Conservative treatment of a complete rupture of the ulnar collateral ligament of the thumb

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to investigate whether applying a conservative treatment for an unstable ligamentous skiers thumb is equal to surgical repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON41004

Source
ToetsingOnline

Brief title
UCL trial

Condition

- Bone and joint injuries
- Tendon, ligament and cartilage disorders

Synonym
gamekeeper's thumb, skier' thumb

Research involving
Human

Sponsors and support

Primary sponsor: Chirurgie
Source(s) of monetary or material Support: subsidie via Landsteiner instituut van het MC Haaglanden wordt aangevraagd

Intervention

Keyword: hand injuries, sports injuries, thumb

Outcome measures

Primary outcome

pain on a VAS scale of 1-10 in rest and during testing of thumb stability

Secondary outcome

- Difference in pinch grip when compared to the healthy side, expressed in no.

of kg and as a percentage compared to the healthy side.

- laxity of the UCL in extension of MCP and 30 degrees flexion, measured with a

goniometer

- range of motion of the thumb, noted as 'limited' or 'unlimited'

- neurovaxcular status, complaints of tingling, hypo/hyperesthesia and/or other

neurovascular complaints of the hand are tested and noted. A difference is made

between temporary (< 8 weeks) and chronic (>8 weeks) complaints.

- result of questionnaire --> Michigan Hand Outcome Questionnaire

Study description

Background summary

A partial or complete rupture of the ulnar collateral ligament of the metacarpophalangeal joint of the thumb, skier*s thumb, is an often-encountered problem. It concerns 86% of all injuries to the base of the thumb. The estimated incidence in the US is approximately 200,000 patients per year [2]. The incidence in the Netherlands is not known. In the last four years, we have diagnosed approximately 85 patients in our own hospital. Skier*s thumb is the result of a hyperabduction trauma of the thumb. It can occur with any fall on an outstretched hand when a thumb that is already in abduction receives an extra valgus stress. Skier*s thumb refers to the fact that this injury is often seen in skiers who fall while holding on to their ski poles. This type of

injury is also seen in other sports, especially those that use a stick or ball, such as hockey or basketball. During a query in our own inner-city hospital, only 10% of the patients had skier*s thumb due to an injury acquired during skiing. Often, these patients also presented with a delay because their injury occurred during a holiday, and they waited until they came back home to see their own physician. A fall on the hand, usually from a bicycle or motorcycle (in which the thumb gets stuck behind the handlebars), is the most common cause of skier*s thumb in our hospital, seen in approximately 40 % of all patients. Another sport, especially soccer or fighting, was the cause in 30%. The ulnar collateral ligament is made up of two parts, the proper collateral ligament (PCL) and the accessory collateral ligament (ACL). The PCL has its origin proximal to the base of the head of the MCP-1 joint and insertion on the volar side of the proximal phalanx. The ACL has its origin just palmar of the PCL and runs parallel to the PCL to its insertion on the proximal phalanx. Together they ensure the ulnar and volar stability of the base of the thumb. However, there are other components that also take part in creating stability in the joint. They can be divided into static and dynamic components. The most important dynamic component is the adductor pollicis muscle. This muscle has its insertion onto the proximal phalanx partly superficial to and partly deeper than the UCL. Most of the time, the distal end of the UCL ruptures. A Stener lesion occurs when this part gets stuck between the proximal edge of the still intact aponeurosis of the adductor. Because this aponeurosis stands between the UCL and the bone, it is thought that this injury cannot heal in this position. Stener lesions occur in 64% to 87% of all complete ruptures and are usually treated by surgical repair. If the MCP joint is in flexion, the PCL and the dorsal capsule are taut and therefore the most important stabilizers in that position. The reverse applies to the ACL and the volar plate, which are taut when the MCP is in extension. This is important to know when testing the stability of the joint. When laxity during testing is only seen with the MCP in flexion, an isolated PCL rupture is suggested. If this laxity is seen in flexion and extension, a complete rupture of the PCL and ACL is most likely. Physical examination Usually the patient has pain, swelling and a hematoma at the ulnar side of the MCP joint of the thumb. Sometimes a mass can be felt in that area, which suggests a Stener lesion; however, it is not pathognomonic. The UCL is tested by first holding the MCP in extension and applying valgus stress to the phalanx. The same is done with the MCP in 30 degrees of flexion. It is important that the thumb of the investigator is placed on the radial side of the MCP joint to apply counter pressure to prevent possible rotational effects. It is difficult to say when a true laxity of the joint is seen, because the normal range of motion of the MCP joint differs per individual. In most of the literature the standard is more than 35 degrees during valgus stress and/or more than a 15 degrees difference compared to the contralateral side to diagnose a total rupture. However, in a recent study in which laxity in healthy test subjects was tested, it was found that 34% of all people have a more than 10-degree left-right difference in extension, and 12% had a difference of 15 degrees or more. In flexion this was seen in 22% and 3% of patients, respectively. The advice of Ritting et al. in a recent review was

