pRESET stent retriever

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- Is Stent Retraction to ReLieve Arterial Cerebral VaSospasm Caused by SAH (Stent-ReLACSS) Using PRELAX the Long-awaited Solution for Treatment of Posthemorrhagic Cerebral Vasospasm? : Treatment of Posthemorrhagic Cerebral Vasospasm with PRESET and PRELAX: Technical Aspects, Efficacy, and Safety Margins in a Case Series

https://www.phenox.net/fileadmin/uploads/produkt_pdf/KIF-0005C_Produktflyer_pREset_01.pdf

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The **pRESET stent retriever** is a modern, self-expanding nitinol device designed for mechanical thrombectomy (MT) in patients with acute ischemic stroke (AIS) due to large vessel occlusion (LVO). This device is part of a growing arsenal of endovascular tools aimed at improving reperfusion outcomes and minimizing neurological damage in stroke patients.

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Key Features 1. **Self-Expanding Nitinol Design**:

1. Made of nitinol, a material known for its flexibility and memory shape, which aids in navigating tortuous cerebral vessels.
2. Self-expansion ensures optimal vessel wall apposition and clot engagement.

2. **Target Use**:

1. Indicated for cases of AIS caused by LVO in the anterior and posterior circulation.
2. Designed for deployment through standard microcatheters, compatible with existing endovascular systems.

3. **Recanalization Efficiency**:

1. Demonstrates high success rates in recanalizing occluded vessels, both in first-pass and subsequent attempts.

2. Effective in combination with adjunctive therapies like aspiration.

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Clinical Performance A systematic review and meta-analysis (Habibi et al., 2024) evaluated the safety and efficacy of the pRESET device: - **Efficacy**:

1. **First-pass success**: 60% (95% CI: 52%–67%)
2. **Final recanalization success**: 90% (95% CI: 83%–95%)
3. Functional independence (mRS 0-2 at 90 days): 43% (95% CI: 34%–52%)

- **Safety**:

1. Overall hemorrhagic complications: 22% (95% CI: 12%–36%)
2. Parenchymal hemorrhage: 7% (95% CI: 4%–13%)
3. Subarachnoid hemorrhage: 10% (95% CI: 5%–17%)
4. Mortality: 18% (95% CI: 12%–25%)

These results suggest that the pRESET device is effective in restoring blood flow and achieving favorable functional outcomes, with complication rates comparable to other stent retrievers.

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Advantages 1. **High Recanalization Rates**:

1. Achieves similar or better rates compared to other market leaders like Solitaire or Trevo.

2. **Versatility**:

1. Effective across a wide range of occlusion sites and clot characteristics.

3. **Ease of Use**:

1. Simplified design enhances maneuverability, reducing procedural complexity.

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Challenges and Considerations 1. **Lack of Head-to-Head Comparisons**:

1. Most available data are observational, with few randomized controlled trials directly comparing pRESET to other stent retrievers.

2. **Potential for Complications**:

1. Although within acceptable ranges, hemorrhagic complications remain a concern, underscoring the need for careful patient selection.

3. **Limited Adoption**:

1. Despite promising results, broader clinical adoption may depend on further validation in diverse populations and healthcare systems.

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Future Directions 1. **Comparative Trials**:

1. Randomized controlled trials comparing pRESET with established devices like Solitaire or Trevo could solidify its place in the therapeutic landscape.

2. **Real-World Data**:

1. Prospective registry data could provide insights into its performance across different patient demographics and clinical settings.

3. **Device Innovation**:

1. Advances in stent retriever technology, such as designs that reduce clot fragmentation or improve safety in fragile vessels, could further enhance outcomes.

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Conclusion The **pRESET stent retriever** is a promising tool for mechanical thrombectomy in LVO-related strokes, with high efficacy and an acceptable safety profile. While its recanalization and functional outcomes are impressive, additional comparative studies are needed to define its role relative to other devices. As evidence accumulates, pRESET has the potential to become a mainstay in endovascular stroke therapy.

Systematic Review and Meta-Analysis

A systematic review and meta-analysis study conducted based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The electronic databases of PubMed, Embase, WoS, and Scopus were systematically reviewed from inception to 8 July 2024.

A total of eight studies involving 1163 patients were included. The pooled mortality rate was 18% with a 95% CI of [12%, 25%]. The rates of any hemorrhagic complication, parenchymal hemorrhage, and subarachnoid hemorrhage were 22% with a 95% CI of [12%, 36%], 7% with a 95% CI of [4%, 13%], and 10% with a 95% CI of [5%, 17%], respectively. The rate of favorable functional outcome (modified Rankin Scale 0-2) at 90 days was 43% with a 95% CI of [34%, 52%]. Successful recanalization rates were 60% with a 95% CI of [52%, 67%] after the first pass and 90% with a 95% CI of [83%, 95%] after the final pass. Rescue devices were used in 13% with a 95% CI of [7%, 24%] of cases.

