Ultra-Minimally Invasive Sonographically Guided Trigger Digit Release: An External Pilot Study

Guillermo Rodríguez-Maruri[1], Jose Manuel Rojo-Manaute[2], Alberto Capa-Grasa[3], Francisco Chana Rodríguez[4], Miguel Del Cerro Gutierrez[5] and Javier Vaquero Martín[4]

[1]Department Physical and Rehabilitation Medicine. University Hospital Marqués de Valdecilla, Santander, Spain.
[2]Unit of Hand Surgery. Department of Orthopaedics. Medcare Orthopaedics & Spine Hospital. Dubai, UAE
[3]Department Physical and Rehabilitation Medicine. University Hospital La Paz, Madrid, Spain
[4]Department of Orthopaedic Surgery. University Hospital Gregorio Marañón, Madrid, Spain
[5] Hand Surgery Unit, Beata Maria Ana Hospital, Madrid, Spain

Received: 9 May 2021
Accepted: 12 September 2021

***Corresponding author:** doctormaruri@gmail.com

DOI 10.5001/omj.2022.49

Abstract

Objective: The most common surgical option for releasing the first annular pulley in trigger digit is classic open surgery followed by blind percutaneous release. However, they have been related to major complications and incomplete releases, respectively. Classic. The intrasheath sonographically guided first annular pulley release has recently 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 trigger digits.

Methods: Thirty patients were 1:1 randomized 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 trigger digit grade III (Froimson). We defined

success if primary (safety and efficacy) and secondary objectives (recruitment rates, compliance, completion, treatment blinding, personnel resources and sample size calculation for the clinical trial) could be matched. We registered the grip strength, the Quick-DASH score and a set of clinical postoperative variables at 1, 3 and 6 weeks and at 3 months. We calculated the sample size for the clinical trial using the Quick-DASH 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 of 84 patients. There were no differences in grip strength. The intrasheath sonographically-guided first annular pulley release showed significantly better scores for the Quick-DASH, until the 6th postoperative week.

Conclusions: The intrasheath sonographically-guided first annular pulley release is safe and efficacious and it shows a trend towards 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.

Keywords: Percutaneous release; trigger finger; ultrasound; ultrasound guided; minimally invasive surgery.

Abbreviations

A1: Annular first; TD: Trigger Digit; USGAR: Ultrasound Guided A1 Pulley Release; COS: Classic Open Surgery; BPR: Blind Percutaneous Release.

Introduction

Trigger digit (TD) is one of the most frequent pathologies of the hand, with incidence rates of 2.2% throughout life in non-diabetic population older than 30 years and with four times higher incidence 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 complication as stiffness (11), complex regional pain syndrome (12) and local persistent pain (13). BPR, despite excellent short-term results, still raise some concerns in terms of achieving a complete release (14), and due to the risk for damaging collateral structures (15). Furthermore, some authors have suggested restricting a BPR to the third and fourth digits (16).

In the past 10 years, ultrasound guided procedures for treating TD have shown excellent results in every digit without major complications (8, 17). Recent randomized control trials showed significant better results with USGAR techniques compared to COS (18) and BPR (19) in terms of early recovery and release rate, respectively. However it still remains unclearthe 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)).

Rojo et al, in 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 preliminary compare clinically an intrasheath-USGAR versus a COS and to evaluate the feasibility of a future clinical trial in terms of safety, efficacy, sample size, and procedures for patients with trigger digits.

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 for this study.

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 of duration. Exclusion criteria were age under 18, previous pathology of the upper limb, malformations and secondary TD. For ambulatory surgery, we excluded patients older than 84 years old, allergies to local anesthesia or latex, smoking more than 20 cigarettes per day, heavy alcohol intake (more than 60 g per day), oral anticoagulation, rheumatic disease, fibromyalgia, active psychiatric disease, blood pressure higher than 155/95 mm Hg (systolic and diastolic, respectively), body mass index ≥40, pregnancy, cardiovascular or noncontrolled renal, hepatic, or hematologic disease, and a hospital admission 6 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; 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.

