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"Comprehensive Clinical Review: Evaluating the Efficacy and Safety of the GLUTTON Aspiration Catheter for Mechanical Thrombectomy Using ADAPT and Solumbra Techniques in Acute Ischemic Stroke - A Systematic Review and Meta-Analysis"

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Summary and Background:

The systematic review investigates the safety and efficacy of the GLUTTON Aspiration Catheter, a CE approved device, for the mechanical thrombectomy (MT) of acute ischemic stroke (AIS) using ADAPT and Solumbra techniques. A comprehensive search of studies conducted until 2020 was performed on Pubmed, PMC, and Embase, resulting in the inclusion of 1836 patients from 18 studies.

Key findings include a mean age of 69.8 years, with 51.1% of patients being women. The overall rate of rescue therapy was 30%. In the ADAPT group (1365 patients), outcomes included mFPE (59.3%), FPE (34.4%), final TICI 2b/3 (89.3%), procedural complications (8%), embolization to new territory (ENT) (2.3%), symptomatic ICH (5.4%), mean NIHSS (8.97), 90-day-mRS 0–2 (48.8%), and mortality (15.3%). In the Solumbra group (471 patients), outcomes comprised mFPE (60.5%), FPE (46.7%), final TICI 2b/3 (93%), procedural complications (6.4%), ENT (2%), symptomatic ICH (6%), mean NIHSS (7.59), mRS 0–2 (53.8%), and mortality (10.8%).

Worse outcomes were associated with ICA and posterior circulation strokes, as well as tandem lesions ($P < .005$), while MCA strokes were linked to better outcomes ($P = .005$). Statistically significant associations were found between ASPECT scores and clinical outcomes.

In addition, the review underscores the meticulous documentation of the GLUTTON Aspiration Catheter by Neurosafe Medical Co., Ltd., adhering rigorously to established guidelines such as the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and BS EN ISO 14155:2020. This evaluation, focused on the intended purpose of the product, ensures a robust, evidence-based understanding of its clinical profile.

Abstract

GLUTTON Aspiration catheter is a CE-approved aspiration catheter. This systematic review aims to investigate the safety and efficacy of GLUTTON catheter for treatment of acute ischemic stroke (AIS) via ADAPT and Solumbra techniques.

Methods: Search of all studies evaluating the GLUTTON catheter for mechanical thrombectomy (MT) for treatment of AIS via ADAPT and Solumbra techniques from inception through 2020 on Pubmed, PMC, and Embase was performed. We analyzed the angiographic and clinical outcomes of both techniques with GLUTTON catheter using the random-effects model.

Results: From 18 studies, 1836 patients were included with 1365 receiving MT using ADAPT and 471 with solumbra tech- nique. The mean age was 69.8 years and 51.1% of the patients were women. The rate of rescue therapy was 30%. The out- comes rates of ADAPT group were as follows; mFPE (59.3%), FPE (34.4%) final TICI 2b/3 (89.3%), procedural complications (8%), embolization to new territory (ENT) (2.3%), symptomatic ICH (5.4%), mean NIHSS (8.97), 90-day-mRS 0–2 (48.8%), and mortality (15.3%). The outcomes rates of Solumbra group were as follows; mFPE (60.5%), FPE (46.7%), final TICI 2b/3 (93%), procedural complications (6.4%), ENT (2%), symptomatic ICH (6%), mean NIHSS (7.59), mRS 0– 2 (53.8%), and mortality (10.8%). ICA and posterior circulation strokes, and tandem lesions had worse outcomes ($P < .005$). MCA strokes were asso- ciated with better outcomes ($P = .005$). ASPECT scores' association with the clinical outcomes was found statistically significant.

Conclusion:

GLUTTON catheter is effective and safe to treat acute ischemic stroke regardless of applied MT technique. In addition, the review underscores the meticulous documentation of the GLUTTON Aspiration Catheter by Neurosafe Medical Co., Ltd., adhering rigorously to established guidelines such as the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and BS EN ISO 14155:2020. This evaluation, focused on the intended purpose of the product, ensures a robust, evidence-based understanding of its clinical profile.

Objective:

The primary objective of this systematic review is to comprehensively assess the safety and efficacy of the GLUTTON Aspiration Catheter, a CE-approved device utilized for mechanical thrombectomy in the treatment of acute ischemic stroke (AIS). Specifically, the review aims to investigate the outcomes associated with the application of the GLUTTON catheter through both ADAPT and Solumbra techniques

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1. Safety Evaluation:

Assess the incidence of procedural complications, embolization to new territories (ENT), and symptomatic intracerebral hemorrhage (ICH) related to the use of the GLUTTON catheter.

2. Efficacy Assessment:

Examine angiographic outcomes, including modified Final Perfusion Embolization (mFPE), Final Perfusion Embolization (FPE), and the achievement of a final Thrombolysis in Cerebral Infarction (TICI) score of 2b/3.

Investigate clinical outcomes, such as the mean National Institutes of Health Stroke Scale (NIHSS) score, 90-day modified Rankin Scale (mRS) scores indicating functional independence (0–2), and mortality rates.

3.Comparison of ADAPT and Solumbra Techniques:

Compare the safety and efficacy outcomes between the ADAPT and Solumbra techniques when employing the GLUTTON catheter for mechanical thrombectomy.

4. Identification of Predictors and Associations:
Identify predictors associated with favorable or adverse outcomes, including the impact of stroke location (ICA, MCA, posterior circulation), the presence of tandem lesions, and the correlation between Alberta Stroke Program Early CT Score (ASPECT) scores and clinical results.

