Surgery versus ultrasound-guided steroid injections for trigger finger disease: protocol of a randomized controlled trial

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ABSTRACT

INTRODUCTION: Trigger fingers have been reported in the literature for over a century; yet, the lack of trials comparing open surgery to corticosteroid injection is pronounced. At the initiation of the present study in 2010, no randomized controlled trials could be found comparing open surgery to corticosteroid injection. In the present randomized controlled trial, we plan to compare the efficacy of a single ultrasound-guided corticosteroid injection with conventional open surgery in terms of ability to correct the trigger finger.

MATERIAL AND METHODS: The study is performed as an open-label single-centre, randomised controlled trial with a one-year follow-up. Patients are randomly assigned to either ultrasound-guided corticosteroid injection (n = 83) or to open surgical release of A1-pulley (n = 83). Follow-up is conducted at 12 weeks and one year after treatment. The affected finger will be assessed using a trigger finger score. Furthermore, any treatment complications, absence from work or sport and use of related medical services or additional treatment are also recorded.

DISCUSSION: The present study will be the first to compare treatment of trigger finger by conventional open surgery with ultrasound-guided corticosteroid injection in a randomized controlled trial. The results will contribute to evidence-based recommendations for the treatment trigger finger patients.

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Trigger finger (TF) is a common disorder believed to affect more than two in a hundred persons during a lifetime [1]. The clinical presentation ranges from patients complaining of morning stiffness of the affected finger, a finger that snaps or triggers on a regular basis, to a finger locked in flexion [2]. The triggering is believed to occur due to a mismatch between the A1-pulley and the flexor tendons, but the exact cause of the disorder is still debated. Histopathological studies reveal disorganization and degradation in the histological layers of the A1-pulley and in severe cases excessive vascular network hyperplasia. However, all studies lack description of a localised inflammation [3, 4]. The diagnosis of TF remains clinical [2, 5]. A variety of treatment modalities have been described. Reports of conservative treatment by oral nonsteroidal anti-inflammatory drugs or splinting show poor results [3, 5]. Injections with corticosteroids cures 60% to 90% of patients [1, 6-11], and in recent years focus has been on ultrasound-guided injections [7, 12]. Accurate placement of the corticosteroid within the tendon sheath is increased by the use of ultrasound [13], but thorough investigation of the consequences is currently outstanding [10, 14]. Only one study describes the use of an ultrasound-guided corticosteroid injection technique in a clinical trial [7]. This study showed favourable results compared with conventional blind injection techniques. The "gold standard" of all treatments remains surgical, with cure rates near 100% after conventional open release of the A1-pulley [15]. Although TF is a very common disorder and results of different treatments are numerous in the current literature, the lack of comparative studies is pronounced [1, 6, 16]. At the initiation of the present study in 2010, no randomized controlled trials could be found by the authors comparing open surgery with corticosteroid injections, and the first such trial has only recently been published, but using conventional "blind" injection techniques [15]. In this randomized controlled trial, we plan to compare the efficacy of a single corticosteroid injection with conventional open surgery in terms of its ability to correct the TF disorder within a one-year follow-up period.

MATERIAL AND METHODS

The contents of this section is in accordance with the CONSORT statement 2010, checklist [17].

Study design

The study is performed as an open-label single-centre randomised controlled trial with a one-year follow-up. Patients will be allocated to one of two interventions, either conventional open surgery (n = 83) or a single corticosteroid ultrasound-guided injection (n = 83).

PROTOCOL ARTICLE

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TABLE 1

Trigger finger classification.

Trigger finger score	Clinical presentation	
	movement	sensation at A1-pulley
I	Normal movement	Without pain or discomfort (-)
IIa	Normal movement	With pain or discomfort (+)
IIb	History of uneven movement	With (+) or without (-) pain or discomfort
III	Uneven movement	With (+) or without (-) pain or discomfort
IV	Locked movement, active correctable	With (+) or without (-) pain or discomfort
V	Locked movement, passive correctable or static	With (+)or without (-) pain or discomfort

Example: Uneven movement at time of physical exam by snapping of the affected finger and pain or discomfort at the A1-pulley give a trigger finger score of III+.

Definition of trigger finger

TF is defined as a finger that displays snapping or uneven movement during flexion and extension. The triggering may be anamnestic or assessed by a physician at a clinical exam. The patient may also complain of tenderness at the level of the A1-pulley in the palm of the hand in the affected digit. No validated disease-specific Danish scoring system exists for TF. We chose to grade the TF according to a Danish, novel and non-validated trigger finger score (TFS) adapted from Quinnell [2] (**Table 1**).

