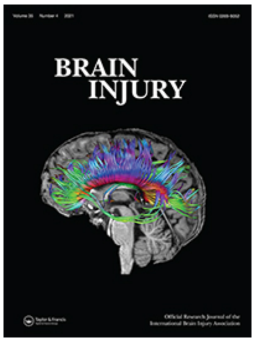

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ARTICLE

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An economic evaluation for the use of decompressive craniectomy in the treatment of refractory traumatic intracranial hypertension

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ABSTRACT

Objectives: The management of intracranial hypertension is a primary concern following traumatic brain injury. Data from recent randomized controlled trials have indicated that decompressive craniectomy results in some improved clinical outcomes compared to medical treatment for patients with refractory intracranial hypertension post-traumatic brain injury (TBI). This economic evaluation aims to assess the cost-effectiveness of decompressive craniectomy as a last-tier intervention for refractory intracranial hypertension from the perspective of the National Health Service (NHS).
Methods: A Markov model was used to present the results from an international, multicentre, parallel-group, superiority, randomized trial. A cost-utility analysis was then carried out over a 1-year time horizon, measuring benefits in quality adjusted life years (QALYs) and costs in pound sterling.
Results: The cost-utility analysis produced an incremental cost-effectiveness ratio (ICER) of £96,155.67 per QALY. This means that for every additional QALY gained by treating patients with decompressive craniectomy, a cost of £96,155.67 is incurred to the NHS.
Conclusions: The ICER calculated is above the National Institute for Health and Care Excellence (NICE) threshold of £30,000 per QALY. This indicates that decompressive craniectomy is not a cost-effective first treatment option for refractory intracranial hypertension and maximum medical management is preferable initially.

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KEYWORDS
Cost-utility; traumatic intracranial hypertension; decompressive craniectomy; traumatic brain injury; economic evaluation

INTRODUCTION

Background

Traumatic brain injury (TBI) is associated with high morbidity and mortality worldwide (1). TBI occurs following blunt or penetrating trauma to the head which can result in primary lesions, including hematomas, contusions and diffuse axonal injury (2). The presence of intracranial mass lesions and cerebral edema can raise intracranial pressure (ICP) impeding cerebral perfusion and resulting in cerebral ischemia (3,4). Increased ICP can further result in brainstem compression, making it the most common cause of death following TBI (5). Thus, controlling ICP to reduce secondary brain injury is a major concern in the management of patients with TBI (6).

Management of elevated ICP following TBI is complex and often involves following a 3-step protocol. Step 1 involves maintaining an ICP below 25 mm HG, by head elevation, sedation, analgesia, temperature and fluid control. Cerebral perfusion pressure is also monitored and managed to ensure a level between 60 and 70 mm Hg (7). If ICP remains elevated, Step 2 is commenced requiring deeper sedation, moderate hypercapnia, repeat osmotherapy and extraventricular drainage if required. However, when conventional treatment using medical therapy fails to lower ICP, Step 3 may be required involving surgical management through decompressive craniectomy to prevent further deterioration (8). Decompressive craniectomy directly reduces ICP by removing a portion of the skull, increasing space and allowing the brain to swell without constraint (9). Previous studies have shown mixed results or no significant improvements for treating refractory intracranial hypertension with decompressive craniectomy compared to standard medical treatment alone, following TBI (10–13). However, several clinical trials have also reported promising evidence indicating improved prognosis and outcomes in those patients receiving a decompressive craniectomy (14,15), particularly within a recent trial reported in 2016 (16).

The Extended Glasgow Outcome Scale (GOS-E) is commonly used to measure global outcomes following TBI for clinical trials. It comprises eight categories: Dead, Vegetative State, Lower Severe Disability, Upper Severe Disability, Lower Moderate Disability, Upper Moderate Disability, Lower Good Recovery, and Upper Good Recovery (17).

Rationale

TBI is the commonest cause of morbidity and mortality in patients up to the age of 40 in the UK (18). The condition results in significant detrimental impacts on quality of life both in the short term and long term, reflected in the magnitude of

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Supplemental data for this article can be accessed on the publisher's website.

the annual incurred costs to the NHS, reported at £15 billion, to manage its consequences (19). Despite a well-recognized need for treatment regimens to be optimized, the evidence base for refractory traumatic intracranial hypertension reports varied clinical efficacy and costs of surgical versus medical management. This justifies a case for the present economic evaluation.