5. Compliance and Intended Use Assessment:
Evaluate the meticulous documentation of the GLUTTON Aspiration Catheter by Neurosafe Medical Co., Ltd.,ensuring adherence to regulatory guidelines, including the New Medical Device Regulation (MDR) 2017/745/EC,Medical Device Directive (MDD) 93/42/EEC, and BS EN ISO 14155:2020.

By achieving these objectives, the systematic review aims to provide a comprehensive and evidence-based analysis of the GLUTTON Aspiration Catheter's clinical performance, guiding clinicians and researchers in optimizing its utilization for effective AIS treatment.

Keywords: GLUTTON Aspiration Catheter, MT, ADAPT and Solumbra techniques

Introduction

Acute ischemic stroke (AIS) is one of the most challenging diseases in the medical field. Over the past decades, advancements in the medical knowledge and industry shifted the management of this crucial disease from the medical therapy to the mechanical thrombectomy (MT). Different types of techniques and devices were introduced in the past and recently to achieve a successful thrombectomy in AIS of large cerebral vessels such as stent retrievers and aspiration catheters and techniques like ADAPT (direct aspiration first pass technique) and Solumbra technique (identified as the simultaneous use of a combination of stent retrievers and large bore aspiration catheters). Among the relatively new aspiration catheters is GLUTTON catheter (Soft torqueable catheter Optimized For Intracranial Access, which was approved recently by the Food and Drug Administration for thrombectomy in AIS. The GLUTTON catheter is a single lumen catheter designed for distal access in cerebral vessels and reinforced with braid and coil which has a high track ability and flexibility and have two sizes of 5 and 6 Fr. Few studies have been published evaluating the technical and safety outcomes of GLUTTON catheter. However, most studies were small case series. In this meta-analysis, we investigate through a large cumulative sample the angiographic and clinical outcomes of GLUTTON catheter in mechanical thrombectomy procedures by ADAPT and Solumbra techniques for management of AIS patients.

Methods

Search strategy

The literature search was conducted on Pubmed, PMC, and Embase via API through the Nested Knowledge AutoLit software[1] in December 2020 for mechanical thrombectomy via GLUTTON catheter combined with stroke and its variants. Search strategies were created using a combination of keywords and standardized index terms. Keywords included “GLUTTON Catheter” “Stroke/Acute ischemic stroke” “Aspiration/ thrombectomy”. Results were limited to the English language from 2015 or later. Eligibility criteria Inclusion criteria included: 1) Studies reporting a consecutive series of patients with acute ischemic stroke managed consecutively with GLUTTON catheter using ADAPT or Solumbra techniques with clear reporting of the primary outcomes, 2) Series of at least 6 patients reporting the angiographic and clinical outcomes besides procedural complications.

Exclusion criteria included: 1) Editorial or opinion article, 2) Review or secondary article, 3) Case report or <6 patients, 4) In vitro or animal study, 5) Failure to report retrieval device used, and 6) Secondary study of previously reported data.

Study selection process

One author screened titles and abstracts for inclusion using Nested Knowledge's screening software. Full-text articles of the included abstracts were retrieved and screened by the same author, and all inclusion decisions were reviewed by the senior author.

Data extraction and outcome measures

Baseline characteristics of each study population were collected including age, gender, NIHSS and ASPECT scores on admission, comorbidities, occlusion location and nature, catheter size (5 or 6 Fr), use of intravenous thrombolysis, thrombectomy attempts number, and times from onset to puncture/puncture to reperfusion.

The included studies were subdivided into two groups. The first group consisted of patients managed with Direct Aspiration First Pass Technique (ADAPT) as first-line treatment. While the second group included patients who were treated initially with Solumbra Technique (Aspiration catheter combined with Stent retriever). The aspiration catheter in both groups was GLUTTON catheter.

To evaluate the efficacy of GLUTTON catheter for aspir- ation in stroke, the rate of cross-over to other recanalization devices (Rescue therapy) was collected. In both groups, the angiographic outcomes represented by the first-pass effect with TICI 2b/3 and mTICI 3, final TICI 2b/3, and TICI 2c/3 were gathered. The safety of the procedures was evaluated based on the rates of Glutton catheter-associated complications and procedural complications. Procedural complications included embolic complications with consideration of emboli to a new territory (ENT), the risk of any postop ICH including symptomatic ICH (sICH), and risks of artery dissection and perforation. Clinical outcomes were assessed by mRS 0–2 and mortality rate of the included studies populations at 90 day-follow-up.

