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Adverse Events Associated with the Use of Guide Extension Catheters during Percutaneous Coronary Intervention: Reports from the Manufacturer and User Facility Device Experience (MAUDE) database

Yuefeng Chen [a], Arhum A. Shah [a], Evan Shlofmitz [a], Nauman Khalid [a], Anees Musallam [a], Jaffar M. Khan [a], Micaela Iantorno [a], Deepakraj Gajanana [a], Toby Rogers [a,b], Hayder Hashim [a], Nelson L. Bernardo [a], Ron Waksman [a,*]

[a] Section of Interventional Cardiology, MedStar Washington Hospital Center, Washington, DC, United States of America
[b] Cardiovascular Branch, Division of Intramural Research, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, United States of America

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ABSTRACT

Background/purpose: We aimed to assess the reported complications and event modes for the GuideLiner and Guidezilla extension catheters.
Methods/materials: The US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database was queried for reported events.
Results: Of the 65 cases with reported GuideLiner-related issues, 15 (23%) involved the inability to pass equipment through or damage to percutaneous coronary intervention (PCI) devices in the GuideLiner catheter, 38 (58%) involved GuideLiner catheter fracture, 9 (14%) involved coronary artery dissection, 2 (3%) involved coronary artery perforation, and 1 (1.5%) involved thrombus formation in the catheter. Of the 408 cases with reported Guidezilla-related issues, 53 (13%) involved inability to pass or damaged PCI devices into the Guidezilla catheter, 117 (29%) involved inability to advance the Guidezilla catheter to the target lesion, 59 (14%) involved kinked Guidezilla catheter, mostly because of partial or complete catheter fracture upon further investigation, 164 (40%) involved a broken Guidezilla catheter, 10 (2.5%) involved coronary artery dissection, 2 (0.5%) involved coronary artery perforation, 1 (0.2%)involved aortic dissection, 1 (0.2%) involved thrombosis formation, and 1 (0.2%) involved no-reflow phenomenon.
Conclusions: Findings from the MAUDE database highlight the complications and modes of events associated with the use of GuideLiner and Guidezilla extension catheters.
Summary: To assess the reported complications and event modes for the GuideLiner and Guidezilla extension catheters, the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database was queried. There were more reports on Guidezilla-related events during the search period. The events for both extension catheters mainly involved the inability to pass equipment through or damage to percutaneous coronary intervention (PCI) devices in the extension catheter, extension catheter fracture, coronary artery dissection and perforation and, occasionally, the death of the patients.

1. Introduction

With the increase in complexity of lesions undergoing percutaneous coronary intervention (PCI), extension catheters have been increasingly used for extra support and for facilitating the delivery of catheter-based devices to the target lesion. The 2 most commonly used extension catheters in the United States are GuideLiner (Teleflex, Minneapolis, MN) and Guidezilla (Boston Scientific, Maple Grove, MN).

The GuideLiner catheter is a coaxial monorail extension system. It consists of a coaxial exchange system with a soft, flexible extension of 20 cm connected to a stainless steel collar and a 125 mm compact metal hypotube. It has an inner diameter of 1 Fr size smaller than the guiding catheter. The GuideLiner V2 catheter has an additional extension of 5 cm and has replaced the stainless steel collar with a polymer collar for increased flexibility. The more recent GuideLiner V3 catheter has a 25 cm extension connecting to the collar and a 17 cm half-pipe

Abbreviations: CABG, coronary artery bypass grafting surgery; FDA, Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience; LAD, left anterior descending coronary artery; LCx, left circumflex coronary artery; LM, left main coronary artery; PCI, percutaneous coronary intervention; RCA, right coronary artery.

* Corresponding author at: MedStar Washington Hospital Center, 110 Irving St., NW, Suite 4B-1, Washington, DC 20010, United States of America.
E-mail address: ron.waksman@medstar.net (R. Waksman).

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before the collar designed to facilitate smooth device entry and delivery. It is available in 5 sizes: 5 Fr, 5.5 Fr, 6 Fr, 7 Fr, and 8 Fr [1,2].

The Guidezilla catheter is a rapid exchange extension catheter system. It has a 25 cm distal extension connected to a stainless steel collar with a stainless steel hypotube in the proximal shaft extending into the collar. The Guidezilla II catheter has replaced the stainless steel collar with a platinum iridium helical collar and reduced the hypotube transition to 6 mm. The Guidezilla II catheter is available in 3 sizes: 6 Fr, 7 Fr, and 8 Fr, with a 40 cm extension also available for the 6 Fr system [3].