METHODS

Choice of analysis and perspective

The aim of this study was to carry out a cost-utility analysis (CUA) of decompressive craniectomy versus medical management in the treatment of refractory traumatic intracranial hypertension. Costs were measured in pound sterling and utility in Quality Adjusted Life Years (QALYs). QALYs represent a standardized measure which can be used to uniformly compare healthcare interventions for optimal resource allocation. Furthermore, the use of QALYs allows for simultaneous consideration of both the quantity and quality of life, a distinguishing feature of a CUA which proves advantageous over a cost-effectiveness analysis. A cost-benefit analysis has not been considered as it was viewed that distilling clinical outcomes into monetary values would introduce inaccuracies.

The fixed healthcare budget in England means there is an opportunity cost associated with every decision made in allocating resources. This necessitates interventions which maximize clinical outcomes within limited resources. The NHS perspective was taken in carrying out this cost-utility analysis, considering only the costs incurred by the NHS to inform decision making in resource allocation. Personal and societal costs as a result of the treatment outcomes were not taken into account.

Modeling

Data for this economic evaluation were obtained from a multicenter, international randomized controlled trial conducted by Hutchinson et al. (16), comparing clinical outcomes following decompressive craniectomy versus ongoing medical management in the management of refractory traumatic intracranial hypertension. Each of these management options resulted in different clinical outcomes, categorized into eight GOS-E scores. The large sample size of 408 patients included in the study increased the statistical power to detect smaller clinically significant differences between the treatment groups. Furthermore, despite being an international study, 71% of patients were recruited from the UK, making the findings highly applicable and relevant for the NHS.

A 12-month time period was used to construct the Markov model as this was the follow-up period utilized in Hutchinson et al.'s (16) study. The probabilities reported in the study (Figure 1) were also used ensuring the model was exhaustive and all outcomes reported were mutually exclusive.

An important consideration when developing the Markov model regarded the outcome of GOS-E 1 (death). The trial by Hutchinson et al. (16) reported deaths, distinguishing between deaths which occurred on discharge from ICU (in-hospital death) and other deaths. Therefore, two branches were added to the outcome GOS-E 1 (death) showing both in-hospital death which incurs costs to the NHS and out-of-hospital death which would not be accounted for by the NHS.

Costs

The costs of decompressive craniectomy and medical treatment were obtained from the 2019/20 National Tariff Payment System (20), which used the HRG4+ phase 3 currency design to set national prices. This currency design covers the total cost of care received by patients from admission to discharge for the procedures. For decompressive craniectomy, the healthcare resource group (HRG) codes AA52A, AA52B, AA52C and AA52D were used. All four codes corresponded to the currency description 'Very Major Intracranial Procedures, 19 years and over' however each code was assigned a different unit cost based on separate complication and comorbidity (CC) scores. Therefore, these costs were averaged to provide the cost of decompressive craniectomy used for Markov modeling. Similarly, the unit costs for the HRG codes AA25C, AA25D, AA25E, AA25F, AA25G were averaged for the cost of medical treatment. The average cost of hemicraniectomy was £10 296 whilst the cost of the ongoing medical treatment was £4221 in 2019/20. The use of recent data meant discounting was not necessary and validity was maximized. The data are also reliable and relevant for the perspective of the NHS as it is published by NHS improvement and NHS England.

Further costs for each GOS-E health state were obtained from a number of sources. The GOS-E outcome score of 1, which corresponds to death, was assigned a cost of £131.83 if the patient died in the hospital. National practice across NHS mortuary services stipulates that after a patient's death, the body is kept temporarily in the hospital mortuary until collected (21). The cost of daily hospital stays sourced from the NICE 2015 Costing Statement (22) was therefore halved under the assumption that a deceased patient would only remain in the hospital for up to half a day before being transferred to external funeral services. The cost was discounted by 5 years with a discount rate of 3.5% in accordance with NICE guidelines (23). An important data limitation here is that both mortuary and hospital beds were assumed to share an almost equivalent cost. If the patient died after discharge, a cost of £0 was assigned as there are no costs of a deceased individual from the perspective of the NHS.