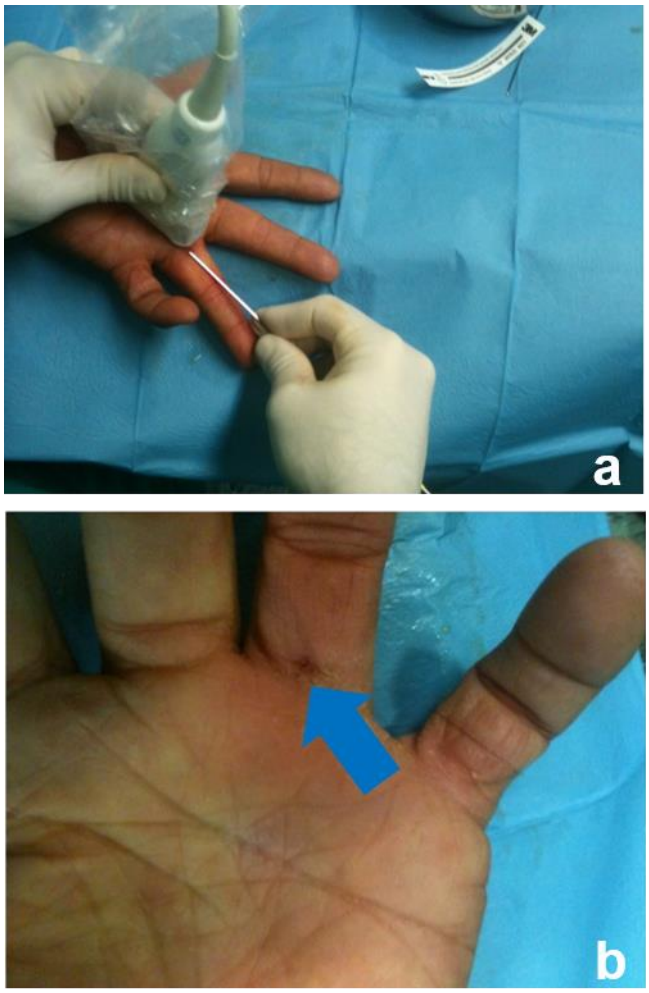

Fig. 1 Surgical details for intrasheath-USGAR. A: distal volar approach at the proximal phalangeal crease. B: skin incision right after surgical release.

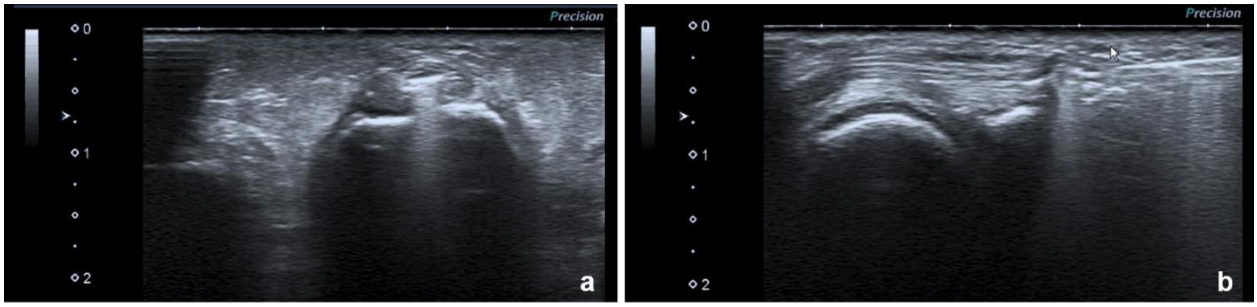

Fig. 2 Ultrasound images of the intrasheath-USGAR procedure: A: introduction of the hook knife inside the tendon sheath with its cutting edge sideways (transverse position). B: A1 pulley release with the edge towards the palm (longitudinal position).

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).

