Healthcare workers opinion regarding outcome following surgical intervention for severe ischaemic stroke
Opinion Regarding Acceptable outcome following decompressive hemicraniectomy for ischaemic stroke

ORACLE Stroke Study

S Honeybul* KM Ho**

*Department of Neurosurgery, Sir Charles Gairdner Hospital and Royal Perth Hospital, Western Australia; **Department of Anaesthesia, Royal Perth Hospital, Western Australia
Objectives: The aim of this study was to assess opinion amongst a wide range of healthcare workers regarding consent and acceptable outcome following decompressive hemicraniectomy in the management of ‘malignant’ cerebral artery infarction

Method:
• Seven Hundred and seventy three healthcare workers at the two major public neurosurgical centres in Western Australia participated
• Two part structured interview
• Participants were asked to record their opinion regarding consent for surgical intervention and acceptable outcome based on the Modified Rankin Score (mRS).
• The evidence for clinical efficacy of the procedure was then presented and they were then asked to reconsider their initial responses.
Opinion Regarding Acceptable outcome following decompressive hemicraniectomy for ischaemic stroke

Part 1
A stroke occurs when the blood supply to the brain is restricted, either through a blockage or bleeding. This cuts off the supply of oxygen to the brain causing damage to the affected tissue.

- May cause paralysis, speech impairment, loss of memory and reasoning ability, coma or death
- Can be ischaemic (blood supply blocked) or haemorrhagic (bleed into the brain substance)
- Third most common cause of death (after cancer and ischaemic heart disease)
In Australia - 1 in 6 people will have a stroke in their lifetime

In 2009, an estimated 381,400 Australians (1.8% of the total population) suffered a stroke. More common in males and those over 65

Stroke was the underlying cause of death for 11,220 people in 2010 and an associated cause for a further 20,793 people.

In 2012 there were over 420,000 people living with the effects of stroke. This is predicted to increase to 709,000 in 2032

Two thirds of these patients will have lost independence
Stroke

“Malignant” supratentorial infarction

- Massive brain swelling may occur in up to 10% of patients with cerebral ischaemic strokes (80% mortality)
- Presents with focal signs – Motor weakness, speech disturbances, visual field defects
- Progressive decline in consciousness (usually within 24 – 48 hrs)
- Eventual brainstem dysfunction, coma and death
Malignant supratentorial infarction

Decompressive hemicraniectomy

Initial presentation – Left hemiparesis

At Day 2 – Drowsy, anisocoria

Decompressive hemicraniectomy

Cranioplasty at 3 months
Modified Rankin Score
American Heart Association

Please assess the patient's Modified Rankin Scale score by asking them the following questions and using the simplified mRS questionnaire algorithm:

- Could you live alone without any help from another person? This means being able to bathe, use the toilet, shop, prepare or get meals and manage finances.
  - Yes
    - Are you able to do everything that you were doing right before your stroke, even if slower and not as much?
      - Yes
        - Score = 0
      - No
        - Score = 1
  - No
    - Are you able to walk without help from another person?
      - Yes
        - Score = 3
      - No
        - Are you bedridden or needing constant supervision?
          - No
            - Score = 4
          - Yes
            - Score = 5
## Decompressive hemicraniectomy

### Outcome - clinical Assessment

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**Unfavourable**

**Favourable**
The ORACLE study
What outcome would be acceptable to you

You have had an ischaemic stroke
You have become progressively more drowsy
You develop unequal pupils
There is an 80% chance of dying without surgical intervention

Q1. Consent?

- 80% mortality without surgery
- 20 - 30% mortality with surgery
- Surgery will not reverse stroke damage
- May survive with effects of a very severe stroke

This is you
Q2. What outcome would you feel to be acceptable?

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The ORACLE study
Consent for decompressive hemicraniectomy following “malignant” middle cerebral infarction

- Yes: 407
- Not sure: 226
- No: 140
The ORACLE stroke study
Acceptable outcome following decompressive hemicraniectomy following “malignant” middle cerebral infarction

Acceptable Outcome (modified Rankin Score)
Opinion Regarding Acceptable outcome following decompressive hemicraniectomy for ischaemic stroke

Part 2
Throughout the 1980’s and 90’s a number of clinical studies reported a reduction in mortality following decompressive hemicraniectomy for patients who developed cerebral swelling following an ischaemic stroke.