GOS-E outcome 2 is a persistent vegetative state (PVS) that was assigned a cost of £70,491 based on the cost of specialist inpatient rehabilitation reported by Lynne Turner-Stokes, 2019 (24). Patients in PVS are often treated in such units at the early stages of their disorder of consciousness whereas at later stages they are cared for in specialized nursing homes. The costs for GOS-E outcomes 3–8 were calculated using data from Sentinel Stroke National Audit Programme (SSNAP) and NHS reference costs 2017/18 (25,26). The modified Rankin scale (mRS) is commonly used to measure the degree of disability and dependence in daily activities of people who have suffered a stroke or other causes of neurological disability. The SSNAP reported the mean number of occupational therapy, physiotherapy and

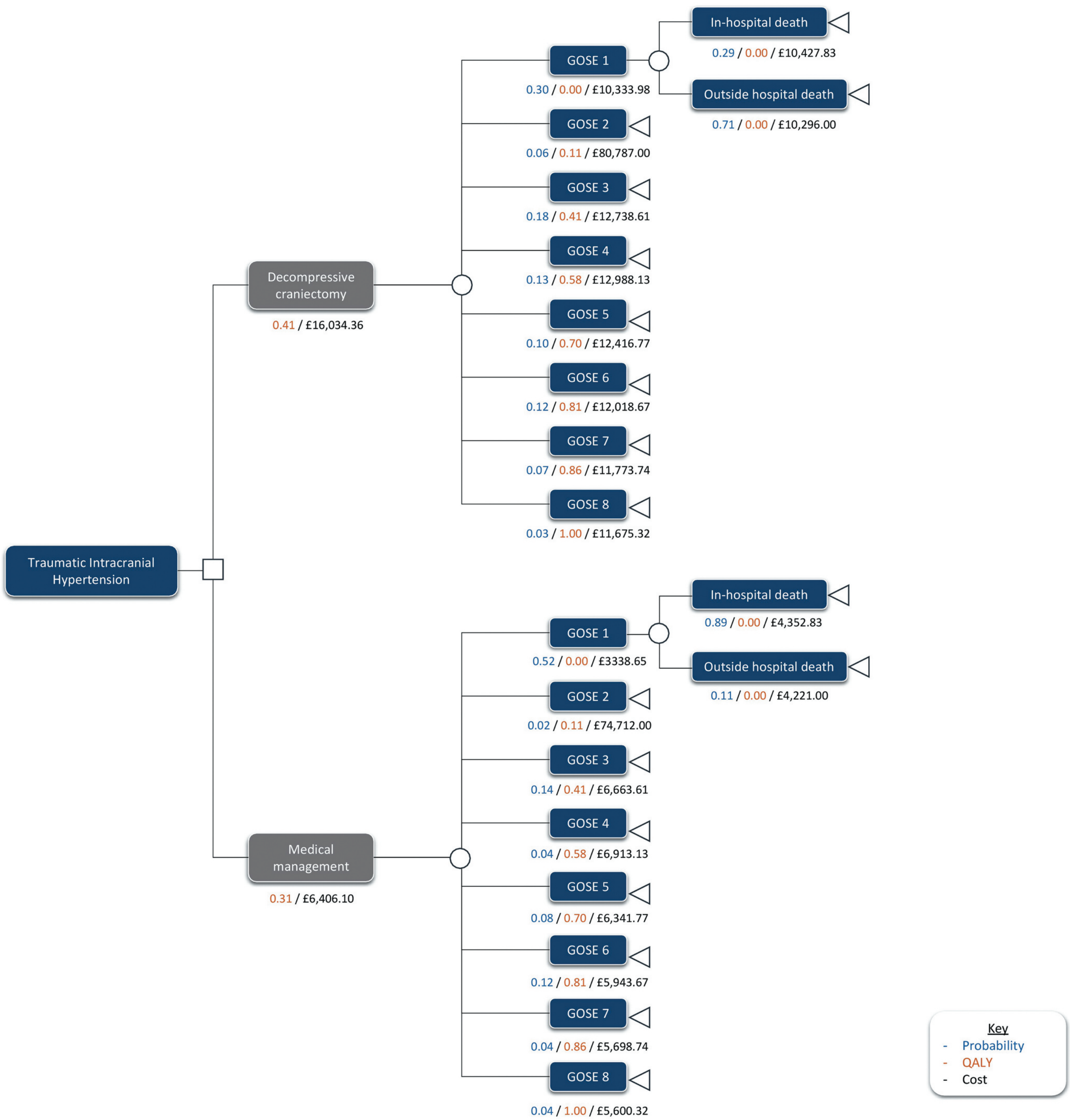

Figure 1. Decision tree for medical management versus decompressive craniectomy for traumatic intracranial hypertension.