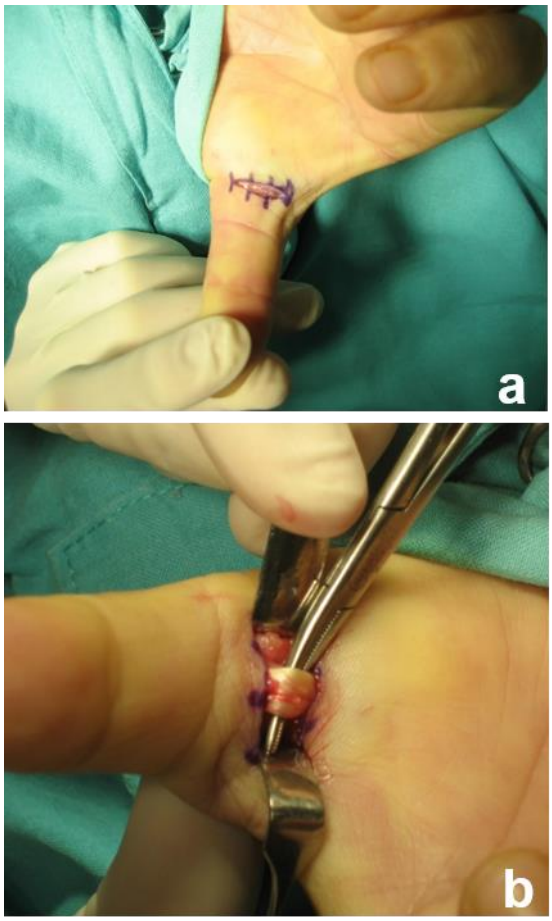

Fig. 3 Surgical details for COS in a trigger thumb. A: location and incision size. B: flexor tendon after A1 pulley release

Success was determined if all feasibility objectives for our pilot study were matched: 1) primary objectives included safety (absence of neurovascular morbidity) and efficacy (no TD recurrence 3 months after surgery); 2) secondary objectives (procedural issues) are defined in Table 1; and 3) sample size calculation using Epidat 3.1 are based on the mean +/- standard deviation values for Quick-DASH (primary outcome measure for a

future randomized clinical trial) at 6th week. A Ten percent more patients were added to the sample for taking into account any possible losses to follow up (23).

Table 1. Procedural issues objectives

Variable	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 (76.9%) of 39 eligible patients included 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 a 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.

The following clinical variables were included, a) preoperatively: symptoms duration, Quick-DASH, active worker or retired and previous conservative treatments; and b) postoperatively at 1, 3 and 6 weeks and 3 months: Quick- DASH, grip strength (JAMAR, Hydraulic Hand Dynamometer. Bolingbrook, IL, USA) and two points discrimination. Recovery time (in days) until they stopped using pain killers, had full digit range of motion and performed their daily activities (including work) were registered. Any complications were reported.

1.1. Statistical Analysis

Mean and standard error of the mean (SEM) were recorded in Quick-DASH, Grip Strength and mean, SEM and range in the clinical variables (SPSS 15.0, Inc, Chicago, IL). T Student-test and chi-square (statistically significant at $p<0.05$) with no power calculation was performed.

Results

Thirty of 39 eligible patients were randomized to either the intrasheath-USGAR or the COS group (Figure 4). Patient's background data showed respectively no significant differences in: average age, 59.67 (range, 36-77) versus 58.13 (range, 42-74) years; previous symptom duration, 11.87 (range, 4-30) versus 12.20 (range, 2-35) months; active workers, 16 (53.3%) versus 13 (40.3%) were active; nor sex, 7 (46.7%) versus 6 (40%) males.

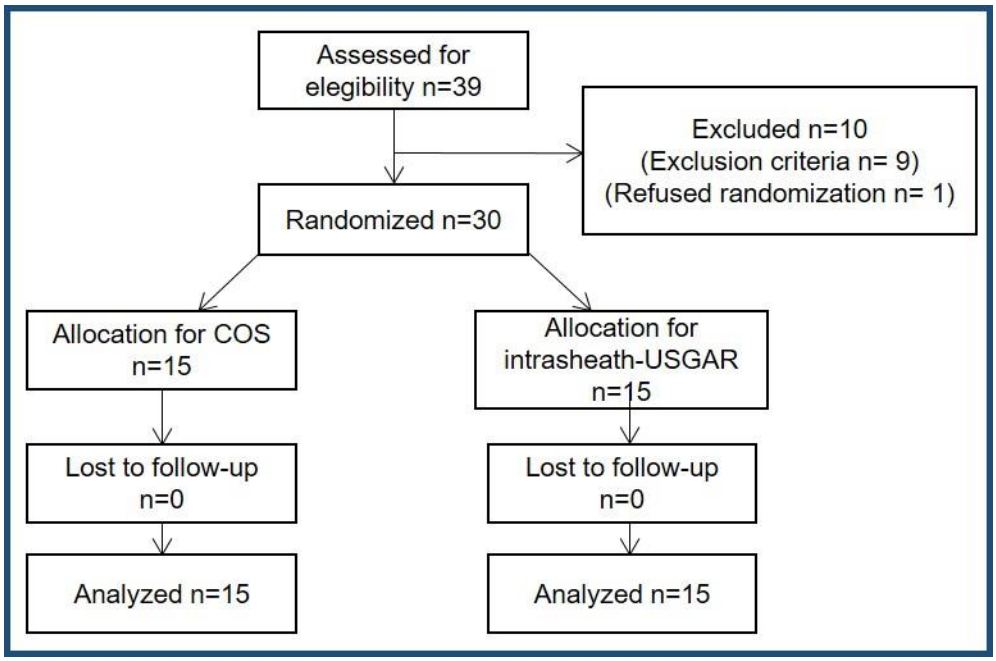

Fig. 4 Patient flow diagram showing participant progress

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 for taking into account any possible losses, adding up to a total of 84.