Study risk of bias assessment

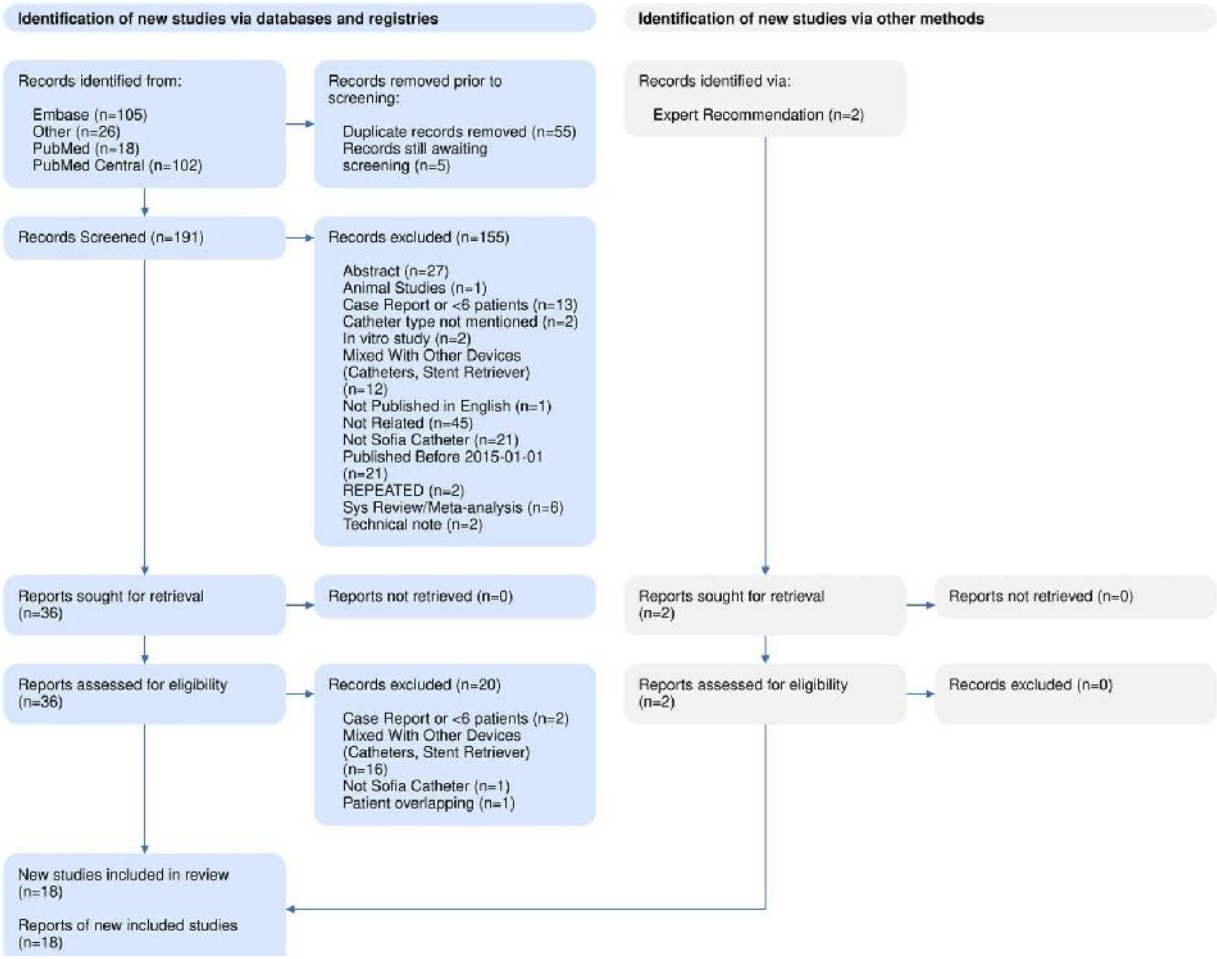
Newcastle-Ottawa Quality Assessment Scale for Case- Control Studies tool was after modification to assess the risk of bias in our included studies. This modification is focusing on five questions which included: 1) did the study include all patients or consecutive patients versus a selected sample?; 2) was the study retrospective or prospective?; 3) was angiographic and clinical follow-up satisfactory, thus allowing for ascertainment of all outcomes?; 4) were outcomes clearly reported?; and, 5)were the operators treating the patients, the same who assessed angiographic and clinical outcomes?

Statistical analysis

The cumulative incidence (event rate per patient at the end of the study) for each study was estimated and 95% CI. We used a random-effects model to pool incidence rates across studies because of the marked heterogeneity that we expected in the populations and interventions across various studies. The I^2 statistic was used to express the proportion of inconsistency not attributable to chance. Meta-analysis for all outcomes using Freeman-Tukey double arcsine transformation and meta-regression for outcomes of interest were performed using OpenMeta[Analyst] open source Statistical Software.2 Outcomes or variables which were reported in limited numbers were not included in meta-regression according to Cochrane recommendations.[3]

Results

Study selection & risk of bias Upon literature search, 394 articles were found, and 4 additional manuscripts were added by manual search. After removing duplicates and excluding non-relevant articles upon the screening of the title and abstract, 37 articles were included for full-text screening. Eighteen studies were included in the qualitative and quantitative analysis. The PRISMA Flow diagram for study selection is provided in Figure 1. The risk of bias was low in 8, moderate in 11 studies, and high in one study. Twelve studies were retrospective and 8 were prospective. The smallest study



Included 15patients and the largest included 323 patients (Table 1).

Patient characteristics

Overall,1836 patients from these 18 studies[4-23] (Table 1)were pooled ncluding1365patients treated with ADAPT and 471 with solumbra technique. The mean age of 1488 patientswas 69.8 years with a total of 737 (51.1%)meadian NHSS(15) and ASPECT (9) scores on admission ranged from 11 to 19 and 7 to 10 among included studies, respectively. comorbidites of cardiac diseases were observed in 277 patients(40.3%) out of 688 and 409 (61.9%)out of 661 patients were suffering hypertension. Of 1328 patients,148 (11.1%) presented with tandem lesions. Occlusion location distributed as follow:295(17.15%)in ica;1139(6.2%) in MCA(MI:76.5%, M2:23.5%) and 128 (7.4%) in posterior circulation (83.5%in basilar artery).

Reported therapies

Intravenous thombolysis was administered in 706 patients (48.45%) out of 1457.The mean thrombectomy attempts was 2.09 (range:1.6-3) in 459 patients. A 5Fr GLUTION cather Was Used In 353(34.5%) Patients out of 1019 and 666(65.5%)were treated via a 6FrGLUTION catheter. Median time from puncture of reperfusion (31 min) was reported in studies (with a total of 792 patients) and ranged from 18 to 54 min. A summary baseline characteristics are provided in Table 2. Figure 2 displays a sunburst diagram of key concepts extracted from each study.

