Acupuncture for the Postoperative Recovery of Hip Fracture Patients: A Pilot Randomized Controlled Trial Study Protocol

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Abstract

Background

Hip surgery is a common and safe medical intervention to restore the functionality and mobility of the hip joint in patients suffering from hip fractures. Despite the advances in surgical techniques, a relatively large proportion of patients suffer from postoperative pain, joint dysfunction and loss of muscle strength[1-8]. These outcomes hinder rehabilitation, which consequently imposes significant economic burden for health systems.

This study aims to assess if the addition of acupuncture to existing postoperative management will improve the following patient outcomes post hip surgery: 1. Postoperative pain and 2. Function (muscular strength and mobility)

Methods

Patients scheduled for hip surgery due to unilateral hip fracture, who fulfilled the inclusion and exclusion criteria, will be randomly allocated to either receive postoperative management ONLY (Conventional analgesics and physiotherapy) or with the addition of acupuncture post hip surgery. Acupuncture will be performed on patients in the intervention group 2x/week from postoperative week (POW 5), a total of 8 acupuncture treatments will be administered.

The two primary outcomes which include the Harris Hip Score and Visual Analogue Scale will be assessed at the following time points: postoperative week (POW) 0, POW 6, postoperative month (POM) 6 and POM 12, while the secondary outcome Timed get Up and Go (TUG) will be assessed at the following time points: POW 6, POM 6 and 12. Besides, length of stay in hospital, any incidences of deep vein thrombosis, adverse events of analgesics and acupuncture will also be recorded.

Hypothesis

The addition of acupuncture to existing postoperative management will reduce pain and enhance functional recovery, better and faster than with postoperative management alone.

(265 words)

Introduction

Hip fractures result in increased disability, morbidity, and mortality risks among the elderly population. A study in Singapore predicts a 30–50% increase in the incidence rates of hip fracture over the ensuing 30 years. With an increasing life expectancy (an average of 83.1 years) and low total fertility rate (1.16 births per woman*),* Singapore has a rapidly aging population and is likely to face significant health care and financial burdens from the rising numbers of hip fractures[5].

Hip surgery is a common and safe medical intervention to restore the functionality and mobility of the hip joint in hip fractures patients. The current surgical techniques used include internal fixation, partial hip replacement and total hip replacement. The current postoperative management for hip surgery is conventional analgesia and physiotherapy.

Despite the advances in surgical techniques, a relatively large proportion of patients still suffer from chronic postoperative pain and joint dysfunction[1-4]. It has also been demonstrated in numerous studies that muscular mass and strength will decrease substantially after hip surgery[6-8]. These outcomes hinder rehabilitation, prolongs length of stay in hospital and time needed to regain independence, which impose great economic burden for patients, health systems and the society at large.

Acupuncture is a key component of TCM and has proved its efficacy in pain control and various clinical symptoms through numerous clinical studies. Currently, in Singapore, acupuncture is used predominantly in the outpatient setting and has been widely accepted as a safe therapy with minimal side effects[9]*.*

In recent years, numerous clinical studies have found acupuncture to be effective in the reduction of postoperative pain [10,11]. There are also reports demonstrating the effectiveness of acupuncture in the recovery of muscle strength, but not in the postoperative patient [12-14].

Besides, current literature suggest that acupuncture might be effective in reducing postoperative pain[10,11] but not in improving functional recovery. There are also indications that acupuncture might aid in the recovery of muscle strength[12-14], but these findings are not specific to rehabilitation post-surgery.

Results from this study will provide data to guide decisions and determine the role of acupuncture in a rehabilitative setting to better improve patient outcomes. Should results show a positive effect of acupuncture in postoperative patients, it could serve as a foundation for future studies and eventually be included in the care pathways of a wider range of surgical procedures.

Methods

This is a single center randomized, single- blind, parallel trial. A total of 90 patients who meet the inclusion and exclusion criteria will be recruited and randomized to either receive standard post-operative hip fracture management (physiotherapy and analgesic) or to receive acupuncture treatment in addition to standard care, in a ratio of 1:1. All patients are recruited from Singapore Khoo Teck Puat Hospital (KTPH) Hip Fracture Unit and acupuncture treatment will be administered in Admiralty Medical Centre, KTPH.