The average (+/- SEM) values for Quick-DASH was significantly lower for intrasheath-USGAR (8.78 +/- 5.66) than for COS (21.66 +/- 6.78) at 6 weeks. Quick-DASH and grip strength results are shown in Figure 5. There were no differences between groups in our clinical variables except for the days taken for returning to normal daily activities, which favoured 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.

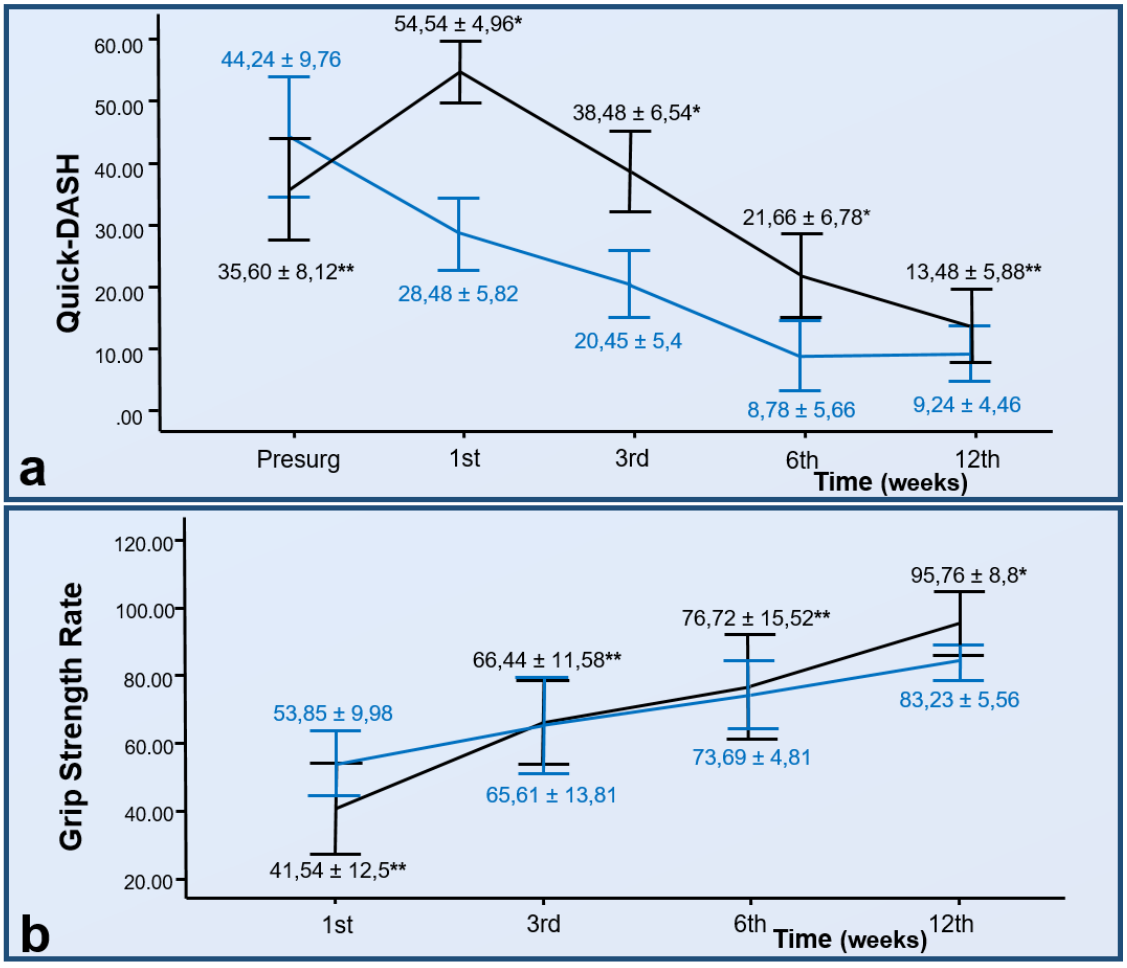

Fig. 5 Quick-DASH (A) and Grip Strength (B) after intrasheath-USGAR (blue) or COS (black). Prior to surgery (Presurg) and postoperatively (3, 6 and 12 weeks). The Grip

