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ORIGINAL ARTICLE

CAN ROTAWIRE STANDALONE! PERFORMANCE OF ROTAWIRE AS A STANDALONE WIRE FOR ROTATIONAL ATHERECTOMY

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ABSTRACT:

BACKGROUND: *With advancements in stent designs and lesion preparation techniques, complex lesions are being increasingly treated using percutaneous approach. Even with advent of new emerging technologies, the importance of Rotational Atherectomy (RA) cannot be undermined as a first line technique for treating complex calcified lesions.*

AIMS & OBJECTIVE: *We looked at several aspects including technique, success rate and safety of Rotawire as a standalone wire for Rotational Atherectomy.*

MATERIAL & METHODS: *This comparative study was carried-out at the angiography department of Punjab Institute of Cardiology, Lahore over a period of two years starting from January 2018 to January 2020 after obtaining approval from institutional review board. Patients with stable ischemic heart disease undergoing angioplasty for calcified coronary lesions and age ranging from 40-90 years were included in the study while patients with previous history of stent placement in last six months or having post-bypass grafts disease were excluded from the study. Total twenty six patients undergoing Rotational Atherectomy were prospectively assigned to standalone Rotawire strategy (strategy-A) Vs the contemporary technique using workhorse wire and exchanges over a micro-catheter (strategy-B). Success rate, wiring fluoro times and complication rate of both strategies were compared.*

RESULTS: *Twenty-six patients underwent Rotational Atherectomy. Strategy-A was selected for 12 and strategy-B for 14 patients, as per operators' discretion. Baseline and procedural characteristics were similar in both groups. Strategy-A was successful in 11 (91.67%) and strategy-B in 14 (100%) of patients (P=0.29). The wire handling fluoro time was significantly lower for strategy-A vs B(36.83 ± 4.80 vs 96.36 ± 24.51 seconds, P value 0.01), however the total procedural fluoro time was not statistically different (17.75 ± 4.78 vs 19.57 ± 3.58 minutes, P value 0.29). Slow flow was the only complication(A=8.3% vs B=7.1%, P value 0.91), treated successfully with final TIMI-III flow in all patients. The microcatheter usage (8.3% vs 100%, P=0.01) and number of PTCA wires usage(1.08 ± 0.29 vs 2.0± 0, p=0.01), was significantly lower for strategy-A. There was no MACCE at 01 month.*

CONCLUSION: *By using proper technique, the Rotawire can be used as a standalone wire for RA assisted interventions. Larger studies can validate it further.*

KEY WORDS: *Calcified lesions, rotational atherectomy, Rotawire standalone.*

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INTRODUCTION:

With advancements in stent designs and lesion preparation techniques, complex lesions are being increasingly treated using percutaneous approach[1].Even with advent of new emerging technologies, the importance of RA cannot be undermined as a first line technique for treating complex calcified lesions.[1-3] Rotational atherectomy imparts differential cutting using diamond crusted burrs. [1,4] Rotational atherectomy mandates placement of a dedicated wire before device advancement. [5,6] Meager work is available on technique for placing a Rotawire across a lesion or using it as a PTCA wire, although enough work is available on other minute details of RA.[7,8] The Rotawire (Boston Scientific, USA) is a monofilament stainless steel wire, with a tapering shaft and short floppy tip(0.009" shaft/0.014" tip)[1].Traditionally, RA operators prefer first placement of a workhorse wire followed by exchange with a Rotawire using microcatheter.[3] But lesions can be wired primarily with a Rotawire[1,9] and stent placement can be accomplished over it. There is scope for research on the potential standalone role of Rotawire.

MATERIALS AND METHODS:

This comparative study was carried-out at the angiography department of Punjab Institute of Cardiology, Lahore over a period of two years starting from January 2018 to January 2020. The study was approved by the institutional ethical review committee and complies with the declaration of Helsinki. Informed consent was taken from all patients. Patients with stable ischemic heart disease undergoing angioplasty for calcified coronary lesions and age ranging from 40-90 years were included in the study while patients with previous history of stent placement in last six months or having post-bypass grafts disease were excluded from the study. Total twenty six patients undergoing Rotational Atherectomy were prospectively assigned to standalone Rotawire strategy (strategy-A) vs the contemporary technique using workhorse wire and exchanges over a microcatheter(strategy-B), as per operators' discretion. Success rate, wiring fluoro