However there remained considerable controversy regarding patient selection, surgical timing and long term outcome.
Early 2000’s three European randomised controlled trials were independently conducted DESTINY, DECIMAL and HAMLET.

Randomised patients to:
- Decompressive hemicraniectomy
- Standard medical therapy

- Age < 60
- Space occupying MCA infarction
- Treated within 48 hours following stroke.
Each of the three trials independently confirmed a reduction in mortality but no significant increase in patients with a favourable outcome.

A pooled analysis of the 93 patients involved in all three trials demonstrated a reduction in mortality from 71% for those patients treated medically to 22% for those patients who had surgical decompression.
Decompressive Hemicraniectomy

Evidence

Early decompressive surgery in malignant infarction of the middle cerebral artery: a pooled analysis of three randomised controlled trials

Katayoun Vahedi, Jeannette Hofmeijer, Eric Juettler, Eric Vicaire, Bernard George, Ale Algra, G Johan Amelink, Peter Schmiedek, Stefan Schwab, Peter M Rothwell, Marie-Germaine Bousser, H Bart van der Worp, Werner Hacke, for the DECIMAL, DESTINY, and HAMLET investigators.

Summary
Malignant infarction of the middle cerebral artery (MCA) is associated with an 80% mortality rate. Non-randomised studies have suggested that decompressive surgery reduces this mortality without increasing the number of severely disabled survivors. To obtain sufficient data as soon as possible to reliably estimate the effects of decompressive surgery, results from three European randomised controlled trials (DECIMAL, DESTINY, HAMLET) were pooled. The trials were ongoing when the pooled analysis was planned.

Methods
Individual data for patients aged between 18 years and 60 years, with space-occupying MCA infarction, included in one of the three trials, and treated within 48 h after stroke onset were pooled for analysis. The protocol was designed prospectively when the trials were still recruiting patients and outcomes were defined without knowledge of the results of the individual trials. The primary outcome measure was the score on the modified Rankin scale (mRS) at 1 year dichotomised between favourable (0–4) and unfavourable (5 and death) outcome. Secondary outcome measures included case fatality rate at 1 year and a dichotomisation of the mRS between 0–3 and 4 to death. Data analysis was done by an independent data monitoring committee.

Findings
93 patients were included in the pooled analysis. More patients in the decompressive-surgery group than in the control group had an mRS≤4 (75% vs 24%; pooled absolute risk reduction 51% [95% CI 34–69]), an mRS≤3 (43% vs 21%; 23% [5–41]), and survived (78% vs 29%; 50% [33–67]), indicating numbers needed to treat of two for survival with mRS≤4, four for survival with mRS≤3, and two for survival irrespective of functional outcome. The effect of surgery was highly consistent across the three trials.

Interpretation
In patients with malignant MCA infarction, decompressive surgery undertaken within 48 h of stroke onset reduces mortality and increases the number of patients with a favourable functional outcome. The decision to perform decompressive surgery should, however, be made on an individual basis in every patient.

Decompressive Hemicraniectomy

Reduced Mortality


Figure 1: Distributions of the scores on the mRS and death after 12 months for patients treated with or without decompressive surgery
Decompressive Hemicraniectomy

Increase in “favourable outcome?”


*Figure 1:* Distributions of the scores on the mRS and death after 12 months for patients treated with or without decompressive surgery.
Decompressive Hemicraniectomy

"Favourable" outcome?

Infarcted brain tissue was not resected. In surviving patients, cranioplasty was undertaken after at least 6 weeks with the stored bone flap or acrylic. After surgery, patients were transferred to an intensive-care unit, but anti-oedema treatment was usually not necessary. In the conservative group, patients received best medical treatment on the basis of published guidelines for the management of acute ischaemic stroke and space-occupying brain oedema.