Rate is calculated as a percentage of the individual's normal grip distinguishing 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 are expressed with the Mean ± SEM. *P < 0.05; **P > 0.05

Table 2. Clinical variables

Variable	Intrasheath-USGAR	COS
Days for stopping oral analgesics	2.4 ± 0.94	10 ± 3.83
Days for complete digit extension	1.86 ± 1	7.26 ± 3,3
Days for complete finger digit	2.8 ± 0,97	8,06 ± 3.55
Days for returning to normal living	4.8* ± 1.91	21.06 ± 4.46

*Values are represented as mean ± SEM. Intrasheath-USGAR: intrasheath ultrasound guided A1 pulley release; COS: classic open surgery. *: statistically significant, P < 0.05*

Discussion

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

Surgical success rate is defined for TD as a postoperative absence of triggering. Different authors (4, 8, 9, 17) have described a variety of 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) type of cutting device. Rojo et al described, first in cadavers (8) 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 Quick-DASH scale as our primary variable given the international validity showed in hand disorders. This study had a follow-up period of 3 months which may seem short however, Rojo et al (20) had previously observed that the USGAR technique showed an almost normal average QuickDASH score by the sixth postoperative week and normal scores by the 6th month. Moreover, Sato et al (26) did not observe any significant differences between their open and minimally invasive groups after the 8th postoperative weeks. Thus, by setting the duration of our pilot study in 3 months we attempted to detect differences between both surgical techniques until the 3rd month, since we believed that both techniques would not have significant differences after this period of 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 to 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 for

achieving a release. At present, a release is taking 3 to 4 minutes. Second, the nature of the procedure made 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 studies (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 Choi et al pilot study (30), we set the success in our recruitment rate in more than 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

In 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.

Acknowledgments

The authors thank Drs. Emilio Rodriguez Bilbao and Eugenio Cerezo López for their essential support and Daragh Malone and Cristina Fernández Buergo for helping with the translation.

Conflict of interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

Ethical Approval

The study was approved and conducted in accordance with the principles of the Ethics Committee of Clinical Investigation of the Gregorio Marañón Hospital, Madrid, Spain.

Informed consent

All participants signed an informed consent for participating in the study

Funding

This study was funded in part by a grant from MAPFRE (volume 19, number 4, October/December, 2008.

https://app.mapfre.com/fundacion/html/revistas/trauma/v21n3/pdf/02_01.pdf

Authors' contribution

GRM contributed to study design and data collection, performed the analysis, interpretation and wrote the article. JMRM performed the study design, the surgical procedures and helped to write the article. ACG contributed to data collection and interpretation. FCR and MCG contributed to data collection and figures. JVM reviewed the article.

References

1. Saldana MJ**.** Trigger digits: diagnosis and treatment. J Am Acad Orthop Surg. 2001;9(4):246-52.
2. Stahl S, Kanter Y, Karnielli E**.** Outcome of trigger finger treatment in diabetes. J Diabetes Complications. 1997;11(5):287-90.
3. Gilberts EC, Beekman WH, Stevens HJ, Wereldsma JC**.** Prospective randomized trial of open versus percutaneous surgery for trigger digits. J Hand Surg Am. 2001;26(3):497-500.
4. Hansen RL, Sondergaard M, Lange J**.** Open Surgery Versus Ultrasound-Guided Corticosteroid Injection for Trigger Finger: A Randomized Controlled Trial With 1-Year Follow-up. J Hand Surg Am. 2017;42(5):359-66.
5. Abe Y**.** Clinical results of a percutaneous technique for trigger digit release using a 25-gauge hypodermic needle with corticosteroid infiltration. J Plast Reconstr Aesthet Surg. 2016;69(2):270-7.
6. Zyluk A, Jagielski G**.** Percutaneous A1 pulley release vs steroid injection for trigger digit: the results of a prospective, randomized trial. J Hand Surg Eur Vol. 2011;36(1):53-6.
7. Jou IM, Chern TC**.** Sonographically assisted percutaneous release of the a1 pulley: a new surgical technique for treating trigger digit. J Hand Surg Br. 2006;31(2):191-9.
8. Rojo-Manaute J, Lopez-Soto V, De las Heras Sanchez-Heredero J, Del Valle Soto M, Del Cerro-Gutierrez M, Vaquero Martín J**.** Percutaneous intrasheath ultrasonographically guided first annular pulley release. Journal of Ultrasound in Medicine. 2010;29:1517-29.

