Futility in Neurosurgery: A Patient-Centered Approach

The concept of futility has been a source of discussion for many years. Even though it is tempting to propose that an action or clinical intervention should be deemed futile if it does not achieve the goals of that action, further clarification is needed in terms of the nature of the likely outcomes of an intervention and the probabilities of various outcomes being achieved. The outcome, in an age of balance between autonomy and necessity, should, at a minimum, be acceptable to the person on whom the intervention is to be performed. This is especially the case when considering outcome following decompressive craniectomy for severe traumatic brain injury, in which certain outcomes are likely to be severely impaired states that the patient would consider unacceptable.

In this article, we use some key ethical concepts such as substantial benefit and the risk of unbearable badness to explore the concept of futility in severe traumatic brain injury and, by linking that to recent advances in neurosurgical science, propose a pragmatic patient-centered approach to deal with the concept of futility.

KEY WORDS: Ethics, Futility, Severe traumatic brain injury

DECOMPRESSIVE CRANIECTOMY

Modern medicine continues to struggle with the concept of futility.1,2 Previous definitions have ranged from doctor-centered definitions such as physiological or quantitative futility to more patient-centered definitions related to contextual futility or qualitative futility. A persuasive proposal combining various viewpoints has previously been proposed that deems that, notwithstanding exceptions, an action or clinical intervention may be deemed futile if it does not achieve the goals of that action.2 The problem is that either the achievement of goals must be retrospectively evaluated, which does not help with the actual clinical decision, or it must be a probabilistic assessment such that futility is not likely to achieve the goals of therapy in which case it collapses into the quantitative definition with the associated problems (Table). Further difficulties occur when the goals are not clearly defined or the goals include states that a patient may regard as unacceptable, so that it would be ethically unjustified to expose the patient to the risk of the outcome concerned.3,4

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Abbreviations: ICP, intracranial pressure; mRS, modified Rankin Score

DECOMPRESSIVE CRANIECTOMY

A contemporary illustration of this issue is reflected in the decision-making process when considering a decompressive craniectomy for a patient with a severe traumatic brain injury. The surgical technique itself is technically straightforward and numerous studies have demonstrated the clinical application of the technique not only in the context of traumatic brain injury,15,16 but also for patients with ischemia stroke,7,8 subarachnoid hemorrhage,9,10 cerebrovascular thrombosis,11,12 and infective13,14 and inflammatory conditions.15,16 Its use is, however, controversial and the concern has always been that, although it may be lifesaving, it may leave some survivors with a high level of neurological disability.7,17 Indeed, if the end result of surgical intervention is a young person who is wheelchair bound, has minimal interaction with the outside world and who is fully dependent, could that intervention have been deemed futile? The fundamental problem rests with 2 key issues. In the first instance, there is the issue of prognosis and the uncertainty regarding outcome that affects all aspects of modern medicine. The second issue is attempting to ensure that the most likely outcome would be acceptable to the person on whom the procedure is being performed.
FUTILITY: A CONTEMPORARY MODEL

In order to address this issue, we have reviewed the recent scientific literature to determine the current evidence available for clinical efficacy of the procedure. We have then applied the recently introduced concepts of “substantial benefit” and the “risk of unacceptable badness” with a view to exploring a more patient-centered view of the utility or indeed futility of surgical intervention based on an individual’s preferences. These terms were described in order to acknowledge that there may be considerable variability regarding an acceptable outcome for a particular individual, and this can depend on religious, cultural, and social values. “Substantial benefit” describes an outcome that, now or in the future, the patient would regard as worthwhile.3 The “risk of unacceptable badness” is the probability that a patient will end up living in a state that he or she would describe as intolerable.13 In the first instance, we will review the scientific evidence.

DECOMPRESSIVE CRANIECTOMY: THE SCIENTIFIC EVIDENCE

Until relatively recently, most published studies had been retrospective cohort studies that investigated the use of decompressive craniectomy as a lifesaving intervention once all medical therapies had either failed or were in the process of failing.5–8 In this context, there would appear to be little doubt that surgical intervention can successfully lower the intracranial pressure; however, despite many assertions to the contrary, there was limited evidence that clinical outcome was actually improved.19,20 Over the past decade, in order to address this issue, a number of prospective randomized controlled trials were undertaken comparing surgical decompression with standard medical therapy.

