

Outcome of Using Angiosculpt in Bifurcation and Osteal Lesions, Efficacy, Safety

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ABSTRACT

Background: Balloon Catheter for AngioSculpt Scoring being considered using a scoring balloon close to the distal tip, cut the percutaneous transluminal coronary angioplasty (PTCA) catheter. The balloon is designed to expand to a specific diameter and length at a particular pressure. At the distal end of the catheter, there is a conventional nylon-blend balloon and a nitinol scoring element with three spiral struts that wrap around the balloon. **Objective:** To evaluate the outcome of using Angiosculpt in bifurcation and osteal lesions beside its efficacy and safety. **Patients and Methods:** This prospective, observational, non-controlled study included 20 with ischemic heart disease (IHD) patients, ischemic with osteal lesions and bifurcational lesion admitted at Wadi Elnil Hospital from January 2019 to May 2020. All patients were subjected to demographic data analysis, clinical examination, ECG. Echocardiography was done for each patient, on admission. Quantitative coronary angiography and PTCA using AngioSculpt then Percutaneous coronary intervention (PCI) with drug-eluting stent (DES) were performed. All patients received proper medications with follow up for morbidity and mortality for 3 months. **Results:** Mean age was 55 ± 23 years and 65% were men. The type of lesion was osteal in 25% of lesions and true bifurcation lesion in 75%. Additional stenting was performed in all lesions after angioplasty with the AngioSculpt balloon. The immediate complication was recorded as perforation in one patient (5%). Coronary complication was localized dissection, which was identified in one patient (5%). Survival was 100% at 6 months. Major adverse cardiac events (MACE) occurred in 10% of patients. Target lesion revascularization (TLR) was not needed at the study group. **Conclusion:** Using the AngioSculpt scoring PTCA balloon for osteal lesions and bifurcation lesion is considered to be safe and effective and leads to satisfactory clinical and angiographic outcome. **Keywords:** Osteal, Bifurcational, AngioSculpt scoring balloon, PCI.

INTRODUCTION

An angioplasty with a balloon leads in acute lumen gain. The mechanisms vary based on the specifics of the lesion. In a severely calcified lesion, balloon inflation is linked with plaque fracture and dissection, but in a fibrotic lesion, plaque compression and vascular stretch contribute more to the gain. A scoring balloon is positioned at the distal tip of the PTCA catheter known as the AngioSculpt Scoring Balloon Catheter. The purpose of the scoring balloon is to reach a particular diameter and length at a specified pressure^[1].

Aim of the study was to evaluate the outcome of Using Angiosculpt in bifurcation and osteal lesions beside its efficacy and safety.

PATIENTS AND METHODS

This prospective, observational, non-controlled study included 20 heart disease (IHD) patients; ischemic with osteal lesions and bifurcational lesion admitted at Wadi Elnil Hospital from January 2019 to May 2020.

Inclusion criteria were patients with documented CAD, preserved EF, target lesion(s) must be osteal lesion or true bifurcation lesion.

Exclusion Criteria were impaired EF, patient on immunosuppressive therapy, contraindication to essential drugs aspirin, heparin, clopidogrel or contrast sensitivity, CKD prepared for dialysis, any other comorbidity such as CVS, cerebral hemorrhage, bleeding varices, pregnancy, target lesion(s), which doesn't match with our inclusion criteria and CTO lesions. **Methods:** Patients were subjected to ECG, lipid profile, kidney function tests, echocardiography to

assess the LV systolic function and coronary angiography including quantitative coronary angiography (QCA), PCI with using 2nd generation and 3rd generation drug-eluting stents (DES).

Study Endpoints: Study endpoints were 6 months. Clinical outcome included death (cardiac and non-cardiac), myocardial infarction, target lesion revascularization (TLR), target vessel revascularization (TVR) and all major adverse cardiac events (MACE).

Ethical consent: The Ethical Institutional Review Board at Benha University approved the study. After explaining our research objectives, written informed consent was obtained from all study participants. This study was conducted in compliance with the code of ethics of the world medical association (Declaration of Helsinki) for human subjects.

Statistical analysis

The data are displayed as the mean standard deviation (SD) for continuous data and as a number (%) for categorical data. Using the student t-test for continuous data and the Chi-square test for categorical data, the level of evidence was determined to be significant when $P < 0.05$.

RESULTS

Baseline clinical characteristics are shown in table (1). Figure (1) showed that male gender patients (65%) and the mean age of patients was 55.23 ± 7.31 years. diabetes mellitus was present in 53.3% of total study population., Hypertension was present in 53.3%. Seventy percent had dyslipidemia, while 53.3% of patients were smokers.