that instead of holding on to a fixed degree limit, the absence of a firm endpoint during testing is a more reliable criterion when clinically diagnosing a complete rupture of the UCL. However, this can only be reliable when the investigator has enough clinical experience with testing the UCL. Often the examination is too painful to perform and the results cannot be interpreted correctly because of an uncooperative patient. Performing the investigation under local anesthesia can be useful. A study by Cooper et al. described how Oberst anesthesia (in which 1*2 ml of lidocaine is injected in the MCP joint on the ulnar and radial side) increases the clinical accuracy from 28% to 98% after an average of one week after the initial trauma. Sometimes the swelling during initial presentation can stand in the way of performing a reliable physical examination. In this case, one can decide to immobilize the hand and re-evaluate it after a week, with or without using Oberst anesthesia. Only the difference between a partial and a total rupture can be diagnosed with a physical examination. A Stener lesion is a type of complete rupture that cannot be differentiated from a total rupture in which the UCL is still close to its insertion. As mentioned before, a swelling at the MCP does suggest a Stener lesion but is not specific for one. This difference can only be visualized by additional imaging or during surgery. The first step in imaging studies is to make a plain radiograph in the AP and lateral direction to diagnose an avulsion fracture that is mostly located on the ulnar side of the proximal phalanx. A fragment is considered to be dislocated if it is displaced more than 1 mm or if it is malrotated. If the plain radiograph shows no avulsion fragment but there is a clinical suspicion of skier*s thumb, further imaging can be performed by doing an ultrasound, CT, arthrogram or MRI. Which technique to use seems to be determined by the physician*s preference; there are no clear guidelines about this. MRI can be seen as a gold standard with a sensitivity of 96%-100% and specificity of 95-100% [15,16]. However, this is a very costly technique, often with long waiting lists. Treatment The treatment of skier*s thumb is different for partial and a complete ruptures. This study only concentrates on complete ligamentous ruptures. If there is an unstable joint for which no firm endpoint is found during testing, surgery is considered the best treatment. This also applies to Stener lesions because the general idea is that the UCL cannot heal if it is not in contact with its insertion, even though no evidence can be found in the literature to support this notion. Also, no trials have even been set up to investigate whether a surgical intervention is really superior to a non-surgical treatment. Some small studies were carried out to see whether non-surgical treatment for a complete rupture could be equal to surgery. Landsman et al. described 40 patients with a total rupture with and without a Stener lesion, which were all treated only by immobilization. Thirty-four patients were successfully treated this way; the other six still had complaints of instability and pain and underwent successfull operations. Another study by Pichora et al.reported that 3 of the 32 patients with total ruptures that were treated non-surgically had persisting complaints that could not be resolved with surgery; the same percentage that could be expected with regular operative treatment (see below) Different surgical techniques can be used. Which one applies depends on the anatomy of the lesion and can often only be decided upon

during surgery. The UCL can be fixated with a suture anchor or with transosseous stitches. Results seem to be independent of the chosen technique, and successful recovery to the patient*s level before the initial trauma occurs in 90%-96% of all patients. This means that the question remains whether the patients mentioned above (with persisting complaints after the first non-surgical and later surgical treatment) would have benefitted from initial surgical intervention. Ideally, the operation takes place within 2 weeks; however, good results can still be achieved after 3*4 weeks. Afterwards, a period of usually 6 weeks of immobilization is applied, after which a new radiograph is made and physical therapy of the hand can be started. When the pain has subsided and the range of motion has completely returned, the hand can be completely used again. Usually this takes about 3 months. Patients with worse outcomes are mostly patients with a delay in presentation. When repaired in a timely manner, complications are rare. When they do occur, it usually concerns neuropraxia of the radial nerve that arises secondary to traction, swelling or stiffness. All are usually temporary in nature. Persistent instability is very rare.

Study objective

to investigate whether applying a conservative treatment for an unstable ligamentous skiers thumb is equal to surgical repair.

Study design

an open randomised controlled trial

Intervention

Patients will get a cast immobilisation instead of an operation.

Study burden and risks

Getting a conservative treatment will lower the burden of the patient (they will not undergo surgery), which is a benefit. Risk of persistent instability/complaints is very low, patients always have the choice to still undergo surgury at a later stage with good results described in the literature. Time of treatment is equal to regular treatment. Patients need to make 1 extra visit one year after initial trauma and need to fill in questionnaires. This does not take a lot of time (approx 15 min per visit)

Contacts

Public

Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

older than 18, presenting with a skier's thumb on the emergency department, with an X-ray showing no fracture and diagnosed with a complete rupture of the UCL on MRI

Exclusion criteria

Younger than 18, multiple injuries of the same hand, not being able to speak Dutch, systemic disease of the musculoskeletal system (such as rheumatoid arthritis or Marfan's disease)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-12-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved	
Date:	13-01-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48129.098.14