Critically Appraised Topic

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Decompressive Craniectomy in Stroke

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Early decompressive craniectomy reduced mortality in patients with malignant middle cerebral artery (MCA) stroke

Clinical Problem: A 30-year-old, right-handed woman was assessed 26 hours after the onset of a large, ischemic infarct involving the right middle cerebral artery territory and was found to have a National Institutes of Health Stroke Scale score of 18.

Clinical Question: Does decompressive craniectomy reduce mortality and/or improve functional outcome in a patient with a malignant stroke syndrome?

Search Strategy: Keywords: 1. "Malignant MCA stroke" AND "decompressive craniectomy" 2. "MCA Stroke" AND "surgery" Sources: Pubmed/Medline, EMBASE, Cochrane, and expert opinion. Limits: English, Meta-analysis, and Randomized Controlled Trial (RCT) (searched separately). Results: One relevant RCT found Decompressive Craniectomy In Malignant Middle Cerebral Artery Infarcts (DECIMAL trial). In the related articles a pooled analysis which included the DECIMAL trial and two other ongoing studies was found. This study was chosen as it pooled the results of three RCT trials (one published and two ongoing).

Clinical Bottom Lines:

1. Early decompressive craniectomy for malignant MCA stroke reduced mortality at one year (NNT [number needed to treat] 2, 95% CI 1.5-3)
2. Early decompressive craniectomy for malignant MCA stroke improved functional outcome on the modified Rankin Scale at one year (NNT 4, 95% CI 2 to 22).

The Evidence: Pooled analysis of 3 multi-centre RCTs (DECIMAL, DESTINY AND HAMLET) comparing the outcome of early decompressive surgery versus "standard" medical treatment in patients with malignant MCA strokes. Only patients who were randomized before 45 hours were included in the analysis. A total of 93 patients (age range: 18 - 60 years-of-age) were randomized. Forty-two patients received medical treatment and 51 received surgical treatment. Outcomes measured were the modified Rankin scale (mRS) at one year and survival at one year. The mRS is a commonly used scale for

measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke, and it has become the most widely used clinical outcome measure for stroke clinical trials. The scale runs from 0-6, running from perfect health without symptoms and death (0 - No symptoms; 1 - No significant disability. Able to carry out all usual activities, despite some symptoms; 2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities; 3 - Moderate disability. Requires some help, but able to walk unassisted; 4 - Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted; 5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent; and, 6 - Dead).

Data:

Outcome Measures at One Year

	Modified Rankin Scale Favourable 0 to 3	Modified Rankin Scale Unfavourable 4 to 6	Survival
Absolute Risk Reduction	23% (95% CI 5-41)	51% (95% CI 34-69)	50% (95% CI 33-67)
NNT	4 (2-22)	2 (1.5 -3)	2 (1.5 to 3)

Comments:

1. The three trials had similar inclusion and exclusion criteria with the exception of the time from stroke to treatment. To standardize this, only patients randomized before 45 hours were included in the analysis.

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2. Randomization was concealed in all three trials.
3. The authors excluded patients older than 60 years of age so the benefit of surgery in reducing mortality in that group of patients is uncertain.
4. Most of the patient population was younger than 50 years-of-age.
5. The treatment for the medical group was not standardized.
6. National Institutes of Health Stroke Scale scores and systolic blood pressure were significantly higher in the medical treatment group at baseline in two trials.
7. There were no reports of harm in the surgical group.
8. Outcome assessment was not blinded in two trials.
9. There was no significant heterogeneity between the three trials in outcome measures.
10. Recommendation for decompressive surgery should be individualized.

REFERENCE ARTICLE APPRAISED

Vahedi K, Hofmeijer J, Juettler E, et al. Early decompressive surgery in malignant infarction of the middle cerebral artery: a pooled analysis of three randomized controlled trials. *Lancet Neurol.* 2007; 6(3): 215-22.

KEY WORDS

Malignant MCA stroke, decompressive craniectomy

APPRAISER

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EXPERT OPINION: Neurosurgery

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Malignant middle cerebral artery stroke – defined as stroke following occlusion of the internal carotid or proximal middle cerebral artery – has a devastating natural history¹. Hacke et al reported a 78% mortality rate over 2-7 days (mean 4 days) attributable to transtentorial herniation².

