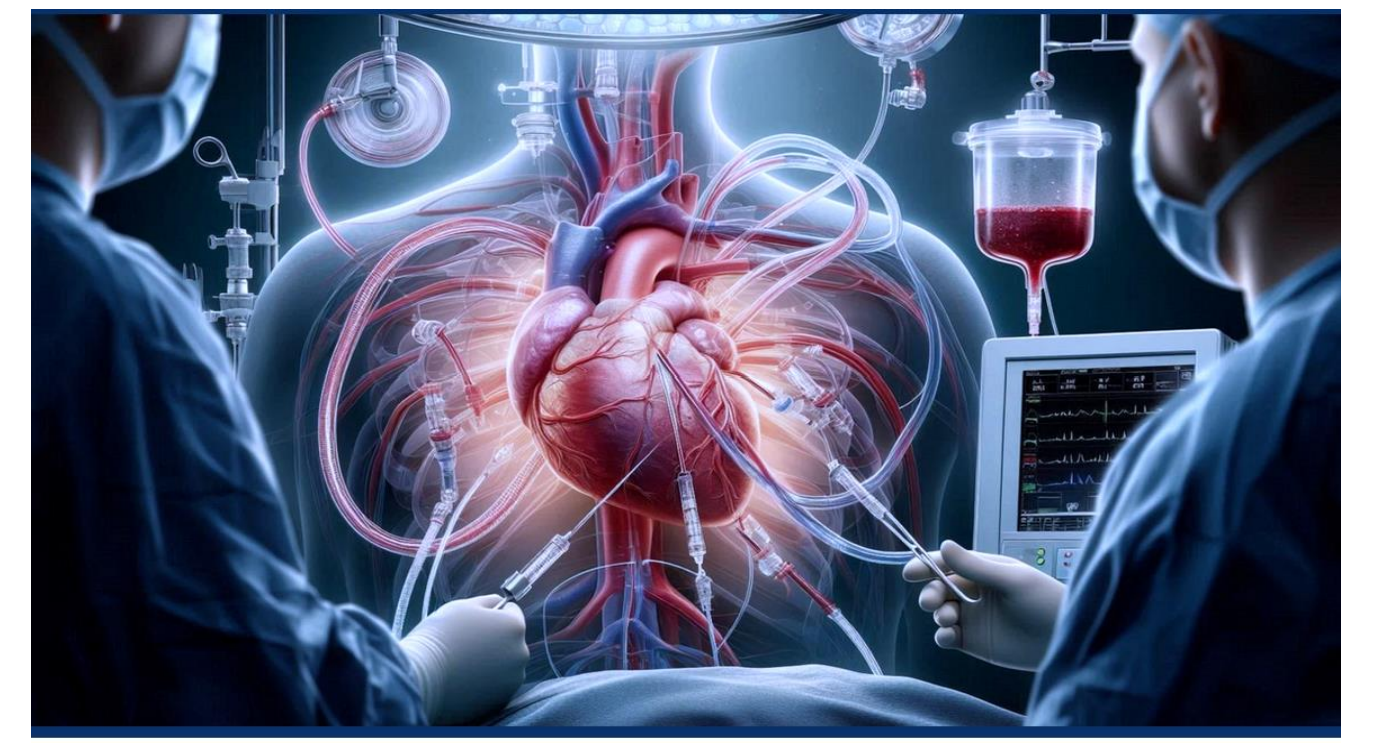


# Reimagining Aortic Arch Surgery: Evidence from a Meta-Analysis

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## ABSTRACT

Octin Health is a surgeon-led medical device innovator, dedicated to advance safety and efficiency in case of aortic arch surgery. The flagship innovation, the Elika Device, is developed and designed to modernize aortic arch interventions by reducing reliance on deep hypothermic circulatory arrest (DHCA) and enabling more physiologically stable surgical conditions.

HITLAB conducted systematic review and meta-analysis of 432 peer-reviewed studies to synthesize evidence on techniques of aortic arch surgery, patient outcomes, associated procedural risk. The review further examined and analyzed key post-operative outcome such as permanent stroke, brain perfusion strategies, temperature exposure across diverse populations and surgical approaches.

The findings highlight common operative metrics like temperature and substantial effect of brain perfusion strategy over stroke outcome in aortic arch surgical techniques, underscoring the ongoing challenges and need for innovations like Elika Device.

## WHY THIS MATTERS?

- In the U.S., about 1.7 per 100,000 people suffer from acute Type A aortic dissections affects, and 5–10 per 100,000 have thoracic aortic aneurysms.
- Among these cases, many require surgery using deep hypothermic circulatory arrest (DHCA), a technique that helps in reducing organ injury but is known to increase bigger health risks such as stroke and kidney complications.
- While high-volume centers achieve better outcomes, access remains limited for rural and low-income patients, who often face delays and higher complication rates.
- Octin Health aims to reduce these disparities by making aortic arch surgery safer and more feasible, expanding access to life-saving care.

