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The Stingray LP balloon (Boston Scientific, Marlborough, MA) is frequently used to facilitate distal true lumen re-entry in case of subintimal guidewire entry during chronic total occlusion (CTO) percutaneous coronary intervention (PCI) [1,2]. There is limited data on the failure modes of the Stingray LP balloon.

We investigated the Manufacturer and User Facility Device Experience (MAUDE) database for reports on Stingray LP failure from January 2016 to December 2020 (the device was approved in December 2015). The database was last accessed on January 3rd, 2021, by two independent reviewers (RM and MM). The MAUDE database is publicly available and de-identified and no institutional review board approval was required. The outcomes this study was the modes of failure and their clinical consequences. The percentages reported in the study represent only the events reported to the MAUDE registry and doesn't represent the overall complications of the Stingray LP balloon as the denominator is unknown.

A total of 95 reports were found during the study period. After excluding duplicates and irrelevant reports ($n = 23$), reports on the initial Stingray balloon ($n = 16$), and Stingray wire reports ($n = 5$), our final cohort included 51 reports. The most common mode of failure was balloon rupture after delivery (45%), followed by failure of the wire to pass through the catheter (15.7%), and shaft fracture (15.7%) (Table 1). Serious clinical consequences were rare with no injury to the patient in 96% of the reports and completed procedure in 87%. Coronary perforation and tamponade occurred in 1 report, emergency cardiac surgery was required in 1 report and no patients died.

Our study is the first to describe the modes of failure of Stingray LP balloon since its approval in 2015. We found that reports on Stingray LP failure were rare (51 over 5 years) with no significant clinical consequences in most cases. The most common Stingray LP balloon malfunction was rupture after delivery. This could be due to balloon deformation during aggressive advancement attemtps, for example through heavily calcified and tortuous coronary segments. Another potential cause of rupture is inflation of the Stingray LP balloon at higher than recommended (3–4 atm is recommended in the instructions for use) pressure.

Preparing the subintimal track can facilitate delivery of the Stingray LP balloon, but also carries a risk of creating a subintimal hematoma that could hinder subsequent reentry attempts. Microcatheter advancement to the reentry zone usually suffices, although in some cases inflation with a small (1.0–1.5 mm) balloon may be required. Aggressive advancement attempts should be avoided as they can compromise the structural integrity of the Stingray LP balloon, that may lead to kinking of the balloon shaft that may not allow subsequent guidewire insertion (15.7% of the reports) and could even lead to balloon shaft fracture (15.7% of the reports).

Inability to visualize the balloon was the mode of failure in 11.8% of the reports. This is likely related to suboptimal balloon preparation, which is laborious requiring aspiration with a 20 cm^3 dry syringe X 3, followed by connection with a 3 cm^3 syringe that contains 100% contrast. Multiple views and use of higher magnification can help better visualize the Stingray LP balloon and its relation with the distal true lumen. Alternatively, the "double blind stick and swap technique" can be used for reentry [3], during which a stiff guidewire is advanced through both exit ports of the Stingray balloon, followed by exchange

Abbreviation: MAUDE, Manufacturer and User Facility Device Experience database; CTO, chronic total occlusion; PCI, percutaneous coronary intervention.

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Table 1
Complications and failure modes of Stingray LP balloon as reported to the MAUDE registry.

	$N = 51$
Target vessel, n (%)	
Left anterior descending artery	10 (19.6%)
Left circumflex	2 (3.9%)
Right coronary artery	22 (43.1%)
Not mentioned	17 (33.3%)
Failure mode, n (%)	
Balloon rupture after delivery	23 (45.1%)
Failure of guidewire to pass through Stingray catheter (stuck wire)	8 (15.7%)
Shaft fracture	8 (15.7%)
Failure to visualize the balloon markers under fluoroscopy	6 (11.8%)
Balloon fracture before delivery	4 (7.8%)
Failure to cross the lesion	3 (5.9%)
Failure of balloon inflation	1 (2%)
Failure of balloon deflation	1 (2%)
Clinical consequences, n (%)	
No injury to the patient	49 (96.1%)
Completed percutaneous coronary intervention	43 (87.3%)
Aborted procedure	5 (9.8%)
Coronary perforation leading to tamponade	1 (2%)
Surgery	1 (2%)
Death	0 (0%)

The percentages reported in the study represent only the events reported to the MAUDE registry and doesn't represent the overall complications of the Stingray LP balloon as the denominator is unknown.

for a polymer jacketed guidewire that is also advanced through both exit ports until reentry is achieved.

Failure to cross the lesion was the mode of failure in 5.7% of the reports, although this does not represent an inherent device failure. Failure to cross may be due to subintimal hematoma formation that could be reduced by aspiration, either though the Stingray balloon itself or through an over the wire balloon or a microcatheter [4,5]. Alternatively the reentry zone may be moved more distally ("bobsled" technique). Reentry failure may also be due to heavy calcification that could be overcome by using stiff tip guidewires.

Our study is limited by the selection bias resulting from the retrospective analysis from the MAUDE and selective optional reporting by healthcare professionals. Moreover, the incidence of each mode of failure cannot be accurately determined as the study lacks a denominator.

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Declaration of competing interest

Khaldoon Alaswad: consulting/speaker honoraria from Boston Scientific, Cardiovascular Systems Inc., Abbott Vascular, Teleflex.

Mir Basir: Consulting/Speaker Abbott Vascular, Abiomed, Cardiovascular Systems, Chiesi, Zoll.

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

Stéphane Rinfret: consulting/speaker honoraria from Abbott Vascular, Boston Scientific, Teleflex and Abiomed.

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