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Ultra-minimally Invasive Sonographically-guided Trigger Digit Release: An External Pilot Study

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ABSTRACT

Objectives: The most common surgical option for releasing the first annular pulley in trigger digit (TD) is classic open surgery followed by blind percutaneous release. However, they have been related to major complications and incomplete releases, respectively. Intrasheath sonographically-guided first annular pulley release has recently been shown to be safe and effective in every digit. The objectives of this pilot study were to preliminary compare clinically an intrasheath sonographically-guided first annular pulley release versus a classic open technique and to evaluate the feasibility of a future clinical trial in patients with TDs. ***Methods***: Thirty patients were randomized 1:1 in an external pilot study comparing the two surgical techniques: a percutaneous sonographically-guided release performed through a 1 mm incision using a hook knife versus a classic open surgery with a 1 cm incision. Inclusion criteria were primary TD grade III (Froimson). We defined success if primary (safety and efficacy) and secondary (recruitment rates, compliance, completion, treatment blinding, personnel resources, and sample size calculation for the clinical trial) objectives could be matched. We registered the grip strength, the QuickDASH score and a set of postoperative clinical variables at one, three, and six weeks and at three months. We calculated the sample size for the clinical trial using the QuickDASH at the end of the follow-up. Outcomes assessors were blinded. ***Results:*** All patients in both groups showed resolution of their symptoms with no associated complications or relapses. Secondary feasibility objectives were matched: 76.9% of eligible patients were included in the study, 3.3% refused randomization, 20 patients per month were recruited, 100% received blinded treatment, 98.5% showed compliance, and 100% completed the study. The sample size for a future clinical trial was 84 patients. There were no differences in grip strength. The intrasheath sonographically-guided first annular pulley release showed significantly better QuickDASH scores, until the sixth postoperative week. ***Conclusions:*** The intrasheath sonographically-guided first annular pulley release is safe and efficacious, and shows a trend toward clinical superiority versus the classic open procedure, which should be confirmed with a clinical trial. Our study shows that a randomized clinical trial is feasible.

Trigger digit (TD) is one of the most frequent pathologies of the hand. In the non-diabetic population, the incidence rate is 2.2% throughout life for those over 30 years old, and the incidence is four times higher in the diabetic population.[1,2] Three different surgical techniques have been described for releasing the first annular (A1) pulley in TD: classic open surgery (COS),[3,4] blind percutaneous release (BPR),[5,6] and ultrasound-guided A1 pulley release (USGAR).[7–9]

COS has been related to dissatisfaction rates of up to 26%[10] and complications including stiffness,[11] complex regional pain syndrome,[12] and persistent local pain.[13] BPR, despite excellent short-term results, still raises some concerns in terms of achieving a complete release,[14] and due to the risk of damaging collateral structures.[15] Furthermore, some authors have suggested restricting BPR to the third and fourth digits.[16]

In the last 10 years, ultrasound-guided procedures for treating TD have shown excellent results in

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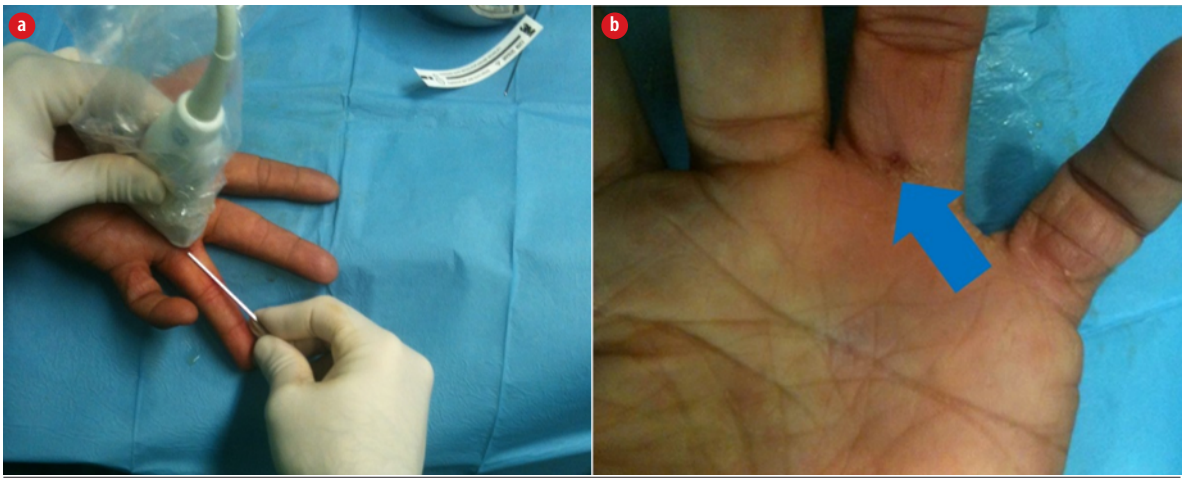