Table (1): Distribution of studied group regarding personal data

	No (20)	%
Age	55.23±7.31	
(Gender male) Sex	13	65
DM	14	70
HTN	12	60
Dyslipidemia	17	85
Smoker	13	65

Data were expressed as mean ± Sd, number (%).

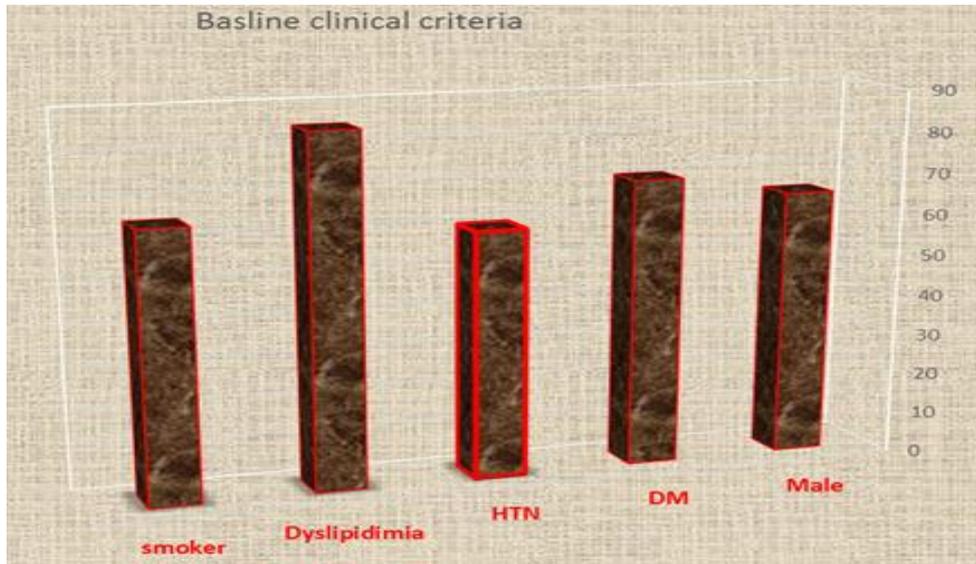


Figure (1): Distribution of studied group regarding personal data

Canadian functional class of studied group:

Table (2) and Figure (2), showed that patients presented with functional class II were 25% and patients with functional class III were 50% and patients with functional class IV were 25%.

Table (2): Canadian functional class of studied patients

Canadian Functional class	No (20)	%	P value
Class I	0	0	
Class II	5	25	
Class III	10	50	0.001*
Class IV	5	25	

*: Significant.

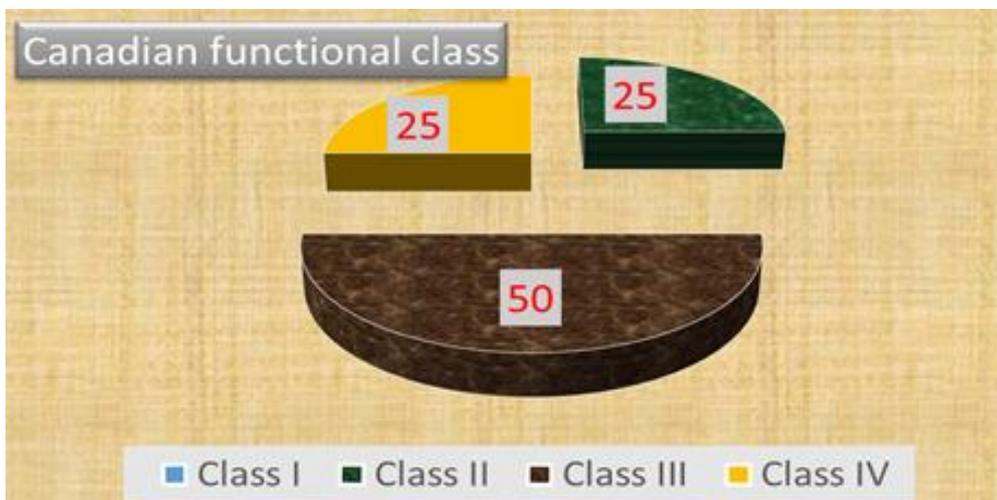


Figure (2): Canadian functional class of studied group

Types of Stents:

In our study 20 patients were treated with 43 DES stent, distributed as 18 Xience V (EES) stents, representing 22.2%, 17 Promus Plus (PES) representing 36.1% while 8 Resolute onex (EES), representing 41.6%. [Table 3] [Figure 3]

