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Needle-tip electrocautery versus steel scalpel incision in neurosurgery: study protocol for a prospective single-centre randomised controlled double-blind trial

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ABSTRACT

Introduction Electrocautery is used widely in surgical procedures, but making skin incision has routinely been performed with scalpel rather than electrocautery, for fear that electrocautery may cause poor incision healing, excessive scarring and increased wound complication rates. More and more studies on general surgery support the use of electrocautery for skin incision, but research comparing the two modalities for scalp incision in neurosurgery remains inadequate. This trial aims to evaluate the safety and efficacy of needle-tip monopolar for scalp incision in supratentorial neurosurgery compared with steel scalpel.

Methods and analysis In this prospective, randomised, double-blind trial, 120 eligible patients who are planned to undergo supratentorial neurosurgery will be enrolled. Patients will be randomly assigned to two groups. In controlled group scalp incision will be made with a scalpel from the epidermis to the dermis and then the subcutaneous tissue and galea aponeurotica will be incised with needle-tip monopolar for scalp incision in supratentorial neurosurgery compared with steel scalpel.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a prospective, single-centre, randomised, controlled, double-blind trial about safety and efficacy of needle-tip monopolar for scalp incision.

⇒ This study is comprehensively conducted to identify differences between these two modalities using a variety of clinical relevant outcomes.

⇒ Our limitation is that we only and strictly recruit patients undergoing supratentorial neurosurgery with a single incision without history of previous neurosurgical craniotomy.

⇒ This trial might be underpowered to ascertain the difference between the two groups because sample size is calculated based on an assumed effect size.

INTRODUCTION

The use of electrocautery dates back to 1909 for removal of tumours.1 Later William T. Bovie invented the first commercial electrocautery device, which was first used clinically in brain tumour resection by neurosurgeon Dr Harvey Cushing in 1926.2 Thereafter, the electrocautery equipment was gradually improved, resulting in the more commonly used monopolar electrocautery and bipolar electrocautery.

Although electrocautery has the advantages of less bleeding, faster speed, complete haemostasis and less sharp injury to operators,3–8 it is currently mainly reserved for incision and separation of subcutaneous tissue and deeper layers as well as haemostasis, while rarely used by surgeons to cut skin for fear that the heat generated by electrocautery may damage the skin tissue and appendages around the incision, resulting in poor incision healing, excessive scarring and devitalised tissue may also become a focus of infection.9 10 Nonetheless, scalpels have other inherent disadvantages, including unclear anatomical hierarchy due to bleeding wounds, the need to ligate blood vessels with sutures, leaving sutures as foreign bodies.
remaining in the body which may lead to wound infection or foreign body reactions, sharp injuries which may lead to infection of blood-borne infectious diseases and unintentionally damaging surrounding vital organs and structures during procedures.11,12 On the other hand, there has been some literature on abdominal incisions showing that there is no statistical difference in postoperative complications between incisions made with conventional scalpel and electrocautery.4–7 13–16 In terms of incision scar cosmesis, Stupart et al in the electrocautery group on the first day after surgery.18 Several other studies have found that incising skin by electrocautery with cutting modality during abdominal, chest, upper extremity and neck surgery reduces incision time, blood loss3–7 and acute postoperative pain.5–7 15

