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Authors: Michael Megaly, M.D, MS; Ramy Sedhom, M.D; Ashish Pershad, M.D; Evangelia Vemmou, M.D; Ilias Nikolakopoulos, M.D; Judit Karacsonyi, M.D, PhD; Marwan Saad, M.D, PhD; Amgad Mentias, M.D; Santiago Garcia, M.D; Dimitri Karmpaliotis, M.D; Mohaned Egred, M.D; M Nicholas Burke, M.D; Emmanouil S. Brilakis, M.D, PhD

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Complications and failure modes of coronary microcatheters: Insights from the manufacturer and user facility device experience (MAUDE) database

Michael Megaly, MD, MS[a,b*], Ramy Sedhom, MD[c*], Ashish Pershad, MD[d], Evangelia Vemmou, MD,[a] Ilias Nikolakopoulos, MD,[a] Judit Karacsonyi, MD, PhD,[a] Marwan Saad, MD, PhD,[e] Amgad Mentias, MD,[f] Santiago Garcia, MD,[a] Dimitri Karmpaliotis, MD,[g] Mohaned Egred, MD,[h] M Nicholas Burke, MD[a], Emmanouil S. Brilakis, MD, PhD[a]

[a] Minneapolis Heart Institute, Abbott Northwestern Hospital, Minneapolis, MN

[b] Hennepin Healthcare, Minneapolis, MN

[c] Albert Einstein Medical Center, Philadelphia, PA

[d] Banner University Medical Center/ University of Arizona, Phoenix, AZ

[e] The Warren Alpert School of Medicine at Brown University, Providence, RI, USA

[f] Roy and Lucille J. Carver College of Medicine, University of Iowa Hospitals and Clinics, Iowa City, Iowa, USA

[g] Columbia University Medical Center, New York, New York

[h] Freeman Hospital, Newcastle upon Tyne Hospitals, NHS Foundation Trust, Newcastle, UK

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Short title: coronary microcatheters complications

*****both authors contributed equally

Address for correspondence

Emmanouil S. Brilakis, MD, Ph.D.

Minneapolis Heart Institute and Minneapolis Heart Institute Foundation, Abbott Northwestern Hospital, Minneapolis, MN, USA.

920 E 28th Street #300, Minneapolis, Minnesota 55407

E-mail: esbrilakis@gmail.com

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Classifications: calcific stenosis, chronic coronary total occlusion, diffused disease

Abbreviations

MC: microcatheters

PCI: percutaneous coronary intervention

CTO: chronic total occlusion

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Introduction

Coronary microcatheters (MCs) are often used in complex and chronic total occlusion (CTO) percutaneous coronary intervention (PCI) [1, 2] to facilitate guidewire manipulation and exchanges, and enhance their penetration force. Coronary MCs can be classified as high profile, low profile, angulated, dual lumen, and plaque-modifying [1]. Despite extensive clinical use, the failure modes of these devices have not been systematically studied. We queried the "Manufacturer and User Facility Device Experience" (MAUDE) database for reports on the most commonly used coronary MCs to better understand their failure modes.

Methods

The MAUDE is an online database created by the Food and Drug Administration (FDA) enlisting adverse events caused by approved medical devices. Reporting is either mandatory (for manufacturers and device user facilities) or voluntary (for healthcare professionals, patients, and consumers). We searched the database from January 2010 to January 2020 for reports on the most commonly used coronary MCs: Corsair and Corsair Pro (Asahi Intecc, Nagoya, Japan), Caravel (Asahi Intecc), Finecross (Terumo, Somerset, New Jersey), and the Turnpike family: Turnpike, Turnpike LP, Turnpike Gold, and Turnpike Spiral (Teleflex, Wayne, Pennsylvania, USA). The database was last accessed on January 25th, 2020, by two independent reviewers (RS and MM). The MAUDE database is publicly available and de-identified. Therefore, no institutional review board approval was required for this study.

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The outcomes of the study included MC failure modes and their clinical consequences. Multiple mechanisms of failure were possible for each reported case. Categorical variables were described as numbers and percentages. All statistical calculations were performed with IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp (2017).

