Original Article

Angiographic Analysis of Trans-Radial Percutaneous Coronary Intervention Cases by the Backup Support of Guide Extension Catheter

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Abstract:

***Background:*The guide extension catheter – *Guidezilla* (Boston Scientific, United States of America) is a useful adjunctive tool in percutaneous revascularization of complex coronary lesions, and provides an extension to the guide catheter with better coaxial alignment, support and stability.*Objective:* The objective of this study was to describe the usefulness and easy deliverability of stent by *Guidezilla*in the trans-radial treatment of complex coronary lesions as our initial experience.*Methods:*This prospective observational study was conducted at the Department of Cardiology, Ibrahim Cardiac Hospital & Research Institute (ICHRI), Dhaka from July 2016 to September 2017. The transradial approach was used in all cases. Clinical, angiographic and procedural data of percutaneous coronary interventions performed using *Guidezilla*, including indications for use of *Guidezilla* were collected and analyzed. *Results:*A total of 19 procedures (in 18 patients) were evaluated. 57.89% of cases were related to left circumflex coronary artery or obtuse marginal branch. The commonest challenge for use of *Guidezilla*was proximal angulation (63.15%) and calcification (47.4%). Commonest type of lesion was ACC/ AHA Type C lesion (63.2%). Successful stent deployment was achieved in 16 of the 19 procedures (84.2%). Among the unsuccessful cases, there was stent damage in one case and distal dissection after deployment of a stent in other. Stent deployment was not possible in two cases, due to diffuse lesion and heavy calcification.*Conclusions:*Guide extension catheter is a good trans-radial back-up support for calcified, complex and tortuous coronary anatomy, which otherwise may have been considered unsuitable for PCI. The use of such support can reduce the necessity for the more expensive alternative of deploying multiple small stents in order to traverse the lesions.**

Key words: Percutaneous Coronary Intervention, Angiography, Catheter.

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Introduction:

The guide extension catheter- Guidezilla is a useful tool in the armamentarium of the interventional cardiologist. As a modified “mother and child” system, it provides an extension to the guide catheter with better coaxial alignment and stability.Its usefulness in everyday cardiac catheterization laboratory practice is indisputable, particularly, where the radial artery is used as a default vascular access route for all types of percutaneous coronary intervention (PCI). A good back-up represents one of the most important conditions to ensure guidewire, balloon advancement and successful deployment

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of stent, which contributes to PCI success.[1]There is difficulty in the use of angioplasty balloons and stents in the presence of calcification, marked tortuosity andchronic total occlusions, leading to a considerable failure of stent deployment (approximately 3%).[1,2]Balloon anchor technique makes delivery of *Guidezilla* through complex, Transradialanatomy easy. This sort of device not only reduces the incidence of surgical revascularization, but also reduces the expense of the patients, in terms of a reduced cost due to a reduced number of stents deployed. Prior to the availability of this device in our catheterization laboratory, it was customary to deploy two or more small length stents in order to traverse the tortuosity and proximal angulation of the vessels. This represents an economic burden for a developing country like Bangladesh, a country only beginning to approachthe lower limit of middle income Gross Domestic Product (GDP), because in addition to the cost of the stent, the majority of the population does not have health insurance coverage.

The use of Buddywire technique,stiffer guide wire, anchoring balloon technique, and deeper intubation of the guide catheter are some of the other measures used to improved back up support in complex lesions.[3-5] Thus, the use of *Guidezilla* is suitable when facing unexpected delivery challenges during PCI, obviating the need for guide catheter exchange.[6]Furthermore, use of *Guidezilla* can also reduce the amount of dye injected, thus it has distinct benefit for patients with chronic kidney disease (CKD)[7] and the elderly, whose renal reserve is poor. There are also other commercially available monorail guide extender catheters, such as *GuideLiner®* catheter (Vascular Solutions Inc.), *Kiwami (*Terumo, Tokyo, Japan), and *Cokatte* (Asahi Intecc).