The pRESET stent retriever demonstrates high recanalization rates and reasonable safety outcomes in patients undergoing mechanical thrombectomy for acute ischemic stroke due to large vessel occlusion. Further randomized trials directly comparing pRESET to other stent retrievers are warranted [1)].

In a multicenter, prospective, randomized, controlled, open-label, adaptive, noninferiority trial with blinded primary end point evaluation. Between October 2019 and February 2022, multicenter participation occurred across 19 research hospitals and/or universities in the US and 5 in Germany. Patients with LVO stroke were enrolled and included up to 8 hours after symptom onset.

Interventions: Patients underwent 1:1 randomization to thrombectomy with the pRESET or Solitaire stent retriever.

Main outcomes and measures: The primary outcome was the difference in the rate of 90-day functional independence across the 2 devices, using a -12.5% noninferiority margin for the lower bound of the 1-sided 95% CI of the difference between pRESET and Solitaire retrievers.

Results: Of 340 randomized patients, 170 (50.0%) were female, and the median (IQR) age was 73.0 (64.0-82.0) years. The study procedure was completed in 322 of the 340 randomized patients. The primary end point of 90-day functional independence was achieved by 95 patients (54.9%; 95% CI, 48.7-61.1) in the pRESET group and in 96 (57.5%; 95% CI, 51.2-63.8) in the Solitaire group (absolute difference, -2.57%; 95% CI, -11.42 to 6.28). As the lower bound of the 95% CI was greater than -12.5%, the pRESET retriever was deemed noninferior to the Solitaire retriever. The noninferiority of pRESET over Solitaire was also observed in the secondary clinical end point (90-day shift in modified Rankin Scale score) and in both angiographic end points (Expanded Treatment in Cerebral Infarction [eTICI] score of 2b50 or greater within 3 passes: 146 of 173 [84.4%] vs 149 of 167 [89.2%]; absolute difference, -4.83%; 95% CI, -10.84 to 1.19; eTICI of 2c or greater following the first pass: 76 of 173 [43.7%] vs 74 of 167 [44.3%]; absolute difference, -0.63%; 95% CI, -9.48 to 8.21). Symptomatic intracranial hemorrhage occurred in 0 patients in the pRESET group and 2 (1.2%) in the Solitaire group. Mortality occurred in 25 (14.5%) in the pRESET group and in 24 (14.4%) in the Solitaire group at 90 days. Findings of the per-protocol and as-treated analyses were in concordance with findings of the intention-to-treat analysis.

In this study, among patients with Large Vessel Occlusion (LVO) stroke, thrombectomy with the pRESET stent retriever was noninferior to thrombectomy with the Solitaire stent retriever. Findings suggest that pRESET offers a safe and effective option for flow restoration and disability reduction in patients with LVO stroke [2].

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Habibi MA, Ahmadvand MH, Delbari P, Sabet S, Zare AH, Mirjani MS, Boskabadi AR, Kolur ZA, Bozorgi M. The safety and efficacy of pRESET stent retriever for treatment of thrombo-embolic stroke; a systematic review and meta-analysis. Neuroradiol J. 2024 Nov 27:19714009241303083. doi: 10.1177/19714009241303083. Epub ahead of print. PMID: 39604086.

2)
Nogueira RG, Lobsien D, Klisch J, Pielenz D, Lobsien E, Sauvageau E, Aghaebrahim N, Möhlenbruch M, Vollherbst D, Ulfert C, Bozorgchami H, Clark W, Priest R, Samaniego EA, Ortega-Gutierrez S, Ghannam M, Lopes D, Billingsley J, Keigher K, Haussen DC, Al-Bayati AR, Siddiqui A, Levy E, Chen M, Munich S, Schramm P, Boppel T, Narayanan S, Gross BA, Roth C, Boeckh-Behrens T, Hassan A, Fifi J, Budzik RF, Tarpley J, Starke RM, Raz E, Brogan G, Liebeskind DS, Hanel RA. Thrombectomy With the pRESET vs Solitaire Stent Retrievers as First-Line Large Vessel Occlusion Stroke Treatment: A Randomized Clinical Trial. JAMA Neurol. 2024 Jan 2. doi: 10.1001/jamaneurol.2023.5010. Epub ahead of print. PMID: 38165690.