Scarcce research has been done concerning the effect of cutting methods on skin incision in neurosurgery. Most of the existing studies on head and neck cancer, craniofacial surgery and neurosurgery have shown no statistically significant difference in the incidence of postoperative wound infection and dehiscence between electrocautery and scalps.9,10 19 This is especially important for the scalp, as poor wound healing often results in hypertrophic scarring and baldness around the incision, seriously affecting the patient’s aesthetic satisfaction. Several more sophisticated, thinner-tip electrocautery devices have appeared, such as needle-tip monopolar and microdissection needles. These devices reduce peri-incisional tissue damage by delivering electrical current through extremely sharp tips to a smaller area of skin than conventional blade-tip electrocautery does. Although Papay et al’s study of bicoronal incisions in 12 patients with craniosynostosis indicated that the microdissection needle group had larger scars than the scalpel group (p<0.05),9 other subsequent studies did not find there was a significant difference in scar formation between microdissection needle and scalpel.19 Sharma evaluated the effect of microdissection needle on 117 incisions undergoing craniomaxillofacial surgery (including 10 scalp incisions) and found no increased risk of postoperative infection or alopecia rates.19 Similar to what was reported in the study of abdominal incisions, Sheikh’s study of 177 skin incisions for neurosurgical procedures (including 85 cranial incisions) revealed that microdissection needle significantly decreased incision blood loss and incision time compared with scalpel, and no evident alopecia was found around scalp incisions, which made him recommend the use of microneedle electrocautery for all neurosurgery procedures, particularly paediatric cases.3 These studies provided some clues for the application of electrocautery in scalp incision. However, there are still some questions that need to be clearly clarified, including the postoperative scar, incision infection, incision pain and baldness around the incision.

This study intends to comprehensively compare the effect and complications of needle-tip monopolar and steel scalpel for scalp incision in supratentorial neurosurgery through a clinical randomised controlled trial.

METHODS AND ANALYSIS

Patient and public involvement
Patients are not directly involved in the design, recruitment or conduct of the study.

Design
This study is a prospective, single-centre, randomised, controlled, double-blind trial. Figure 1 illustrates the flow chart of the study. This trial will be carried out at the department of neurosurgery in West China Hospital, Sichuan University.

Patient population: inclusion and exclusion criteria
Patients will be considered eligible if they meet all of the following inclusion criteria:

1. Age ≥18 years old.
2. Patient will receive neurosurgical supratentorial craniotomy with a single incision.
3. The patients consent to receive long-term follow-up.
4. Patient or their legally authorised representative has provided written informed consent.

The following patients will be excluded:

1. Patient suffering from diseases that affect wound healing, such as poorly controlled diabetes, scarring constitution, severe infection, multiple organ failure.
2. History of previous neurosurgical craniotomy.
3. Patient has baldness.
4. Patient has been included in other clinical studies, and the intervention measures will affect the results of the present study.
5. Other circumstances that the investigator considers inappropriate to participate in this clinical trial.

Randomisation
In this study, a simple random method is used. A random number table is generated by a computer, and serially coded opaque envelopes are used to store the random grouping barcode. All eligible patients will be randomly allocated to either needle-tip monopolar group (intervention group) or steel scalpel group (control group). The patient and the follow-up evaluator are blinded to the type of modality used to make the incision. The incision blood loss, incision length and incision-related operation time are recorded by one of the assistants of the operating surgeons and the information is conveyed to the follow-up evaluator without revealing the group of
the patient. Once the final statistical analyses have been completed, the randomisation sequence will be disclosed.

**Intervention**

In addition to the incision modality, the surgical treatment plan is formulated by the doctor based on the comprehensive consideration of the patient’s condition and the wishes of the patient’s family. In scalpel group the patients are incised from the epidermis to the galea aponeurotica with a steel scalpel, while the patients in needle-tip monopolar group are first incised with a steel scalpel from the epidermis to the dermis, and then the subcutaneous tissue layer and galea aponeurotica are incised with a needle-tip monopolar on cutting mode. In both groups bipolar can be used with coagulation mode for haemostasis of bleeding vessels if necessary. After opening the galea aponeurotica, diathermy is used in the desired mode as needed to carry out the complete operative procedure. During the operation the incision length will be measured by using a sterile flexible ruler in centimetres.

**Primary outcomes**

Scar score (at 90 days): the POSAS and VSS will be used to assess the appearance of the wound at 90 days after surgery.

**Secondary outcomes**

1. Incision pain (at 1 day, on discharge, at 90 days): Assessed using visual analogue scales.

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**Figure 1** Trial flow chart.
2. Incision blood loss (intraoperative collection): The gauze exclusively used during making incision, incision suture and haemostasis is weighed by an electronic scale with an accuracy of 1 g. The mass of the sterile gauze is calculated both before and after use. The difference in mass per 1 g is counted as 1 mL of blood. No suction is used during incision and suturing. Blood loss is calculated in millilitre.