Studies have shown that these catheters are effective at increasing procedural success rate in complex percutaneous interventions with a relatively low adverse event and complication rate, consisting mainly of coronary artery dissection or perforation and stent dislodgement [2,4–8]. However, comprehensive analysis of extension catheter-related adverse events is limited. Therefore, we used the post-marketing surveillance data from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database to assess the reported complications and modes of events for the GuideLiner and Guidezilla extension catheters.

2. Materials and methods

2.1. MAUDE database

The MAUDE database is a reporting system mandated by the FDA for post-market surveillance. It includes reports of adverse events involving medical devices that occur after device approval. It allows for post-market safety monitoring of approved devices [9,10]. The database is publically searchable online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. MAUDE reporting can be mandatory (for manufacturers, importers, and device user facilities) or voluntary (for healthcare professionals, patients, and consumers). The reporting system is updated monthly. Each medical device report contains information on the device, event date, whether the device was returned to the manufacturer, date returned, free text description of the event by the user, and manufacturer's narrative.

2.2. Data collection

The MAUDE database was queried for all reported events involving the PCI extension catheters GuideLiner or Guidezilla. Two independent reviewers (YC and AS) identified 65 device reports for GuideLiner from May 1, 2010, to August 30, 2018, and 408 device reports for Guidezilla from June 1, 2016, to August 30, 2018. All reports were screened, and only events that occurred during PCI were included for the final analysis. Modes of events and device-related patient complications were analyzed.

3. Results

There were 65 cases of GuideLiner-related events and 408 cases of Guidezilla-related events reported in the search periods. Most of the reports mentioned that the device was used in a severely calcified lesion and tortuous coronary artery. The size and the generation of the catheters were not routinely specified. Of note, 29 cases were related to GuideLiner V2, 2 cases were related to GuideLiner V3, and 95 cases were related to Guidezilla II. The catheters were returned to the manufacturer for further investigation in 13 of 65 (20%) GuideLiner cases and 274 of 408 (67%) Guidezilla cases, but no technical explanation was provided for the catheter fracture or damage.

3.1. Lesion location

For GuideLiner catheters, 1 device was used for left main coronary artery (LM) disease, 3 for left anterior descending coronary artery (LAD) disease, 3 for left circumflex coronary artery (LCx) disease, 8 for right coronary artery (RCA) disease and, in the remaining 50 cases, the target vessel was not specified. For Guidezilla catheters, 5 were used for LM disease, 91 for LAD disease, 45 for LCx disease, 86 for RCA disease, 2 for ramus intermedius artery disease, 1 for saphenous vein graft disease and, in the remaining 178 cases, the target vessel was not specified (Table 1).

Table 1
Target vessels.

	GuideLiner	Guidezilla
Number of events	65	408
Target vessels		
LM, n (%)	1 (1.5%)	5 (1.2%)
LAD, n (%)	3 (4.6%)	91 (22.3%)
Lcx, n (%)	3 (4.6%)	45 (11%)
RCA, n (%)	8 (12.3%)	86 (21%)
RI, n (%)		2 (0.5%)
SVG, n (%)		1 (0.2%)
Unspecified, n (%)	50 (77%)	178 (43.6%)

LM: left main coronary artery; LAD: left anterior descending artery; Lcx: left circumflex artery; RCA: right coronary artery; RI: ramus intermediate artery; SVG: saphenous vein graft.

3.2. Modes of adverse events

The modes of adverse events are reported in Table 2. Of the 65 reported GuideLiner-related issues, 15 (23%) involved inability to pass or damaged PCI devices into the GuideLiner catheter, of which 5 had difficulty advancing the stent and 8 had stent detachment from the stent balloon prior to deployment. Thirty-eight (58%) involved GuideLiner catheter fracture, with the majority at the collar and with the fractured segments having been retrieved non-surgically without further complications. Nine (14%) involved coronary artery dissection, of which 5 were successfully treated with stenting and 2 with coronary artery bypass grafting surgery (CABG), while treatment was unknown for 1 patient. Two (3%) involved coronary artery perforation, of which 1 was successfully treated with stenting. One (1.5%) involved thrombus formation in the catheter, but no further complications were reported after the catheter was removed. There were 2 reported deaths: 1 following a coronary artery dissection and the other in the setting of a coronary artery perforation.