Results

A total of 467 reports were found during the study period. After the exclusion of peripheral interventions, duplicate reports, and unclear reports, our final cohort included 378 coronary MCs events (**Figure 1).** Approximately 37% of the lesions were CTOs, with the retrograde approach used in 32.6% of those procedures (**Supplementary Table 1)**

The most commonly reported failure mechanism was tip fracture (80.7%). Tip fracture was associated with over-torquing (46.2%) or forceful pulling of the MC (26.6%). The tip was retrieved in 35.7% of the cases. Other failure mechanisms included the MC tip getting stuck in the lesion (33.6%), the guidewire getting stuck in the MC (10.3%), proximal shaft and hub separation (5.3%), shaft fracture or twisting (1.1%), and outer coil or polymer dislodgement (2.1%) **(Figure 2, Table 1).** The most commonly reported clinical consequences of MC failure was aborted PCI (14.6%) and conversion to surgery (7.1%)**.** The mechanism of failure and clinical consequences of each microcatheter are shown in **Supplementary Table 2.**

Discussion

Our study is the first to systematically report the failure modes of commonly used coronary MCs. The principal findings are that: 1) the most commonly reported MC failure mode

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was tip fracture (80.7%), most commonly due to over-torquing (46.2%) and forceful pulling of the MC (26.6%); 2) the primary mechanism of tip fracture of non-torqueable MCs (e.g., Caravel) was forceful pulling of the MC; and 3) the primary mechanism for tip fracture in high profile MCs (e.g., Corsair) was over-torquing.

In our analysis, the most commonly reported failure mechanism was tip fracture secondary to over-torquing and forceful pulling of the MC after it became stuck in the lesion. It was most commonly observed in low profile MCs, which have a weaker connection between tip and shaft. The tip was retrieved successfully in 35.7% of cases. Operators need to be familiar with the manufacturer's instructions for use:low profile MCs (e.g., Caravel) should not be torqued, as torquing may predispore to tip fracture. Such microcatheters should also not be used in heavily calcified lesions due to increased risk of tip entrapment [3]. When MC tip fracture occurs, attempts can be made for retrieval using various techniques[4], such as snares or twirling guidewires; alternatively, the fractured tip can be left in situ, which is often the preferred option [5], with the lost tip often covered with a stent [3].

Prolonged guidewire manipulation through a MC may result in guidewire entrapment. In our analysis, entrapment was reported in 33.6% of cases, mostly with large MCs. Flushing with saline before insertion may help prevent this complication. If the guidewire starts feeling "sticky," the MC should be replaced to avoid encasement within the MC that may require removal of the entire system, resulting in loss of wire position.

Limitations

Our study is a retrospective analysis from the MAUDE database with the selection bias resulting from optional reporting by healthcare professionals. There is potential for significant

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underreporting of these events given the voluntary nature of disclosure. Second, the nature of the database limits the accuracy of the correlation between the device failure and clinical adverse events. Finally, the incidence of microcatheter failure cannot de determined, as the study lacks a denominator.

Conclusions

Coronary MCs are essential tools in contemporary PCI beyond CTO PCI. The most common failure mechanism reported in the MAUDE database was MC tip fracture due to over-torquing and forceful pulling. Operators should be aware of MCs' limitations and mechanisms of failure to prevent malfunctions and be ready to manage them should they occur.

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Impact on daily practice

Our study is the first systematic report of coronary microcatheters malfunction. The most commonly reported MC failure mechanism was tip fracture, most commonly due to over-torquing and forceful pulling of the MC. We encourage the systematic collection of the frequency and type of microcatheter failure in prospective registries, which would allow determining the prevalence of microcatheter malfunction and optimal prevention and treatment strategies

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Conflicts of interest

Santiago Garcia: consultant for Surmodics, Osprey Medical, Medtronic, Edwards Lifesciences, and Abbott. Grant support from Edwards Lifesciences and the VA Office of Research and Development.

M. Nicholas Burke: Consulting and speaker honoraria from Opsens Medical. Shareholder, Egg Medical, and MHI Ventures.

Dimitri Karmpaliotis: speaker honoraria. Boston Scientific, Abbott Vascular, and Abiomed

Emmanouil Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), CSI, Elsevier, GE Healthcare, InfraRedx, Medtronic, Siemens, and Teleflex; research support from Regeneron and Siemens. Shareholder: MHI Ventures.

