NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Suture fixation of acute disruption of the distal tibiofibular syndesmosis

Suture fixation of acute disruption of the distal tibiofibular syndesmosis is used to treat some types of severe ankle injury, when the ligaments between the 2 bones of the lower leg (the tibia and the fibula) become damaged at the ankle joint. The procedure involves drilling a small hole in both bones immediately above the ankle and passing a special strong 'thread' through these holes, before pulling the 'thread' tight and securing it so that it holds the 2 bones in place with the aim of allowing the injury to heal.

The National Institute for Health and Care Excellence (NICE) is examining suture fixation of acute disruption of the distal tibiofibular syndesmosis and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about suture fixation of acute disruption of the distal tibiofibular syndesmosis.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 January 2015

Target date for publication of guidance: April 2015

1 Provisional recommendations

1.1 Current evidence on the efficacy and safety of suture fixation of acute disruption of the distal tibiofibular syndesmosis is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

2 Indications and current treatments

2.1 Syndesmotic injuries at the ankle joint are injuries to the ligaments that connect the tibia and fibula. They are the most severe ligament

injuries to the ankle, and occur either in isolation or at the same time as an ankle fracture. The most common mechanisms causing syndesmotic injuries are external rotation and/or hyperdorsiflexion. These injuries can occur during activities such as sports or dancing, and from falls or slipping on ice. Patients with isolated syndesmotic injuries such as acute ankle sprains have acute ankle instability, pain and functional problems.

2.2 Isolated syndesmotic injuries can sometimes be treated conservatively with immobilisation, limited weight bearing, ankle exercises, compression and elevation. Distal tibiofibular syndesmosis, syndesmotic injuries with persistent symptoms and all syndesmotic injuries occurring with ankle fractures are normally treated by surgical rigid fixation with syndesmotic screws (either single or double screws). The screws are often removed at a subsequent operation. Other fixation methods include bolt fixation and syndesmotic hooks, both of which may also be removed at a subsequent operation, and staples or direct repair.

2.3 Anatomical reduction of the syndesmosis is desirable because any abnormal shift of the talus in the ankle mortise causes development of early and progressive osteoarthritis.

3 The procedure

3.1 Suture fixation of acute disruption of the distal tibiofibular syndesmosis is done with the patient in the supine position, either under general or spinal anaesthesia, with antibiotic prophylaxis and tourniquet control. An incision is made on the lateral aspect of the ankle to access the joint. If there is any associated fracture of the tibia or fibula, this is first reduced and internally fixed using standard ankle fixation techniques. After fracture fixation,

syndesmosis integrity is evaluated using either a hook test or an external rotation test under intraoperative fluoroscopy. The syndesmosis is reduced to obtain precise anatomical alignment, and maintained in position using a clamp with the ankle in a neutral position.

3.2 A small tunnel is drilled through the fibula and the tibia under image guidance. A polyethylene-based suture loop, threaded with an oblong metal button, is then inserted through the tunnel (and the vacant hole in a fracture fixation plate, if used) using a needle. After it has passed through the tibia, the button is pulled back so that it lies flat against the medial cortex of the tibia. The ends of the suture loop on the lateral side of the fibula are pulled tight against the fibula (or the fracture fixation plate) and secured by drawing a second metal button onto the surface of the fibula or the plate. Once both buttons are flush with the bone, a small knot is made with the free ends of the loop to secure the system and stabilise the joint. If additional stability is needed, a second suture loop can be inserted through the same or another tunnel.

3.3 The incisions are closed and the ankle is placed in a below-the-knee cast. The ankle should be non-weight bearing for the first 2 weeks, partial weight bearing from 2 weeks to 6 weeks, and full weight bearing after 6 weeks. Rehabilitation is provided once the ankle has healed. The polyethylene-based suture loop is usually left in place. The potential advantages of this procedure include a more rapid return to weight bearing, maintenance of physiological micro-motion between the tibia and the fibula, and avoiding further surgery to remove the device.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 A randomised controlled trial of 70 patients with acute ankle syndesmosis rupture compared suture fixation (n=34) against screw fixation (n=36). Sixty five patients completed the study (suture fixation, n=33; screw fixation, n=32) and were included in the analysis. The study reported that patients with suture fixation had significantly better functional scores than those in the screw fixation group (measured with the Olerud and Molander Ankle Score) at 12 months (93.3 versus 87.6, p=0.046), but the difference was not significant at 3 months (68.8 versus 60.2, p=0.067) or 6 months (84.2 versus 76.9, p=0.082). Statistically significant better American Orthopaedic Foot and Ankle Society (AOFAS) scores were seen at 3 months in the suture fixation group compared with the screw fixation group (78.6 versus 70.6, p=0.016), but these were not significant at 6 months (87.1 versus 83.8, p=0.260) or 12 months (93.1 vs 89.9, p=0.260). A retrospective case series of 49 patients with ankle diastasis treated with suture fixation (a slightly modified technique was used in 31 patients) reported that the mean AOFAS score was 85.57 and the mean Foot and Ankle Disability Index score was 81.20 at a 24-month average follow-up.

4.2 A non-randomised comparative study of 50 patients with distal tibiofibular diastasis comparing suture fixation (n=25) against screw fixation (n=25) reported no significant difference in the average time to full weight bearing between the suture fixation group and

screw fixation group at an average follow-up of 10.8 months and 8.2 months respectively (mean time 5.5 weeks versus 10.5 weeks, but the difference was not significant).