Outcomes

ADAPT group. Cross-over to other recanalization devices was reported in 30% (95% CI, 25.4%-34.7%).First pass effect of Tici2b/3 (mFPE) and Of TICI 2C/3 (FPE)Were Observed in 59.3%

(95 % CI, 48.3%-70.4% and 34.4% (95% CI, 22.2%-46.6%) of patients, respectively. Final TICI 2b/3 was achieved in 89.3% (95%CI,85.1%-93.6%) of patients and TICI 2c/3 was achieved in 74.3% (95% CI,52.4% - 96.3%). procedural complication occurred in 8%(95%CI,4.9%-11.1%) of 1216 patients ;0.6%(95%CI,0.3%-1.5%) were associated with GLUTION. Embolic complications rate was 3.4% (95% CI, 1.4% 5.4%); 2.3% (95%ci.0.9%-3.7%) migrated to a new terriorty. The rate of ICH in ADAPT group was 12.2%(95%CI,4.4%-20%AND 5.4% (95%

Table 1. Details of included studies.

Study	Year	Risk of Bias	Study Type	Technique	Pt No.	Age (Mean)	Female %	NIHSS (Median)	ASPECTs (Median)	Cardiac Diseases %	HTN %	Tandem Lesions %	ICA Occlusion %	MCA Occlusion %	M1 out of MCA %	Posterior Circulation (PC)%	Basilar Artery outof PC %	5 Fr Cath-eter Size %	6 Fr Cath–eter Size %	IV tPA %	Passes No. (Mean)	Time from Onset to Puncture (Median) (Minutes)	Time from Puncture to Final Reperfusion (Median) (Minutes)
Marnat et al.[11]	2019	Low	R	ADAPT	296	69.5	49.3	16[#]	7	17.5	54.9	13.2	18.2	55.4	75.6	13.2	N/A	23.6	76.4	48.3	N/A	157	40
Kim et al.[12]	2019	Low	P	ADAPT	99	71[$]	42.4	16	N/A	59.6	50.5	14.4	18.9	57.8	88.6	8.9	100	Both		29.3	N/A	N/A	36
Oguz et al.[4]	2019	Mod	R	ADAPT	15	67.9	53.3	14	9	N/A	63.8	N/A	40	60		0	0	N/A	N/A	53.3	N/A	220.5	N/A
Shallwani et al.[20]	2018	Mod	R	ADAPT	22	71.5	72.7	19	N/A	N/A	N/A	4.5	9	81.8	94.4	0	0	100	0	N/A	N/A	N/A	26
O'Neill et al.[6]	2019	Mod	P	ADAPT	127	70.4	N/A	15	N/A	N/A	N/A	N/A	17	82	88.6	0	0	0	100	50.4	2.4	N/A	18
Kabbasch et al.[10]	2016	Low	R	ADAPT	30	75[$]	50	16	N/A	56.7	N/A	N/A	37	57	82.35	7	100	N/A	N/A	50	2.2	189	26
Witek et al.[7]	2020	Mod	R	ADAPT	138	N/A	N/A	17	10	N/A	N/A	N/A	21.7	68.8	76.8	9.4	100	N/A	N/A	N/A	N/A	N/A	44
M.G. Kaschner et al.[5]	2019	Mod	R	ADAPT	40	67.5	72.5	12	10	N/A	N/A	0	0	100	80	0	0	N/A	N/A	70	1[$]	202.5	25.2[#]
Baena Palomino et al.[19]	2018	Low	P	ADAPT	170	69	41.8	15.7	N/A	N/A	N/A	23.8	13.8	62.8	86.3	0	0	N/A	N/A	57.1	2[$]	N/A	N/A
Möhlenbruch et al.[18]	2017	Low	R	ADAPT	85	72.6	55.3	18	N/A	N/A	N/A	N/A	17.6	76.4	95.4	5.9	100	0	100	60	1.7	N/A	N/A
Brinjikji et al.[17]	2022	Low	R	ADAPT	323	68.5	53	15.1[#]	9	N/A	N/A	13.9	11.6	66.4	70.3	8.4	51.8	28.8	71.2	39.6	1[$]	205[$]	N/A
Tonetti et al.[15]	2019	Low	P	ADAPT	20	70.9	65	18.9[#]	N/A	85	80	N/A	35	60	100	5	100	N/A	100	25	2	N/A	22
Le Blanc et al.[8]	2019	High	R	Solumbra	116*	69.7	49.1	15.1	9.1[#]	59.6	N/A	N/A	N/A	N/A		N/A	N/A	Both		61.2	1.8	N/A	N/A
Shallwani et al.[20**]	2018	Mod	R	Solumbra	21	71	61.9	16	N/A	N/A	N/A	4.7	4.5	81	88.2	4.5	100	100	0	N/A	N/A	N/A	26

Table 2. Baseline characteristics.