Table (3): Types of stents

	N	%
Xience V (EES)	18	41.9
Promus Element (PES)	17	39.5
Resolute Onex (SES)	8	18.6

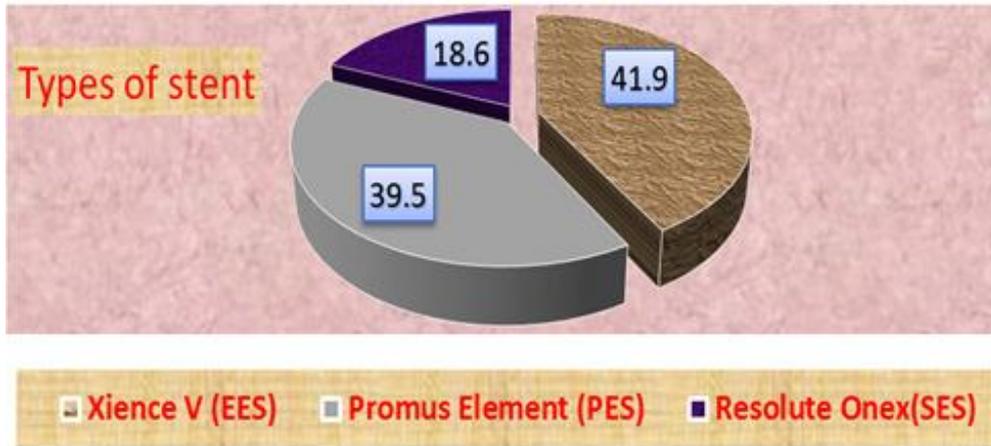


Figure (3): Types of stents

Procedural angiographic details:

Table (4) shows procedure angiographic details, **A-** comparison between MLD before the procedure and after AngioSculpt inflation was statistically highly significant with acute lumen gain more than 81%.

B- comparison between MLD after AngioSculpt inflation and after stent inflation was statistically non-significant. AngioSculpt inflation pressure used to predilate the lesion was insignificantly lower than stent inflation pressure.

Post stenting dilatation non-compliant (NC) balloon were in 16 patients, represented 80%, while only 4 patients, represented 20% need post stenting dilatation using NC balloon. The difference between both was statistically highly significant. [Table 4 and Figure 4]

Table (4): Procedural angiographic details

	Angiographic details			P value
	Pre procedure	Post AngioSculpt	Post Stent	
Minimal lumen diameter (MLD), mean ± SD	1.363±0.33(A)	2.453±0.46	2.772±0.36(B)	A0.001* B 0.891
Inflation pressure mean ± SD		11.45±1.55 (9-13)	12.9± 0.99 (11-14)	0.673
		N (20)	%	0.001*
Post stenting using NC		4	20	
Angiographic success		16	80	

*: Significant

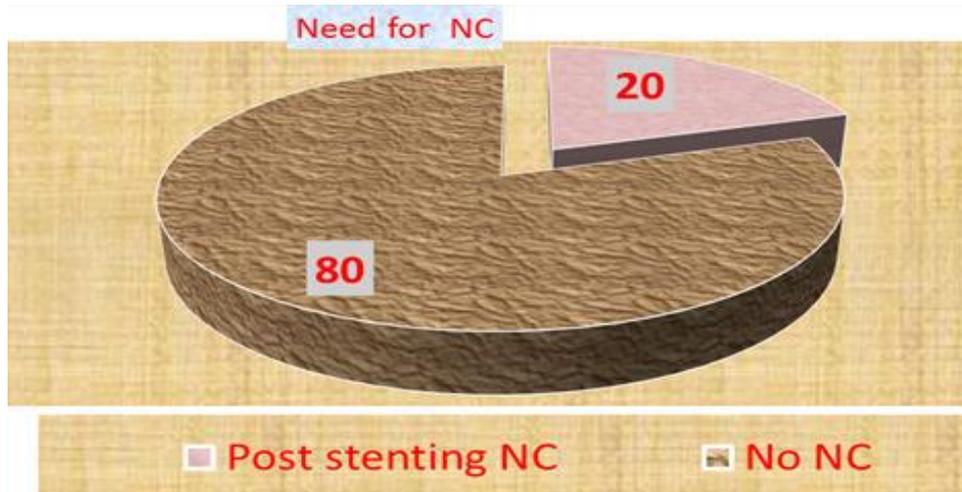


Figure (4): Need for NC among the studied participants

Procedure related complications and mortality:

The procedure related complications are shown in figure 5 and table 5. Coronary dissection was managed by DES stent insertion. Acute renal failure was managed by hemodialysis for two session.