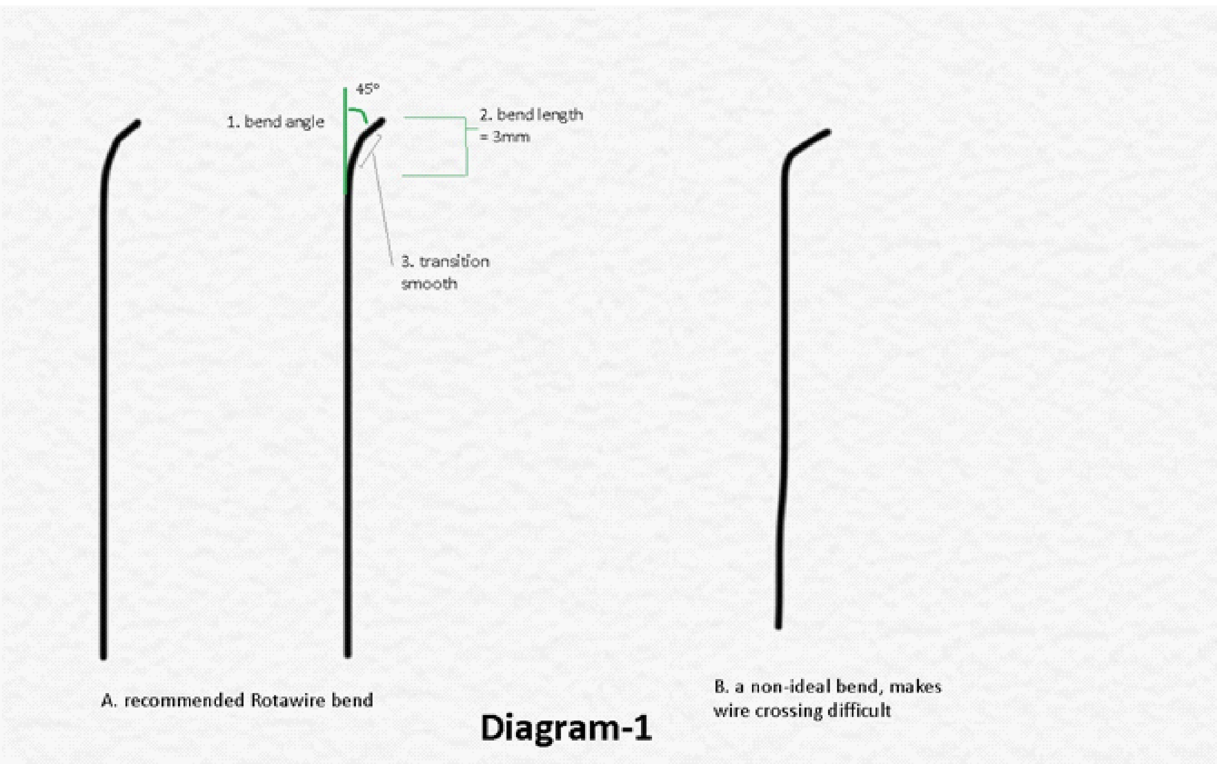

Fig-1: An ideal tip bend of RotaWire to facilitate direct maneuvering

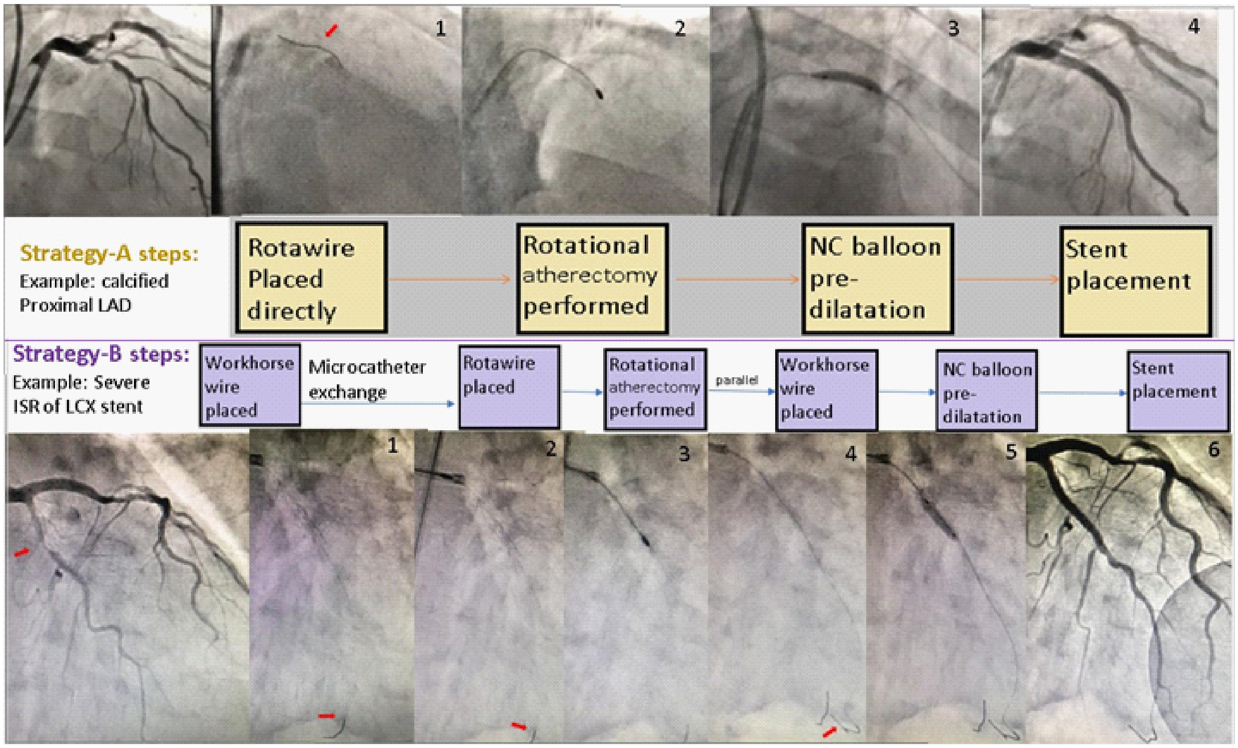

Fig-2: Comparison of steps for strategy-A vs strategy-B
LAD: left anterior descending artery, LCX: left circumflex artery, ISR: in-stent restenosis, NC: non-compliant. Note; the diagonal branches remained patent but got slow flow (TIMI-II flow) in the LAD case.

times and complication rate of both strategies were compared.

Technique; Strategy-A involved direct placement of a Rotawire across the lesion. A smooth 45° bend was made just near the tip of Rotawire(diagram-1). The bend transition should not be sharp, to avoid entry into small side branches or making wire prone to kink and fracture[1,9].After introducing into the guide, entire of the external part of Rotawire was removed out of its casing and laid straight on the sterile field. It eases wire maneuverability. Now gentle advancement of Rotawire was performed into the index artery under fluoro guidance. A continuous clock and counter clockwise torqueing(60°-90°) of the wire shaft was carried out while advancement. This facilitates smooth wire advancement by dissipating any stored push on the wire and preventing sticking of wire tip on irregular luminal surfaces. Wire torquer or thumb and Index finger can be used for this maneuver. While reaching at a bend inside the artery, the wire tip should be directed towards the lesser curvature of that segment. The