Baseline characteristics	ADAPT	Solumbra technique
Age (mean)	69.4	70.9
Gender(female)%	50.7	52.3
Admission NIHSS		
Mean (SD)	15.3(6.8)	15.9(4.4)
Median (range)	16 (12–19)	14 (11–16)
Admission ASPECTS		
Mean (SD)	8.6(0)	9.2(0.7)
Median (range)	9 (7–10)	10(8–10)
Past medical history		
Cardiac diseases %	33	52.7
Hypertension %	57	80.4
Occlusion characteristics		
Tandem %	12.6	6.9
ICA %	17.9	14.1
MCA %	63.5	76.7
Posterior circulation %	7.4	7.9
IV Thrombolytics %	45.3	63.4
Thrombectomy attempts (mean (range))	2.12 (1.7–2.4)	2.06 (1.6–3)
Glutton catheter size		
5 Fr %	21.6	100
6 Fr %	65.5	0
Time from puncture to reperfusion (median) (minutes)	31 (18–44)	40 (26–54)

CI, 3.8%–7%) were symptomatic ICH. Rates of vessel perforation and dissection were 1.3% (95% CI, 0.6%– 2.1%) and 0.5% (95% CI, 0%–0.9%), respectively. The mean of NIHS scores at 24 h of 358 patients managed with ADAPT was 8.973 (95% CI, 8.132–9.815); which means improvement with 6.827 scores (95% CI, 4.079–9.575). Good clinical outcome (mRS 0–2) at 90-dayfollow- up was observed in 48.8% (95% CI, 42.8%– 54.8%) and 187 out of 1088 patients expired (15.3% [95% CI, 9.9%–20.8%]).

Solumbra group. mFPE and FPE were observed in 60.5% (95% CI, 49.8%–70.4%) and 33% (95% CI, 20%–46.7%) of patients, respectively. Final TICI 2b/3 was reported in 93% (95% CI, 89.4%–96.7%) and TICI 2c/3 was achieved in 60.4% (95% CI, 46.6%–74.3%). Procedural complications occurred in 6.4% (95% CI, 1.6%–11.2%) of 333 patients; 0.6% (95% CI, 0.4%–1.7%) were associated with GLUTTON. Embolic complications rate was 2.3% (95% CI, 0.7%–3.9%); 2% (95% CI, 0.5%–3.5%) migrated to a new territory. The rate of ICH in Solumbra groups was 9.9% (95% CI, 2.8%–17.1%); 6% (95% CI, 2.8%–9.1%) of patients experienced sICH. Rates of vessel perforation and dissection were 1.9% (95% CI, 0.3%–4.1%) and 0.7% (95% CI, 0.3%–1.6%), respectively. The mean of NIHS scores at 24 h of 193 patients managed with Solumbra was 7.588 (95% CI, 6.609–8.566); which means improvement with 6.827 scores (95% CI, 4.079–9.575). Good clinical outcomes (mRS 0–2) at 90-day-follow-up were observed in 53.8% (95% CI, 21.6%–86%) and 44 out of 352 patients expired (10.8% [95% CI, 5.5%–16.2%]). No statistically significant difference in outcomes was noted between the two treatment groups (Table 3).

Meta-regression results

The rate of rescue therapy was found to increase with old age (P = .017) and tandem lesions (P = .012), and to decrease with female gender (P = .029). Regardless of treatment type, meta-regression results showed that a higher rate of final TICI 2b/3 was achieved in strokes of the MCA (P = .046) and lower in strokes of the posterior circulation (P = .065). The more the IVT was administered, the higher the rate of TICI 2b/3 was observed, but not statistically significant (P = .324). Longer median time from a puncture to reperfusion was associated with less successful recanalization (P = .0018), and a higher risk of ICH (P = .012) and mortality (P = .089). Patients who presented with good ASPECT scores (>7) showed lower rates of overall procedural complications (P = .022), embolic complications (P = .031), ICH (P = <.0001), and mortality (P = .005). The risk of embolic complications was lower in patients with tandem lesions (P = .003) and HTN (P = .004) and higher in patients who experienced strokes in the posterior circulation (P = <.0001). The mortality rate was more common in patients with tandem lesions (P = .0.022), ICA (P = .001), and posterior circulation (P = .051) strokes and less in those who suffered MCA strokes (P = .004). No significant difference by utilized GLUTTON catheter size was noted in any of the outcomes except for mortality rates, whichshowed to decrease with small catheter size (p = 0.017). Detailed results of meta-regression are provided in Table 4.

Discussion

This meta-analysis of 1865 patients compared the efficacy and safety of GLUTTON aspiration catheter between ADAPT (1365 patients) and Solumbra techniques (471 patients) as first-line treatment in AIS and overall demonstrated similar clinical and angiographic out comes between both techniques.

Among 1365 patients who underwent MT via ADAPT using GLUTTON catheter, rates of mFPE (59.3%) and FPE (34.4%) were similar to the mFPE (48%) and FPE (29%) rates reported in a recent large systematic review of 16870 AIS patients managed with ADAPT and had various technical, anatomical, and clinical characteristics.22 In our meta-analysis, successful recanalization (TICI 2b/3) rate in ADAPT group (89%) was similar to that of Penumbra (82.3–93.1%),[23,24] and other aspiration catheters (85–94%) in various retrospective cohorts,[15,25] and few clinical trials such as THERAPY (70%), ASTER (84.9%), and COMPASS (76%).[23,26,27]

Rescue therapy rate (30%) was similar to the literature (32.8%).[23] Although many results of this meta-analysis suffer considerable heterogeneity attributed to the

