vs. 23 min, $p = 0.64$). The median number of passes required for recanalization was lower in the direct aspiration group (1 vs. 2, $p = 0.01$). Although there was no difference in successful recanalization (TICI 2b-3) between the groups (86.1% vs. 88%, $p = 0.71$), there was a lower rate of complete recanalization (TICI 2c-3) in the direct aspiration group (46% vs. 51.7%, $p = 0.007$). There was also a lower rate of adjunctive treatments (defined as the use of GP IIb/IIIa inhibitors, P2Y12 inhibitors, and/or salvage angioplasty and/or stenting) required in the direct contact aspiration group (36.1% vs. 44.4%, $p < 0.001$). There were no differences in discharge NIHSS scores (5 vs. 4, $p = 0.21$) or in-hospital mortality (22.2% vs. 22.5%, $p = 0.92$).

Conclusions In the NVQI-QOD registry, stent-retriever techniques were associated with higher rates of complete recanalization when compared to direct contact aspiration alone, but successful (TICI 2b-3) recanalization rates were similar. There were no statistically significant differences in procedure times, clinical outcomes at discharge, or in-hospital mortality.

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P-011 RESCUE OF NEGLECT AND LANGUAGE IMPAIRMENT AFTER STROKE THROMBECTOMY

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Introduction Although National Institutes of Health Stroke Scale (NIHSS) scores provide an objective measure of clinical deficits, data regarding the impact of neglect or language impairment on outcomes after mechanical thrombectomy (MT) is lacking. We assessed the frequency of neglect and language impairment, rate of their rescue by MT, and impact of rescue on clinical outcomes.

Methods This is a retrospective analysis of a prospectively collected database from a comprehensive stroke center. We assessed right (RHS) and left hemispheric strokes (LHS) patients with anterior circulation large vessel occlusion (ACLO) undergoing MT to assess the impact of neglect and language impairment on clinical outcomes, respectively. Safety and efficacy outcomes were compared between patients with and without rescue of neglect or language impairment.

Results Among 324 RHS and 210 LHS patients, 71% of patients presented with neglect whereas 93% of patients had language impairment, respectively. Mean age was 71 ± 15 , 56% were females, and median NIHSS was 16 (12-20). At 24 hours, MT resulted in rescue of neglect in 31% of RHS and rescue of language impairment in 23% of LHS patients, respectively. RHS patients with rescue of neglect (56% vs 34%, $p < 0.001$) and LHS patients with rescue of language impairment (64% vs 25%, $p < 0.01$) were observed to have a higher rate of functional independence compared to patients without rescue. After adjusting for confounders including 24-hour NIHSS, rescue of neglect among RHS patients was associated with functional independence [$p = 0.01$] and lower mortality [$p = 0.01$]. Similarly, rescue of language impairment among LHS patients was associated with functional independence [$p = 0.02$] and lower mortality [$p = 0.001$].

Conclusion Majority of LHS-ACLO and of RHS-ACLO patients present with the impairment of language and neglect, respectively. In comparison to 24-hour NIHSS, rescue of these deficits by MT is an independent and a better predictor of functional independence and lower mortality.

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P-012 THROMBECTOMY ASPIRATION POST-MARKET STUDY IN ACUTE STROKE: THE TAPAS STUDY

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Introduction The Q Aspiration Catheter offers a novel design in which the proximal three-quarters of the catheter shaft is replaced with a pusher wire and the aspiration source is attached directly to the 8F guide catheter. This design results in an increased aspiration force due to the larger 8F guide catheter lumen. This first clinical study was designed to provide initial safety and performance data on the Q Aspiration Catheter. The study was a multi-center, observational, post market study utilizing the Q Catheter as first-line therapy during mechanical thrombectomy for acute ischemic stroke in Spain.

Methods Patients with AIS treated with MT using the Q Aspiration Catheter as first line therapy between March 2019 and January 2020 were identified at four high volume centers in Spain. Patients 18-85 years of age who had anterior or posterior LVO with an ASPECTs score 6-10 and were within 8 hours of onset/last known well were eligible to participate. Baseline demographics, procedural data, post procedure neuroimaging, and clinical outcomes were reported. A follow up visit was conducted to assess mRS.

Results A total of 45 patients provided written informed consent. Average patient age at presentation was 72.4 (range 49-84) and 53.3% were male. Thrombolytic therapy was given in 46.7% (21/45) and NIHSS was 14.4 (range 1-26) at presentation. Occlusion site was 42 (94%) in the anterior circulation: ICA-T in 9 patients (20%), M1 MCA in 25 (56%), and M2 MCA in 8 (18%). Occlusion site in the posterior circulation was 3 (6%). The Q Catheter was successfully delivered to the occlusion 89% (40/45) of the time, successful delivery increased to 96% (43/45) when including a stent retriever for anchoring. Successful revascularization of final mTICI 2b-3 was achieved in 93% of patients (42/45). First pass success of mTICI 2b-3 with only a Q Catheter aspiration was achieved in 49% (21/43), this increased to 56% (24/43) when a stent retriever was used as an anchor. Overall successful revascularization using the Q Catheter, alone or with a stent retriever, was 77% (33/43). Three patients required angioplasty and an implantable stent due to intracranial stenosis of atherosclerotic plaque. ENT occurred in 2% (1), sICH rate was 2% (1) and not related to the device or procedure, mortality during the study period was 13% (6). During the study period, 55.5% of the subjects had a Modified Rankin score of 0-2 at follow up. **Conclusion** The Q Aspiration Catheter is a novel technology that showed comparable deliverability and revascularization

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

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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

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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