Figure 1: Surgical details for intrasheath-USGAR. **(a)** Distal volar approach at the proximal phalangeal crease. **(b)** Skin incision right after surgical release.

every digit without major complications.[8,17] Recent randomized control trials showed significantly better results with USGAR techniques than COS[18] and BPR[19] in terms of early recovery and release rate, respectively. However, it remains unclear the optimal surgical device (needle[9] or hook knife[8,17]), the positioning of the instrument (extrasheath[17] or intrasheath[8]), or the direction of the cut (anterograde[9] or retrograde[8,17]).

The authors of a cadaveric study[8] described a safe area palmar to the tendon sheath for releasing A1 pulley with a new intrasheath percutaneous ultrasound-guided technique (intrasheath-USGAR) using a hook knife. The same authors, in a later prospective clinical study, showed the efficacy and safety of their technique.[20]

The objectives of this pilot study were to compare clinically intrasheath-USGAR versus COS, and to evaluate the feasibility of a future clinical trial in terms of safety, efficacy, sample size, and procedures for patients with TD.

METHODS

This randomized, parallel-group, controlled, external pilot study was performed in Madrid, Spain, in an ambulatory setting, between April and October 2010, with a follow-up of three months. Institutional review board approval and written informed consent were obtained.

We used Froimson's classification[21] ranging from grade I to IV: 'pain without catching' (grade I), 'catching solved with active flexion/extension' (grade II), 'catching that needs passive flexion/extension' (grade III), and 'fix contracture' (grade IV). Inclusion criteria were patients with signs of primary grade III TD for at least two months. Exclusion criteria were age < 18, previous pathology of the upper limb, malformations, and secondary TD. For ambulatory surgery, we excluded patients > 84 years old, allergies to local anesthesia or latex, smoking more than 20 cigarettes per day, heavy alcohol intake (> 60 g per day), oral anticoagulation, rheumatic disease, fibromyalgia, active psychiatric disease, blood pressure > 155/95 mmHg, BMI ≥ 40, pregnancy, cardiovascular or noncontrolled renal, hepatic, or hematologic disease, and hospital admission six months before surgery.[20] The second author confirmed the inclusion criteria and performed all the procedures with a portable ultrasound scanner (LOGIQ Book XP Pro, 5-11 MHz 8L, GE Healthcare, Madrid, Spain). Outcome assessors were blinded by covering the patient's digit. We performed concealed allocation (1:1), by an independent blocked computer-generated list, assigning patients to one of the two study groups: intrasheath-USGAR or COS.

The USGAR followed the technique described by Rojo-Manaute et al,[20] which consisted of introducing a sonographically guided 16-gauge Abbocath (Abbott Laboratories, North Chicago, IL) 1 cm distal to the volar metacarpophalangeal crease of the thumb and the volar proximal phalangeal crease of the rest of the fingers aiming for a point of entry in the volar tendon sheath located 3 mm distal from the base-shaft junction of the proximal phalanx. We then placed our cutting tool [Figure 1] (a retrograde knife, 5151-A; Orthomed SA, St Jeannet, France;

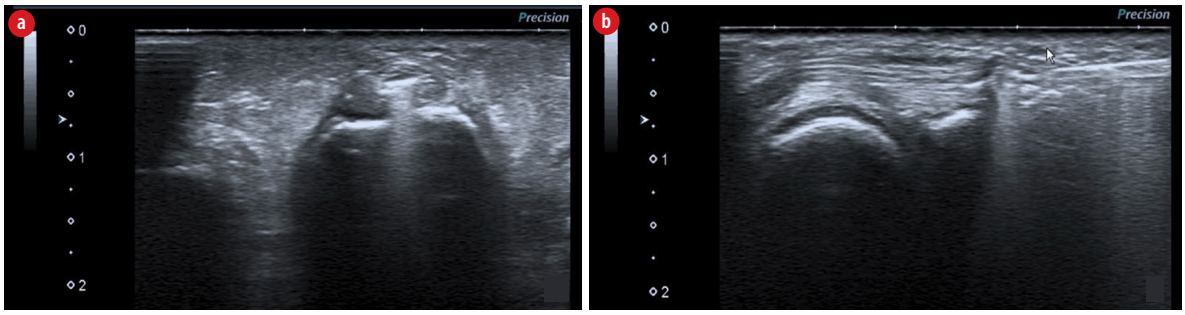

Figure 2: Ultrasound images of the intrasheath-USGAR procedure. **(a)** Introduction of the hook knife inside the tendon sheath with its cutting edge sideways (transverse position). **(b)** A1 pulley release with the edge toward the palm (longitudinal position).