The GuideExtension Catheter-*Guidezilla* 6F (5-in-6) (Boston Scientific, USA) that was used in this study has a minimal internal diameter of1.45 mm. This catheter consists of a monorailsystem, which extends to the distal end of the guide catheter ('mother-child' fashion), with a length of 25 cm, a thickness of1Frless than the guide catheter and a design that minimizes trauma onthe artery wall. The monorail continues proximally with a thin hypotube.The 1x1 braidof *Guidezilla* helps to straighten the vessel without lengthening it.The technique begins with engaging the guiding catheter(mother) and positioning the guide.Once the guide catheter and guide wire are placed, the Guide Extension catheter can be advanced over the guide wire through the hemostatic valve as an extension to the guide catheter. Subsequently, the procedure can be continued as usual, without need for disconnection and reattachment.

Material & Methods:

This prospective observational study was conducted at the Department of Cardiology, Ibrahim Cardiac Hospital & Research Institute (ICHRI), Dhaka, Bangladesh during the period extending from July 2016 to September 2017. Demographic characteristics, risk factors, left ventricular ejection fraction (EF), angiographic and procedural data of PCI done in patients with the use of Guide Extension Catheter - *Guidezilla* were collected. The Transradial approach was used in all cases.

All consecutive cases oftrans-radial PCI where *Guidezilla* was used for support,were prospectively included in the study. A total of 19 procedures were performed in the 18 patients. The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Informed written consent was taken from patients or next of kin. Prior ethical approval was obtained from the ethical review committee of ICHRI.

Image Acquisition and interpretation:Coronary angiography was donebytrans-radial route, either right or left. Right radial approach was used as default vascular access route. Left radial route was reserved for graft vessel angiography where LIMA grafts were made in post coronary artery bypass graft (CABG) cases. Routine pre-medication was administered with special attention to those with prior history of allergy. Iodinated contrast media was used. In cases of CKD, iso-osmolar non-ionic media Iodixanol (*Visipaque)* was used. Image interpretation and was performed by two independent readers and disagreement between readers regarding treatment strategy was resolved by Heart Team discussion. Coronary arteries were segmented according to a modified version of the American College of Cardiology(ACC)/ American Heart Association (AHA) 15-segment model (which includes the ramus intermedius, if present, as segment 16).[8] Each coronary segment was visually analyzed with regard to the presence of stenosis and its severity was classified as follows: no lesion, eccentric plaque (<30% diameter), mild lesion (30–49% stenosis), moderate lesion (50–69% diameter stenosis), severe stenosis (70–98% of diameter), subtotal stenosis (99%), or total occlusion (100%). Obstructive coronary artery disease (CAD) was defined as a stenosis ≥70% in at least one coronary segment, except left main stem where stenosis ≥50% was considered significant.[9]Significant lesions were classified according to Modified ACC/AHA Task Force Criteria for Lesion Morphology as Type A, B1, B2 and C lesions.[10]

The indication for *Guidezilla* use, efficacy and peri-procedural complications were noted. Success of the procedure was defined as the achievement of optimal angiographic outcome with no significant residual stenosis and a distal Thrombolysis in Myocardial Infarction (TIMI) 3 flow after stenting.[9] All peri-procedural complications were noted.

Patients were followed up during hospital stay and any adverse outcomes were noted.Data were processed and analyzed using software using SPSS 16.0 (Statistical Package for the Social Sciences by SPSS Inc., Chicago, IL, USA, 2007).

Results:

A total of 19 consecutive procedures (in 18 patients) were evaluated, (15 males and 3 females). Mean age was 62.3 ± 11.2 years and (range 43-81) years. 15 (83.33%) males and 3 (16.67%) females were included. Table I shows the baseline patient characteristics. A great majority of the subjects were dyslipidaemic (77.8%), followed by hypertensive (72.2%) and diabetic (66.7%). Smoking and CKD each comprised of 27.8% each. The most frequent indication for PCI among the study subjects was stable ischaemic heart disease (SIHD) which constituted 38.9%, followed by unstable angina (UA) comprising 33.3%. Non-ST elevation myocardial infarction (NSTEMI) and ST elevation myocardial infarction (STEMI) comprised of 16.7% and 11.1% respectively.The majority (55.6%) of patients undergoing PCI had normal LV systolic function, defined as LVEF of e"55%; (38.9% patient) had mild LV dysfunction (LVEF 45-54%) and 5.6%moderate LV dysfunction (LVEF 30- 44%) LV systolic dysfunction respectively.Majority (38.9%) of patients underwent PCI with the indication of stable ischaemic heart disease (SIHD) followed by unstable angina (33.3). Two (11.1%) of the patients presented with STEMI.