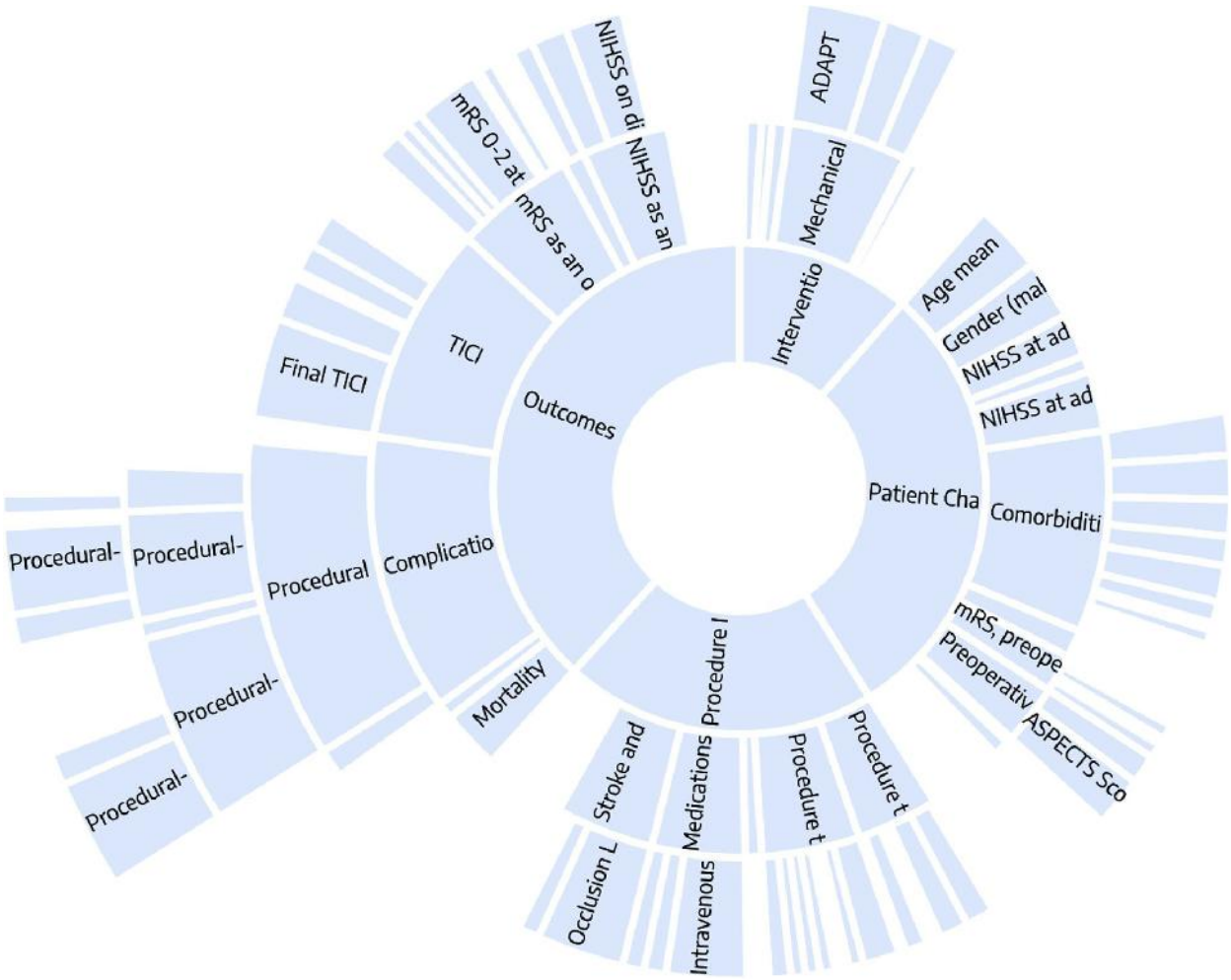


Figure 2. A sunburst diagram of key concepts extracted from each study.

variation in institutions' treatment protocol, utilized devices, and neuro-interventionists' experience, these results demonstrate a high efficacy of GLUTTON catheter for aspiration in AIS. The complication rate related to GLUTTON catheter was very low with a procedural complication rate of 8%; which included emboli to new territory (ENT), artery perforation, and dissection with rates of 2.3%, 1.3%, and 0.5%, respectively. The risk of ENT in our study is lower but the rate of postprocedural symptomatic ICH is higher than that of Penumbra catheter (ENT: 5.7%, sICH: 2.4%) as reported by Lapergue et al.23 Rates of procedural artery perforation and dissection are very low and similar to the generalpopulation.[28] Ninety-day favorable clinical outcomes were similar to the rates reported in the literature but the 90-day mortality rates (22.6–27%) are higher than what we found in this meta-analysis (15.3%).[15,23] These results demonstrate the safety and efficacy of GLUTTON aspiration catheter as a frontline technique to achieve MT with ADAPT in AIS patients, similarly to previously approved aspiration catheters.

In the cohort who received Solumbra technique, the rate of successful recanalization (TICI 2b/3)

with GLUTTON catheter (93%) was high as previous reports of patients treated with Penumbra aspiration system (81.9%).[29–31] In our meta-analysis, the Solumbra technique showed better angiographic outcomes (60%) on the first pass than that of stent retriever (23%) in the TRACK registry,[32] and in a recent meta-analysis comparing stent retriever (32.6%) with Solumbra technique (40.8%, p < .001).[33] Hesse et al. compared the clinical and technical outcomes of all available MT techniques (ADAPT, Stent retrieve were the highest (86%, p < .001) and the rates of ENT (p = 0.19) and number of attempts (p < .001) were the lowest in Solumbra group.[34] Upon the comparison of the angiographic and clinical outcomes of both techniques in our meta-analysis, we can note similar efficacy and safety of ADAPT and Solumbra. The Final TICI 2b/3 rates of Solumbra and ADAPT techniques using GLUTTON catheter were similar. Furthermore, there was no statistically significant discrepancy in the final com- plete recanalization (TICI 2C/3) rates among both ADAPT and Solumbra groups in this meta-analysis. The device and procedure-related complications were almost similar with no statistically significant difference in clinical outcomes overall. Solumbra technique is thought that it provides higher feasibility to achieve successful recanalization due to the use of two distinct MT systems in concurrent time which eliminates the need for rescue therapy when ADAPT fails. Furthermore,

Table 3. Meta-analysis results.