It makes surgical sense that a substantial decompressive procedure should provide room for the mass effect of the expanding edematous hemisphere and therefore reduce mortality from herniation. It is not so intuitive that such a procedure would have a significant effect on functional prognosis – i.e., the major concern is that such heroic surgery would save the lives of patients who would then go on to a poor functional outcome.

The accompanying article looks at a meta-analysis of data from three trials (DESTINY³, DECIMAL⁴) and HAMLET. This meta-analysis showed a reduction in case fatality rate and improvement in functional outcome (defined as mRS<4) in patients under the age of 60 years and operated on within 48 hours of symptom onset⁵.

Interestingly, the HAMLET trial – looking at surgical decompression within four days of malignant MCA stroke – showed that surgical decompression within four days of symptom onset did not reduce the probability of a poor functional outcome (in this case defined as mRS<5) compared to

best medical treatment although it did reduce the case fatality rate⁶. They also combined their end-results with the previous two trials for another meta-analysis showing that patients undergoing surgery within 48 hours of symptom onset experienced a significantly better functional outcome.

That the DESTINY and HAMLET trials, on their own, failed to show significant functional benefit with surgical decompression may relate to the fact that they required at least two-thirds of the MCA territory be involved with infarction for inclusion as compared to at least 50% for the DECIMAL trial.

Nevertheless, these are results that we need to take notice of when caring for young patients with malignant MCA infarction. Surgical decompression should be considered, and if deemed appropriate, done early (< 48 hours). Surgical decompression should consist of a duraplasty and the creation of a large bone flap; a substantial craniectomy (at least 12 cm diameter), including temporal, frontal, parietal and occipital bones, with temporal squama taken down to the middle fossa floor^{7,8}. The risk of too small a craniotomy is the progressive herniation of brain through the defect with further damage to brain at the edges of the defect.

I would like to see future studies address the appropriateness of surgical decompression beyond 48 hours, since this is the time frame when deterioration from edema tends to peak; I would like to see the specific issues of dominant vs. non-dominant MCA infarctions assessed with respect to quality of life following surgical decompression.

REFERENCES

1. Lanzino DJ, Lanzino G. Decompressive craniectomy for space-occupying supratentorial infarction: rationale, indications and outcome. *Neurosurg Focus.* 2000; 5(5) article 3:1-7.
2. Hacke W, Schwab S, Horn M, et al. 'Malignant' middle cerebral artery territory infarction: clinical course and prognostic signs. *Arch Neurol.* 1996; 53: 309-15.
3. Juettler E, Schwab S, Schmiedek P, et al. Decompressive Surgery for the Treatment of Malignant Infarction of the Middle Cerebral Artery (DESTINY): a randomized, controlled trial. *Stroke.* 2007; 38: 2518-25.
4. Vahedi K, Vicaut E, Mateo J, et al. Sequential-design, multicenter, randomized, controlled trial of early decompressive craniectomy in malignant middle cerebral artery infarction (DECIMAL trial). *Stroke.* 2007; 38: 2506-17.
5. Vahedi K, Hofmeijer J, Juettler E, et al. Early decompressive surgery in malignant infarction of the middle cerebral artery: a pooled analysis of three randomised controlled trials. *Lancet Neurol.* 2007; 6: 215-22.
6. Hofmeijer J, Kappelle LJ, Algra A, et al. Surgical decompression for space-occupying cerebral infarction (the Hemicraniectomy After Middle Cerebral Artery infarction with Life-threatening Edema Trial [HAMLET]): a multicentre, open, randomised trial. *Lancet Neurol.* 2009; 8: 326-33.
7. Kerr FW. Radical decompression and dural grafting in severe cerebral edema. *Mayo Clin Proc.* 1968; 43: 852-64.
8. Park J, Kim E, Kim GJ, et al. External decompressive craniectomy including resection of temporal muscle and fascia in malignant hemispheric infarction. *J Neurosurg.* 2009; 110: 101-5.