Octin Health through their Elika Device is committed to address inequities by underscoring de-risking aortic arch surgery in lower-volume settings, therefore, enabling more safe, timely, and life-saving care for patients regardless of geography or socioeconomic status

## RESULTS

### Part A: Surgical Temperature

#### Descriptive Statistics

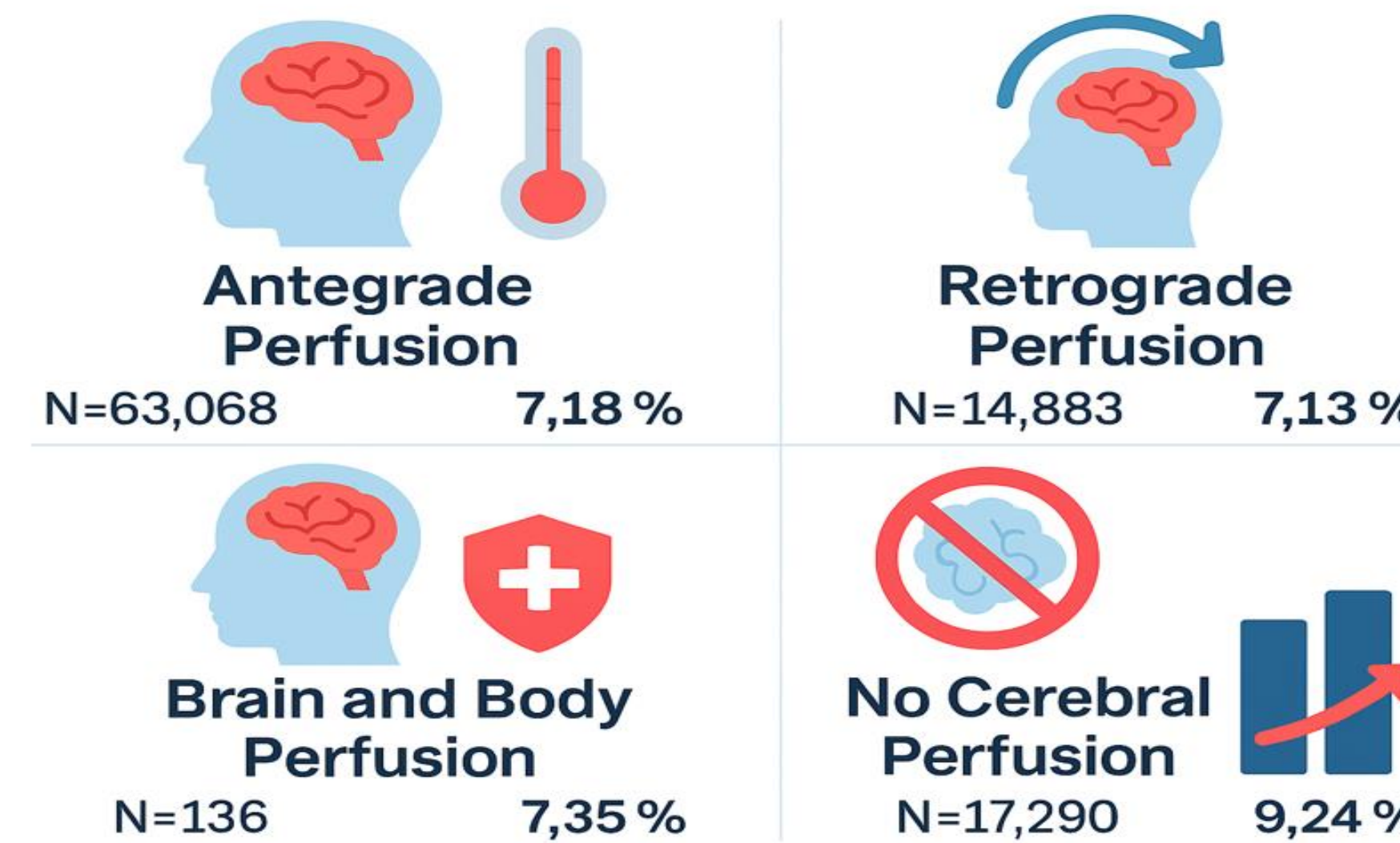
Temperature	Sample Size(N)	Mean ± SD(°C)	Median (°C)
<b>Profound</b>	1530	12.04 ±1.86	10.0
<b>Deep</b>	57824	18.18 ± 1.51	19.0
<b>Low-Moderate</b>	70128	22.50 ±1.16	22.5
<b>High-Moderate</b>	111620	25.93 ±1.17	24.7
<b>Mild</b>	9330	30.29 ±1.46	30.0
<b>Normothermia</b>	397	36.57 ±0.45	36.50
<b>Overall</b>	250829	23.17±3.42	24

#### Findings

- The range 10-37°C (difference 27°C) showed substantial variation in cooling strategies used across studies.
- The total sample size of 250,829 patients in the data set showed median temperature of 24°C suggesting that most studies employed mainly moderate hypothermia, clustering around 23-24°C.

