

rates as other commercially available catheters with no safety concerns. More prospective clinical data is needed to fully assess the Q Aspiration Catheter.

Abbreviations AIS (acute ischemic stroke), MT (mechanical thrombectomy), ASPECTs (Alberta Stroke Program Early CT Score), mTICI (modified TICI score), NIHSS (National Institute of Health Stroke Scale), mRS (modified Rankin Scale), ENT (embolization to a new territory), sICH (symptomatic intracranial hemorrhage)

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P-013

NAVIGATING THE WALRUS: A LARGE BORE BALLOON GUIDE CATHETER FOR ACUTE ISCHEMIC STROKE THROMBECTOMY

¹GM Cortez*, ²RD Turner, ³A Monteiro, ⁴AS Puri, ³AH Siddiqui, ⁵J Mocco, ²J Vargas, ⁴AL Kuhn, ⁵S Majidi, ²MI Chaudry, ¹A Aghaebrahim, ²AS Turk, ¹E Sauvageau, ¹R Hanel. ¹Neurosurgery, Baptist Health System- Jacksonville, Jacksonville, FL; ²Neurosurgery, Prisma Health Upstate, Greenville, SC; ³Neurosurgery, University at Buffalo, Buffalo, NY; ⁴Radiology, University of Massachusetts Medical Center, Worcester, MA; ⁵Neurosurgery, Icahn School of Medicine at Mount Sinai, New York, NY

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Introduction The utilization of Balloon-guide catheter (BCG) in acute ischemic stroke treatment has been associated with increased rates of successful recanalization, first-pass effect, and reduced procedural times. The Walrus BGC is the first in class, 0.087" inner diameter and variable stiffness, designed to overcome some of the early technical constraints associated with previous models of BGCs. We aim to evaluate the performance and safety of the Walrus BGC.

Methods A retrospective review of 5 US comprehensive stroke centers was performed between August-2019 and December-2020. Consecutive patients who underwent mechanical thrombectomy using the Walrus BGC were included. Performance analysis included the ability to track the device and enable therapeutic delivery. Baseline characteristics, procedural outcomes, adverse events, and functional outcomes were retrieved.

Results A total of 338 patients underwent mechanical thrombectomy using the Walrus BGC. The Walrus was successfully tracked into distal vasculature and allowed therapeutic device delivery in 99.1% of cases. Regarding thrombectomy first-pass modality, stent-retriever was used in 59.2% (200/338); aspiration on 138 (40.8%). Twenty-two different intermediate catheters were successfully accommodated into the Walrus BGC, with large ID ≥ 0.070 " aspiration catheters used in 71.9% (243/338) of the cases. Successful vessel recanalization (mTICI-2b/3) was achieved in 94.4% (319/338), with a rate of first-pass mTICI-2b/3 of 64.8% (219/338). Mean puncture-to-recanalization was 37.5 ± 25 min, and a median number of passes was 1 (IQR,1-2). Walrus-related adverse event was 0.6%, corresponding to 2 vessel dissections. Functional independence was 50% (161/252) and mortality 25% (63/252). Unfavorable outcomes were more likely in patients older than 80yo, unsuccessful reperfusion, longer procedure times, and a higher number of passes ($p < 0.05$).

Conclusion The Walrus BGC presents as a safe surrogate to previous BGCs, demonstrating good trackability, a large inner diameter that allows use of largest available aspiration

catheters, with a great safety profile. Procedural outcomes are in equipoise with historical data.

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P-014

REPERFUSION CATHETER MALFUNCTION DURING STROKE INTERVENTION: AN ANALYTICAL REVIEW OF THE FDA'S MAUDE DATABASE

D Bageac*, B Gershon, R De Leacy. *The Mount Sinai Hospital, New York, NY*

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Background In December 2020, the JET7 Xtra Flex reperfusion catheter was voluntarily recalled after reports of injury and death associated with device malfunction. The FDA's MAUDE (Manufacturer and User Facility Device Experience) database aggregates reports of adverse events and product problems involving medical devices. We present the first analytical review of all MAUDE reports involving FDA cleared reperfusion catheters in order to summarize safety events to date and characterize unique modes of device failure.