above maneuver can be continued, but with a lesser degree of clock-anticlock torque(30-45 degree). If the wire tip gets directed towards larger curvature of the bend or gets stuck at a point, it can be slightly pulled and rotated away from that point and then re-advanced. After securely placing the Rotawire into distal vessel, rotational atherectomy was performed followed by Non-compliant (NC) balloon dilatation and stent placement on the same wire. In most cases after successful RA, the operator would cut the Rotawire roughly at 60cm from Y-connector exit. This made subsequent wire handling quite easy. We labeled it as an "Ablate and amputate strategy".

In Strategy-B, the default first step was to place a workhorse wire across the lesion and exchange it with Rotawire over a microcatheter. This was followed by RA and re-exchange with a workhorse wire for completion of the procedure (diagram-2).

Baseline risk profile and angiographic characteristics were noted in all patients. Using AHA classification,[10,11] lesion's complexity was scored as type-A=1, B1=2, B2=3, C=4. Calcification was graded on fluoroscopy as moderate and severe.[12] Vessel tortuosity[13,14] proximal to the lesion was scored as mild=1, moderate=2, severe=3. Eccentric calcified lesion or presence of calcified nodule has shown to be associated with adverse outcomes[15-17]. Eccentricity of calcified lesion was scored as, non-eccentric lesion=0, eccentric lesion=1, eccentric calcified nodule=2.