This study protocol has received ethical approval from the National Healthcare Group Domain Specific Review Board (2019/01168)

Written Informed Consent will be obtained from all study participants. Detailed information about the study and sufficient time will be provided for participants to understand the study and for clarifications. Patients will be also informed that they can withdraw from the study at any given point without any penalties.

Recruitment criteria

Inclusion criteria

- Patients who have undergone hip surgerydue to unilateral hip fracture
- Ambulatory with or without aid prior to hip fracture
- Patients aged 40-99 (male), 55-99 (female)
- Able provide consent for the study and acupuncture treatment
- Able to attend treatment sessions

Exclusion Criteria

- Patients with morbid obesity (Body Mass Index >40)
- Patients with communication barriers such as aphasia or language
- Local or systemic infection or dermatological disease
- Existing treatment with anti-neoplastic, oral corticoid or immunosuppressive drugs
- Needle phobia or inability to stay still for 30min during acupuncture retention
- History of psychiatric disease, kidney failure on peritoneal dialysis, substance abuse.
- If there exist any postoperative complications that deviate from standard management resulting in interference of patient's clinical evaluation

Randomization:

Patients will be randomized to either Group A, where they receive postoperative management AND acupuncture, or Group B, where they receive postoperative management ONLY.

The method of randomization is as follows: 1) KTPH CRU Biostatistician (non-study team member) will use a random number generator to create a random sequence for the first 45 subjects (Subject 1 to 45), 45 subjects in each group, and repeat the process for the next 45 subjects (Subject 46 to 90). There will be a corresponding subject number in running sequence to each randomized generated number. The randomized numbers will then be categorized into 2 groups, odd numbers into either acupuncture or control group then even numbers into the other. 2) 90 opaque sealed envelopes will be prepared for 90 subjects. The subject number will be written on the front of each envelope. Inside each envelope, there is an insert stating the group which the subject is allocated to. 3) These sealed envelopes will be handed over to the study team. The study team member will take the relevant envelope in accordance with the subject number to check what group the subject is allocated to.

Intervention

Hip surgery will be carried out for all patients in Group A and B. Both groups A and B will undergo standard postoperative management program. Standard postoperative management program include: conventional analgesia and physiotherapy POD 1, 2 and 3, followed by 5x/week until discharge. Post-

discharge, patients will continue physiotherapy 1-2x/ week for 3 months depending on their rate of recovery.

In addition to standard care, Acupuncture will be performed on patients in Group A 2x/week from postoperative week (POW) 5 to POW 8, a total of 8 acupuncture treatments will be administered. From the 2nd to 8th treatment, electro-acupuncture and infrared therapeutic lamp will be used. All treatment will be administered by registered TCM practitioners with at least 2 years of experience. The acupuncture needles to be used for this study are Kinhong/ Mac sterile acupuncture needles for single use. Either 0.25 x 50mm needles or 0.25 x 25mm needles will be employed depending on the acupuncture point and the depth of needling. The depth of needle insertion will range from 1-1.5cm, according to the thickness of the subcutaneous fatty tissue at the site of the acupuncture points. The needles will be left in situ for 20 minutes. Therapeutic effects are assessed to be optimal when the patient experiences a momentary local sensation of heaviness or numbness, termed De Qi in the classical acupuncture literature. Electrical stimulation will be delivered at 2Hz for 20 min, at an intensity below individual patient's pain threshold. 4 acupuncture points will be stimulated in pairs. The following acupuncture points will be used bilaterally for this study:

1) Li 4 (*Hegu*)

2) St 36 (*Zusanli)*

3) Sp 6 (*Sanyinjiao*)

4) Sp 9 (*Yinlingquan*)

5) Sp 10 (*Xuehai*)

6) Kd 3 (*Taixi*)

7) Gb 34 (*Yanglinquan*)