speech and language therapy consultations for patients for the mRS scores 0–5 (Supplementary Table 1). Since mRS scores 0–5 correspond closely with GOS-E scores 8–3 in their description of function (Supplementary Table 2), the mean costs calculated for mRS scores using discounted NHS reference cost data (Supplementary Table 3) were assigned to corresponding GOS-E outcomes (Supplementary Table 4) (25–27). The assumption was made that the annual long-term care costs of patients with varying levels of disability post-stroke (delineated by mRS scores) could be applied to patients of the corresponding degree of disability post-traumatic brain injury (GOS-E scores).

Benefits

Health outcomes were measured in QALYs. One QALY equates to one year in full health and can be defined as the quality of life (QoL) multiplied by the length of life (LoL) (28).

QALY = QoL x LoL

Hutchinson et al. reported GOS-E scores, an eight-point scale used to classify clinical outcomes for patients post-TBI, which were used to derive the QALYs (Table 2Table 3) (16). A study reporting on health status post-TBI was used to obtain the quality of life values (QoL) for each GOSE score (29). No further adjustments were required as health outcomes reported

Table 1. Probabilities associated with terminal nodes of the surgical arm and medical arm of the Markov model.

Node	Probability at 12 months in Surgical Arm	Probability at 12 months in Medical Arm
GOS-E 1 (Death)	0.304	0.52
Death in hospital	0.288	0.892
Death outside of hospital	0.712	0.108
GOS-E 2 (Vegetative state)	0.062	0.017
GOS-E 3 (Lower severe disability)	0.18	0.14
GOS-E 4 (Upper severe disability)	0.134	0.039
GOS-E 5 (Lower moderate disability)	0.103	0.078
GOS-E 6 (Upper moderate disability)	0.119	0.123
GOS-E 7 (Lower good recovery)	0.072	0.039
GOS-E 8 (Upper good recovery)	0.026	0.045

Table 2. QALYs derived from GOS-E scores.

GOSE	QoL	QALY
1	0.00	0.00
2	0.11	0.11
3	0.41	0.41
4	0.58	0.58
5	0.70	0.70
6	0.81	0.81
7	0.86	0.86
8	1.00	1.00

Table 3. The expected costs and QALYs gained from the two therapeutic branches over the 1-year time horizon.

Average expected cost of decompressive craniectomy branch = £16,034.36 Average expected QALYs of decompressive craniectomy branch = 0.41 QALY	Average expected cost of medical management branch = £6,407.00 Average expected QALYs of medical management branch = 0.31 QALY

Table 4. The ICER, NHB and NMB of both the original model and sensitivity analyses.

	ICER (£/QALY gained)	NHB (QALYs)	NMB (£)
Original model	96,155.67	− 0.22	− 6,623.68
Sensitivity analysis 1	38,764.58	− 0.02	− 706.30
Sensitivity analysis 2	195,894.01	− 0.55	−16,609.75

by Hutchinson et al. were over a 1-year period (QALY = QoL x 1) (16Table 1).Table 4

RESULTS

The Markov model demonstrated that both the expected cost and benefit of decompressive craniectomy as initial treatment for TBI exceed that of initial medical management. Specifically, the expected cost of the decompressive craniectomy arm over the 12 months amounted to £16,034.36 whereas medical management alone totaled £6,407.00 (Δ £9,627.36). The expected QALY gained from decompressive craniectomy is 0.41, 0.10 QALY greater than that of medical management (0.31 QALY).