### Part B: Stroke Rate by Brain Perfusion Category

#### Summary Statistics



#### Findings

- Antegrade Cerebral Perfusion (ACP) was the most used technique, applied in 63,068 patients, with a stroke rate of 7.18% (4,530 events).
- Retrograde Cerebral Perfusion (RCP) was used in 14,883 patients and showed a similar stroke incidence of 7.13% (1,061 events).
- Brain and Body Perfusion was applied in a smaller cohort of 136 patients, demonstrating a stroke rate of 7.35% (10 events).
- In contrast, **No Cerebral Perfusion (No CP) had the highest stroke rate at 9.24%, occurring in 1,597 events among 17,290 patients.**

## OBJECTIVES & METHODOLOGY

**Part A:** To find the average temperature among all the patients under the included studies.

**Part B:** To find the average stroke rate of the patients and how it has varied with different brain perfusion strategies.

Step	Description
Study selection	Out of 432 studies, studies with temperature categories and corresponding sample sizes were included (N = 314).
Temperature categories	Further step filtration ensured the comparator groups were perfusion categories: <ul style="list-style-type: none"> <li>• Profound Hypothermia (<math>\leq 14^\circ\text{C}</math>)</li> <li>• Deep Hypothermia (<math>14.1\text{--}20^\circ\text{C}</math>)</li> <li>• Moderate Hypothermia (<math>20.1\text{--}28^\circ\text{C}</math>) low-moderate (<math>20\text{--}24^\circ\text{C}</math>) and high-moderate (<math>24\text{--}28^\circ\text{C}</math>)</li> <li>• Mild Hypothermia (<math>28.1\text{--}34^\circ\text{C}</math>)</li> <li>• Normothermia (<math>\geq 35^\circ\text{C}</math>)</li> </ul>
Descriptive statistics	Descriptive statistics for mean, standard deviation, and median temperature were calculated and reported for each temperature category.

Step	Description
Study selection	Out of 432 studies, only those reporting both stroke outcomes and brain perfusion categories were included. Further step filtration ensured the comparator groups were perfusion categories (N=44).
Brain perfusion categories N = 44	Antegrade Cerebral Perfusion (ACP) Retrograde Cerebral Perfusion (RCP) Brain and Body Perfusion No Cerebral Perfusion (No CP) Statistical analysis was conducted using SPSS Software Version 23.0, with a significance threshold of $p < 0.05$ .
Statistical analysis	Summary statistics was used to present the number and percentage of stroke events within each brain perfusion category. Binary Logistic Regression was performed to evaluate the effect of different brain perfusion strategies on stroke outcomes.

### Logistic Regression: Stroke and Brain Perfusion Strategy

No Cerebral Perfusion (No CP)	Retrograde Cerebral Perfusion (RCP)	Brain + Body Perfusion
Strongest and only significant predictor in the model	No meaningful association	No statistically significant effect
<b>OR 1.315</b> 95% CI: 1.239 $p < 0.001$ ▲ Highly significant	<b>OR 0.992</b> 95% CI: 0.925 $p = 0.819$	<b>OR 1.026</b> 0.538–1.954 $p = 0.939$
Model Summary $\chi^2(3) = 86.001, p < 0.001$ Reference Category: ACP (Antegrade Cerebral Perfusion)		

#### Findings

- The results revealed that neither RCP (OR = 0.992, 95% CI: 0.925–1.063,  $p = 0.819$ ) nor Brain + Body Perfusion (OR = 1.026, 95% CI: 0.538–1.954,  $p = 0.939$ ) showed significant difference in terms of stroke outcomes odds from ACP.
- No CP showed significantly higher odds of reporting more stroke outcome as compared with ACP (OR = 1.315, 95% CI: 1.239–1.396,  $p < 0.001$ ).
- **No CP represents approximately a 31.5% increase in odds relative to ACP for causing stroke event in aortic arch surgery.**

## CONCLUSION

Overall, in case of temperature, findings indicate a prevalent adoption of moderate hypothermic temperature strategy (20–28°C), which reflects balance between cerebral protection and reduced systemic complications compared with deep or profound cooling strategies.

Stroke risk varies considerably by brain perfusion technique. Overall, the absence of cerebral perfusion was associated with higher likelihood of stroke outcomes, while both retrograde and combined (brain + body) perfusion strategies produced comparable results to the antegrade perfusion strategy.

## ACKNOWLEDGEMENTS

Authors would like to acknowledge the HITLAB research team for study support and implementation, and the solution developers for their work and technical support throughout the study.