The trials used largely similar outcome measures. In DECIMAL, outcomes were assessed by a neurologist unaware of treatment allocation; in DESTINY, outcome was assessed unblinded; and in HAMLET, the score on the mRS was determined independently by three investigators masked to treatment allocation on the basis of a narrative written by an unblinded independent study nurse and, if necessary, this process was followed by a consensus meeting.

Procedures

Patients included before Nov 1, 2005, in any of the three trials and fulfilling the prospectively defined eligibility criteria listed in the panel were used for this pooled analysis. A broad range of baseline characteristics and outcome measures was obtained in the individual trials. For the pooled analysis we used the following prespecified baseline characteristics: age; sex; time between stroke onset and randomisation; medical history; physical examination (blood pressure, body temperature); presence of aphasia; and score on the National Institutes of Health stroke scale (NIHSS) at randomisation.

In the pooled analysis, the primary outcome measure was the score on the mRS at 1 year dichotomised between favourable (mRS 0 to 4) and unfavourable (mRS 5 and death). Secondary analyses included a dichotomisation of the mRS, in which favourable outcome was defined as a score of 0–3 and unfavourable outcome as a score of 4 to death, and case fatality at 1 year. The mRS measures functional outcome after stroke. Scores range from 0 to 6: 0 indicating no symptoms at all; 1 indicating no significant disability despite symptoms, being able to carry out all usual duties and activities; 2 indicating slight disability, being unable to carry out all previous activities, but able to look after own affairs without assistance; 3 indicating moderate disability, requiring some help, but being able to walk without assistance; 4 indicating moderately severe disability, being unable to walk without assistance and unable to attend to own bodily needs without assistance; 5 indicating severe disability, being bedridden, incontinent, and requiring constant nursing care and attention; and 6 indicating death.

Statistical analyses

Data analysis was undertaken according to a prespecified protocol by an independent data monitoring committee. The distributions of the mRS were compared between
**Decompressive Hemicraniectomy**

"Favourable" outcome?

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- Unfavourable
- Favourable
Decompressive Hemicraniectomy

“Favourable” outcome?


Figure 1: Distributions of the scores on the mRS and death after 12 months for patients treated with or without decompressive surgery.
Decompressive Hemicraniectomy

Destiny II trial

Hemicraniectomy in Older Patients with Extensive Middle-Cerebral-Artery Stroke

Eric Jüttler, M.D., Ph.D., Andreas Unterberg, M.D., Ph.D., Johannes Woitzik, M.D., Ph.D., Julian Bösel, M.D., Hemasse Amiri, M.D., Oliver W. Sakowitz, M.D., Ph.D., Matthias Gondan, Ph.D., Petra Schiller, Ph.D., Ronald Limprecht, Steffen Luntz, M.D., Hauke Schneider, M.D., Ph.D., Thomas Pinzer, M.D., Ph.D., Carsten Hobohm, M.D., Jürgen Meixensberger, M.D., Ph.D., and Werner Hacke, M.D., Ph.D., for the DESTINY II Investigators*

Patients were eligible for inclusion in the study if they were 61 years of age or older, had clinical symptoms of acute unilateral middle-cerebral-artery infarction with an onset of symptoms less than 48 hours before the initiation of treatment,
Decompressive Hemicraniectomy

Destiny II trial

**CONCLUSIONS**

Hemicraniectomy increased survival without severe disability among patients 61 years of age or older with a malignant middle-cerebral-artery infarction. The majority of survivors required assistance with most bodily needs. (Funded by the Deutsche Forschungsgemeinschaft; DESTINY II Current Controlled Trials number, ISRCTN21702227.)

**DISCUSSION**

The DESTINY II trial was stopped for reasons of efficacy after the reductions in deaths and severe disability at 6 months had become significant. This treatment effect remained stable after inclusion of all randomly assigned patients and after 12 months of follow-up.
Figure 1: Distributions of the scores on the mRS and death after 12 months for patients treated with or without decompressive surgery.
between the groups (Table 2). Among surviving patients, 63% of those in the hemicraniectomy group and 53% of those in the control group gave retrospective consent to treatment (Table S5 in acceptable to others. A majority of patients and caregivers gave retrospective consent to the treatment they received. This result should be interpreted with caution, given that 25 of 42 survivors (16 in the hemicraniectomy group and 9 in the control group) could not adequately answer this question because of severe aphasia or neuropsychological deficits. Nonetheless, this finding is consistent with observations in younger patients.31
Opinion Regarding Acceptable outcome following decompressive hemicraniectomy for ischaemic stroke