Based on these expected outcomes, the incremental cost-effectiveness ratio (ICER) was calculated, which evaluates the benefits gained from an intervention in light of its associated costs. To determine whether decompressive craniectomy is a cost-effective intervention, the ICER was subsequently compared to the National Institute for Health and Clinical Excellence (NICE) cost-effectiveness threshold value of £30,000/QALY gained (30).

$$ICER = \frac{Cost(Decompressive\,Craniectomy) - Cost(MedicalManagement)}{QALY(Decompressive\,Craniectomy) - QALY(MedicalManagement)}$$
$$= 96,155.67 perQALY\,gained$$

Furthermore, the net monetary benefit (NMB) and net health benefit (NHB) were calculated to translate the ICER into monetary and health units, respectively (Supplementary Tables 5 and 6).

Sensitivity analysis

Two one-way sensitivity analyses were performed to challenge assumptions which introduced uncertainty into the Markov Model.

Sensitivity analysis 1

Within the Hutchinson et al. study, it is broadly defined that an outcome of GOS-E 1 (death) to GOS-E 3 (upper severe disability) is viewed as 'unfavorable' (16). In line with this, an outcome of GOS-E 4 to GOS-E 8 can be seen as 'favorable'. The initial Markov model has been redesigned below to reflect this categorization of outcomes into 'favorable' or 'unfavorable' (Figure 2).Figure 3

A key limitation of the trial conducted by Hutchinson et al. was that 37.2% of patients initially assigned to the medical group (67 patients), ultimately underwent decompressive craniectomy (16). However, this could not be accurately incorporated into the initial Markov model, as the outcomes in the study were reported in the intention-to-treat population. Since no further information was provided as to which specific patients within the medical group underwent the surgical procedure, it is not evident whether these patients had a favorable or unfavorable outcome. Therefore, in order to capture this uncertainty within the Markov model, an additional sensitivity analysis has been performed to calculate the ICER based on the most likely redistribution of 67 patients from the medical arm into the surgical arm.

This was done by removing patients from the unfavorable and favorable medical arms based on the existing probability of each outcome and re-distributing them proportionately to the surgical arm. This proportionate redistribution yielded an ICER of £38,764.58/QALY gained.

Sensitivity analysis 2

The current model assigned costs of decompressive craniectomy and ongoing medical management with prices reported by the National Tariff. Although the national tariff specifies the price that is payable for the delivery of healthcare services, the actual cost incurred by the NHS through the provision of these services is frequently higher (31). The patient-level information and costing systems (PLICS) traces resources used by patients