Of the 408 reported Guidezilla-related issues, 53 (13%) involved inability to pass or damaged PCI devices into the Guidezilla catheter, of which 21 had difficulty advancing the stent, 9 had the stent damaged or detached from the stent balloon, and 23 had difficulty advancing the other PCI devices. One hundred seventeen (29%) reports involved inability to advance the Guidezilla catheter to the target lesion, of

Table 2
Mode of adverse events.

Mode of events	GuideLiner (n = 65)	Guidezilla (n = 408)
Unable to pass or damaged PCI devices, n (%)	15 (23%)	53 (13%)
Difficulty advancing stent	5	21
Stent damage or detached from the stent balloon	8	9
Difficulty advancing the other PCI devices	2	23
Unable to advance or pass catheter to target lesion, n (%)		117 (29%)
Catheter complete fracture		40
Catheter partial fracture		62
Catheter kinked, n (%)		59 (14%)
Catheter fracture, n (%)	38 (58%)	164 (40%)
Coronary artery dissection, n (%)	9 (14%)	10 (2.5%)
Coronary artery perforation, n (%)	3 (3%)	2 (0.5%)
Aortic dissection, n (%)		1(0.2%)
Thrombus formation in the catheter, n (%)	1 (1.5%)	1 (0.2%)
No-reflow phenomenon and hypotension		1 (0.2%)
Death, n (%)	2 (3%)	1 (0.2%)

which 40 were found to have complete catheter separation at the collar and 62 had partial separation at the collar on visual inspection later. Fifty-nine (14%) involved kinked Guidezilla catheter, mostly because of partial or complete catheter fracture at the collar upon further investigation, except 9 devices that had different degree of damage to the catheter. One hundred sixty-four (40%) reports involved broken Guidezilla catheters, with most of the cases at the collar and the fractured segments having been retrieved non-surgically without further complications, except for 1 patient who underwent CABG but the fragment was not removed. Ten (2.5%) cases involved coronary artery dissection, of which 6 were successfully treated with stenting, 2 with CABG, and 1 with conservative management after failed stenting. Two (0.5%) cases involved coronary artery perforations that were contained by prolonged balloon inflation. One (0.2%) case involved aortic dissection that was transferred for surgery; 1 (0.2%) involved thrombus formation at the collar but no further complications were noted after removing the catheter; 1 (0.2%) involved no-reflow phenomenon and hypotension, which was treated with cardiopulmonary support for 1 week; and 1 patient died following coronary artery dissection.

4. Discussion

The main findings of this study are as follows: There are more reported adverse events for Guidezilla extension catheter than GuideLiner extension catheter in the MAUDE database; and the most common extension catheter-related events are catheter or other PCI device damage or, less commonly, coronary artery dissection or perforation, aortic dissection, and occasionally, thrombus formation and death.

The extension catheters are designed for deep seating in the coronary artery to provide additional support and to assist the delivery of interventional devices to the target lesion during PCI. The GuideLiner and Guidezilla catheters are available in the United States. The former was approved by the FDA in November 2009 and the latter in March 2013. Both have been widely used to support PCI via both the radial and femoral approaches for complex coronary anatomy, including heavy calcification, extreme vessel tortuosity and angulation, previously deployed proximal stent, chronic total occlusion, anomalous origin of coronary artery, and bypass grafts. The precise number of devices used during the study period is unknown. It has been estimated that an extension catheter is used in approximately 1 in 20 PCI cases [11,12]. With the support of extension catheters, the procedure success rate of complex PCI has been reported to be 80–99% [2,4–8,13]. They can also be used for thrombus aspiration, retrieval of entrapped devices, and selective contrast injection [11].

The safety and efficacy of both catheters has been well-established. For the GuideLiner catheter, the rate for failed PCI device delivery ranges from 7% to 19.8% because of prohibitive vessel anatomy, insufficient advancement of GuideLiner catheter, inability to cross the lesion with wire or balloon, catheter kink, oversized stent, and clinical reasons [5,6,12]. The incidence of stent dislodgement was 0.7% to 2.2% [4,6,12]. The incidence of other complications was as follows: 0.7% to 6% for coronary dissection [5,6,12], 1.5% for air embolism [4], 0.3% for ventricular tachycardia, and 1.1% for pressure damping and hypotension with catheter intubation [6]. A decline in device-associated complications over time was noted by Waterbury et al. and was considered to be attributed to operator learning curve, patient selection, and improvement in catheter design [6]. Compared to the first-generation device, the GuideLiner V2 catheter has additional extension of 5 cm and the stainless steel collar is replaced with a polymer collar for increased flexibility. The GuideLiner V3 catheter adds a 17 cm half-pipe before the collar, which is designed to facilitate smooth device entry and delivery [1]. Alkhalil et al. reported that with the GuideLiner V2 catheter, the procedural success rate was 86%, and the adverse event rate was 10% for proximal collar and stent interaction with stent deformation or stripping, 1% for longitudinal stent deformation within the target vessel, and 2% for other causes of failed stent delivery. With the GuideLiner V3 catheter, the procedural success rate was 93%, and the averse event rate was 0.8% for longitudinal stent deformation, 1.6% for stent stripping due to interaction at the leading edge of the catheter, and there was no proximal collar/stent interaction [14]. This study suggests that the modification of V3 GuideLiner might have contributed to the decrease in catheter-related complications.