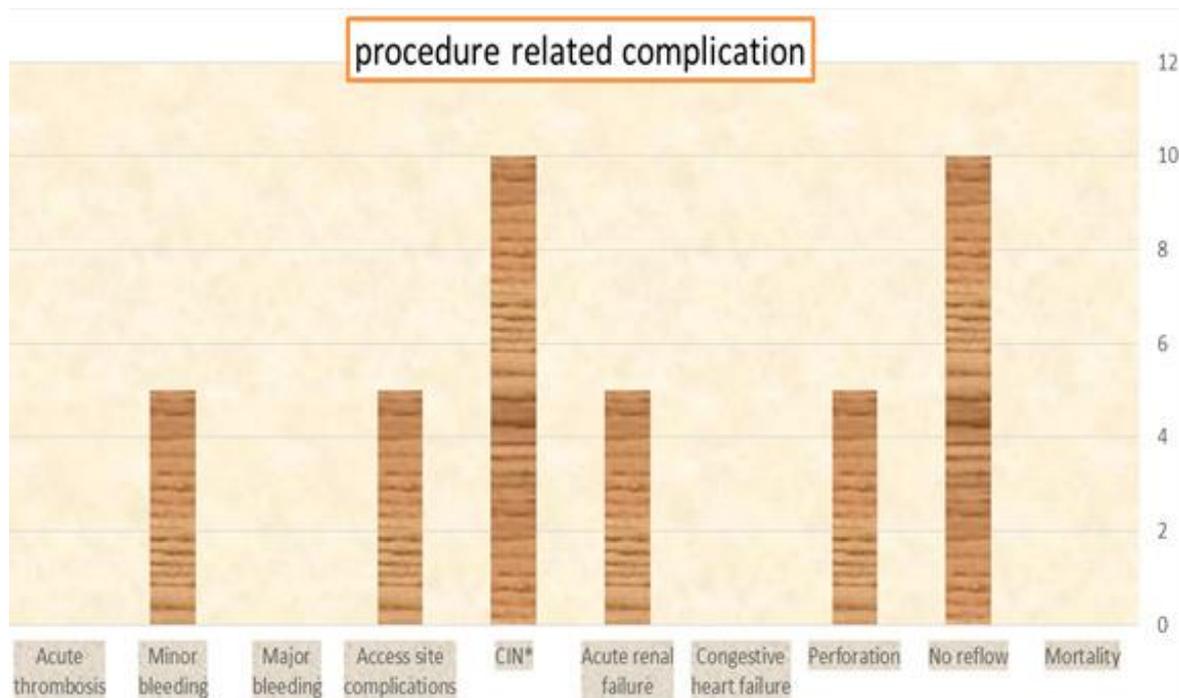


Figure (5): Procedure related complications among the studied participants.

Table (5): Procedure related complication

Procedure related complication	NO	%	P-value
Mortality	0	0	-
Dissection	1	5	0.6
No reflow	2	10	0.05*
Perforation	1	5	-
Congestive heart failure	0	0	-
Acute renal failure	1	5	-
CIN*	2	10	0.05*
Access site complications	1	5	0.6
Major bleeding	0	0	-
Minor bleeding	1	5	0.6
Acute thrombosis	0	0	-

*: Significant

Six months clinical and angiographic outcome:

Six months clinical outcome is presented in table 6 and figure 6. There were no reported cases of mortality, stroke or stent thrombosis at follow up.

Table (6): Six months clinical outcome

6 months clinical outcome	N0	%	P value
MI	0	0	-
HF	1	5	0.683
Angina requiring hospitalization	1	5	0.483
Arrhythmia	2	10	0.854
Stroke	0	0	-
Death	0	0	-



Figure (6): Six months clinical and angiographic outcome

DISCUSSION

When refractory lesions are dilated, exceeding the acceptable pressure limits, typically highlights the non-uniform balloon expansion and increasing the risk of vascular injury (the so-called "dog-boning" effect) [2].

In the present study we used The AngioSculpt PTCA balloon catheter as predilatation therapy for treating ostial and bifurcational lesion plus DES stent with encouraging result.

In the present study we reported improvement of the MLD before the procedure and after AngioSculpt inflation, with acute lumen gain more than 81% with 100% angiographic success. These results are in agreement with Costa *et al.* [3] who found that with predilatation with AngioSculpt in de novo calcified lesion, ISR resulted in acute lumen gain more than 80 %, with total angiographic success 98.5% and 100% in ISR.

