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Letter to Editor "Study protocol for a multicenter randomized controlled pilot study on decompressive laparotomy vs. decompressive craniectomy for intractable intracranial pressure after traumatic brain injury: The SCALPEL study"

Dear Editor

This letter aims to explore the SCALPEL study, a groundbreaking pilot investigation into a new approach for treating severe traumatic brain injury (TBI), concerning the published study "Study protocol for a multicenter randomized controlled pilot study on decompressive laparotomy vs. decompressive craniectomy for intractable intracranial pressure after traumatic brain injury: The SCALPEL study" by Benny Kölbel a et al.

This study aims to compare the effectiveness and safety of decompressive laparotomy (DL) and decompressive craniectomy (DC) in managing intractable intracranial pressure (ICP) after severe TBI [Kölbel et al., 2023]. The study assesses the patients' outcomes, including the Extended Glasgow Coma Scale (GCS), and will also monitor compartmental pressure values and complications. The protocol has been approved by multiple university ethics committees and is designed to provide high-quality prospective data on this treatment approach.

TBI causes a significant number of trauma-related deaths and greatly affects the quality of life worldwide. Managing the increased ICP that results from TBI is crucial because it can worsen brain damage. Treatments to control ICP include positioning the patient's head to improve blood flow, using medications, and in severe cases, performing surgeries like DC or DL. DL, which involves relieving pressure by performing surgery on the abdomen, is being explored as a potentially safer alternative. DC appears to be a beneficial intervention for patients with severe TBI and refractory elevated ICP, offering improved outcomes when used alongside other therapies [Güresir et al., 2022].

The SCALPEL trial is an international clinical investigation exploring a novel approach to treating severe traumatic brain injury. It compares DL, an abdominal surgery, to the standard treatment of DC, which involves removing part of the skull. This innovative approach targets high intracranial pressure, a critical complication of TBI, by manipulating pressure within the body's interconnected systems. To ensure patient safety, SCALPEL utilizes a two-stage design. The initial phase cautiously enrols a small group of participants before expanding enrollment if the results are promising. This multi-centre study leverages expertise from various surgical fields, including neurosurgery, trauma surgery, and general surgery, reflecting the collaborative nature of the research. If DL proves to be safe and effective, it has the potential to revolutionize the treatment of severe TBI [Decraene et al., 2023].

The SCALPEL trial pilot study investigating DL as a treatment for severe ICP in TBI patients. This two-stage, randomized controlled trial will involve multiple hospitals, starting with at least 10 German level 3 centres. The initial phase focuses on safety and recruitment feasibility by enrolling 10 patients per treatment arm (DL vs. standard care) and may expand to include 80 more patients. Conducted ethically following international guidelines, SCALPEL brings together researchers, statisticians, and experienced clinicians from various specialities to ensure patient safety and clinician involvement. The pragmatic design incorporates best practices for both DL and standard treatments to evaluate the effectiveness of DL in a real-world setting [Hutchinson et al., 2023].

The study findings demonstrated the effectiveness of DC in this patient population. However, a critical observation was the significant association between persistently high post-operative ICP and increased mortality rates. This underscores the necessity for meticulous monitoring of ICP following surgery. Furthermore, pre-operative GCS scores emerged as a strong positive predictor of neurological outcomes for two weeks and two months post-operatively. These results highlight the paramount importance of both vigilant ICP monitoring and pre-operative GCS assessment in optimizing patient management strategies and potentially improving outcomes after DC surgery for severe TBI [Chandankhede et al., 2023].

DL is being explored as a new surgical approach for TBI patients with severe ICP that doesn't respond to other treatments. While DC, removing part of the skull, is the current standard procedure, it carries risks. DL is an abdominal surgery, a potentially less invasive option with comparable effectiveness in reducing ICP and improving outcomes for TBI patients.

The SCALPEL trial employs strict inclusion criteria to ensure patient suitability and study generalizability. Participants must be within the age range of 18–65 years and possess a documented TBI confirmed by an abnormal CT scan. Furthermore, they require the presence of invasive ICP monitoring demonstrating refractory ICP exceeding 20 mmHg for 1–12 h following the implementation of conventional treatment protocols. Written informed consent is mandatory, obtained either directly from the patient or their legally authorized representative. The study protocol accommodates specific situations where enrollment may proceed via a designated peer proxy [Florez-Perdo et al., 2023].

In conclusion, the SCALPEL study has the potential to significantly advance the understanding and treatment of severe TBI by providing high-quality data on the comparative effectiveness of DL and DC. The outcomes of this trial could inform clinical practices and ultimately improve patient care and survival rates in cases of severe TBI.

Ethics approval

Not applicable.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Abbreviation:

TBI	Traumatic Brain Injury
DL	Decompressive Laparotomy
DC	Decompressive Craniectomy
ICP	Intracranial Pressure
GCS	Glasgow Coma Scale

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