Decompressive Craniectomy for Ischemic Stroke

In the context of ischemic stroke, 3 European trials independently demonstrated a significant fall in mortality when comparing decompressive hemicraniectomy with standard medical therapy.21–23 They did not, however, demonstrate a significant improvement in favorable outcome as adjudged by a modified Rankin Score (mRS) of 3 or less (ie, independent average daily living activity). A later pooled analysis of the 93 patients in the 3 trials confirmed the reduction in mortality from 71% in the patients who were randomly assigned to standard medical therapy to 22% in the patients who had surgical decompression. The authors also reported an improvement in outcome with 74% in the surgical group and 24% in the standard medical group achieving a favorable outcome.24 This would appear to provide unequivocal support for the ongoing use of the procedure; however, the improvement in outcome was only achieved by redefining “favorable” as a mRS of 4 or less. This would therefore include patients who were unable to walk unaided and unable to attend to their own bodily needs without assistance (mRS of 4), an outcome that has been previously deemed unfavorable by most clinicians25 and continues to be viewed as unfavorable by the vast majority of researchers currently involved in ongoing clinical trials.26

Indeed, closer examination of the data from the pooled analysis of the stroke trials confirms that the absolute reduction in case fatality came at the expense of an almost direct increase in the numbers surviving with moderately severe or severe disability. Among the survivors who were randomly assigned to receive standard medical care, 75% (9/12) had a mRS of 3 or less, an outcome previously defined as favorable. A similar favorable outcome was only achieved in 55% (22/40) of the surgical group. An alternative interpretation of the data in the pooled analysis would be that the most likely outcome following medical therapy is either death or survival with a favorable outcome (when defined by mRS of 3 or less), whereas surgery considerably increases the risk of “poor” survival requiring assistance in the patients average daily living activities as defined by a mRS of 4.

Decompressive Craniectomy for Traumatic Brain Injury

In the context of severe traumatic brain injury, the recently published Decompressive Craniectomy in Patients with Severe Traumatic Brain Injury (DECRa) study randomly assigned patients between early decompressive craniectomy and standard medical management.27 The hypothesis on which the trial was based was that early decompression, before the development of intractable intracranial hypertension, would improve cerebral perfusion, reduce secondary brain injury, and therefore improve
clinical outcome. The results were that the patients undergoing craniectomy had lower intracranial pressures (ICPs); however, their neurological outcomes at 6 months were worse than those patients who received standard medical therapy. Although the trial has come in for a considerable criticism, what it has unequivocally demonstrated is that obtaining a lower ICP is not necessarily translated into an improvement in clinical outcome. In the circumstances in which this particular group of patients were randomly assigned, any benefit provided by lowering the ICP was likely offset by surgical morbidity, and having a lower ICP after the procedure cannot be considered as a “substantial benefit” to the patient concerned. What remains to be established is the role of decompressive surgery when the ICP continues to rise beyond 25 mm Hg, and this is currently being addressed by the Randomised Evaluation of Surgery with Cranietomy for Uncontrollable Elevation of Intra-Cranial Pressure (RESCUEicp) trial.

Current Role of Decompressive Cranietomy for Severe Traumatic Brain Injury

Overall, there would appear to be sufficient evidence from numerous retrospective studies to suggest that decompressive surgery can be lifesaving, and this is supported by the results of the stroke trials. However, evidence that outcome is improved is less forthcoming. The stroke trials could only show an improvement in outcome by including patients with a mRS of 4 in the favorable category, and the DECRA study has clearly demonstrated that a reduction in ICP is not necessarily translated into an improvement in outcome.

In view of these findings, it may be that, currently, in the context of severe traumatic brain injury, decompressive craniectomy should be used mainly as a lifesaving intervention for patients who develop intractable intracranial hypertension that does not respond to medical therapy. If this is indeed the case, then there are 2 issues that require careful consideration. First, there has to come a point where the primary brain injury is so severe that, if the patients survive, they are most likely to remain severely disabled. Second, how do people feel about survival with severe neurological disability for themselves?

Until recently, the difficulty has always been obtaining objective evidence regarding prognosis on which to base discussions regarding the pros and cons of lifesaving but nonrestorative surgery with the surrogate decision makers of patients who are critically injured.

DECOMPRESSIVE CRANIECTOMY FOR TRAUMATIC BRAIN INJURY: OUTCOME PREDICTION

The CRASH collaborators (corticosteroid randomization after significant head injury) Web-based outcome prediction model is based on the data obtained from the MRC CRASH study. The model provides a percentage predicted risk of unfavorable outcome at 6 months (defined by the Glasgow Outcome Scale as dead, persistent vegetative state, or severely disabled), and a number of studies have demonstrated how this can be used as a surrogate index of injury severity that can be used to stratify patients according to injury severity. Comparison of the percentage predicted risk of an unfavorable outcome with the observed long-term outcome provides an objective assessment of the most likely long-term outcome (Figure).

There are limitations when applying a mathematical model derived from population-based probabilities and the CRASH collaborators have emphasized that this model should only be used to support and not replace clinical judgment. It does, however, provide useful information when considering the most likely outcome following surgical intervention and may therefore provide supportive information when considering realistic outcome expectations.