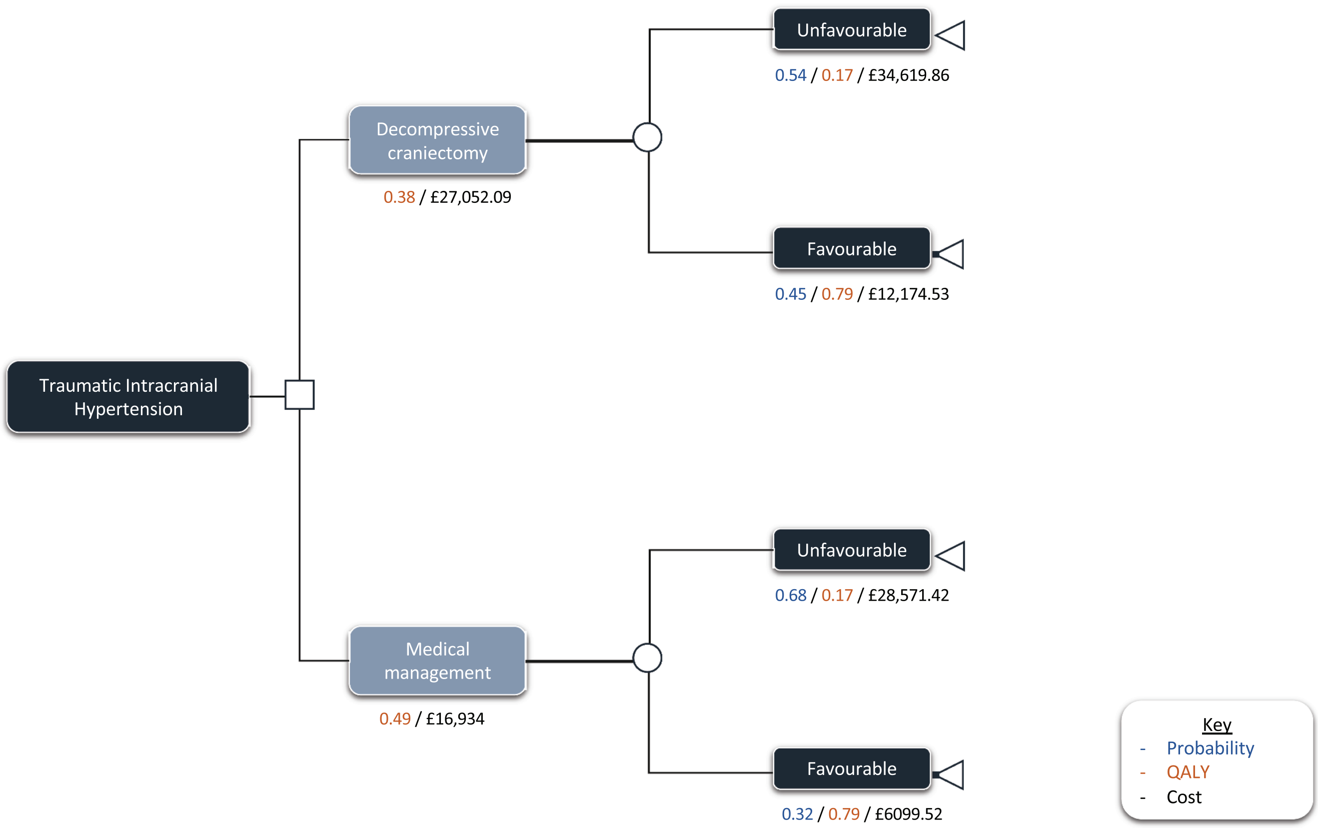

Figure 2. The redesigned Markov model, in which GOS-E outcomes have been categorized into either 'favorable' or 'unfavorable'.

to provide more accurate cost information of a patient's journey (32). These data have not been updated since 2014/15 and therefore the more recent 2019/20 National Tariff data were used for Markov modeling (20). However, to test the robustness of the calculated ICER, a sensitivity analysis was conducted using the discounted cost data from PLICS 2014/15 (32). This produced an ICER of £196,894.01/QALY gained.

DISCUSSION

This economic evaluation sought to investigate whether decompressive craniectomy is a cost-effective surgical intervention treatment of refractory traumatic intracranial. The ICER calculated considerably exceeds the NICE cost-effectiveness threshold of £30,000/QALY (30), demonstrating that decompressive craniectomy is not a cost-effective treatment. This comparison has been presented on a cost-effectiveness plane (Figure 4). Moreover, both the NMB and NHB which expressed the ICER in pound sterling and QALYs, respectively, yielded a value below 0, reiterating that this intervention is not cost-effective. Following a sensitivity analysis to account for patients in the medical arm that subsequently underwent decompressive craniectomy the ICER calculated was £38,764.58/QALY. Whilst this value is closer to the NICE cost-effectiveness threshold, the original conclusion remains unchanged that decompressive craniectomy is not a cost-effective last-tier treatment option for refractory intracranial hypertension according to NICE thresholds.

The second sensitivity analysis using PLICS cost data from 2014/15 produced an ICER approximately doubled in magnitude, further strengthening our main finding that decompressive craniectomy is not a cost-effective option to treating refractory intracranial hypertension in patients post-TBI.

The cost-effectiveness calculation incorporates the costs of both the initial treatment option as well as the costs associated with the treatment outcomes. Therefore, there are two main factors contributing to the higher ICER, exceeding the NICE cost-effectiveness threshold. Firstly, decompressive craniectomy is a more costly procedure compared to ongoing medical treatment. Secondly, whilst decompressive craniectomy is effective in reducing mortality rates relative to ongoing medical treatment, it also results in a higher incidence of patients surviving in a vegetative state. PVS results in a high level of dependency on others which accounts for high average annual costs (£70,491) that contribute to decompressive craniectomy not being cost-effective.

Four economic evaluations have previously assessed the cost-effectiveness of decompressive craniectomy; however, none have been performed from an NHS perspective. These economic evaluations have generated widely contrasting ICERs with certain studies concluding decompressive craniectomy to be cost-effective while others concluded it to not be cost-effective.