or 010600 Acufex hook knife, 3.0 mm; Smith & Nephew, Memphis, TN) in an intrasheath position [Figure 2] and pushed it to the proximal cutting point to release the A1 pulley by turning the edge toward the palm and pulling it to the point of entry.

COS was performed under local anesthesia without ischemia by performing a 1 cm incision at the metacarpophalangeal crease and releasing the A1 pulley under direct visualization, after dissecting the skin and subcutaneous tissue [Figure 3].[22]

Success was determined if all feasibility objectives for our pilot study were matched. Primary objectives included safety (absence of neurovascular morbidity) and efficacy (no TD recurrence three months after surgery). Secondary objectives (procedural issues) are defined in Table 1. Sample size calculation was done using Epidat 3.1 based on the mean ± standard deviation values for QuickDASH (primary outcome measure for a future randomized clinical trial) at six weeks. Ten percent more patients were added to the sample for taking into account any possible losses to follow-up.[23]

The clinical variables included preoperatively were symptoms duration, QuickDASH, active worker or retired, and previous conservative treatments. Postoperatively at one, three, and six weeks, and three months we measured QuickDASH, grip strength (JAMAR, Hydraulic Hand Dynamometer. Bolingbrook, IL, USA) and two points of discrimination. We also recorded the recovery time (in days) until they stopped using pain killers and the time taken to have full digit range of motion and resume their daily activities (including work). Any complications were also reported.

Mean and standard error of the mean (SEM) were recorded for QuickDASH, grip strength, and mean (SEM) and range for the clinical variables. We used SPSS Statistics for Windows, version 15.0 (SPSS Inc., Chicago, Ill., USA) for the analysis. Student's *t*-test and chi-square (statistically significant at $p < 0.050$) with no power calculation was performed.

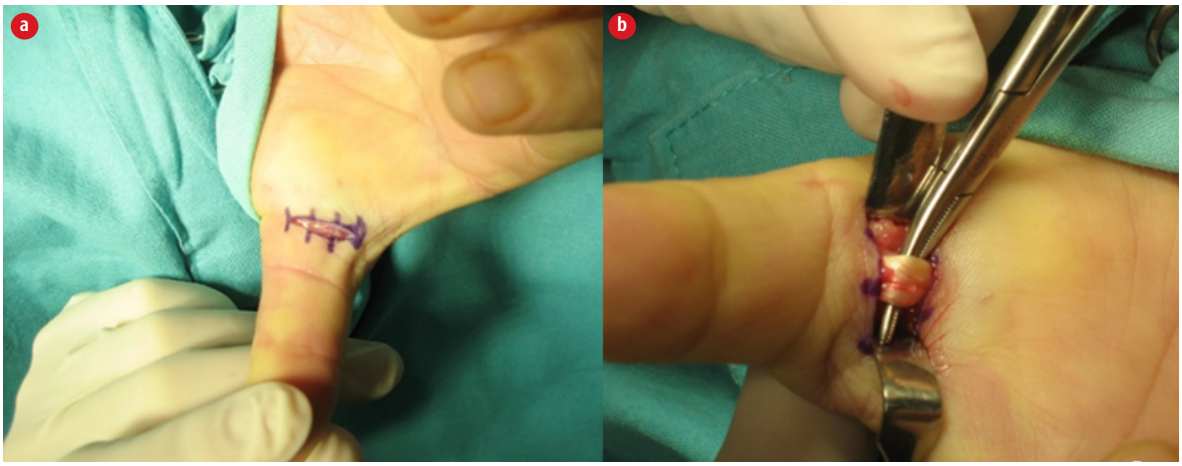

Figure 3: Surgical details for COS in a trigger thumb. **(a)** Location and incision size. **(b)** Flexor tendon after A1 pulley release.

Table 1: Procedural issues objectives.