8) Ren 6 (*Qihai)*

9) *Auricular point - Kuan*

10) *Auricular point - Shen Men*

Outcome measures

Primary Outcomes 1. Modified Harris Hip Score for assessing pain and function 2. Visual Analogue Scale (VAS)-100 for assessing the pain intensity. Secondary Outcomes 3. Timed get Up and Go (TUG) test for assessing function (Gait and speed). The TUG will be performed thrice during each assessment, and the average time will be taken. 4. Lower extremity muscle strength will be measured using a portable dynamometer. The subject's operated and non-operated side will be measured. The primary outcomes will be assessed at the following time points: at postoperative week (POW) 0, POW 6, postoperative month (POM) 6 and POM 12, while the secondary outcomes will be assessed at the following time points: POW 6, POM 6 and 12. Length of stay in hospital, any incidences of deep vein thrombosis, adverse events of analgesics and acupuncture will also be recorded.

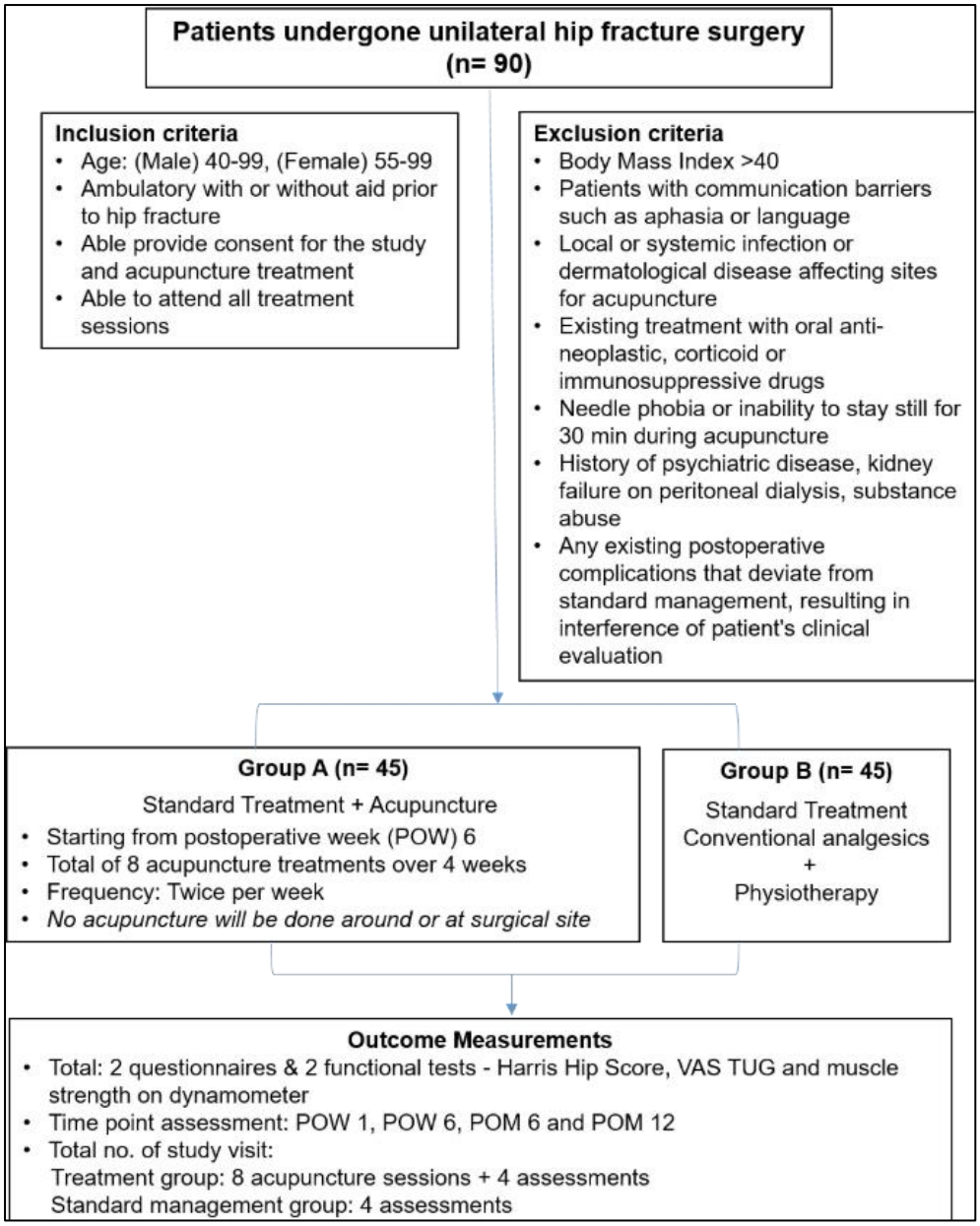

Fig 1: Flow chart showing

This research will not uncover any incidental findings as no lab test and radiological examinations will be collected as part of this study.

Informed Consent

1. Ethics approval will be sought from the National Healthcare Group Domain Specific Review Board (NHG DSRB) following consultation with the KTPH clinical research unit and the in-house statistician
2. Patients will be provided with a detailed information pack with sufficient time to understand and ask questions
3. If they are happy to proceed, a written consent form will be completed in keeping with guidance from the NHG DSRB
4. Patients will be able to withdraw from the study at any given point

Data storage

1. Each patient will be provided with a unique identifier so that their progress can be tracked.
2. No identifiable information will be stored
3. Study data will be stored on a secure, password protected computer in the institution and no information will be stored on removable devices
4. Any hard copies will also be stored in the patient's individual medical records

Statistical Analysis

Two-sample t-test or non-parametric t-test will be used to compare continuous variables (e.g., KOOS, VAS) between group A and group B. Chi-square and Fisher's exact test will be used to compare categorical variables (e.g., race) between group A and group B. Within each group, paired t-test or non-parametric test will be considered to compare baseline with each of follow-ups. Repeated ANOVA or generalized estimating equation (GEE) model (for missing data) will be considered to compare group A with group B over time while adjusting baseline covariates such as age, gender, ethnicity and baseline pain score.