Table I

Patient baseline characteristics

Total Patients (n=18)	
Age in years (Mean ± SD)	62.3 ± 11.2 (range 43-81)
Gender	
Male	15 (83.33%)
Female	3 (16.67%)
Risk factors	
Diabetes	12 (66.7)
Hypertension	13 (72.2)
Dyslipidaemia	14 (77.8)
Smoker	5 (27.8)
Chronic kidney disease	5 (27.8)
Left ventricular ejection fraction (EF) %	
Normal (LV EF e"55%)	10 (55.6)
Mild LV dysfunction (LV EF 45 -54%)	7 (38.9)
Moderate LV dysfunction (LV EF 30 - 44%)	1 (5.6)
Indications for Percutaneous Coronary Intervention	
ST elevation myocardial infarction	2 (11.1)
Non- ST elevation myocardial infarction	3 (16.7)
Unstable angina	6 (33.3)
Stable ischaemic heart disease	7 (38.9)

Table II depicts the overall summary of lesion characteristics, procedural details, and complications. In all cases, it was possible to properly use the *Guidezilla*, obtaining a deep and selective intubation of the target artery. The target vessel was the left circumflex (LCx) coronary artery or obtuse marginal (OM) branch in the majority of cases (57.89%), followed by left anterior descending artery (26.3%) and right coronary artery (15.8%). The commonest challenge encountered requiring increased back-up support of Guide Extension Catheter was proximal angulation (63.2%) and severe calcification (47.4%). In two cases (10.5%) the indication for use was chronic total occlusion (CTO). Commonest type of lesion was ACC/ AHA lesion Type C (63.2%), followed by type B2 lesion (26.3%). Successful stent deployment was achieved in 16 of the 19 procedures (84.2%).

Table-II

Lesion characteristics, procedural details, and complications

Target vessel, n (%)	
LAD	5(26.3)
LCX	11(57.9)
RCA	3(15.8)
Proximity/ location of lesion, n (%)	
Proximal	5(26.3)
Mid	9(47.4)
Distal	5(26.3)
ACC/ AHA Lesions type, n (%)	
A	0 (0.0)
B1	2(10.5)
B2	5(26.3)
C	12(63.2)
Challenge requiring *Guidezilla,*n (%)	
Severe calcification	9(47.4)
Proximal tortuosity	4(21.1)
Chronic total occlusion	2(10.5)
Proximal angulation	12(63.2)
Stent type, n (%)	
BMS	2(11.1)
DES	16(88.9)
Procedural success, n (%)	16(84.2)
Procedural failure, n (%)	3(15.8)
Complications, n (%)	
Major complication	1(5.3)
Stent damage/ fracture	1(5.3)
Distal dissection	1(5.3)

Table III demonstrates the key angiographic, procedural data and procedural success pertaining to each case in which *Guidezilla* was used. In case number 6, PCI was opted for despite a relatively high Syntax score of case 27, as the patient refused to undergo coronary artery bypass graft (CABG) surgery.

Table-III

Summary of angiographic, procedural data and procedural success pertaining to each case