Methods All publicly available MAUDE datasets were downloaded and linked, and all events associated with catheters carrying product code 'NRY' were extracted. Product code 'NRY' encompasses all devices intended to restore blood flow by removing thrombus/clots in patients experiencing ischemic stroke. Note that this review does not include catheters used off-label for aspiration thrombectomy.

Event characteristics including device type, malfunction and adverse events were collected directly as reported on MedWatch Form 3500. In order to characterize procedure-specific details, narrative information submitted in MedWatch Form 3500 Sections B and H was coded by 2 independent raters.

Results Between 1/1/2003 and 8/31/2020, there were 1,808 reperfusion catheter defects and/or malfunctions reported in the MAUDE database. Of these, 93.4% did not result in any adverse effect on patients. There were 112 malfunctions associated with an adverse event, of which 98 (87.5%) resulted in injury, and 14 (12.5%) resulted in death. A summary of malfunctions is available in table 1. When interpreting these findings, it is important to note that FDA surveillance of these devices does not include data on the number of units sold, thus event rates cannot be determined or compared across devices.

Of 14 reported deaths, 13 involved malfunctions of the Jet 7 Xtra Flex catheter. All of these cases reported mechanical failure at the tip of the catheter, 10 of which involved tip rupture or ballooning following contrast injection. Ballooning was unique to the Jet 7 Xtra Flex, and was also responsible for 3 patient injuries and 37 cases of malfunction that did not result in adverse outcomes.

One death and 45 injuries involved the 3 MAX Reperfusion catheter. All of these events were caused by catheter fracture leading to fragment embolization or vessel injury. This mechanism of failure was not unique to the 3 MAX, and was present in 61.2% of all malfunctions resulting in injury.

Among malfunctions that did not result in adverse events, the majority (59.1%) were attributable to damage that

Abstract P-014 Table 1 Malfunctions by catheter and outcome. Abstract table limit requires category 'Other'

Catheter	Death	Injury	No Adverse Event	Total
3 MAX	1	45	322	368
5 MAX	0	9	374	383
ACE 60	0	1	57	58
ACE 64	0	12	75	87
ACE 68	0	4	247	251
Jet 7	13	19	258	290
Penumbra 032	0	1	139	140
Penumbra 054	0	2	55	57
Other	0	5	200	174

occurred on the back table during device preparation. Detailed descriptions of unique malfunction mechanisms for each catheter are omitted from this brief abstract but are available for presentation.

Conclusion Reperfusion catheter failures resulting in injury or death are rare. These findings suggest that current methods of FDA surveillance have effectively identified outliers.

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P-015 THE ZOOM SYSTEM DEMONSTRATES HIGHER FIRST PASS EFFECT AND FASTER REPERFUSION AS COMPARED TO A CONSECUTIVE CONTEMPORANEOUS SERIES OF ASPIRATION CATHETERS: ANALYSIS FROM A MULTICENTER RETROSPECTIVE COHORT

¹S Majidi*, ²J Vargas, ³H Hawk, ⁴S Nimjee, ⁴A Zakeri, ⁵M Mokin, ⁶R Kellogg, ¹R DeLeacy, ⁷G Cortez, ⁷A Aghaebrahmin, ⁷E Sauvageau, ⁷R Hanel, ⁸A Siddiqui, ⁹M Oselkin, ⁹E Marlin, ²A Turk, ²R Turner, ²I Chaudry, ¹⁰J Milburn. ¹Neurosurgery, Mount Sinai Health System, New York, NY; ²Neurosurgery, Prisma Health – Upstate, Greenville, SC; ³Radiology, Erlanger Health System, Chattanooga, TN; ⁴Neurosurgery, Ohio State University, Columbus, OH; ⁵Neurosurgery, University of South Florida, Tampa, FL; ⁶Neurosurgery, University of Virginia, Charlottesville, VA; ⁷Neurosurgery, Baptist Medical Center, Jacksonville, FL; ⁸Neurosurgery, University of Buffalo, Williamsville, NY; ⁹Neurosurgery, St Luke's University Health Care, Bethlehem, PA; ¹⁰Radiology, Oschner Health, New Orleans, LA

