ABSTRACT

Introduction The ongoing need for dural tenting sutures in a contemporary neurosurgical practice has been questioned in the literature for over two decades. In the past, these sutures were supposed to prevent blood collecting in the potential space between the skull and the dura by elevating the latter. Theoretically, with modern haemostasis and proper postoperative care, this technique should not be necessary and the surgery time can be shortened. Unfortunately, there is no evidence-based proof to either support or reject this hypothesis.

Methods and analysis The systematic review will be performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement and The Cochrane Handbook for Systematic Reviews of Interventions. Eight electronic databases of peer-reviewed journals will be searched, as well as other sources. Eligible articles will be assessed against inclusion criteria. The intervention is not tenting the dura and this will be compared with the usual dural tenting sutures. Where possible, ‘summary of findings’ tables will be generated.

Ethics and dissemination Ethical committee approval is not required for a systematic review protocol. Findings will be presented at international neurosurgical conferences and published in a peer-reviewed medical journal.

PROSPERO registration number CRD42018097089.

INTRODUCTION

In the early days of neurosurgery, extradural haemorrhage (EDH) contributed to high mortality after craniotomies. Almost a century ago, Walter Dandy reported dural tenting sutures as an effective way of preventing postoperative EDH. Over time, his technique gained in popularity and significance to finally become a neurological standard. Dural tenting is a well-known method of stitching the dura to the bone or pericranium after craniotomy. This decreases the extradural space where EDH could arise and compresses dural vessels, which are potential sources of EDH. These sutures are known by many names (box 1). In addition, some terms distinguish dural tenting sutures that are placed in the centre of the dural opening from those near the edge, as was originally described by Dandy. These central tenting sutures are named after J. L. Poppen, and are one of his many contributions to neurosurgery.

Throughout the last 20 years, several researchers have expressed their growing doubt about the role of tenting sutures in contemporary neurosurgical practice. There have been several retrospective reports questioning the ongoing need for dural tenting sutures. Apparently, Dandy’s explanation about intraoperative haemostasis under hypotensive conditions being deceiving and subsequently causing EDH may be obsolete. These days, proper anaesthesiology, including normovolaemia and normotension, enables real-time evaluation of the haemostasis. The latter has been further improved by modern haemostatic agents, such as bone wax, electrocautery, oxidised cellulose polymer materials, collagen sponges and so on. Altogether, these improvements may be enough for effective and actual extradural haemostasis. Reports of some surgeons avoiding dural tenting sutures, in some papers or in day-to-day practice, further support this explanation.

STUDY RATIONALE

There is a risk of EDH formation—supposedly decreased with the use of dural tenting...
sutures—in the postoperative period and this should not be ignored. However, as mentioned earlier, studies (the majority retrospective) have implied not tenting the dura is safe. Dural tenting prolongs the time of surgery, which may be a reason to omit these sutures. Moreover, the sutures may potentially increase the risk of adverse effects, such as cerebrospinal fluid (CSF) leak and damage to cortical matter or blood vessels with subsequent subdural or intracerebral haemorrhage. There have also been several reports of more unusual complications like subdural hygroma, granuloma or pial arteriovenous fistula. Thus, refraining from dural tenting sutures would shorten the surgery and reduce the operative risk.

Therefore, evaluation of this procedure is interesting from the surgical point of view and by modern, evidence-based standards. Not a single systematic review has been performed to date to establish the necessity of dural tenting. Moreover, its impact on short-term postoperative headaches or CSF leak has not been established in an evidence-based manner. Thus, a systematic review is necessary and subsequently allows for a meta-analysis. However, many researches have evoked a priori preparation of protocols for a systematic review. The aim of registration and/or publication of protocols is to increase the quality of subsequent systematic reviews. This is achieved by external editorial systems reducing publication bias and improving transparency and accuracy.

OBJECTIVE
To prepare a protocol for a systematic review that will determine the safety of not tenting the dura during an elective craniotomy.

METHODS AND ANALYSIS
The review will be conducted according to the Cochrane Handbook for Systematic Reviews of Intervention and data will be reported in coherence with the PRISMA statement recommendations. The quality of evidence for each outcome will be assessed according to the Grading of Recommendations Assessment, Development, and Evaluation framework. EndNote X8.2 (or newer version) and Review Manager 5.3 (or newer version) software will be used for electronic data management. This review has been registered with PROSPERO (registration number: CRD42018097089). Moreover, this protocol follows the PRISMA-P 2015 statement.

Eligibility criteria
The type of studies included will be primarily randomised controlled trials (RCT) and quasi-RCTs. Moreover, to obtain enough statistical power, the study will also include cross-over studies, published in English literature after 1970, and case series.

Participants
The participants will include all patients who qualify for a craniotomy, regardless of their diagnosis. Demographic criteria will not be limited.

Interventions and comparisons
As tenting the dura is a widely accepted reference method, it is the authors’ firm belief that the intervention should be not tenting the dura. Thus, patients with dural tenting sutures would constitute a control group. However, different allocations of control and intervention groups will be included as well as a comparison of dural tenting and not tenting. The intervention will be considered in a dichotomous manner using minimum information, such as ‘tenting the dura’ and, conversely, ‘not tenting the dura’, regardless of the number, position, or type of sutures.