Variables*	Event/ Total	ADAPT Technique (1365 patients)	I^2%	Event/ Total	Solumbra Technique (471 patients)	I^2%	P value
Rescue Therapy	369/1175	30 (25.4–34.7)	60.85		–	-	-
mFPE (TICI 2b/3)	370/580	59.3 (48.3–70.4)	82.64	49/81	60% (95% CI, 51.8% - 68.1%)	71.78	0.961
FPE (TICI 2C-3)	313/872	34.4 (22.2–46.6)	92.6	16/48	33% (95% CI, 20%–46.7%)	-	-
Final TICI 2b/3	1232/ 1422	89.3 (85.1–93.6)	86.51	322/353	93% (95% CI, 89.4%–96.7%)	49.11	0.563
Final TICI 2c/3	587/786	74.3 (52.4–96.3)	98.2	29/48	60.4% (95% CI, 46.6%–74.3%)	-	0.588
Glutton Complications	6/460	0.6 (0.3–1.5)	19.86	0/217	0.6 (0.4–1.7)	0	0.945
Procedural Complications	95/1216	8 (4.9–11.1)	74.63	24/333	6.4 (1.6–11.2)	73.09	0.745
Embolic Complications	40/1078	3.4 (1.4–5.4)	73.81	9/333	2.3% (0.7–3.9)	0	0.328
ENT	29/1078	2.3 (0.9–3.7)	56.78	6/333	2 (0.5–3.5)	0	0.616
Any ICH	210/1078	12.2 (4.4–20)	93.51	23/217	9.9 (2.8–17.1)	65.35	0.621
sICH	45/755	5.4 (3.8–7)	0	13/217	6 (2.8–9.1)	0	0.307
Artery Dissection	6/909	0.5 (0–0.9)	0	3/285	0.7 (0.3–1.6)	0	-
Artery Perforation	12/855	1.3 (0.6–2.1)	0	3/149	1.9 (0.3–4.1)	0	-
NIHSS at 24 h**	358	8.973 (8.132–9.815)	0	193	7.588 (6.609–8.566)	33.81	-
Change in NIHSS at 24 h***	358	−6.827 (−4.079, −9.575)	70.66	193	−6.906 (−4.051, −9.762)	76.22	0.435
mRS 0–2 at 90 days	572/1150	48.8 (42.8–54.8)	72.63	59/99	53.8 (21.6–86)	90.01	0.741
Overall Mortality	187/1088	15.3 (9.9–20.8)	82.82	44/352	10.8 (5.5–16.2)	65.27	0.368

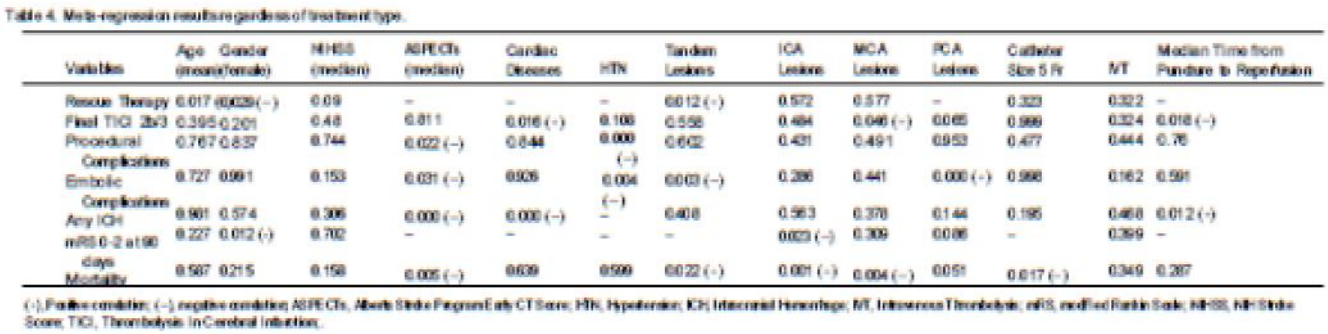
*All variables except for NIHSS values were reported as % (95% CI).
**Reported as mean.
***Reported as mean difference.
ENT, Emboli to New Territory; FPE, First Pass Effect; ICH, Intracranial Hemorrhage; mRS, modified Rankin Scale; NIHSS, NIH Stroke Score; TICI, Thrombolysis In Cerebral Infarction;.

despite the reported shorter procedure time in ADAPT,[30,35] the need for rescue therapy in ADAPT is not low and can increase the time to achieve reperfusion mainly in complicated cases. Almandoz et al. reported a significant correlation of Solumbra technique with higher rates of post thrombectomy SAH (p = 0.03) and ICH (p = 0.01), and poor clinical outcomes (p = 0.015) in a total of 55 patients treated with a combination of stent retriever and Penumbra aspiration catheter.[30] However, the authors did not find a significant difference between the Solumbra and ADAPT groups in terms of time from puncture or from onset to reperfusion. We did not find a noteworthy difference among all clinical and angiographic outcomes of ADAPT and Solumbra

techniques given the relatively high rescue therapy in our cumulative cohort. Further multi-center registries and clinical trials are warranted to determine the ideal thrombectomy technique based on the clinical and anatomic characteristics of the ischemic lesion and size and type of aspiration catheter and stent retriever.