The procedure related complications were mortality 0%, coronary dissection in 5 %, which was managed by DES stent insertion, no reflow phenomenon occurred in 10%, while coronary

perforation in 5% was treated by graft stent and acute renal failure in 5% of studied group was managed by hemodialysis for two sessions, contrast induced nephropathy occurred in 10% of patients, there was 0% major bleeding but minor bleeding occurred in 5 % of patients, and there was 0% acute stent thrombosis.

These results are in line with those of Fonseca *et al.* [4] who discovered no MACE hospital stay, the early experience with the AngioSculpt scoring balloon appears to have a significant impact on the angioplasty of complex coronary lesions with no perforation and only 3.4% dissection. And in agreement with Kanai *et al.* [5] who found AngioSculpt scoring less balloon slippage. Since it wouldn't crush or destroy calcified plaque, there wouldn't be any perforation or no-reflow issue, which would lead to a successful dilatation of heavily calcified coronary arteries without significant dissection.

In comparison to Grip trial, which studied 157 patients who were treated for ISR with the GRIP™ balloon, no perforation were recorded but dissection

was in 3%. Freedom from major adverse cardiac events (MACE: cardiac mortality, myocardial infarction, and target lesion revascularization) was the effectiveness objective [6].

In comparison to **RESCUT**, which studied 428 patients who were treated for ISR with CBA, there was no coronary complication, as no perforation were recorded, but dissection in 4.8%, balloon slippage in 6.6%, no-reflow in 6.6%, MI in 0.5%, and bleeding or vascular complications 4 1.8% were found [7].

In comparison with **Puck et al.** [8], who treated 50 patients with calcified lesion treated by Rot ablator, with higher procedural complication rate, coronary dissection rate of 6%, but there was no perforation. 7.6% of patients had no reflow phenomena, 6.6% had severe spasm or abrupt vessel closure, 11.2% had abrupt vascular closure, and 8% had myocardial infarction. The fact that more than a quarter of the elective patients had signs of minor myocardial damage, as determined by elevated post-procedural troponin levels, however, suggests that distal embolization of the atherectomy fragments may result in detectable but clinically insignificant myocardial micro-injury.

Our results disagree with **pivotal study**, which studied safety and efficacy of the AngioSculpt in U.S.A on 200 patients with 219 lesion, reported higher dissection rate of 13.7%, there were 1% non-Q wave MI, 1.5% Q wave MI, and 0.5% TLR by PTCA and 0.5% TLR by CABG. Confirmed thrombosis was 0.5% [9].

In the present study at 6 months follow up there were no reported cases of mortality, HF occurred in 3.3% of patients, angina requiring hospitalization in 3.3% of patients, dysrhythmia (AF) in 6.6% of patients, no reported cases of stroke at follow up, (ISR) was reported in 3.3% of patients, TLR was reported in 3.3% of patients. There were no reported cases of stent thrombosis or late loss in general study.

And these results are in agreement with **Byrne** who found that ISR in the scoring-balloon group was lower compared with the control group (18.5% vs. 32%; $P = 0.03$). TLR (scoring-balloon group, 16.8%; control group, 22.6%; $P = 0.25$) and death/MI (scoring balloon group, 3.3%; control group, 3.4%; $P > 0.99$) did not significantly differ between the groups. There were no cases of target lesion thrombosis [10].

Our results disagree with **ALSTER** trial, which found TLR/TVR was 6.6% overall. Twelve-month MACCE was 12.5% for ASB and 15.4% in the historical control group, the higher MACE can be explained by higher risk patients because **ALSTER** trial was performed in patients with LM disease [11].

In comparison **Lee et al.** [12], who used CBA vs rotaplator, found at nine-month clinical follow no cardiac death or nonfatal MI in the two group, two patients in each group required TLR, all of them received repeated intervention, (3.4% in group 1 vs 3.4% in group 2) during the 9-month follow-up period.

CONCLUSION

The analysis of the current study revealed a high procedural success rate in a real-world, sequential series of patients treated for ostial and bifurcation lesions with low inflated pressure compared to NC balloon. Overall, the frequency of significant cardiac adverse events was rather low, allowing for the estimation of the difficulty of planned PCI.

RECOMMENDATION

Using AngioSculpt in treating type C lesion is considered effective and safe in majority of cases with minor procedure related complication. Strict follow up is recommended for the patients who treated with high-risk lesion.

STUDY LIMITATIONS

The results are from single center Wadi Elnil Hospital. The sample size is relatively small. The study did not cover all the types of lesions, as total occlusion, because calcific lesion were excluded; the study did not cover patients with acute coronary syndrome. No advanced tools were used, only controlled angiography, no use of intravascular ultrasound (IVUS) or optical coherence tomography (OCT). The follow up period is relatively short period

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