Outcomes
The outcomes that are considered likely to be meaningful are: reoperation due to EDH and the postoperative 30-day mortality. However, the latter is not suitable for a primary endpoint as it is affected by many factors (for instance, preoperative condition of the patient and type of intracranial lesion) and the heterogeneity of the group. Thus, reoperation due to EDH should be the primary outcome, as it is the most accurate way to measure the safety of not tenting the dura.

Information sources
The systematic review will cover standard bibliographic databases: MEDLINE, PUBMED, EMBASE, Google Scholar, Cochrane Library, ProQuest, ScienceDirect, as well as trial registers (clinicaltrials.gov, EU register, ISRCTN), conference abstracts and grey literature searched with Google Web Search, and systematic review registers (PROSPERO). Moreover, the references of all relevant articles will be scanned.

Search strategy
The search strategy for PUBMED and EMBASE is presented in box 2. Box 3 provides additional search phrases that may support and/or modify the main search. A PRISMA flow diagram will be included in the review.

Study records
Selection process
All search results will be imported into EndNote and the software will remove any duplicates. Then, two
independent reviewers (LP, PK) will perform a preliminary screening of titles and abstracts for inclusion. At this stage, all conflicts will be included. Next, the full text of studies will be obtained, and two reviewers will apply inclusion criteria to identify relevant studies to be included in the systematic review. Conflicts will be discussed, and when needed, a third reviewer (AM) will be involved.

The review will contain a table of included and excluded studies with their characteristics and reasons for inclusion and exclusion.

Data collection process and data items

Data will be extracted by one author (LP) using a previously prepared standardised form at the study level. The following data will be obtained: (1) characteristics of the group of participants (age, sex and diagnosis); (2) type of surgery (supratentorial versus infratentorial versus skull base, elective versus emergency and craniotomy versus craniectomy) and indication (aneurysm, tumour, trauma, epilepsy and so on); (3) definition of an intervention (number of tenting sutures, information about wound drainage and haemostatic agents used during closure of the dura) and a control group; and (4) outcome measures (number of EDH, number of reoperations, deaths, midline shift and size and volume of extradural collections), as discussed earlier.

Risk of bias in individual studies

The risk of bias in the individual studies will be assessed at the study level. It will be performed by one author (LP) using the Cochrane collaboration’s risk of bias tool and checked by a second reviewer (PK).

Data synthesis

There will be two categories of data collection depending on the type of endpoint, either binary or continuous. Risk ratios will be calculated to measure the risk of specific events, such as reoperation due to extradural haematoma, CSF leak, death and the standardised mean differences for the midline shift, volume and size of the extradural collection. We will pool the results using a random-effects meta-analysis, with standardised mean differences for continuous outcomes and risk ratios for binary outcomes, and calculate 95% CIs and two sided p values for each outcome. The heterogeneity of effect measures between the studies will be assessed using both the $\chi^2$ test and the I2 statistic. We will consider an I2 value greater than 50% to be indicative of substantial heterogeneity.

Subgroup analysis

If sufficient data are available, we plan to conduct subgroup analyses according to craniotomy versus craniectomy, supratentorial versus infratentorial surgery, skull base versus no skull base in range of the surgery, and elective versus emergency surgery. Such actions will allow the identification of potential sources of heterogeneity.

Patients and public involvement

This type of study does not require patients and or public involvement.

DISCUSSION

The choice of proper eligibility criteria is important when conducting a systematic review. In this protocol, there was a lot consideration regarding the choice of population,
intervention, comparison and outcome. Some authors regard only craniotomies as suitable for the study, in contrast to craniectomies. The reason for this is that restored bone allows the measurement of the potential fluid collection volume in intracranial-extradural space and the assessment of how it affects the whole brain in the closed cranial cavity. Nevertheless, it is reasonable to include studies with craniectomies.

Other valuable endpoints could include any new neurological deficit or previously existing deterioration, an external or internal CSF leak requiring treatment, deterioration of postoperative headaches, extradural fluid collection (EDH, CSF, air and so on), and the midline shift. None of these will be included if there is not enough data for testing.

Examining the most basic and elementary procedures may, surprisingly, be the most challenging and intimidating task. Due to a lack of such actions, it is possible that most brain surgeons have been using surgical techniques that bring no benefit and only extend the operation. Hence, there is a great need for this study. The results may finally determine if dural tenting sutures are necessary in modern neurosurgery.

**Ethics and dissemination**

Ethical committee approval is not required for a systematic review protocol. Findings will be presented at international neurosurgical conferences and published in a peer-reviewed medical journal.

**Contributors** LP guarantor of the review. LP conceived the presented idea and prepared the manuscript; PK critically revised the manuscript; AM validated the final version of the manuscript; JŻ analyzed the data; DJ, JF, and KW contributed to the design of the study; PL and PL helped supervise the project; RR, DS, and TT provided the methodologic background. All authors reviewed the final manuscript.

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**Author note** In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

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