Time from diagnosis to surgical treatment of ankle fractures, and clinical outcome

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Introduction

Ankle fracture classification

Ankle fractures are a common fracture, the fourth most common fracture in Sweden, affecting all age groups, can significantly affect quality of life adversely and often requires surgical intervention [1,2]. Even though clinical outcome after treatment of ankle fractures depend on multiple factors, stability and joint function are crucial [3]. Several classification systems for ankle fractures have been established, aiding in determining treatment depending on the stability and predicted functional outcome of the fracture. Three major ankle fracture classification systems exist. The Lauge-Hansen classification of ankle fractures, established in 1950 by Danish physician Niels Lauge-Hansen, is oriented using the presumed trauma mechanism together with radiological findings [4]. The Danis-Weber classification system uses the level of fracture, as seen on imaging, related to the ankle joint and the distal tibiofibular syndesmosis ligament complex for fracture classification [2,4]. The most widely used classification system in research is the AO/OTA, which expands on the Danis-Weber system by classifying fractures by three subgroups, A, B and C, depending on level of fracture, but allows for classifying of more complex fractures as well as correlating to the Lauge-Hansen system [4,5].

As demonstrated, classification of ankle fractures revolves around involvement of the three malleoli of the ankle, the lateral, medial and posterior, as well as involvement of the syndesmosis ligament – a ligament complex stabilizing the ankle joint between the distal tibia and fibula [6]. Main operation indications for ankle fractures are significant fracture displacement, especially of the medial malleoli, ankle malalignment and evidence of damage to the syndesmotic ligament [7]. A large proportion of ankle fractures consist of bi- or trimalleolar fractures, as well as suprasyndesmotic fibula fractures, which often require treatment by open reduction internal fixation (ORIF) [2,7,8]. Although indications for surgical treatment can vary depending on patient factors, fractures requiring surgery in general are, defined by AO/OTA:

1. Infrasyndesmotic bi- or trimalleolar fractures: A2 and A3.
2. Transsyndesmotic bi- or trimalleolar fractures: B2 and B3.
3. Suprasyndesmotic fractures: C1, C2, and C3.

Timing of surgery

Common practice in orthopedic clinics is timing the operation regarding to soft tissue affection since factors as local swelling, blisters and signs of infection in the operation area is regarded or known as negatively impacting outcome after surgery [9,10]. Swelling in particular is regarded as a general risk factor affecting both soft tissue healing as well as negatively impacting surgical conditions. Therefore the presence of, or the risk of development of, swelling often leads to postponed surgical intervention of ankle fractures [10]. Although several risk factors adversely affecting operational outcome both in short and in long term has been established [3,11,12,13], evidence regarding the effect of timing of the operation as treatment in ankle fractures requiring ORIF as an isolated factor remains uncertain. While some studies does not suggest timing having impact on outcome [14], others do suggest timing impacts both risk of complication and recovery [10,15,16].

Outcome measures

Several definitions of outcome after ankle fracture exist including patient-reported outcome measures (PROMs), clinical markers, complication frequency and functional outcome. Scoring systems for evaluation of ankle function can be used as follow-up or prospectively. The Olerud-Molander Ankle Score (OMAS) is a well-established PROM which uses 9 parameters including pain, stiffness, swelling and functional abilities self-reported by patients following an ankle fracture [17**,**18]. The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-hindfoot scale combines both patient self-reported elements as well as clinician-assessed variables [19], creating an outcome measure taking both patient reported symptoms and clinical findings into account.

Objective clinical markers include:

- Radiographic findings - evidence of healing such as fracture union, absence of healing such as mal-union or non-union, radiographic signs of post-traumatic osteoarthritis (PTOA) including joint space narrowing or osteophytes and hardware failure of osteosyntesis material.
- Measures in clinical examinations - local pain, range of motion (ROM) in the ankle joint, degree of mobilization, ability to walk without aid and presence of gait abnormalities. [8,12,20]

Apart from this, further outcome measures include frequency of complications following surgery, including, as before mentioned, hardware failure and non- and mal-union, but also superficial as well as deep postoperative infections, problems with soft tissue healing and the need for reoperation [8].

Functional outcomes consist of markers such as time needed before return to pre-injury levels of work, daily activities and sports [21].

Surgery of ankle fractures is often delayed for reasons such as local swelling. Associations between delayed time to surgery with outcome measures such as a higher risk of postoperative infections and lower clinical function has been observed – while there is evidence suggesting most ankle fractures could safely be treated within the first 24 hours from injury [10,22,23]. Could a deeper understanding on the effects of surgical delay contribute to more effective and optimized care of ankle fracture patients treated at the orthopedic clinic at Växjö Central Hospital?

Aim

This study will aim to examine the association between time from diagnosis to ORIF and clinical outcomes of bi- and trimalleolar ankle fractures (AO/OTA 44-A2, A3, B2, B3) and suprasyndesmotic ankle fractures (AO/OTA 44-C1-C3).

Research question

Does timing of surgery affect clinical outcome in patients treated for ankle fracture with ORIF at the ortophedic clinic at Växjö Central Hospital?

Material and method

Study design

This study will be designed as a retrospective cohort study using medical records from patients treated with ORIF for ankle fractures at the Orthopedic clinic at Växjö Central hospital.