3. Incision-related operation time (intraoperative collection): From the skin incision to the complete opening of the galea aponeurotica, including complete haemostasis and the time used for suturing.

4. Incision infection (on discharge, at 2 weeks, 90 days): involving the skin or subcutaneous tissue of the incision and having at least one of: purulent drainage, positive culture, signs or symptoms of infection or diagnosis by a physician.

5. Incision healing (on discharge, at 2 weeks, 90 days): Poor healing is defined as incision dehiscence and the need for re-suturing. Wound healing disorders will also be recorded.

6. Alopecia around the incision (at 90 days): The follow-up evaluator will ask the patient whether he/she feels alopecia. If the patient can not answer the question, the evaluator will ask the patient’s caregiver.

Duration of surgery and preoperative and postoperative haemoglobin values are gathered as baseline data.

We will provide periodic communications via phone to remind participants of the upcoming visit, as well as to acknowledge their support, to complete follow-up as fully as possible.

Data safety and monitoring board

This study will be carried out as per the principles of Declaration of Helsinki and good clinical practice guidelines. Non-blinded reviews of all patients’ efficacy and safety data will independently be undertaken by an independent data safety and monitoring board (DSMB) comprised of physicians and neurosurgeons. The DSMB will call a meeting at least every 6 months and an interim analysis conference will be conducted when half cases have finished 90 days follow-up. All data will be entered electronically by one clerk and examined by another and stored securely at West China Hospital where the data originated.

In our study an adverse event (AE) will be defined as incision-related undesired medical events that occur in subjects, such as incision infections. Serious AEs (SAEs) include persistent poor healing or suppuration of incision, requiring debridement and death. AEs and SAEs will be collected after the subject has provided informed consent and enrolled in the study. All AEs occurring after receiving intervention and until follow-up completed will be recorded. All AEs and SAEs should be reported to the DSMB.

Sample size estimates

No previous study has investigated the quantitative difference in incisional scarring between needle-tip monopolar and scalpel in neurosurgery. Based on the results of Okereke et al’s study and subsequent other promising results, elucidating that there was no significant differences in wound complication rates between incisions created by electrocautery and steel scalpel for head and neck surgery.³ ¹⁰ ¹¹ ¹⁹ Contrary to others, Papay et al admitted that there was not a difference in wound complications between the two modalities, but revealed a statistically significant wider scar in patients undergoing bicoronal incisions using microdissection needle versus the scalpel.¹⁰ Considering the small final sample size (12 patients completing the follow-up necessary for study inclusion) of Papay et al’s study and subsequent other
research which favours electrocautery,¹¹¹⁹ we incline to the latter and we conduct a prospective, single-centre, randomised, controlled, double-blind trial exclusively in supratentorial neurosurgery to further confirm it.

Our study still has some demerits. First, we aim at patients undergoing supratentorial neurosurgery with a single incision without history of previous neurosurgical craniotomy. These rigorous inclusion criteria might place a restriction on the generalisation of our findings. Second, the sample size in this trial is calculated based on an assumed effect size. Accordingly, it is possible that this trial might be underpowered to ascertain the difference between the needle-tip monopolar and the scalpel group in incisional POSAS scores at postoperative 90 days. Notwithstanding, we believe a well-designed trial could also assist us to better comprehend the properties of needle-tip monopolar.

ETHICS AND DISSEMINATION

This study has been validated by the ethics committee of West China Hospital, and has been registered at Chinese Clinical Trial Registry. Informed consent will be obtained from each involved patient and/or their designated representative. Final results from this trial will be promulgated through publications. Any protocol modification will be authorised by the ethics committee of West China Hospital, and then renewed on the Chinese Clinical Trial Registry.

Contributors WX, MF, ZW and JW designed the trial and drafted the manuscript. CT, UM, LL and XH reviewed and modified the manuscript. All authors read and consented to the final manuscript.

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Competing interests None declared.

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