Data will be analyzed by the in house statistician from KTPH.

Discussion

Although surgical techniques have advanced greatly, a relatively large proportion of hip fracture patients still suffer from chronic postoperative pain and joint dysfunction[1-4]. It has also been demonstrated in numerous studies that muscular mass and strength will decrease substantially after hip surgery[6-8]. These outcomes hinder rehabilitation, prolongs length of stay in hospital and time needed to regain independence, which impose great economic burden for patients, health systems and the society at large.

Acupuncture is a key component of TCM and has proved its efficacy in pain control and various clinical symptoms through numerous clinical studies. Currently, in Singapore, acupuncture is used predominantly in the outpatient setting and has been widely accepted as a safe therapy with minimal side effects[9].

In recent years, numerous clinical studies have found acupuncture to be effective in the reduction of postoperative pain [10,11]. There are also reports demonstrating the effectiveness of acupuncture in the recovery of muscle strength, but not in the postoperative patient [12-14].

To our knowledge, there are currently no clinical studies being conducted to investigate the effectiveness of acupuncture on BOTH pain and functional recovery post hip surgery. Usichenko et al. demonstrated that auricular acupuncture could reduce analgesic requirement, but did not assess the effect that acupuncture has on enhancing functional recovery post hip surgery[11]. The overall aim of this proposal is to assess if the addition of acupuncture to existing postoperative management could decrease postoperative pain and enhance functional recovery of the post-surgical hip joint. Results from this study will provide data to guide decisions and determine the role acupuncture in the rehabilitative setting to better improve patient outcomes. We hypothesize that the addition of acupuncture to postoperative management will improve patient outcomes and hence, reduce length of hospital stay and enable faster return to independence and continued active lifestyle. This would consequently reduce the financial burden on the patients and health care institutions.

Conclusion

In summary, this study evaluates the impact of adding acupuncture to standard management of hip fracture patients after surgery. Results from this study will generate greater interest in the use of acupuncture among physicians, surgeons and various health bodies. This will result in wider national

and possibly international-level collaborations to further investigate the use of acupuncture for other clinical symptoms.

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