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Background Modern aspiration catheters have revolutionized thrombectomy outcomes. The Zoom System is series of catheters, with ID's of 0.045, 0.055, 0.071, and 0.088, that are advertised as being designed to support superior stroke thrombectomy performance. We aimed to preliminarily evaluate such claims by retrospectively assessing technical outcomes in a consecutive series of M1 ELVOs in which aspiration was the first line approach.

Methods We performed a retrospective multicenter analysis of consecutive ELVO patients with M1 occlusion treated within 24 hours from the time of last known well. Patients were divided into two cohorts: those in whom the Zoom 088 or 071 was the initial technology used to attempt reperfusion and those in whom any other aspiration catheter was used for initial reperfusion attempt. The primary outcome was excellent reperfusion (TICI \geq 2C) on first pass. Secondary outcomes included the rate of excellent reperfusion and successful reperfusion (TICI \geq 2B), access to successful reperfusion time, and occurrence of downstream emboli. All data was self-adjudicated. No outside funding was provided for this analysis.

Results Total of 660 patients with acute M1 occlusion who underwent thrombectomy were identified. Zoom System catheters (088 or 071) were used as primary aspiration catheter in 172 patients, while 488 patients were treated with other aspiration catheters (ranging from 064 to 074). The baseline mRS score, admission NIHSS score, the rate of intravenous thrombolytic therapy, symptom onset to hospital arrival, and use of anesthesia were not different between the cohorts. The primary outcome, first pass excellent reperfusion, was significantly higher in the Zoom System cohort (51% vs 41%, p=0.02). The rate of excellent reperfusion was significantly higher in the Zoom cohort (68% vs 59%, p=0.04), however, there was no difference in the rate of successful reperfusion (96% vs 94%, p=0.78). Access time to final reperfusion was significantly faster in the Zoom cohort (27 vs 35 minutes, p<.0001). After adjusting for confounding factors (age, thrombectomy technique, use of secondary aspiration catheter), access time to TICI 2B (30 vs 35 minutes, p=0.028) and final recanalization (25 vs 31 minutes, p=0.018) were significantly shorter in the Zoom System cohort.

Conclusion This retrospective, multicenter, consecutive real-world experience suggests that using Zoom 088 or 071 as primary aspiration catheter may demonstrate superior technical outcomes for M1 thrombectomy.

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P-016 ASSOCIATION OF CEREBRAL MICROBLEEDS AND CLINICAL OUTCOMES FOLLOWING ENDOVASCULAR STROKE THERAPY

¹H Saber*, ²J Saver, ¹V Szeder, ¹M Nour, ¹K Khatibi, ¹L Ponce Mejia, ¹S Tateshima, ³G Colby, ¹N Kaneko, ¹R Jahan, ¹G Duckwiler, ²D Liebeskind. ¹Interventional Neuroradiology, UCLA, Los Angeles, CA; ²Neurology, UCLA, Los Angeles, CA; ³Neurosurgery, UCLA, Los Angeles, CA

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Introduction/Purpose Cerebral microbleeds (CMBs) are associated with the risk of hemorrhagic and ischemic stroke. We investigated the association between presence of CMBs and clinical outcomes following endovascular therapy (EVT) for emergent large vessel occlusion (ELVO) stroke.

Materials and Methods This is a retrospective analysis of consecutive adult patients undergoing EVT for an ELVO with available pre-interventional MR imaging between 2013-2019. Pretreatment GRE MRI sequences were analyzed in all patients to explore the frequency and location of prior microbleeds. Primary outcomes included post-interventional intracerebral hemorrhage (ICH) and favorable outcome defined as functional independence with modified Rankin Scale scores of