All other authors have no conflict of interest

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Figure Legends

Figure 1. Reports of microcatheter failure in the MAUDE database.

Figure 2. Failure modes of coronary microcatheters.

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Table 1. Microcatheter failure mechanisms and clinical consequences.

Failure method, n (%)	**N=378**
Tip fracture	305 (80.7%)
Due to over-torquing	141 (46.2%)
Due to forceful pulling	81 (26.6%)
Tip was retrieved	109 (35.7%)
Tip stuck in the lesion	127 (33.6%)
Guidewire stuck in the microcatheter	39 (10.3%)
Proximal shaft and hub separation	20 (5.3%)
Shaft fracture and twisting	4 (1.1%)
Outer coil or polymer dislodgement	8 (2.1%)
Clinical consequences	
Death	3 (0.8%)
Perforation	7 (1.9%)
Dissection	5 (1.3%)
Surgery	27 (7.1%)
Aborted percutaneous coronary intervention	55 (14.6%)
Periprocedural myocardial infraction	3 (0.8%)

PCI, percutaneous coronary intervention.

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Figure 1:

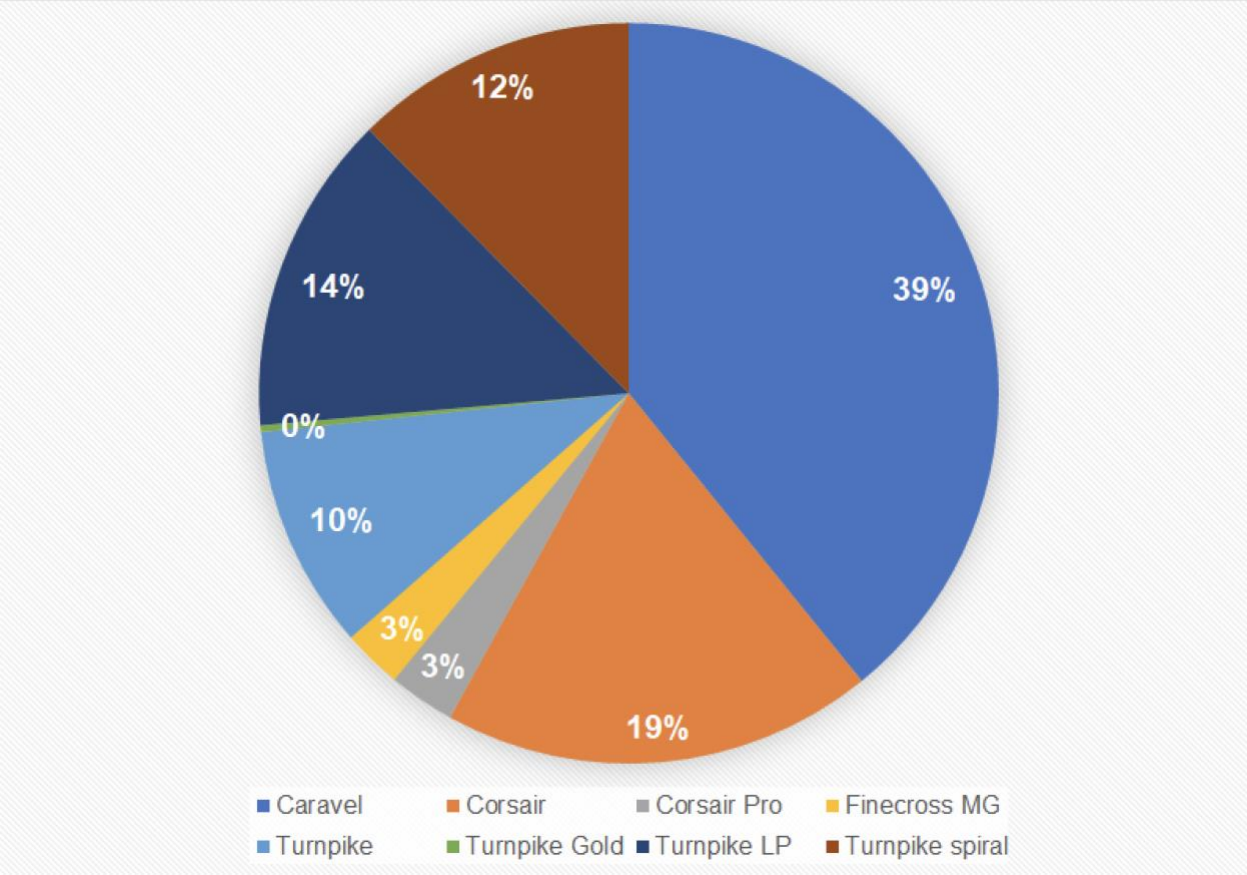

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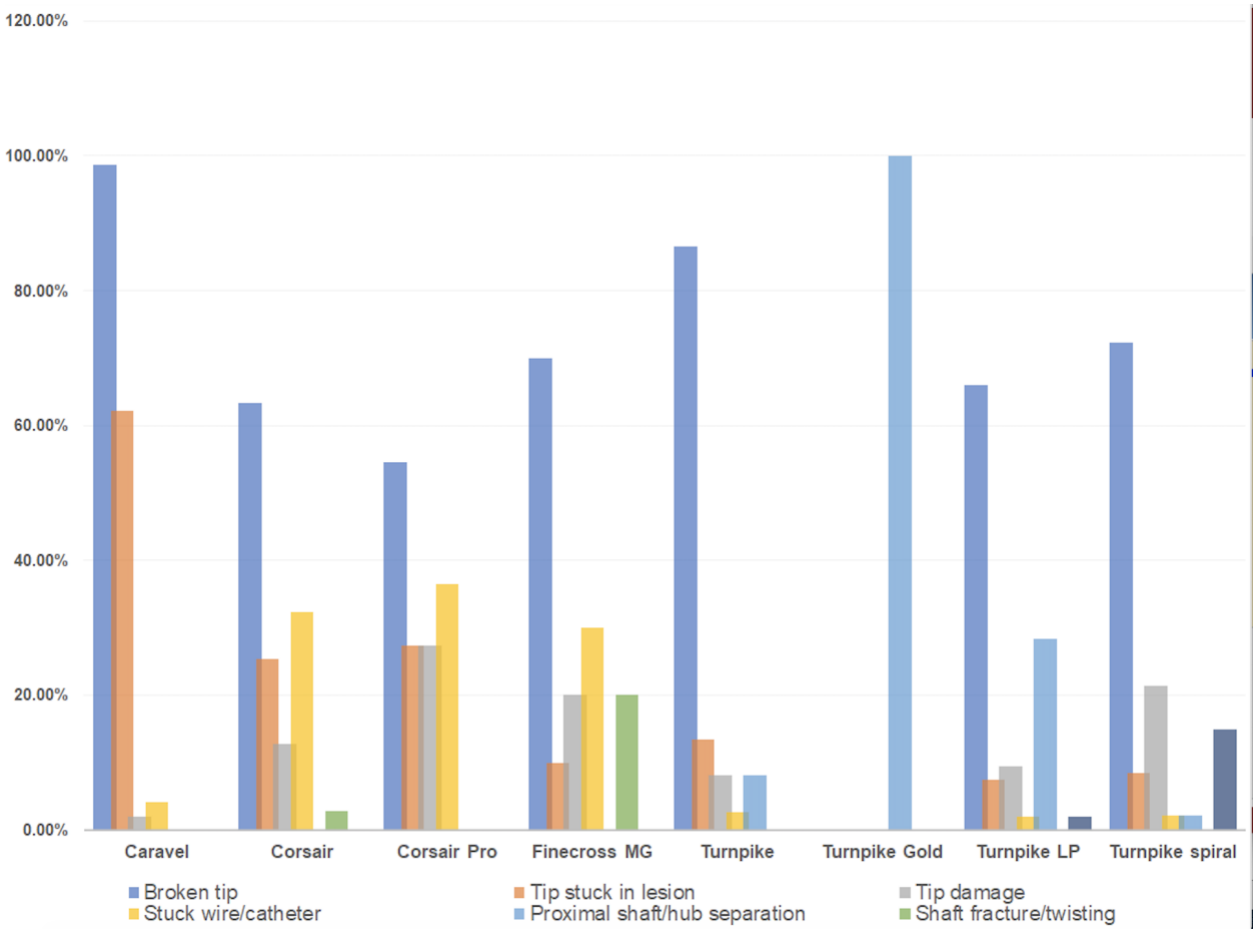
Figure 2:



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SUPPLEMENTARY MATERIAL

Supplementary Table 1: Microcatheter type and lesion characteristics of the included reports.

Characteristics	**N=378**
Microcatheter type	
Caravel, n (%)	148 (39.2%)
Corsair, n (%)	71 (18.9%)
Corsair Pro, n (%)	11 (2.9%)
Finecross MG, n (%)	10 (2.6%)
Turnpike, n (%)	37 (9.8%)
Turnpike Gold, n (%)	1 (0.3%)
Turnpike LP, n (%)	53 (14%)
Turnpike Spiral, n (%)	47 (12.4%)
Target vessel	
Left main coronary artery, n (%)	5 (1.3%)
Left anterior descending artery, n (%)	93 (24.6%)
Diagonal, n (%)	4 (1.1%)
Left circumflex, n (%)	65 (17.2 %)
Right coronary artery, n (%)	104 (27.5%)
Lesion type	
Chronic total occlusion, n (%)	141 (37.3%)

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Retrograde approach used n (%)	46 (12.2%)
Tortuous lesion, n (%)	58 (15.3%)
Calcified lesion, n (%)	225 (59.5%)
In-stent restenosis, n (%)	9 (2.4%)

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Supplementary Table 2: Failure mechanism and clinical consequences according to microcatheter type.

n (%)	Caravel (n=148)	Corsair (n=71)	Corsair Pro (n=11)	Finecross MG (n=10)	Turnpike (n=37)	Turnpike Gold (n=1)	Turnpike LP (n=53)	Turnpike Spiral (n=47)
Mechanism of failure								
Tip fracture	146 (98.6%)	45 (63.4%)	6 (54.4%)	7 (70%)	32 (86.5%)	0 (0%)	35 (66%)	34 (72.3%)
Due to over-torquing	53	26	4	2	11	0	25	20
Due to forceful pulling	71	4	0	2	0	0	3	1
Tip was retrieved	55	11	3	2	13	0	15	10
Tip stuck in the lesion	92 (62.2%)	18 (25.4%)	3 (27.3%)	1 (10%)	5 (13.5%)	0 (0%)	4 (7.5%)	4 (8.5%)

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Guidewire stuck in the microcatheter	6 (4.1%)	23 (32.4%)	4 (36.4%)	3 (30%)	1 (2.7%)	0 (0%)	1 (1.9%)	1 (2.1%)
Proximal shaft and hub separation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (2.7%)	1 (100%)	15 (28.3%)	1 (2.1%)
Shaft fracture and twisting	0 (0%)	2 (2.8%)	0 (0%)	2 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Outer coil or polymer dislodgement	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.9%)	7 (14.9%)
Clinical consequences								
Perforation	1 (0.7%)	4 (5.6%)	1 (9.1%)	0 (0%)	0 (0%)	0 (0%)	1 (1.9%)	0 (0%)
Dissection	1 (0.7%)	1 (1.4%)	0 (0%)	1 (10%)	0 (0%)	0 (0%)	0 (0%)	2 (4.3%)
Death	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.9%)	1 (2.1%)
Emergency surgery	7 (4.7%)	5 (7%)	2 (18.2%)	1 (10%)	4 (10.8%)	0 (0%)	3 (5.7%)	5 (10.6%)

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Aborted PCI	17 (11.5%)	7 ((9.9%)	7 (63.6%)	4 (40%)	6 (16.2%)	0 (0%)	6 (11.3%)	8 (17%)
Myocardial infarction	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (5.7%)	0 (0%)

PCI, percutaneous coronary intervention.

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