Various characteristics of occlusive lesions have been reported, however, their association with MT outcomes in AIS has not been well analyzed and documented. Tandem lesions often show poor clinical and angiographic outcomes referring to their difficult management,[36] represented by their high rescue therapy and mortality rates in our study. Old patients are prone to higher rates of MT failure and need of rescue therapy possibly due to the common prevalence of atherosclerosis and arterial wall stiffness in the elderly population supported by the report of Kyselyova et al.[37] Catheter size is a subject of ongoing debate in the literature. Brinjikji et al. investigated the impact of the various sizes of GLUTTON catheter on the clinical outcomes and reported no significant difference (p = .09).[17] However, stratification of outcomes by size of the aspiration catheter is low particularly in the retrospective studies with heterogeneous characteristics of aspiration catheters and stent retrievers. Thus, results of subgroup meta-analysis or meta-regression evaluating the impact of catheter size on the outcomes of ADAPT group were highly limited with the small number of included studies reporting catheter size. Conclusively, we were unable to conclude a generalizable results stratified by the catheter size and stent retriever types. On the other side, report rates of baseline stroke characteristics were better in the neurology and stroke literature. ICA has a larger diameter than MCA increasing its thrombus burden, which illustrates the worse safety outcomes, and higher embolic complications and mortality in ICA stroke patients. Posterior circulation strokes had worse angiographic and clinical outcomes, similar to a previous report.[38] Therefore, ICA and posterior circulation strokesshould be approached with attention to the patient age and initial clinical status using MT techniques with high effectiveness. Initial clinical status -assessed particularly with admission ASPECTS- of AIS patients is a good

Table 4. Meta-regression results regardless of treatment type.



Variables	Age	Gender (male/female)	NIHSS (median)	ASPECTs (median)	Cardiac Diseases	HTN	Tandem Lesions	ICA Lesions	MCA Lesions	PCA Lesions	Catheter Size 5 Fr	MT	Median Time from Puncture to Reperfusion
Rescue Therapy	0.017	0.029 (-)	0.09	–	–	–	0.012 (-)	0.572	0.577	–	0.323	0.322	–
Final TICI 2b/3	0.395	0.201	0.48	0.811	0.016 (-)	0.105	0.556	0.484	0.046 (-)	0.065	0.988	0.324	0.018 (-)
Procedural Complications	0.767	0.837	0.744	0.022 (-)	0.844	0.000 (-)	0.602	0.431	0.491	0.953	0.477	0.444	0.76
Embolic Complications	0.727	0.991	0.153	0.031 (-)	0.926	0.004 (-)	0.003 (-)	0.286	0.441	0.000 (-)	0.988	0.162	0.591
Any ICH	0.901	0.574	0.306	0.000 (-)	0.000 (-)	–	0.408	0.563	0.378	0.144	0.195	0.468	0.012 (-)
mRS 0-2 at 90 days	0.227	0.012 (-)	0.702	–	–	–	–	0.023 (-)	0.309	0.086	–	0.399	–
Mortality	0.597	0.215	0.158	0.005 (-)	0.639	0.999	0.022 (-)	0.001 (-)	0.004 (-)	0.051	0.017 (-)	0.349	0.287

(-), Positive correlation; (-), negative correlation; ASPECTs, Alberta Stroke Program Early CT Score; HTN, Hypertension; ICH, Intracranial Hemorrhage; MT, Intravenous Thrombolysis; mRS, modified Rankin Scale; NIHSS, NIH Stroke Score; TICI, Thrombolysis In Cerebral Infarction.

predictor of MT clinical and safety outcomes. Time is still a very crucial factor in the management of AIS patients despite the evolution of thrombectomy techniques; the longer the time from puncture to recanalization, the worse the angiographic and clinical outcomes.

Further anatomical characteristics and confounders (laterality, vessel dominance, stenosis ratio, BATMAN scores, etc.)have a crucial impact on AIS patients' outcomes and are to be investigated in future studies.

Limitations

This meta-analysis is limited mainly to the retrospective method of data collection in the included studies; which are commonly uncontrolled as well. Furthermore, variability in the treatment protocols among institutions, neuro-interventionist experience, and patients and stroke characteristics had a significant role in the high heterogeneity in the results of this meta-analysis. Investigation of the association of many of these confounders and strokes characteristics with outcomes was not possible due to their limited report. The type of the used stent retrievers in the Solumbra group, size of GLUTTON catheter, the ratio of given intravenous PA regimen before the procedure, and time of the patients' admission can be considered among these variables. Publication bias is quite likely as many studies reported outcomes of specific locations like MCA strokes, or specific catheter sizes, and the role of device manufacturer in the research cannot be clearly understood. Conclusively, the overall certainty in the evidence at present is rated low.

Conclusion

GLUTTON catheter is a safe and effective device for mechanical thrombectomy in acute ischemic stroke. ADAPT and Solumbra techniques have both demonstrated very good angiographic and clinical outcomes with the use of GLUTTON catheter. However, the rate of rescue therapy in ADAPT was not negligible. ICA and poster- ior circulation strokes have worse outcomes and are associated with high mortality. Finally, given the high confounding in our sample, further well-conducted clinical trials comparing ADAPT and Solumbra techniques are warranted to provide better treatment protocol with attention to the clinical and anatomic confounders of AIS patients. meticulous documentation of the GLUTTON Aspiration Catheter by Neurosafe Medical Co., Ltd., ensuring adherence to regulatory guidelines, including the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and BS EN ISO 14155:2020., authorship, and/or publication of this article.

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