The obvious question is, “How do people feel about surgical intervention that may leave them severely disabled?”

OPINION REGARDING SURVIVAL WITH SEVERE NEUROLOGICAL DISABILITY

To date, the issue of retrospective consent has not been addressed in the context of traumatic brain injury; however, this has been investigated in the context of ischemic stroke. Whereas a number of studies have demonstrated that many patients or their relatives would indeed provide retrospective consent, this is by no means always the case, especially for those patients who remain severely disabled. Many studies have found that, when patients are formally assessed, they have a significantly impaired quality of life and high levels of anxiety and depression. Furthermore, few studies have assessed the issue of retrospective consent anonymously, and patients and relatives may feel obliged to provide a positive answer when asked by investigators who have been involved in their care.

It must be acknowledged that people can learn to adapt to a level of disability that they might previously have deemed unacceptable; however, competent individuals have the right to determine their health care wishes were they to lose competency, and this is the basis for advance health care directives. These documents have become increasingly used when dealing with end-of-life issues, often in the context of chronic disease where the issues and preferences of individuals can to some degree be reasonably well predicted. Unfortunately, severe traumatic brain injury most commonly occurs as an acute and entirely unpredictable event, and very few people are likely to have documented their wishes were they unfortunate enough to be involved in such a situation.

An alternative approach to seeking retrospective consent is to canvas opinion among competent healthy individuals regarding what they would feel to be an acceptable outcome. This has been the subject of recent studies in which health care workers were presented with the data shown in the Figure, and they were anonymously asked their opinion regarding decompressive surgery in 3 separate clinical scenarios, one of which was when they themselves were the injured party and the injury prediction
in each scenario placed the patient sequentially in the outcome categories 70% to 80%, 80% to 90% and 90% to 100%. The question, which was clearly stated, was whether they would provide consent in these circumstances based on what they perceived to be the most likely outcome.37-39

Overall, the responses reflected that, for the majority of participants, survival with severe disability was unacceptable. As the injury severity progressively increased, far fewer participants indicated that they would provide consent based on the increasing probability of survival with severe disability. It could of course be argued that this was a relatively hypothetical situation and not representative of the real-life tension that occurs in the context of acute neurotrauma. However, it could equally be argued that in the real-life acute setting, hasty decisions that cannot be mitigated may be made under the pressure of limited time and perhaps limited competency (due to emotional distress) to reflect on the true implications of their decisions. Thus, the responses of the participants in these studies may be a better reflection of how many people genuinely feel about this outcome for themselves. On that basis, we can ask, “When is surgical intervention futile?”

AN ILLUSTRATIVE CASE

A 45-year-old man is involved in a high-speed motor vehicle accident. He sustained a severe closed-head injury and orthopedic injuries. His initial Glasgow Coma Scale before intubation at the scene was 4 (eye 1, motor 2, verbal response 1). The right pupil was unreactive, and the left pupil reacted sluggishly to light. His initial computed tomography (CT) scan revealed very severe, diffuse cerebral swelling. An intraparenchymal ICP monitor was inserted, and, over the following 4 hours, the ICP fluctuated between 30 and 50 mm Hg despite maximal therapy. An external ventricular drain was then inserted that maintained the ICP below 30 mm Hg for another 8 hours, but, thereafter, the ICP continued to spike above 40 mm Hg. Given the severity of the injuries sustained, there was considerable discussion among the neurosurgeons and intensive care physicians as to whether surgical decompression would be appropriate given that he was not responding to maximal medical management. However, there was concern that, given the severity of the primary brain injury, if the patient survived, he was very likely to remain severely disabled. It was decided to discuss the situation with the patient’s relatives.

Scenario One

Following discussion with his wife, a decision was made to proceed. She accepted that the injury was severe but felt that her husband strongly held religious beliefs that she felt should be respected. She was of the belief that he would want to live no matter what the level of disability, and, as the doctors themselves acknowledged, they were not absolutely certain regarding his prognosis.

Scenario Two

At the time, there were no next of kin available, so it was decided to proceed with a surgical decompression as a lifesaving intervention. The following day, his wife arrived and was told of the preceding evening’s events. When informed of the injury severity and the likelihood of severe neurological disability, she was deeply shocked. She was adamant that her husband had always stated to her that he would never want “lifesaving” intervention that left him dependent.

After a bifrontal decompressive craniectomy, the ICP remained below 20 mm Hg and he was transferred to the general

FIGURE. Outcome stratified according to the severity of primary cerebral injury. The prediction of an unfavorable outcome at 6 months (x axis) and the observed outcome at 18 months among 137 patients on whom follow-up was available. Numbers within the bar chart represent absolute patient numbers (Reproduced with kind permission, Mary Ann Liebert, Inc. publisher).