Evidence that mRS of 4 (moderately severe disability) is acceptable
Survival with severe disability

? Our bias?
The disability paradox: high quality of life against all odds

Gary L. Albrecht *, Patrick J. Devlieger

University of Illinois at Chicago, School of Public Health, 2035 West Taylor Street, Chicago, IL 60612, USA

Abstract

This paper builds on the work of Sol Levine to examine a disability paradox: Why do many people with serious and persistent disabilities report that they experience a good or excellent quality of life when to most external observers these individuals seem to live an undesirable daily existence? The paper uses a qualitative approach to
Decompressive craniectomy for severe traumatic brain injury: is life worth living?

Clinical article

Stephen Honeybul, F.R.A.C.S.,1 Courtney Janzen, B.Kin.(Hons), M.O.T.,2 Kate Kruger, Dip.O.T.,2 and Kwok M. Ho, F.C.I.C.M., Ph.D.3
The ORACLE study

Part 2. Would provide consent now

You have had an ischaemic stroke
You have become progressively more drowsy
You develop unequal pupils
There is an 80% chance of dying without surgical intervention

Decompressive craniectomy?

Q1. Consent?
The ORACLE study

Consent for decompressive hemicraniectomy following “malignant” middle cerebral infarction

Fifty-seven (14%) and 129 participants (57%) changed from accepting and unsure about decompressive craniectomy to not accepting decompressive craniectomy, respectively. Conversely, only 6 (4%) and 62 participants (27%) changed from not accepting and unsure about decompressive craniectomy to accepting decompressive craniectomy, respectively (P=0.001).
The ORACLE study

Part 2. What outcome would be acceptable to you now

Q2. What outcome would you feel to be acceptable

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The ORACLE stroke study

Acceptable outcome following decompressive hemicraniectomy following “malignant” middle cerebral infarction

Acceptable Outcome (modified Rankin Score)
The ORACLE study

What outcome would be acceptable to you

- Initially, 407 (52.7%) felt that they would provide consent for a decompressive craniectomy as a life-saving procedure but only a minority of them considered mRS 4 or 5 as an acceptable outcome (for mRS ≤ 4: n=67, 8.7%; for mRS=4: n=57, 7.4%)

- After introducing the concept of disability paradox and the evidence of benefits of decompressive craniectomy, there was a significant change in the attitudes of the participants. More participants were unwilling to accept decompressive craniectomy as a life-saving procedure (18.1% vs. 37.8%) but, at the same time, more were willing to accept mRS 4 or 5 as an acceptable outcome (for mRS ≤ 4: n=92, 11.9%; for mRS=4: n=79, 10.2%)

- Nevertheless, the proportion of participants willing to accept mRS 4 or 5 as an acceptable outcome was still relatively small.
Informed consent – Fundamental tenet of modern medicine

Two principles:
1. The patient must be informed.
   • This requires the individual to have a clear understanding of the facts, implications, and future consequences of an action.
2. The individual concerned must also be competent.
   • This requires adequate reasoning faculties in order to fully understand the relevant facts at the time consent is given.

In the context of decompressive hemicraniectomy for stroke both of these principles may challenged.
Decompressive Craniectomy
An Inconvenient Truth

Honeybul S* KM Ho**
GR Gillett FRACS‡

*Department of Neurosurgery, Sir Charles Gairdner Hospital and Royal Perth Hospital, Western Australia; **Department of Anaesthesia, Royal Perth Hospital, Western Australia; ‡Centre for Neuromuscular and Neurological Disorders, University of Western Australia; ‡Dunedin Hospital and Otago Bioethics Centre, University of Otago, Dunedin, New Zealand
What is the most difficult ethical dilemma facing science today?

Sir David Attenborough: How far do you go to preserve an individual human life?

Stephen Hawking: That’s a good one, yes