Study population/selection

This study will include ankle fracture patients treated with comparable methods of ORIF regardless of specific surgeon, at at the Växjö Central hospital between january 2020 and December 2024 meeting the following inclusion criteria:

- Ankle fracture diagnosed using ICD10 per:
    - S8240
    - S8250
    - S8260
    - S8280
- Fractures meeting criteria for AO/OTA 44-A2, A3, B2, B3, C1, C2 and C3
- Treated by ORIF, medically recorded using ICD10 per:
    - NHJ60
    - NHJ62
    - NHJ40
    - NHJ41
- Age 18<

Patients will not be included if meeting the following exclusion critera:

- Complex fractures
    - Pilon fractures
    - Open fractures

- Multitrauma
- Comorbidities including:
    - Dementia
    - Prior ipsilateral ankle fracture
    - Neurological conditions affecting ipsilateral ankle joint
- Inability to attend follow-up

This study will aim to include at least 200 patients covering complete annual cohorts to minimize effects of seasonal variation. A power analysis will be conducted to confirm statistical adequacy based on expected effect sizes for complication rates. If deemed needed the timeframe for inclusion of patients might therefore be adjusted.

Methods

Data collection

Data will be extracted from medical records using ICD-10 diagnose codes and procedural codes as stated in study population section. Data will be recorded in an external excel sheet sorting data per in columns for following variables.

- Patient ID
- Age
- Sex
- Date and time of diagnosis (time of radiographic confirmation of ankle fracture).
- Time to surgery
- Fracture type
- ASA classification
- Risk factors
    - Smoking, obesity, known osteoporosis, diabetes mellitus, immunosuppression (treatment including long term steroid use, biological therapy, and preexisting immunodeficiency disorders).
- Outcome variables

Definitions and variables

The primary exposure will be time to surgery from radiographically confirmed fracture, divided into three groups, <24h, 24-48h, and >48h. All variables vill be binary, assigned values of 1(yes, or 2(no), for data processing simplicity. Only complications directly related to orthopaedic surgery will be regarded.

- **Radiographic healing**:
    - Adequate radiological findings in line with healing at 6 weeks follow up. Bridging callus, abscence of fracture line, stability in fracture and hardware positions.
- **Complications**

    - Need of reoperation
    - Radographic findings not in line with healing: non-union or mal-union, hardware failure
    - Superficial postoperative infection
        - Purulent drainage from only skin and subcutaneous tissue
        - Positive wound culture and/or need of antibiotic treatment.
    - Deep postoperative infection;
        - Diagnosed within 1 year postoperatively
        - At least one criteria of:
            - Purulent drainage
            - Deep insicion deliberately or spontaneously reopened, with positive deep wound culture AND fever (>38°C); localized pain or tenderness
            - Deep Abscess
    - Soft tissue healing problems
        - Failure of the wound to close within 2-3 weeks, necrosis, wound dehiscence, cronic wound complications in need of recurrent wound care or surgical intervention.

Outcome variables

- Local pain at 6 week follow up
- Need for additional opioid and non-opioid analgesics after hospital stay
- Degree of mobilization
    - Ability to walk without aid
    - Gait abnormalities
- Functional outcome:
    - Delayed return to pre-injury levels of work (>3 months post surgery) [24]
    - Failure to return to pre-injury daily activities (3 months post surgery) [20]
    - Failure to return to pre-injury levels of recreative activities, eg. Sports (>6 months post surgery) [25]

The use of PROMs or other clinical assessment scales will not be included as these are not routinely used in patient follow-up at the orthopedic clinic at Växjö Central Hospital and therefore would not be feasible for a retrospectives study.

Statistical analysis

Descriptive statistics will be used to establish baseline characteristics and outcome variables. A power analysis will be performed to determine the sample size required to detect significant differences in outcome. T-test (if variables are normally distributed) and chi-squared test will be performed to assess differences between groups . Multivariable logistic regression analysis will be used to adjust for confounders to assess the independent effect of time to surgery on each outcome variable. Statistical analyses will be performed using IBM SPSS statistics v29, with a significance level of $p<0.05$.

Ethics

Conducting a medical record reviews inherently poses a risk to patient privacy, requiring ethical conciderations as well as determining whether there is a need of approval of the Swedish ethical review authority (Etikprövningsnämnden, EPM). This project proposal, however is developed within the framework of the scientific methodology course for resident physicians and thus falls under the legal student exemption. Further, the project is part of the mandatory internal quality assurance that healthcare departments are required to perform continously and based on these premises there is no need of an application to the EPM. Permission to review relevant medical records will be obtained from the clinical director at the ortophedic clinic.

A lay summary of the project will be submitted to the registry of Region Kronoberg and assigned a case number. This number will be noted in the medical records examined enabling patients to take part of the general project information and, if they wish, contact the responsible researcher.

A register of personal and project relevant data will be established. Permission for this will be obtained from the Region Kronoberg GDPR officer. This will exclusively be managed on Region Kronoberg computers, provided with firewall and security applications. A USB-memory storing the data will be kept in locked premises of the Orthopedic Clinic at Växjö Central Hospital. Researchers involved in this project alone will have access to these data.

Time plan

Project proposal **spring 2025.**
Defence and presentation of project proposal **april 2025.**
Gathering of data, **spring 2025.**
Processing of data, statistical analysis and writing of article, **summer-autumn 2025.**
Presentation of article, **autumn 2025.**

Funding

In total 10 weeks full time (400hrs) work including the scientific metolody course for Staffan Ingemarsson included in the orthopedic residency, and 20 hours supervised work with project proposal and project via Region kronoberg FOU.

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Appendices

Appendix A:

Data protocol sheet