Case no.	Culprit artery	ACC/AHA lesion type	Syntax Score	Challenge	Guide	Wire	Balloon support	Stent type and size, mm	Result
1	M to D-RCA	C	17	Tortuosity and calcification	AR2	Sion Blue	no	Cre8 4x38, AvantGarde3.5 ×12, CC Flex3.0x08	Distal dissectio n
2	P-LAD	C		Proximal angulation and calcification	JL 3.5	Sion Blue	no	Xience Prime2.75x28	Success
3	M-LCx to OM2	B2	8	Proximal angulation	JL 3.0	Sion Blue	no	Promus Element Plus 2.75x28, 3.0x38	Success
4	PLB	C	20.5	Tortuosity	JR 3.5	Sion Blue	no	Endeavor Resolute2.25x24, 3.0x12	Success
5	M-LCx to Principal OM	C	11	Proximal angulation	XB 3.5	Sion Blue	no	Promus Element Plus 2.5x20	Success
6	P-LAD	B2	27	Proximal angulation and calcification	JL 3.5	Sion Blue	no	Promus Premier2.5x16	Success
7	M-LCx to Principal OM	C	12	Tortuosity	JL 3.5	Sion Blue	no	Promus Element Plus2.5x32	Success
8	M-LCx	B1	3	proximal angulation	JL 3.0	Sion Blue	yes	Promus Premier2.25x32	Success
9	Principal OM	C		CTO, proximal angulation, Calcification	XB 3.0	PT2	no	AvantGarde-Stent damage	Failure
10	D-LCx	C		proximal angulation and calcification	BL 3.0	PT2	yes	Xience V 2.5x23,2.75x18	Success
11	P-LAD	C	18	Calcification	XB 3.5	Sion Blue	no	Promus Premier2.5x38	Success
12	P-LCx	C		CTO,Calcification and proximal angulation	JL 3.5	PT2	yes	Stent not deployed	Failure
13	M-RCA	C	25.5	Tortuous and calcification	JR 3.5	Sion Blue	no	Promus Premier2.75x24	Success
14	P-LAD	B2		Calcification	JL 3.0	Sion Blue	no	Promus Premier2.25x32	Success
15	OM2	B1	13	Proximal angulation	JL 3.0	Sion Blue	no	Promus Element Plus2.5x20	Success
16	D-LCx	B2	5	Proximal angulation	BL 3.5	Sion Blue	no	Xience Alpine 2.75x23	Success
17	M-LCx to Principal OM	C		Proximal angulation	XB 3.5	Sion Blue	no	Ultimaster3.0x38	Success
18a	D-LAD	B2		high LM take-off, proximal angulation	JL 3.0	PT2	no	Promus Premier-2.25x20	Success
18b	L-PDA	C		high LM take-off, calcification, distal-most lesion	JL 3.0	Sion Blue	yes	Stent not deployed	Failure

3 cases were recorded as unsuccessful (Case numbers 9, 12 and 18b), all of which were related to LCX or OM branch as the target vessel. Among them, there was stent damage in case number 9, which was observed prior to deployment of stent and as such is considered to be a complication mediated by Guidezilla. As such, two small cobalt chromium stents sized 2.25x16mm and 2.5x16mm were deployed instead of the longer DES stent which was damaged (Figures 1 and 2) in order to traverse the proximal angulation.

Distal dissection *after* deployment of stent was noted in case number 1, and as such, was a complication that was not mediated by *Guidezilla*.Drug eluting stents (DES) were predominantly used among the patients in this series, with the exception being in case 9, described above.

Stent deployment was not possible in two cases (numbers 12 and 18b). In case number 12, failure of stent deployment in proximal LCXwas due to heavy calcification, proximal angulation and the lesion being a CTO in an 81-year-old elderly male.

In case number 18b, stenting of the left- posterior descending artery (L-PDA) was unsuccessful due to heavy calcification, high left-main take off and distal-most location of the target lesion. The majority of stents deployed were drug-eluting stents (88.9%), except two cases (11.1%) in which cobalt chromium stents were deployed. Only a single major complication related to *Guidezilla* was reported, that of stent damage in case number 9.

Minor complications such as radial spasm was observed in 3 cases, and pressure dampening in 4 cases both of which are known to be acceptable complications in the trans-radial use of Guide Extension Catheter.Radial spasm was successfully overcome by the use of injectable fentanyl and verapamil. Pressure dampening was managed by careful pullback of the guide extension catheter, and thus was devoid of patient-related ischaemic symptoms. In-hospital follow up of all patients was uneventful, with no further complications detected.

Fig.-1: *Image shows the deformed distal end of stent balloon showing stent strut fracture*

Fig.-2: *Zoomed in view of distal end of stent balloon showing stent strut fracture (arrow).*

Discussion:

The strength of support offered by the radial approach is significantly lower thanthat for femoral access, which confers an extra difficultyin the percutaneous treatment of complex coronary lesions.[11] The results of this study show that the Guide Extension Catheter was useful tool for approaching challenging coronary lesionsusing radial access. Most of the lesions in our study were of ACC/AHA types B2 and C, reflecting the complexity of the lesions requiring extra back-up support.