For the Guidezilla catheter, the rate for failed PCI device delivery ranges from 1% to 7.7% because of difficult vessel anatomy and complex lesion morphology [7,8]. The incidence of stent stripping was 3.8% to 6% [8,15], and the incidence of coronary dissection was 0.5% [7]. The new generation of Guidezilla catheter incorporates design changes, including replacing the stainless steel collar with a platinum iridium helical collar to improve visibility and smooth device interaction and reducing the hypotube length from 19 mm to 6 mm to improve device interaction. No previous study has compared the efficacy and safety of the 2 different generations of Guidezilla catheters.

The MAUDE database demonstrates that in most of the reported cases, the catheter was used in a severely calcified and tortuous vessel, but the adverse event can occur in any of the major coronary arteries or bypass graft. It should be noted that there were more reports of device failure and complications on the Guidezilla catheter, but without a known denominator, the incidence cannot be estimated. Currently, extension catheters are recommended as an adjunctive tool for performing complex PCIs. Direct comparison between the 2 catheter systems has not been reported. It is beyond the scope of this study to compare system performance and assess whether one device was associated with fewer complications. It should also be noted that when there is difficulty advancing the Guidezilla catheter or kinked catheter, most likely the catheter has completely or partially separated and should be withdrawn. In some cases, an extension catheter was involved in coronary artery dissection or perforation, but whether the catheter was the major cause of the issue is hard to determine because multiple devices were used. Death related to extension catheter-induced complications was not previously reported in the literature but was reported in the MAUDE database.

Precautions should always be taken to avoid adverse events when an extension catheter is used. When advancing an extension catheter through a curved guide catheter, unintentional rotation of the extension catheter can occur, resulting in tangling with the guidewire [16]. The extension catheter should not be twisted during advancement over the guidewire, and forceful manipulation should be avoided when inserting a 4.0 mm stent into the extension catheter [7]. Intracoronary pressure should be closely monitored and catheter pullback performed as necessary when pressure damping and hypotension occur. Withdrawal of the system should be performed when resistance is encountered upon advancing the catheter or when the catheter is damaged or broken. Fractured segments can generally be retrieved with snaring, but sometimes surgery may be necessary. Coronary artery dissection or perforation can be managed with stenting or, occasionally, surgery. Thrombus formation can be managed with catheter removal and optimal anticoagulation. We have found the following strategies to be helpful to avoid extension catheter-related complications on our practice: Advance the extension catheter over a balloon shaft; avoid direct injection using a powered injector through the extension catheter since the concentrated jet can result in coronary artery perforation or, more commonly, dissection; assure full and therapeutic anticoagulation during the procedure; maintain activated clotting time ≥ 250 s; and aspire and de-air the guide catheter after removal of the extension catheter.

4.1. Limitations

There are several limitations with this study that need to be considered: 1) The MAUDE database reporting is inconsistent, and complications can be underreported; 2) Details regarding the procedure are generally limited, making it difficult to establish the cause of the reported events, such as operator error, interaction with other devices, or device defect; and 3) The total number of reported devices used by the reporting

facility or from the manufacturer during the research timeframe is unavailable, so the incidence of adverse events cannot be estimated.

5. Conclusions

Findings from the MAUDE database highlight the complications and modes of adverse events associated with the use of GuideLiner and Guidezilla extension catheters. The incidence of the events is unknown, but there were more reports of Guidezilla-related events during the search periods. Operators should be aware of possible device-related complications and use guide extension catheters with caution to prevent and minimize adverse events.

