RESCUE ASDH Trial

http://www.rescueasdh.org/

More refined guidelines and hopefully class I evidence will be established with the ongoing trials: randomized evaluation of surgery with craniectomy for patients undergoing evacuation of acute subdural hematoma (RESCUE ASDH Trial), prospective randomized evaluation of decompressive ipsilateral craniectomy for traumatic acute epidural hematoma (PREDICT-AEDH), and pragmatic explanatory continuum indicator summary (PRECIS) [1].

Two-thirds of traumatic brain injury (TBI) patients undergoing emergency neurosurgery have an acute subdural hematoma (ASDH) evacuated. These hematomas have been associated with a high mortality rate and low rates of functional recovery [2].

In addition, parenchymal injuries – such as contusions – and brain swelling are often found in patients with ASDH [3].

Miller et al. reported that two-thirds of the 48 patients with an evacuated ASDH had raised ICP in the post-operative period; raised intracranial pressure (increased ICP was defined as persistent elevation of mean ICP >20 mmHg during the period of continuous monitoring of ICP in the ICU) [4].

Importantly, half of the patients with raised ICP developed uncontrollable intracranial hypertension leading to herniation and death. Wilberger et al. observed that 40% of their cohort of 101 comatose patients who underwent a craniotomy for an ASDH had an ICP which remained <20 mmHg in the post-operative period, while 43% had a sustained period of uncontrollable intracranial hypertension with ICP peaking >45 mmHg [5]

Importantly, the authors observed that the mortality rate was ~40% in the former but close to 95% in the latter subgroup. These studies provide convincing evidence that, firstly, ICP can be elevated after ASDH evacuation and, secondly, elevated ICP leads to higher mortality.

In a retrospective cohort comparison study of 91 patients who had an operation for an ASDH, 56% received a primary DC, while the rest a craniotomy [6].

The standardised morbidity ratio was lower in patients who had a DC (0.75; 95% CI 0.51–1.07) compared to those who had a craniotomy (0.90; 95% CI 0.57–1.35). Although the 95% confidence intervals overlap, this study supports the hypothesis that a primary DC (i.e. bone flap left out after ASDH evacuation) may lead to better outcomes compared to a craniotomy (i.e. bone flap is replaced) due to better control of brain swelling and intracranial hypertension in the post-operative period. This hypothesis is also supported by a published two-centre non-experimental CER study, which found that post-operative ICP was better controlled and patient outcomes were better in the centre with greater utilisation of primary DC [7].

However, there is a paucity of high-quality evidence in the literature regarding the best surgical strategy (primary DC or craniotomy) for this group of patients and surgical decision making is often haphazard [8].

In a survey of UK surgeons, a significant variation in the surgical management of ASDH was observed with 41% of the respondents using primary DC <25% of the time but approximately one-third using DC in >50% of such cases [9].

On this background, the RESCUE-ASDH study was funded by the UK National Institute for Health Research (NIHR) as a multi-centre, pragmatic, parallel group randomised trial that aims to compare the clinical and cost-effectiveness of primary DC versus craniotomy for the management of adult head-injured patients undergoing evacuation of an ASDH. The trial was designed as a collaborative effort involving members of the British Neurosurgical Trainee Research Collaborative (BNTRC; www.bntrc.org.uk) and British Neurotrauma Group (BNTG; www.ukneurotrauma.org.uk), clinicians and academics with an interest in TBI, members of the Cambridge Clinical Trials Unit, health economists and service user representatives.

The criteria which are being used to determine eligibility of individual patients are:

Inclusion criteria: Adult head-injured patients (>16 years) ASDH on CT* The admitting neurosurgeon feels that the haematoma needs to be evacuated either by a craniotomy or DC (bone flap at least 11 cm in both instances)* * Patients with additional lesions (e.g. intracerebral haemorrhage, contusions) can be included

Exclusion criteria: Bilateral ASDHs both requiring evacuation Previous enrolment in RESCUE-ASDH study Severe pre-existing physical or mental disability or severe co-morbidity which would lead to a poor outcome even if the patient made a full recovery from the head injury. Eligible patients are randomised to craniotomy or DC intra-operatively after evacuating the ASDH. Patients with significant brain swelling preventing safe replacement of the bone flap are not suitable for randomisation and are being followed-up in the context of an observational cohort.

The primary outcome measure is the extended Glasgow Outcome Scale (GOSE) at 12-month post-injury (Table 1). The secondary outcome measures are:

Table 1. Table 1. The eight categories of the extended Glasgow Outcome Scale (GOSE). GOSE at 6 months quality of life (EQ-5D) at discharge from neurosurgical ward, 6 and 12 months Glasgow Coma Scale (GCS) on discharge from the intensive care unit (ICU) and from neurosurgical ward length of stay in ICU, neurosurgical and rehabilitation unit discharge destination from acute neurosurgical ward serious adverse events and surgical complications subsequent complications/re-admissions within the 1-year follow-up period return to operating theatre for cranial surgery within 2 weeks after randomisation incidence of hydrocephalus therapy intensity level in the post-intervention period economic evaluation Analysis will be performed on an “intention-to-treat” basis with a proportional odds model adjusted for covariates. Retrospective studies suggest a favourable outcome (moderate disability or good recovery) in ~35% of patients undergoing evacuation of ASDH. 11 The sample size of 990 patients (495 in each arm; 10% drop out rate) will allow us to detect the equivalent of an 8% absolute difference in favourable outcome [90% power and two-sided significance 0.05 (35% versus 43%)]. This corresponds to the equivalent of an 8% treatment effect.

The internal pilot phase of the study started in UK in autumn 2014. We are now just over 1 year since recruitment started and the study has achieved the following milestones (as of 29th November 2015):

64 patients have been randomised from 15 UK sites. 57 patients have been enrolled in the observational study cohort. 21 centres are now open to recruitment in UK and 2 more in set up.

1)

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