In our present study, the lesion morphologyis very much similar to Dursun et al. (2016)[12] who presented a 64 patients study using the *GuideLiner®* catheter, with the majority of patients having ACC/AHA types B2/C lesions.In the present study success of stent deployment is 16 out of 19 cases (84.2%), which also very much resembles the study by to Dursun et al. (2016)[12], although it was through trans-femoral route. In addition, we found that this device showed an excellent safety profile since no coronary dissection was induced. This is also true for our study, there was no major complication other than a stent damage in undeployment condition.

García-Blas et al. (2015)[13] reported the usefulness and Safety of a Guide Catheter Extension System of PCI done by trans-radial route. In a study that showed striking similarities to our study in terms of patient profile, number and success rates, they reported successful stent deployment in 16 cases out of 18(81%) in comparison to 84.1% reported in our study.Unsuccessful cases were a chronic total occlusion and a diffusely diseased LAD. They also reported a single coronary dissection as the only significant peri-procedural complication.

Our results also complied with that of Insights from the *Twenty GuideLiner registry reported by de Man FH et al. (2012)* [14]who reported similar lesion morphologies and but differences in terms of challenges requiring the use of guide extension catheter.Where 23% of lesions were calcified and 17% were CTO. In comparison, our series reported 47.4% of heavy calcification and 10.5% CTO.[14] They reported a device success rate of 93% (65/70) with only two minor complications of air embolism and stent dislodgement.Our study also reported a single significant complication of stent damage (stent fracture at the distal end of the stent) prior to its deployment, which is a complication mediated by *Guidezilla*.

The most common indication for *Guidezilla* use for back-up support in a complex coronary lesion where there is difficulty or inability to place a stent or balloon. This problem occurs mainly in complex calcified lesions or tortuous arteries, as reflectedin the type of lesions treated in our series. Using *Guidezilla* support resulted in optimal angiographic results in 84.21% ofcases in our series, cases in which successful stent deployment would not have been otherwise been possible. These results are also consistent with thosefrom other studies, so we believe that this level of efficacy makes this device a very useful tool and a first-line alternativein this kind of selected cases.[14-17]Thus, deep coronary intubation with a guide catheter is oneof the strategies that can increase support, but is limited byits aggressiveness on the vessel wall.[5] Moreover, whileintubating the guide, aortic wall contact is lost and the stabilityof the catheter decreases. The specific design of theproximal hypotube of *Guidezilla* minimizes arterial wall trauma and allows theguiding catheter to remain steady in the aorta while theextensor device advances in the artery.

The complication of stent damage described is the deformation or even dislodgement of the stent before its deployment. This may occur at the transition between the hypotube and the monorail, especially if this area is locatedon a curve of the guide catheter.[14,18,19]This is one of the challenges encountered while using *Guidezilla* and operators need to be wary of this complication, as occurred in case number 9 in our series.

The present study, albeit small, provides some "real-life" insight into efficacy, limitations, and the potential risk of this device. However, it is not without limitations. Thispreliminary study included a relatively small number of patients from a single center, and as such may not be able to provide a scientific level of insight in terms of efficacy andcomplications, that may have been derived from a larger, randomized study. Furthermore, we cannot exclude that in certain cases, alternative techniques to improve back-up and support (e.g., deep intubations or buddy wires) could also have led to procedural success.

Conclusion:

The percutaneous treatment of complex coronary lesions is still a challenging problem, especially when using the Transradial approach. This study has demonstrated the safe and effective use of Guidezilla for the percutaneous treatment of complex lesions in the presence of unfavorable tortuous coronary anatomies and in complex, heavily calcified lesions, which may have otherwise been considered unsuitable for PCI. Its use increased the support for advancing angioplasty balloons and stents using the radial approach, thereby improving the success rate of the procedures. Furthermore, with this back-up support it is possible to deploy a single longer stent in lesions which were previously stented with two small stents owing to complex anatomy. Thus, it has good economic value as well. Procedural success rate was high and there were no major complications. In case of the failure of "traditional tips and tricks" to improve the back-up in challenging cases, it can be employed as a "bail-out strategy". However, with the growing experience with such a device, it can also be used as a first strategy to face anatomical difficulties.

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