Declarations of interest

Ron Waksman: Advisory Board: Abbott Vascular, Amgen, Boston Scientific, Medtronic, Philips Volcano, Pi-Cardia LTD, Cardioset; Consultant: Abbott Vascular, Amgen, Biosensors, Biotronik, Boston Scientific, Medtronic, Philips Volcano, Pi-Cardia LTD, Cardioset; Grant Support: Abbott Vascular, AstraZeneca, Biosensors, Biotronik, Boston Scientific, Chiesi; Speakers Bureau: AstraZeneca, Chiesi; Investor: MedAlliance.

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Nelson L. Bernardo: Conducts training for Cook Medical; Speakers Bureau for Medtronic.

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References

[1] Boukhris M, Azzarelli S, Tomasello SD, Elhadj ZI, Marza F, Galassi AR. The GuideLiner catheter: a useful tool in the armamentarium of the interventional cardiologist. J Tehran Heart Cent 2015;10:208–14.
[2] Huang MS, Wu CI, Chang FH, Chang HY, Lee PT, Chen JY, et al. The efficacy and safety of using extension catheters in complex coronary interventions: a single center experience. Acta Cardiol Sin 2017;33:468–76.
[3] Waggoner T, Desai H, Sanghvi K. A unique complication of the GuideZilla guide extension support catheter and the risk of stent stripping in interventional & endovascular interventions. Indian Heart J 2015;67:381–4.
[4] de Man FH, Tandjung K, Hartmann M, van Houwelingen KG, Stoel MG, Louwerenburg HW, et al. Usefulness and safety of the GuideLiner catheter to enhance intubation and support of guide catheters: insights from the Twente GuideLiner registry. EuroIntervention 2012;8:336–44.
[5] Garcia-Blas S, Nunez J, Mainar L, Minana G, Bonanad C, Racugno P, et al. Usefulness and safety of a guide catheter extension system for the percutaneous treatment of complex coronary lesions by a transradial approach. Med Princ Pract 2015;24:171–7.
[6] Waterbury TM, Sorajja P, Bell MR, Lennon RJ, Mathew V, Singh M, et al. Experience and complications associated with use of guide extension catheters in percutaneous coronary intervention. Catheter Cardiovasc Interv 2016;88:1057–65.
[7] Ma J, Hou L, Qian J, Ge L, Zhang F, Chang S, et al. The safety and feasibility of GuideZilla catheter in complex coronary interventions and an observational study. Medicine (Baltimore) 2017;96:e8172.
[8] Chen CY, Huang YY, Tang L, Hu XQ, Fang ZF, Zhou SH. Guidezilla extension catheter for percutaneous interventional therapy of complex lesions via a transradial approach: case series from a single-center experience. Cardiol J 2018;25:171–8.
[9] Gurtcheff SE. Introduction to the MAUDE database. Clin Obstet Gynecol 2008;51:120–3.
[10] Omar A, Pendyala LK, Ormiston JA, Waksman R. Review: stent fracture in the drug-eluting stent era. Cardiovasc Revasc Med 2016;17:404–11.
[11] Duong T, Christopoulos G, Luna M, Christakopoulos G, Master RG, Rangan BV, et al. Frequency, indications, and outcomes of guide catheter extension use in percutaneous coronary intervention. J Invasive Cardiol 2015;27:E211–5.
[12] Sharma D, Shah A, Osten M, Ing D, Barolet A, Overgaard CB, et al. Efficacy and safety of the GuideLiner mother-in-child guide catheter extension in percutaneous coronary intervention. J Interv Cardiol 2017;30:46–55.
[13] Guelker JE, Blockhaus C, Kroeger K, Wehner R, Klues H, Bufe A. The GuideLiner catheter: a supportive tool in percutaneous coronary intervention of chronic total occlusion. J Saudi Heart Assoc 2018;30:69–74.
[14] Alkhalil M, Smyth A, Walsh SJ, McQuillan C, Spence MS, Owens CG, et al. Did the use of the Guideliner V2(TM) guide catheter extension increase complications? A review of the incidence of complications related to the use of the V2 catheter, the influence of right brachiocephalic arterial anatomy and the redesign of the V3(TM) Guideliner and clinical outcomes. Open Heart 2016;3:e000331.
[15] Ma M, Diao KY, Liu XJ, He Y. Early clinical experience with Guidezilla for transradial interventions in China. Sci Rep 2018;8:5444.
[16] Hashimoto S, Takahashi A, Yamada T, Mizuguchi Y, Taniguchi N, Hata T, et al. Spontaneous rotation of the monorail-type guide extension support catheter during advancement of a curved guiding catheter: the potential hazard of twisting with the coronary guidewire. Cardiovasc Interv Ther 2018;33:379–83.