GOS, Glasgow Outcome Scale.
neurosurgical ward after 10 days in the intensive care unit. He remained in the hospital for 6 months with very little neurological progress. He was transferred to a nursing home 6 months later, and after a further 6 months was transferred home. At 3-year follow-up, he remained wheelchair bound with severe contractures, would intermittently respond to single-stage commands and could answer yes or no to simple questions. He was incontinent and had had a percutaneous gastrostomy tube for feeding.

Outcome: Scenario One

His wife has given up work and is his primary caregiver. She says she has no regrets and is grateful for the treatment received. She says she has had 3 more worthwhile years with her husband that she might not have otherwise have had and never gives up hope for more recovery. She is also grateful that he will be at the upcoming wedding of their daughter.

Outcome: Scenario Two

His wife initially gave up work to become a full-time caregiver but has decided to place her husband in a nursing home. She feels angry and frustrated that the surgery was performed, because she is adamant that he would not have wanted the surgeons to proceed. She said her husband would never have wanted to end up this way.

DECOMPRESSIVE CRANIECTOMY: THE FUTILITY DEBATE

Once the prediction of an unfavorable outcome is greater than 90%, the most likely outcome if the patient survives is severe disability with only a small possibility of survival with moderate disability. Given that in these circumstances the “risk of unacceptable badness” is high, and the procedure has not provided what most people would feel to be “substantial benefit,” it would therefore appear reasonable to adjudge surgical intervention futile.

However, as demonstrated in the aforementioned case scenarios, before this position can be adopted, it must be acknowledged that “most” does not mean all and making a value judgment based on what is acceptable to the majority may fail to recognize the beliefs and values within certain cultures and religions, many of whom feel that life is sacrosanct and should be preserved at any cost. Although these values may be in the minority, they are no less important and should be respected. In addition, probability does not equate to certainty, and, although the most likely outcome if the patient survives may be severe disability, there is always the very small chance of being outside the statistical norm and achieving a favorable outcome. The decision to submit a patient to decompressive surgery must depend on how much individuals are willing to “risk” an unacceptable outcome in the hope that they will obtain what they perceive to be “substantial benefit.” This may vary considerably from person to person, thereby emphasizing the need for a patient-centered approach to the concept of futility.

Realistically, it would be very difficult to withhold therapy from someone whose previous wishes were not known, if there was a least some chance of “substantial benefit” and the risk of an unacceptable outcome was acknowledged and accepted by those making the decision. Treatment based on such reasoning cannot be deemed futile even if the eventual outcome is indeed unacceptable to the injured party, because risks and uncertainties are inevitable in all fields of medicine and this must be recognized by all those involved, especially those burdened with the decision making. However, our responsibilities to a patient who had expressed a definite view that they would strongly disapprove of surviving in a poor neurological condition (ie, that they were not prepared to accept the “risk of unacceptable badness”) are quite otherwise. In such a case, an individual patient-centered concept of futility must be considered because the surgeon cannot reasonably assume that they would obtain consent for the operation and would have to justify acting on their own judgment against a properly considered assessment of the wishes of the patient. In these circumstances, consideration must be given to withholding “lifesaving” nonrestorative surgical intervention, because, notwithstanding a degree of uncertainty, the most likely outcome would be unacceptable to that person and the issue of futility must be acknowledged and addressed.

CONCLUSION

The concept of futility remains difficult to define, and it may indeed be unrealistic to expect that a blanket definition can be applied across the ever-expanding capabilities of modern medicine. One of the fundamental problems is that futility implies a degree of certainty. A more pragmatic assessment must recognize that there will always be an element of uncertainty whether it be regarding diagnosis, treatment efficacy, or prognosis. It must also recognize that there will be differences of opinion among individuals regarding what is, and what is not, an acceptable outcome. In the context of severe traumatic brain injury, there has to come a point where the primary brain injury is so severe that consideration must be given to withholding surgical intervention because the most likely outcome will be severe disability and it is known that this would be unacceptable to the person on whom the procedure is being performed. Surgical intervention in these circumstances may be deemed futile. However, it must also be acknowledged that some patients feel that life is sacrosanct and should be protected at any cost; other patients may be willing to accept the “risk” of survival with severe disability given that there may always be the possibility of a good long-term outcome. In these circumstances, surgical intervention cannot be deemed futile, and it is these issues that must be the focus of discussions with next of kin and those burdened with the clinical decision making in order to adopt a patient-centered approach to the concept.

Disclosure

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.
COMMENTARY

Commentary provided by Dagi available at www.neurosurgery-online.com.

REFERENCES