Variables	Definition of success	Results
Recruitment rates	70% of eligible patients included. ≤ 5% of eligible patients refused randomization. 10 patients included in the study per month.	30 of 39 eligible patients included (76.9%). 1 (3.3%) refused randomization. 20 patients included per month.
Blinding	> 90% of the randomized patients.	100% were operated blindly.
Compliance	> 90% of cases completed all interviews.	Compliance was 98.5%.
Completion	More than > 90% completed the last interview.	Completion was 100%.
Human resources	The wound concealment and data gathering in our protocol could not overload the capacity of our auxiliary staff.	The concealment of the operated digit supposed a saturation. Patients were instructed to cover the digit with an adhesive dressing by themselves before the interview. Suspected complications were assessed by an independent experienced hand surgeon without revealing the study group.

RESULTS

Thirty of 39 eligible patients were randomized to either the intrasheath-USGAR or the COS group [Figure 4]. Patient's background data showed no significant differences in average age (59.6 (range: 36–77) vs. 58.1 (range: 42–74) years), previous symptom duration (11.8 (range: 4–30) vs. 12.2 (range: 2–35) months), active workers (16 (53.3%) vs. 13 (40.3%)), or sex (7 females (46.7%) vs. 6 males (40%)).

There was no neurovascular morbidity or recurrence in both groups. The results for our feasibility objectives are detailed in Table 1. We calculated that a randomized controlled trial would require a sample size of 76 patients (power: 80%; confidence level: 95%). Ten percent more patients were added to the sample to consider any possible losses, giving a total of 84.

The average values for QuickDASH was significantly lower for intrasheath-USGAR (8.7±5.6) than for COS (21.6±6.7) at six weeks. QuickDASH and grip strength results are shown in Figure 5. There were no differences between groups in our clinical variables except for the number of days taken to return to normal daily activities, which favored the USGAR group [Table 2]. In the COS group, we had a case with local moderate pain that persisted until the third month. No major complications were reported in either group.

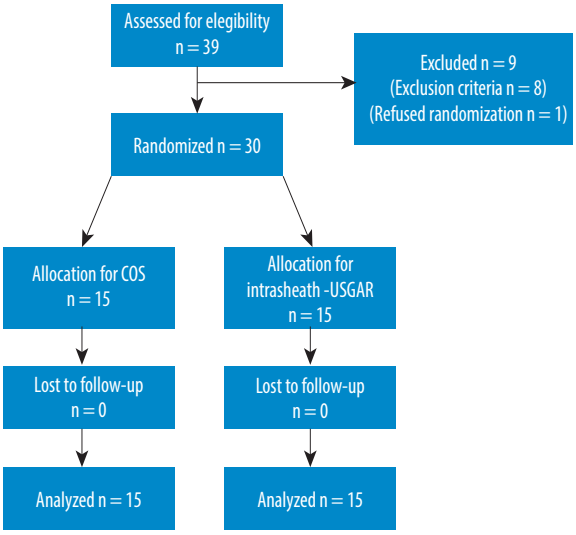

Figure 4: Patient flow diagram showing participant progress.

DISCUSSION

The goal when treating TD is to fix the mechanical mismatch between the A1 pulley and the flexor tendon. Surgically, COS[3,4] and BPR[6,19] have shown a similar success rate (> 90%). However, despite these promising results, the difficulty of obtaining a complete release in BPR,[14] the risk of injuring collateral structures,[15] and major complications associated with COS[4,12] have raised some doubts about the two traditional surgical options.

The surgical success rate is defined for TD as a postoperative absence of triggering. Different

Table 2: Clinical variables.

Variables	Intrasheath-USGAR	COS
Days for stopping oral analgesics	2.4 ± 0.9	10.0 ± 3.8
Days for complete digit extension	1.8 ± 1.0	7.2 ± 3.3
Days for complete finger digit	2.8 ± 0.9	8.0 ± 3.5
Days for returning to normal living	4.8* ± 1.9	21.0 ± 4.4

Values are represented as mean±SEM. Intrasheath-USGAR: intrasheath ultrasound guided A1 pulley release; COS: classic open surgery.
**: statistically significant, p < 0.050.*