A study conducted from the perspective of the Australian healthcare system reported an ICER of 682,000 USD/QALY gained concluding that decompressive craniectomy was not cost-effective given a cost-effectiveness threshold of 100,000

Figure 3. One-way sensitivity analysis with proportional re-distribution of patients from the medical arm into the surgical arm.

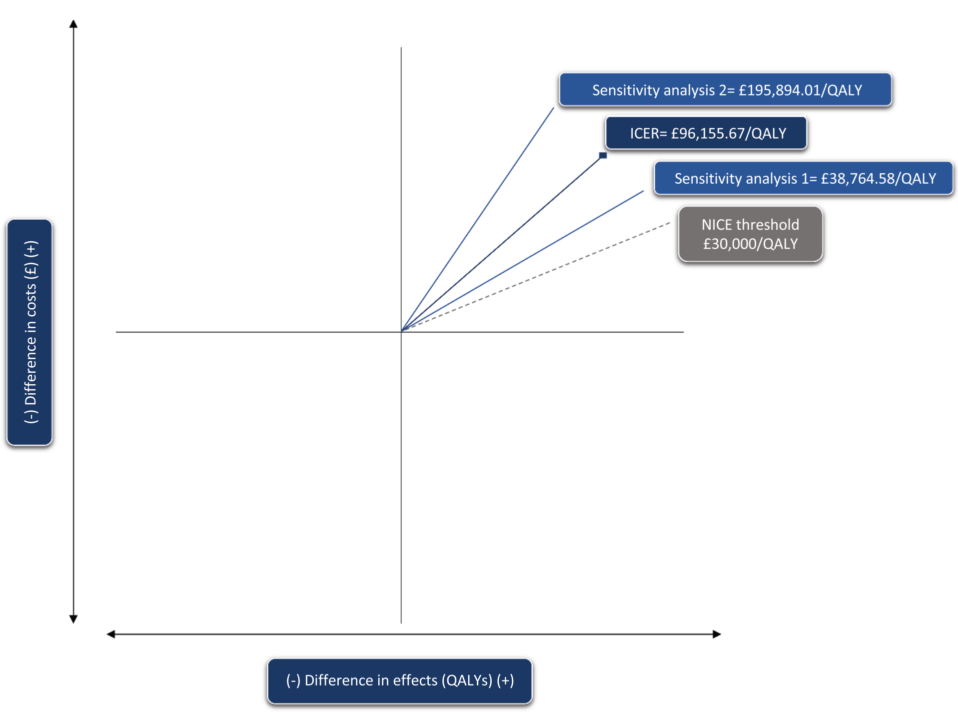

Figure 4. Cost-effectiveness plane.

USD/QALY gained (33). However, the ICER reported was markedly greater than that reported in this economic evaluation (£96,155.67/QALY gained). One key difference was the choice of comparator against decompressive craniectomy; in the present economic evaluation, this was ongoing medical treatment, whereas in the Australian study this was the withdrawal of life support due to a high likelihood of death occurring. This constitutes a key difference in the respective study designs since the large differences in the cost of the comparator would have a direct impact on the ICER generated. Furthermore, the Australian study was conducted from a societal perspective which meant that societal costs were accounted for in addition to medical costs which serves as an additional explanation for the greater total costs and reduced cost-effectiveness (33).

An economic evaluation performed in Finland found decompressive craniectomy to be a highly cost-effective procedure generating a cost per QALY of 17,900€, significantly below their cost-effectiveness threshold of 50,000€ (34). This opposing result to our economic evaluation is likely related to the median follow-up period of 67 months, compared to the 12 months we report in this study. It has been shown that recovery can occur over a period of several years, indicating that the use of a longer time horizon may have captured utility improvements occurring beyond the 12 months after decompressive craniectomy (35). This is in line with their results, which reported good outcomes (69%), and therefore higher utility, despite a high mortality rate. This differs from the present analysis, which demonstrated reduced mortality with relatively limited improvements in favorable outcomes (34).