Participants

Patient recruitment is conducted at a single outpatient clinic. Eligibility criteria are defined in **Table 2**. A general practitioner refers the patients to our outpatient clinic upon suspicion for TF. All referred patients will be assessed for eligibility by an orthopaedic surgeon dedicated to the project. Inclusion of patients will be performed at a level of person [18, 19]. If a patient presents with more than one affected digit, the patient and surgeon arbitrarily choose only one for inclusion. After obtaining written informed consent, the patient is randomized to receive either corticosteroid injection or open surgery. Follow-up will be performed at 12 weeks and 12 months (**Figure 1**). No patients will receive further treatment of the study TF within the early follow-up period of 12 weeks. However, in case of failure during the late follow-up period, further treatment may be instituted. Treatment is performed purely by open surgery of any remaining TF, or TF that arises in the follow-up period in order to avoid any systemic effect of additionally injected corticosteroid.

Interventions

Group 1

The corticosteroid injections will be ultrasound-guided using a Mindray M7 (Mindray Medical Int. Ltd.) with a linear array transducer and performed at 12 MHz. The patient is seated opposite the physician with the hand resting on a table, palm upwards, fingers pointing to the physician. The area of the affected A1-pulley is prepared, in plenty, with an aqueous solution containing ethanol 85% vol., which is used both as an antiseptic measure and as the connecting media between the skin and the transducer. The transducer in now placed in the long-axis direction on the volar side of the affected finger identifying the flexor tendons in the full length of the ultrasound image to ensure proper mid-axial alignment. The metacarpophalangeal joint is to be seen at the distal end of the image (see Figure 1). A corticosteroid solution containing 1 ml of triamcinolonacetonid 40 mg/ml (Kenalog, Bristol-Myers Squibb AB) and 1 ml of lidocaine 10 mg/ml is prepared in a syringe mounted with a 23G blue needle. A mid-axial, palmar access by non-touch technique, just distally to the metacarpophalangeal joint, is used for needle penetration in the skin. The advancement of the needle is followed in the ultrasound

TABLE 2

Eligibility criteria.

Inclusion
Trigger finger in any one of the five digits including trigger thumbs
≥ 18 years of age
≥ trigger finger score IIb
Exclusion
Insulin-dependent diabetes mellitus
Rheumatoid arthritis
Amyloidosis
Mucopolysaccharidosis
Previous treatment of trigger finger in the included digit
Dupuytren's contracture affecting the included digit
Medical contraindications to the corticosteroid

FIGURE 1

The ultrasound image identifies the flexor tendon, the metacarpophalangeal joint and the A1-pulley. The advancement of the needle is followed on the ultrasound image, to the penetration of the A1-pulley. A guided injection into the tendon sheath is then performed with clear visualisation of proximal intra-sheath jet flow and expansion of the sheath. Then, 1 ml of the corticosteroid solution is placed intra-sheath and the last 1 ml is injected subcutaneously in close proximity to the A1-pulley.

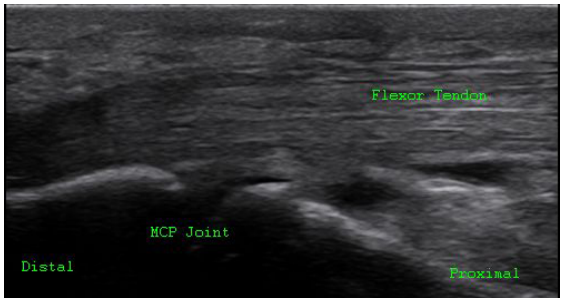

image to the penetration of the A1-pulley. A guided injection into the tendon sheath is now performed. When performed correctly clear visualisation of proximal intrasheath jet flow and expansion of the sheath is seen. If this is not seen or resistance is felt during injection, this indicates intra-pulley or intra-tendon location of the needle. The position of the needle is then altered slightly as appropriate to achieve visualisation of jet-flow and expansion of the sheath. After placement of 1ml of the corticosteroid solution, the needle is withdrawn just superficially to the A1-pulley, and the last 1ml is injected subcutaneously in close proximity to the A1-pulley. The needle is now fully withdrawn. Aspiration is performed when passing through the layer of dermis to minimize iatrogenic skin reactions. A simple Band-Aid is applied. The patient is informed to keep the finger still for the next 24 h to minimize the risk of immediate "wash-out", after which no further restrictions are implemented.

Group 2

Open surgery follows the outpatient clinic's standard regimen and will be performed as day-care surgery. Topical antiseptic skin scrub of the surgical area (the entire hand) is performed with a solution of chlorhexidine 0.5%/ethanol 85% vol. Local anaesthesia with approximately 2 ml of lidocaine 10 mg/ml + adrenalin 5 µg/ml are placed with a palmar injection at the position of skin incision. A tourniquet placed around the upper arm is inflated after elevation of the entire arm for a minimum of 30 sec. At the level of the A1-pulley, a transverse palmar incision is then made. The incision merely affects the dermis and after this only blunt dissection is done to the A1-pulley. Small retractors are placed to protect the neurovascular bundle and remove surrounding subcutaneous tissue and to leave the flexor tendons and A1-pulley adequately exposed. A small round-tipped dissection scissor is used to split the A1-pulley. Caution is taken to avoid partial lesions in the A2-pulley or flexor tendons. Free movement of the flexor tendons is mandatorily assured before proceeding. The skin is now closed with non-resorbable sutures and the tourniquet is released. A small compressive dressing is applied to the wound. The patient is instructed to remove the dressing after 24 hours and to apply a standard Band-Aid to protect the wound and sutures. The patients are also informed to contact a general physician after 7-10 days for removal of the sutures. Patients are advised to take a sick leave for one to two weeks depending on the type of work performed. Finally, the patients are told to perform active movements of the affected finger following the first 24 h post-operatively.