Study outcomes: Primary outcome was strategic success. Strategic success was defined as successful completion of procedure, using the default strategy selected in that patient. Any patient needing cross-over to the other technique would be labeled as strategy failure. The Wire-handling Fluoro Time was recorded from successful guide engagement till the Rotawire is securely positioned distal to the lesion, in strategy-A. For strategy-B, it included the fluoro time for initial Rotawire placement plus re-exchange with a workhorse wire after lesion ablation. Total Procedural Fluoro Time was the total fluoro time during that procedure. Any complications like slow flow, spasm, dissection, perforation, failure to deliver a stent, stent under-expansion and major bleed were noted. Both groups were followed for MACCE (death, myocardial infarction, stroke, target lesion revascularization[18] and major bleeding[19]) at one month. Strategy success, procedural success,[20] fluoro time and rate of complications were compared in both groups. The mean number of PTCA wires and micro-catheters used were also compared.

STATISTICAL ANALYSIS:

Data was analyzed using SPSS version 21. Continuous variables were presented as means ±SD. Categorical variables were presented as percentage. Independent samples T test was used to compare the means.

RESULTS:

Twenty-six patients underwent RA for calcified lesions (n=25) or severe ISR(n=1). Strategy-A was selected for 12 and strategy-B for 14 patients, as per operators' discretion. Mean age was 58.9(±10.5) years. Minimum age was 30 years, for a post CABG female with familial dyslipidemia. Maximum age was 83years. Baseline (Table-1) and procedural characteristics (Table-2) were similar in both groups. Strategic success was achieved in 91.67% of group-A and 100% of group-B(p=0.29). The Rotawire proved to be successful as a standalone wirein11 out of 12 patients, only a single patient needed placement of a BHW wire(Abbott vascular) for precise stent positioning, after RA of an ostial right coronary artery lesion. The fluoro time needed for wire handling was significantly lower for strategy-A vs strategy-B (36.83 ± 4.80vs 96.36 ± 24.51seconds, P = 0.01), however the total procedural fluoro time was not statistically different (17.75 ± 4.78 vs 19.57 ± 3.58 minutes, P = 0.29). The rate of procedural complications was similar (8.3% vs 7.1%, P value 0.91).The only complication was significant slow flow that occurred among one patient in each group, successfully treated by using intracoronary vasodilators. There was no major bleed. Only a single patient had femoral access site hematoma (in group-A), that resolved spontaneously. There were no major adverse events in both groups at 01 month. The micro-catheter usage (8.3% vs 100%, p= 0.01), and number of PTCA wires usage(1.08 ± 0.29 vs 2.0, P = 0.01), was significantly lower for strategy-A vs strategy-B.

DISCUSSION:

Rotational atherectomy is an indispensable tool

Table 1: Baseline characteristics and risk profile

		GROUP-A (Standalone RotaWire, n=12)	GROUP-B (conventional strategy, n=14)	P Value
Mean age (years)		59.5 ± 14.5	58.4 ± 5.7	0.80
Gender	Male Female	08 (66.7%) 04 (33.3%)	11 (78.6%) 03 (21.4%)	0.52
Hypertension		07 (58.3%)	12 (85.7%)	0.13
Diabetes		07 (58.3%)	05 (35.7%)	0.27
Dyslipidemia		08 (66.7%)	09 (64.3%)	0.90
Positive Family history		04 (33.3%)	07 (50%)	0.41
Smoking		04 (33.3%)	06 (42.9%)	0.63
Previous CABG		01 (8.3%)	01 (7.1%)	0.91
NSTEMI		5 (41.7%)	10 (71.4%)	0.14
UA		7 (58.3%)	04 (28.6%)	0.14

