents, though onyx versus XIENCE on side branch rewiring in order to evaluate their difference in fluoroscopy time and the amount of design material.

In this study, there was no significant difference between two groups for time of fluoroscopy and consumed material, but there was a significant negative correlation in onyx group between angle and severity of ostial (stenosis) with time of fluoroscopy and consumed material. Also there was a negative significant correlation between Dye and angle of branch, finally, there was not a significant correlation between Dye and time of fluoroscopy with other measured parameters.

Steigen et al. (2006) compared the two methods of Simple Versus Complex Stenting in their study. Although the results of their study did not show significant difference for cardiac death, myocardial infarction, stent thrombosis, target-vessel revascularization, or combinations thereof after 6 months, but the amount of consumed contrast 40%, and fluoroscopy time 21% and procedure time, 23% was higher in complex method comparing to simple method. The increasing of this issues is correlated with the risk of injury to myocardium.

In other study, Minami et al. 2016, compared two Xience V and Resolute Integrity stents with the OCT method, they investigated Branch Orifice after Bifurcation Stenting, their results showed that in the subgroup without SB dilatation The% open area was not significantly different between the two stents, while in the sub-group with SB dilatation, % open area in the Xience group was significantly higher than the Resolute Integrity group [13].

Dubois et al 2012, in their study demonstrated the homogeneous stent strut coverage and the low late luminal loss in the main vessel reflect proper healing characteristics of the TRYTON Stent in combination with the XIENCE-V™ stent. However, proximal main vessel edge and ostial SB restenoses together with overall clinical outcomes do not fulfill expectations of a dedicated bifurcation stent[14]

A randomized 3-month follow-up OCT study showed that the percentage of uncovered struts was 11.7% for a polymer-coated rapamycin-eluting stent and 2.8% for a nonpolymer rapamycin-eluting stent [15]. Xie et al showed that the frequency of uncovered struts was 15% for sirolimus-eluting stents and 0.1% for bare-metal stents at 3-month follow-up OCT evaluation[16]. Kim et al. 2013, showed early stent strut coverage on the basis of serial OCT evaluation was comparable between Resolute Integrity stent and Xience 3 months after stent implantation[17].

It seems that physicochemical characteristics of stents can be effective on long-term prognosis of patients, the though polymer existing in drug-eluting stents plays central role in maintenance of local inflammatory process in wall of arteries, that potentially may lead to late stent thrombosis.

Limitations

One of limitations of this study was low volume of evaluated sample, another important limitation is related to deficiency of systematic evaluation, which prevents accurate evaluation. Finally, a 6-months period of follow-up can help the results to be improved.

CONCLUSIONS

Although in the present study there was no significant differences between the two groups for evaluated indices, but it seems that follow-up of patients for mortality rate, heart attack re-requirement to angiography and surgery in different periods of time, can be helpful in order to assessment of more appropriate stent.

AUTHORS' CONTRIBUTIONS

All authors had equal role in design, work, statistical analysis and manuscript writing.

CONFLICT OF INTEREST

The authors declare no conflict of interest

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