An economic evaluation performed from the US societal perspective found that aggressive treatment of TBI, which includes decompressive craniectomy, was cost-effective (36). Although cost-effectiveness decreased as age increased, it was still considered to be more cost-effective than routine care even at the age of 80, with an ICER of 88,507 USD per QALY gained. However, this conclusion is on the background of a lenient cost-effectiveness threshold of 100,000 USD which represents a fundamental difference between the US healthcare system and the NHS. Although a more lenient cost-effectiveness threshold has been proposed in the US, there has been no suggestion of an alteration to the existing NICE cost-effectiveness threshold of £30,000/QALY in the UK (30). Even if the threshold was to be made more lenient, it is unlikely to increase by a proportion that results in decompressive craniectomy being deemed cost-effective. The authors used a 6-month time horizon to assess GOS, with the assumption that this remained static across the remainder of the patient's life. Interestingly, the use of GOS within the three economic evaluations discussed differs from the use of GOS-E in Hutchinson et al.'s (16) study. The GOS-E is a revised scale that allows for improved differentiation and classification of outcomes compared to GOS, which may contribute to the differences observed in our findings (37).

Finally, a US study comparing decompressive craniectomy with induction of barbiturate coma reported an ICER of 9,565 USD/QALY, showing that decompressive craniectomy is highly cost-effective (38). Although the administration of barbiturates was not obligatory for all patients in the medical treatment arm of Hutchinson et al.'s study, 87.2% received a barbiturate infusion. However, the dose was not specified to imply the induction of a barbiturate coma, which meant that a direct comparison of the US study with our economic evaluation was not feasible (16).

Limitations

The findings of this economic evaluation should be considered in the context of several limitations. Firstly, the utility values associated with each GOS-E score were taken from a study by Kosty and colleagues which was subject to key biases (28). Despite adopting the reliable standard gamble approach to ascertain quality of life, the utility estimates are limited by the non-representative population sample used to elicit preferences, unevenly distributed in age and education level. Variables such as education level and age can affect individual risk aversion with differing directions of causality (39); this was unaccounted for in the utility scores.

Furthermore, another limitation of the trial data used for this economic evaluation is that 37.2% of patients in the medical group underwent decompressive craniectomy. This situation may have understated the observed treatment effect of decompressive craniectomy as outcomes were reported in the intention-to-treat population. Therefore, the average QALY gained by patients randomized to the medical group may have been overstated which could have inflated the ICER.

An additional limitation of this analysis lies in the 1-year time horizon considered for post-TBI outcomes, as this was the time period reported in Hutchinson et al.'s study. Future cost-utility analyses could explore randomized controlled trials reporting on a longer time frame of outcomes to account for further accumulated costs.

CONCLUSION

This cost-utility analysis for the use of decompressive craniectomy in the management of refractory intracranial hypertension produced an ICER of £96,155.67/QALY gained. This surmounts the NICE cost-effectiveness threshold of £30,000/QALY gained (30), indicating that the use of surgical intervention as the initial treatment for refractory intracranial hypertension following TBI is not cost-effective and maximum medical management should be preferred initially. Although from an economic perspective the use of decompressive craniectomy is not recommended, the trial by Hutchinson et al. reported a 22% lower mortality rate in patients undergoing decompressive craniectomy compared to those only receiving medical treatment (16). This markedly lower rate raises questions as to whether cost saving should be prioritized for a procedure which proves to be lifesaving for many individuals.

FUTURE SCOPE

This economic evaluation is based on outcome data reported in a trial conducted by Hutchinson et al. (16), which included all patients aged between 10 and 65 years. The present evaluation concluded that decompressive craniectomy is not cost-effective based on this broad participant inclusion criterion. However, it is important to recognize that younger patients generally demonstrate improved recovery compared to older patients following TBI (40). Future studies should therefore aim to also report outcomes stratified by age, enabling differences in the cost-effectiveness of decompressive surgery between age groups to be identified.

Secondly, the study by Hutchinson et al. (16) does not report patient outcomes stratified by the severity of TBI. An Australian study demonstrated that patients with more severe TBI, exhibit greater QALY improvement following decompressive craniectomy (33). Hence, a more in-depth cost-utility analysis taking into account the severity of TBI could help identify specific patient cohorts in which surgery may prove more cost-effective to implement for the NHS.

Lastly, outcomes measured over a longer time horizon may provide greater insight into the cost-effectiveness of decompressive craniectomy as recovery from TBI can occur over a period of several years.

Disclosure of interest

The authors report no conflict of interest.

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Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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