Outcome parameters

The primary outcome parameter is the TFS. The primary endpoint will be analysed as a dichotomized value defined as success or failure of the intervention. If the patient maintains a TFS of I or IIa at the one-year follow-up, the patient is believed to be cured and the endpoint a success.

Secondary outcome parameters are a) topical pain at the site of the procedure assessed by a numerical rating scale b) duration of absence from work, c) post-procedural complications, and d) use of related medical services.

Sample size estimation

The estimation of sample size was performed on simple frequencies of patients reaching the primary outcome parameter given a two-sided alpha (risk of type 1 error) of 0.05, a power of 80% and a group ratio of one. We expected to find a 20% absolute difference between groups. Under the assumption that 90% in the surgical group and 70% in the corticosteroid group would reach the primary outcome, 144 patients would be needed. Furthermore, incorporating a drop-out rate of 10%, a total inclusion of 166 patients is planned for the study population.

Randomization procedure

The schedule for randomisation was generated by randomization software "Research randomizer" (Urbaniak, GC, & Plous, S) The allocation number was placed in concealed opaque C5 envelopes by an independent staff member who was not part of the research team. The envelopes have then been kept in a locked location, only accessible to dedicated members of the research team. Following informed written consent, the envelopes will be consecutively opened by the medical staff together with the patient, and the patient will be randomised to either CS injection or open surgery.

Data analysis

Data analysis will be performed by intention-to-treat. Independency of data will be assured at the level of person thereby including only one finger per patient. Normality of continual data will be assessed by visual inspection of qq-plots. Descriptive statistics will be calculated for baseline data. The primary outcome will be analyzed using χ^2-test as all expected frequencies exceeds five. Comparison between groups concerning secondary outcome parameters and baseline characteristics will be performed by Student's T-test for data normally distributed and Mann-Whitney rank sum test for categorical or skewed data. Spearman rank correlation will be used to test the strength of the association between baseline data, primary and secondary outcome parameters. All analyses will be performed in STATA 11.2 (STATA corp., TX).

Ethics and trial registration

This study does not involve the testing of new biomaterials or medicines that are not already commercially available. Thus, patients will not be subjected to any risks not already existing under current treatment regimens for TF [5, 20].

Approval has been obtained from the Danish Data Protection Agency (1-16-02-119-11) and by The Central Denmark Regional Committees on Biomedical Research Ethics (M-20110157).

The study is registered with Clinicaltrials.gov: NCT 01486420. Dissemination of results will be performed irrespective of the nature of the results.

Funding

No external funding is received for the study. No individual reimbursement is made to any participant. All patients in the study receive treatment within the tax-supported Danish national public healthcare service system providing universal coverage and free and equal access to public health care services (Ministry of Health).

DISCUSSION

The present study will be the first study comparing treatment of TF by conventional open surgery with ultrasound-guided corticosteroid injection in a controlled randomized trial. Conventional open surgery remains the "gold standard" in treatment of TF disorder with an expected rate of cure of 100%. However, as with any open surgical procedure, complications may occur. Primarily, minor complications such as superficial infections and scar tenderness [20], but also major complications such as nerve damage, bowstringing, deep infection and development of arthrofibrosis [20]. Corticosteroid injections have a lower cure rate, but they may constitute a relevant first-line treatment modality with very few complications, mainly minor cosmetic complications such as fat necrosis and skin hyperpigmentation or benign systemic side effects for example hyperglycaemia in diabetics. Major complications in terms of case reports of tendon ruptures and the possibility of deep infection rarely occur [1, 5]. Adherence to strict antiseptic protocols and the use of ultrasound when injecting should reduce risk of the last two kinds of complications. The described method of ultrasound-guided local corticosteroid injections has been used by one of the authors (JL) since 2009. The only previous randomized controlled trial comparing open surgery, percutaneous release, and corticosteroid injections only included patients with confirmed triggering at time of exam [15]. We speculate that the Quinell type 1 TF with pain at the A1-pulley and morning stiffness may be key candidates for corticosteroid injections [7] and thus that the results by Sato et al may be biased by selection towards a favourable surgical result. Furthermore, the study by Sato et al also used conventional blinded injection techniques. In the present study, we hope to establish the efficacy of ultrasound-guided corticosteroid injections for TF and to evaluate this modality as a first-line offer in the treatment of TF compared with open surgery.

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