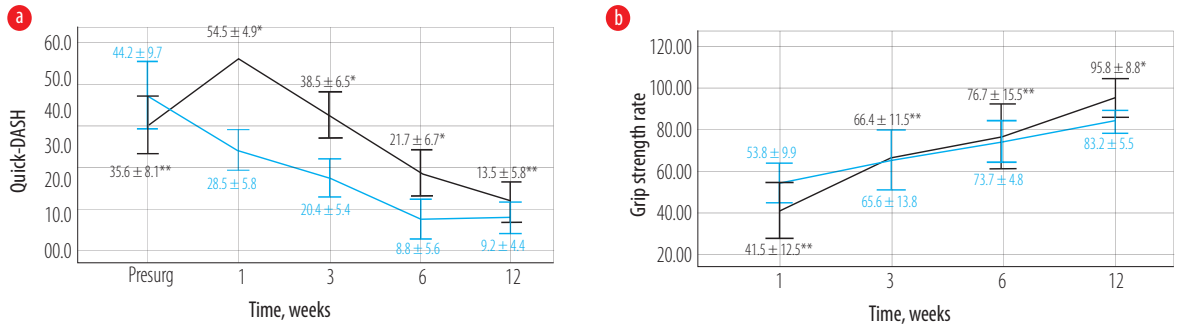

Figure 5: (a) QuickDASH and **(b)** grip strength after intrasheath-USGAR (blue) or COS (black). Prior to surgery (Presurg) and postoperatively (three, six, and 12 weeks). The grip rate is calculated as a percentage of the individual's normal grip distinguishing the dominant or non-dominant hand. Strength of dominant uninjured side - 10% = calculated normal strength of the injured non-dominant side or strength of non-dominant uninjured side+10% = calculated normal strength of the injured dominant side. Variables expressed as mean±SEM. $^{*}p < 0.050$; $^{**}p > 0.050$.

authors[4,8,9,17] have described various USGAR techniques for treating TD, with excellent success rates (91%–100%) in every digit without major complications. Unfortunately, there are still some concerns about its generalization, efficacy, and safety due to multiple factors: 1) the relative position of the cutting device respective to the synovial sheath; 2) the direction of the cut; and 3) cutting device. Rojo et al,[8] described first in cadavers and then clinically,[20] an intrasheath-USGAR with excellent clinical results in terms of safety and efficacy, generalizable to every digit without major complications.

The purpose of pilot studies is to assess the feasibility in terms of safety, efficacy, procedural issues, and sample size calculation.[24,25] Our external pilot study showed that our USGAR release for TD was safe and effective in both groups and that we matched our procedural objectives for recruitment, blinding, compliance, and completion rates [Table 1].[24] The concealment of the operated digit supposed a saturation of our auxiliary staff, so we asked patients to cover the digit with an adhesive dressing by themselves before the interview with the data collector. We used the QuickDASH scale as our primary variable given the international validity shown in hand disorders. Our study had a follow-up period of three months, which may seem short, however, a previous study observed that the USGAR technique showed an almost normal average QuickDASH score by the sixth postoperative week and normal scores by the sixth month.[20] Moreover, the authors of another study[26] did not observe any significant differences between their open and minimally invasive groups after the eighth postoperative week. Thus, by setting the duration of our pilot study to three months we attempted to detect differences between both surgical techniques until the third month, since we believed that both techniques would not have significant differences after this time based on the previous literature. Our preliminary clinical results showed that intrasheath-USGAR had a shorter recovery time for restarting normal daily activities.

Our limitations were related to the procedure and the scarce existing literature about pilot studies.[25] First, a single surgeon performed all the operations with the intention of standardizing the procedure and avoiding interindividual differences and there is a learning curve to the USGAR technique. Our first clinical patient took 35 minutes to achieve a release. At present, a release takes three to four minutes. Second, the nature of the procedure made it impossible to blind the type of surgery made to each patient participating in the study. This issue has been addressed in the CONSORT 2010 guidelines[27] which points out that "in certain trials, especially surgical trials, blinding of participants and surgeons is often difficult or impossible". Third, we included all the parameters found in the literature for this kind of pilot study (safety, efficacy, recruitment rates, blinding, compliance, completion rates, preliminary results, and sample size calculations).[25,28] However, there is no a clear guideline for establishing the success thresholds for each of these variables. Thus, what we did was set the thresholds based on the more accepted methodology at the moment.[29] According to the pilot study by Choi et al,[30] we set the success in our recruitment rate in > 70%. Similarly, we fixed

the sample size calculation in 30 patients based on the recommendations for pilot studies given by Lancaster et al,[24] who recommend taking at least 30 patients, and Arnold et al,[28] who suggested a median number of 52 (average 59.6, range 20–120).

CONCLUSION

A randomized clinical trial comparing COS versus intrasheath-USGAR is feasible in terms of potential safety, efficacy, and sample size calculation. The protocol of data gathering should be modified in the patients' concealment item. The posterior clinical trial will confirm or refuse the generalization of the new intrasheath-USGAR technique in patients with symptomatic TD.

Disclosure

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