9. Rajeswaran G, Lee JC, Eckersley R, Katsarma E, Healy JC**.** Ultrasound-guided percutaneous release of the annular pulley in trigger digit. Eur Radiol. 2009;19(9):2232-7.

10. Thorpe AP**.** Results of surgery for trigger finger. J Hand Surg Br. 1988;13(2):199-201.

11. Lim MH, Lim KK, Rasheed MZ, Narayanan S, Beng-Hoi Tan A**.** Outcome of open trigger digit release. J Hand Surg Eur Vol. 2007;32(4):457-9.

12. Callegari L, Spano E, Bini A, Valli F, Genovese E, Fugazzola C**.** Ultrasound-guided injection of a corticosteroid and hyaluronic acid: a potential new approach to the treatment of trigger finger. Drugs R D. 2011;11(2):137-45.

13. Guler F, Kose O, Ercan EC, Turan A, Canbora K**.** Open versus percutaneous release for the treatment of trigger thumb. Orthopedics. 2013;36(10):e1290-4.

14. Hoang D, Lin AC, Essilfie A, Minneti M, Kuschner S, Carey J, Ghiassi A. Evaluation of Percutaneous First Annular Pulley Release: Efficacy and Complications in a Perfused Cadaveric Study. J Hand Surg Am. 2016 Jul;41(7):e165-73.

15. Habbu R, Putnam MD, Adams JE**.** Percutaneous release of the A1 pulley: a cadaver study. J Hand Surg Am. 2012;37(11):2273-7.

16. Eastwood DM, Gupta KJ, Johnson DP**.** Percutaneous release of the trigger finger: an office procedure. J Hand Surg Am. 1992;17(1):114-7.

17. Chern TC, Jou IM, Yen SH, Lai KA, Shao CJ**.** Cadaveric study of sonographically assisted percutaneous release of the A1 pulley. Plast Reconstr Surg. 2005;115(3):811-22.

18. Nikolaou VS, Malahias MA, Kaseta MK, Sourlas I, Babis GC**.** Comparative clinical study of ultrasound-guided A1 pulley release vs open surgical intervention in the treatment of trigger finger. World J Orthop. 2017;8(2):163-9.

19. Lee SH, Choi YC, Kang HJ**.** Comparative study of ultrasonography-guided percutaneous A1 pulley release versus blinded percutaneous A1 pulley release. J Orthop Surg (Hong Kong). 2018;26(2):2309499018772368.

20. Rojo-Manaute JM, Rodriguez-Maruri G, Capa-Grasa A, Chana-Rodriguez F, Soto Mdel V, Vaquero-Martin J**.** Sonographically guided intrasheath percutaneous release of the first annular pulley for trigger digits, part 1: clinical efficacy and safety. J Ultrasound Med. 2012;31(3):417-24.

21. Froimson AI**.** Tenosynovitis and tennis elbow. In: DP G, ed. Green's operative hand surgery. 3rd ed. New York: Churchill Livingstone; 1993:1995-8.

22. Ryzewicz M, Wolf JM**.** Trigger digits: principles, management, and complications. J Hand Surg Am. 2006;31(1):135-46.

23. Whitley E, Ball J**.** Statistics review 4: sample size calculations. Crit Care. 2002;6(4):335-41.

24. Lancaster GA, Dodd S, Williamson PR**.** Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract. 2004;10(2):307-12.

25. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.

26. Sato ES, Gomes Dos Santos JB, Belloti JC, Albertoni WM, Faloppa F**.** Treatment of trigger finger: randomized clinical trial comparing the methods of corticosteroid injection, percutaneous release and open surgery. Rheumatology (Oxford). 2012;51(1):93-9.

27. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol. 2010;63(8):e1-37.

28. Arnold DM, Burns KE, Adhikari NK, Kho ME, Meade MO, Cook DJ, et al. The design and interpretation of pilot trials in clinical research in critical care. Crit Care Med. 2009;37(1 Suppl):S69-74.

29. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10:1.

30. Choi PT, Beattie WS, Bryson GL, Paul JE, Yang H**.** Effects of neuraxial blockade may be difficult to study using large randomized controlled trials: the PeriOperative Epidural Trial (POET) Pilot Study. PLoS One. 2009;4(2):e4644.