4.3 The randomised controlled trial of 70 patients reported that there were no significant differences in return to previous work or sporting activities between the suture fixation and screw fixation groups at 12-month follow-up (return to work, 97% versus 88%, p=0.19; return to sporting activities, 79% versus 69%, p=0.41).

4.4 The randomised controlled trial of 70 patients reported that adequate syndesmosis reduction was achieved in both groups. Patients in the screw fixation group had a statistically significantly higher mean radiological 'loss of reduction' compared with those in the suture fixation group (medial clear space 0.41 mm versus 0.05 mm, p=0.02; lateral tibiofibular clear space 1.34 mm versus 0.32 mm, p=0.0005).

4.5 The randomised controlled trial of 70 patients reported no significant difference in the range of ankle motion (dorsal and plantar flexion, and ankle circumference) or in ankle pain (Visual Analogue Scale for pain) between the screw and suture fixation groups at 6-and 12-month follow-up.

4.6 A retrospective comparative case series of 35 patients (12 in the suture fixation group and 23 in the screw fixation group) reported that no patients in the suture fixation group had recurrent diastasis at discharge, while 1 patient in the screw fixation group had syndesmotic diastasis.

4.7 The specialist advisers listed key efficacy outcomes as maintaining ankle stability and anatomic reduction of the tibiofibular

syndesmosis, and assessment of ankle pain, function and range of movement using common foot and ankle scoring systems (the AOFAS score, the Olerud and Molander Ankle Score and the Manchester–Oxford Foot Questionnaire).

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Device removal was reported in: 25% (6/24) of patients in a retrospective case series of 24 patients at a mean follow-up of 20 months; 17% (3/18) of patients treated with a standard suture technique in a case series of 49 patients at a mean follow-up of 24 months; 8% (8/102) of patients in a retrospective case series of 102 patients at a median follow-up of 85 days; 17% (2/12) of patients in the suture fixation group in a retrospective comparative case series of 35 patients at a mean follow-up of 12.4 weeks; and 11% (4/37) of patients in a retrospective case series of 37 patients at a mean follow-up of 23.6 months. The reported reasons for device removal in these studies included: prominent knot causing local skin irritation a few months after surgery (n=10); persistent pain with activity and restriction of motion in the ankle (n=1); deep wound infection or infectious sinus formation on the lateral side (n=2); osteomyelitis surrounding the device (n=3); radiological track widening (caused by painful aseptic osteolysis, n=2); failed stabilisation of the syndesmosis (n=2); unexplained pain (n=1); small stitch abscess in the medial ankle wound (n=1); peroneal

nerve injury with neuropraxia (n=1); and osteochondral defect (n=1).

5.2 Subsidence of the suture buttons into the bone (caused by osteolysis of the bone adjacent to the buttons) was reported in 17% (4/24) of patients in the case series of 24 patients. The suture buttons subsided 2–4 mm into the cortex of either the fibula or tibia, seen on final radiographs at 32-month mean follow-up.

5.3 Non-fatal pulmonary emboli and symptomatic deep vein thrombosis were each reported in 2% (2/102) of patients in the case series of 102 patients at a median follow-up of 85 days (further details were not reported).

5.4 Tibialis anterior tendon entrapment from the medial suture button in close proximity to the peroneal nerve was reported in the immediate postoperative period after double suture fixation in a case report of 1 patient with re-fracture of a Weber B, biomalleolar ankle fracture and distal tibiofibular diastasis. The suture and a screw were removed and a second suture was inserted through the plate. Paraesthesia resolved completely and the patient returned to pre-fracture mobility after 6 weeks.

5.5 Heterotopic ossification within the syndesmosis intraosseous ligaments adjacent to the sutures (seen on computed tomography) was reported in 13% (3/24) of patients in the case series of 24 patients.

5.6 Distal tibiofibular synostosis after suture fixation of an ankle fracture with syndesmotic instability was reported in a case report of 1 patient. Six weeks after surgery, radiographs showed some signs of callus formation between the tibia and the fibular, but synostosis

and anterior ankle pain occurred at 1-year follow-up (management details were not reported).

5.7 Enlargement of suture drill holes in the tibia and fibula were reported in some patients in the case series of 24 patients. Further details were not reported.

5.8 Acute fracture of the tibia and fibula through the suture button fixation tunnel, previously done for syndesmotic disruption, was reported in a case report of 1 patient. The suture device was removed without difficulty and open reduction and internal fixation of the fracture were done. At 12month follow-up, the patient returned to high intensity sport activity and radiographs revealed a well-healed tibia and fibula.

5.9 The specialist advisers listed anecdotal events as difficulty with tightening the device sufficiently, and malreduction or failure of the fixation as a result of soft tissue interposition (medial button). Reported additional theoretical adverse events include loss of fixation or stability of the syndesmosis (rediastasis), especially in older people who have osteopenia or osteoporosis, malreduction of the syndesmosis before fixation, and suture failure.

6 Committee comments

6.1 The Committee noted that suture fixation of acute disruption of the distal tibiofibular syndesmosis may be followed less frequently by reoperation for device removal compared with fixation by screws. It was also advised that there is a theoretical advantage with the less-rigid fixation provided by sutures, which may allow some normal movement of the fibula.

6.2 The Committee was advised that there are significant differences between the suture and screw fixation techniques, and that using a precise suture knotting technique is particularly important in avoiding subsequent problems.

6.3 The Committee noted the paucity of long-term follow-up data but it was advised that these data would be difficult to collect and it perceived no special long-term safety concerns. Nevertheless, it recognised that publication of long-term outcomes (of at least 5 years) could guide future use of this procedure.

7 Further information

7.1 For related NICE guidance, see the NICE website.

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