



Study protocol

Early mobilisation after surgery in patients with elbow fracture-dislocation

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Study protocol elbow fracture-dislocations study

Background

Fractures in the elbow joint can affect young people in high-energy violence such as contact sports and falls from a great height. The type of fracture and the degree of fragmentation are determined by the direction and force of the violence. Older people can also suffer from elbow fractures after low-energy trauma. The elbow fractures can be combined with simultaneous dislocation of the radius or ulna in relation to the humerus and ligament injuries laterally or medially. Elbow dislocations represent 10% of all elbow injuries (Casanova et al). The degree of dislocation and joint surface involvement determines whether surgery is appropriate. In an elbow dislocation with simultaneous fracture of the ulna and or radius, surgery with internal fixation and or caput radi prosthesis is often indicated. After the surgery, the patients receive a plaster for a number of weeks, which can vary slightly depending on where in the country you are having surgery. Immobilization for 3 weeks is the most common post-operative recommendation (Ndeye Fatou Coulibaly et al). However, there is no scientific evidence to support that period of immobilization and patients are often very stiff when the plaster is removed and have difficulty getting started with range of motion exercises. A common complication of elbow fractures combined with soft tissue injuries is "stiff elbow" (Morrey et al). Stiffness in the elbow can be secondary to so-called "heterotopic ossification", which means that bone material is formed in normally soft tissues (Ring et al). This condition may be due to various factors and, among other things, the immobilization time after surgery seems to play a significant role (Abrams et al, Wiggers et al). Patients often become very stiff and in some cases when functional mobility cannot be achieved, patients need to undergo another operation (capsule release) in order to increase mobility in the elbow joint. After a capsule release, a tough rehabilitation period will follow. There is a prospective study (Giannicola et al) where 76 patients who had surgery after fracture dislocation in the elbow were followed. They reported that early range of motion exercises, initiated already 2 days postoperatively, had had good results. However, there are no randomized studies in the field. In light of this, we want to investigate whether a shorter immobilization time in a plaster and faster initiation with unloaded range of motion exercises could improve elbow function and avoid stiffness more than standard treatment that involves immobilization in a plaster for 3 weeks post-operatively.

Overall purpose:

Investigate if early mobilisation, starting exercise treatment 3 days after surgery, can lead to better elbow function and fewer complications than standard treatment in patient with fracture dislocation in the elbow.

Issues:

Can early mobilisation (starting 2-3 days after surgery) after fracture dislocation in the elbow lead to improved elbow function compared to usual treatment?

Can early mobilisation after fracture dislocation in the elbow lead to fewer stiff elbows?

Can early mobilisation after fracture dislocation in the elbow lead to fewer reoperations (capsule releases)?

Can early mobilisation after fracture dislocation in the elbow lead to improved patient satisfaction?

Material and method:

Recruitment

Patients over 18 years with a trauma operated at the University Hospital in Linköping with a radiological verified elbow fracture-dislocation will be asked to participate in the study

Inclusion criteria:

Patients over 18 years of age with radiologically verified fracture dislocation in the elbow operated on with internal fixation and or caput radi prosthesis.

Exclusion criteria:

Fracture caused by intentional violence

Ongoing malignancy or previous radiotherapy to the affected arm

Neurological disease

Cervicalgia or herniated disc

Associated vessels or nerve damage

Patient who does not want to participate in the study

Dementia

Inclusion procedure

Patients with a trauma operated at the University Hospital in Linköping with a radiological verified elbow fracture dislocation will be asked to participate in the study. A physiotherapist provides oral and written information about the study (Appendix X). If the patient accept to participate and meet all inclusion criteria, they are immediately after surgery randomised to one of the following groups; A) Early mobilisation where unloaded range of motion exercises are initiated 3 days after surgery and the plaster can be removed 5 times a day for performing those or to; B) Standard treatment which means that the patients are immobilised in a plaster for 3 weeks (usual regime). The same physiotherapist who informs the patients about the study performs the randomisation. Patients are consecutively randomised using a computer-based system which assign the patients group affiliation. The number and group affiliation (A or B) becomes the patient code. Patients receive oral and written information about the study and are asked if they want to participate before the surgery if possible otherwise immediately after surgery. If the patient agrees to participate, a physiotherapist, who is not involved in the rehabilitation and follow-up of these patients, will hold the randomization and fill in all the data into the computer based system that will randomly assign the patients to either early mobilisation or standard treatment. Thereafter, the physiotherapist including the patients will contact the treating physiotherapist at the orthopedic clinic. The patient will the get information regarding restrictions and continued rehabilitation. The patients in the early mobilisation group will primarily manage their training at home with the support of a physiotherapist who sees the patient once a week for the first 3 weeks. Patients will document the movement training in an exercise diary. After 3 weeks, all patients will follow the usual rehabilitation guidelines and continue their training with the help of a physiotherapist in primary care. Home training will continue to be important and will be documented in an exercise diary. All

patients will be followed-up by physiotherapist and then a medical doctor according to current practice 3 weeks and 3 months after surgery. There will also be a follow-up after 12 months and this is outside the usual clinical practice.

At 3v, 3- and 12 months, the following variables will be evaluated; *Primary outcome measure:* Elbow function is evaluated with the Oxford elbow score (Dawson et al), which is a disease-specific questionnaire that assesses pain, function and psychological status related to the elbow joint. The questionnaire has 12 questions with five answer alternatives in three subscales (pain, function and psychosocial impact). Each subscale gives a maximum of 16 points and in total the three subscales result in a value somewhere between 0-48 where zero is poor function and 48 is good function. Each subscale can then be converted to a value between 0-100 points. The lowest clinically relevant value where patients themselves experience that there has been a change is 10 points in subscale elbow function (Guyver et al). Our primary time point will be the difference in elbow function between the two groups at 12 months. Secondary dimensions: Activity level - The activity scale is an instrument designed for the patient to rate their degree of activity before the injury and after 1 year to be able to assess whether the patients have returned to their previously estimated activity level. Mobility: Flexion and extension as well as pronation and supination will be measured with a digital goniometer starting in the anatomical basic position. Patient satisfaction - patient global impression of change (PGIC) (Ferguson et al). Subjective seven-point scale with questions about satisfaction after treatment. The number of reoperations and other complications will be documented in the two groups. Heterotopic ossification - X-ray examination at 3 weeks, 3 months and 12 months

Sample size calculation We based the calculation on the primary outcome measure Oxford Elbow Score where we need 27 patients in each group to detect a difference of 10 points between the groups in subscale function (0-100) with a standard variation of 13 points ($\beta = 0.80$, $\alpha = 0.05$). A difference of 10 points has been proven a clinically relevant difference (Guyver et al).

It is of great importance to clarify the optimal immobilisation time for patients who have undergone surgery after fracture dislocation in the elbow. If early mobilisation is well tolerated and our hypothesis that it would improve elbow function and at the same time reduce the risk of the most common complication which is stiffness in the elbow, there is a great benefit for patients and society as the risk of possible reoperations decreases.

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