UA; Unstable Angina, NSTEMI; Non ST-Elevation Myocardial Infarction

Table 2: Procedural characteristics and outcomes

	GROUP-A(Standalone RotaWire, n=12)	**GROUP-B** (conventional strategy, n=14)	**P Value**
Radial Access	08 (66.7%)	13 (92.86%)	0.10
LAD	09 (75%)	08 (57.1%)	0.35
LCX	1 (8.3%)	3 (21.4%)	0.36
RCA	2 (16.7%)	3 (21.4%)	0.76
Ostial lesions	1 (8.3%)	0	0.34
Severe Calcification	12 (100 %)	11 (78.6%)	0.09
Vessel Tortuosity score (1-3)	1.50 ± 0.67	1.21 ± 0.58	0.26
Lesion Eccentricity score (1-3)	1.0 ± 0.74	0.64 ± 0.50	0.17
AHA lesion score (1-4)	2.83 ± 0.58	2.64 ± 0.75	0.47
Strategic success	11 (91.67%)	14 (100%)	0.29
Procedural success	12 (100%)	14(100%)	
PTCA wire/Rotawire handling flouro time (Seconds)	36.83 ± 4.80	96.36 ± 24.51	0.01
Total procedural fluoro time (minutes)	17.75 ± 4.78	19.57 ± 3.58	0.29
Slow flow	1 (8.3%)	1 (7.1%)	0.91
Temporary pacing	1(8.3%)	0	0.34
Micro-catheters usage	1 (8.3%)	14 (100%)	0.01
Mean PTCA wires usage	1.08 ± 0.29	2.0 ± 0	0.01

LAD: left anterior descending artery, LCX: left circumflex artery, RCA: right coronary artery. Vessel Tortuosity Score: mild=1, moderate=2, severe=3. AHA Lesion score: Type-A=1, B1=2, B2=3, C=4. Lesion Eccentricity score: Non-eccentric=0, eccentric=1, eccentric calcified nodule=2. Note; PTCA wire usage included the Rotawire itself.

for the interventional cardiologist. During review of literature, we found more or less similar comments on the suboptimal performance of Rotawire as a PTCA wire[1,3]. This has never been verified in any designed studies. At times we do come across micro-catheter un-crossable calcified lesions, mandating attempts at direct Rotawire placement.[9] For example in case of CTO vessels with severe calcification sometimes the smallest balloon cannot cross, same can be the case with a calcified nodule.[15] In such situations, dedicated micro-catheters are used to cross the lesion site, these include torquable micro-catheters (Turnpike, Corsair etc.). But with severe calcification in the CTO segment even these catheters can fail to cross the lesion, like in the case study by Kaneko et al.[9] In such situations sometimes direct placement of the Rotawire as a parallel wire can be attempted to subsequently perform rotational atherectomy. The cross-ability of calcified lesions by use of direct rotawire has not been studied as such. In this study, we have aimed to assess the success rate of direct placement of rota wire across the lesion. To our knowledge, this is the first study to describe in detail the technique and maneuvering of Rotawire for direct placement. After performing successful atherectomy using rota burr, traditionally a workhorse wire is now placed across the lesion, while the rota wire is still in place. In our study we have utilized the already placed rota wire to complete the rest of the procedure as well, that will include balloon dilatations and stent placements on it. Hence the standalone performance of a Rotawire to complete the angioplasty procedure has been evaluated. The stainless steel Rotawire has a glossy surface and tapering distal shaft before ending up in a 22mm floppy part. Although the slippery and thin wire shaft offers less resistance, but less torque-ability and long length makes it difficult to maneuver through vessel bends. Laying the wire straight on sterile field and using a wire torquer makes it more steerable. Once inside, the wire can be navigated through the calcified artery as described above. The technique has shown high success rate and safety. Many operators for cath labs have high volume of patients and avoid complex procedures to save time. This is one of the causes for less wide use of rotational atherectomy.

In this study we have tried to simplify the procedure of rotablation by minimizing the number of steps in the procedure. Moreover the additional cost of equipment used during RA can be a limiting factor for its easy acceptance. By using our strategy, the micro-catheter usage and additional workhorse wire usage is not needed. This leads to a significant fall in rotablation related procedural cost. Lesser micro-catheter and additional PTCA wires usage makes it more cost effective. The strategy of rota wire as standalone wire Vs. traditional technique can be opted by various operator according to their level of ease and acceptance.[1] But in our opinion, a standalone Rotawire strategy can initially be selected for most of the cases, but if needed one can always switch to the traditional technique.

CONCLUSIONS:

Crossing the lesion directly with a Rotawire can be adapted as a default initial step for wire placement. By careful use, the Rotawire can act as a standalone wire to complete RA assisted PCIs in a good fraction of patients. This might make RA more cost effective as well. Larger studies can be designed to validate this.

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