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Pain experience and functional outcome of inpatient versus outpatient anterior cruciate ligament reconstruction, an equivalence randomized controlled trial with 12 months follow-up

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ABSTRACT

Background: Arthroscopic reconstruction of the anterior cruciate ligament (ACL) has traditionally been performed in an inpatient setting. Outpatient treatment may offer the advantages of cost reduction and higher patient satisfaction.
Hypothesis/purpose: We investigated whether ACL reconstruction in an outpatient setting is equally safe as in an inpatient setting and whether comparable functional outcomes can be achieved. We hypothesized that the outcomes of outpatient ACL reconstruction result in similar outcomes as inpatient ACL reconstruction.
Study design: A prospective randomized controlled trial was conducted at one centre.
Methods: Forty-six patients were randomized to outpatient treatment or a 2-day admission after ACL reconstruction. The functional outcome was evaluated with the Lysholm, Tegner and International Knee Documentation Committee scores. Safety of the procedures was judged according to pain experience and readmission rate. The duration of follow-up was 1 year after ACL reconstruction. The patients were provided with a simple postoperative analgesic protocol. The linear mixed effect model for repeated measures was used for testing the differences between the study groups.
Results: No significant differences were found between the study groups in all the outcome measures. No readmissions were recorded related to pain. One complication was recorded in the outpatient group versus three in the inpatient group.
Conclusion: This study indicates that outpatient care after ACL reconstruction yields comparable functional results and postoperative pain experience as inpatient care and is a safe option. A simple analgesic protocol provides adequate pain relief during the postoperative phase. Level of evidence: I.

1. Introduction

Reconstruction of a ruptured anterior cruciate ligament (ACL) has been subject to many changes during the past decennia. Operative techniques, timing of surgery [1], anesthesiology regimens [2] and rehabilitation protocols have been in a constant process of development. Operative techniques improved less invasive arthroscopic procedures, and new anatomical insights led to better anatomical isometric placement of the graft [3,4]. Initially, rehabilitation protocols were very restrictive since it was deemed necessary to protect the reconstructed graft. In contrast to our traditional assumption, it was shown that non-compliant patients showed a faster rehabilitation and performed better without the expense of stability [5]. More recently, a Roentgen stereophotogrammetric analysis confirmed this interesting finding in a study of accelerated versus non-accelerated rehabilitation [6]. Over time, the role of the physiotherapist has changed, since it became evident that simple merely home-based physiotherapy protocols yield good results [7–12]. In the rehabilitation process it is important that the autonomy of the patient is enhanced because this is positively related with rehabilitation adherence, and this effect is mediated by patients' treatment motivation [13]. Physiotherapists can encourage this autonomy. This support can be given in both inpatient and outpatient settings. Important advantages of outpatient ACL reconstruction are a considerable cost reduction [14–17] and higher patient satisfaction [18]. According to the Scandinavian ACL registries; in Norway, Sweden and Denmark ACL reconstructions are performed as an outpatient procedure in 38%, 56% and 79% of patients respectively [19]. And although the use of standard operating procedures in day case ACL reconstruction in an English NHS hospital has been shown to result in a 92% discharge on the day of surgery [20], the actual number of true day case procedures in the English NHS is only 19.2% [21]. No official healthcare

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reports exist on the share of outpatient ACL reconstruction in the Netherlands, however, it is our impression that a significant amount of care is still on an inpatient basis. Therefore, we questioned whether outpatient ACL reconstruction when compared with inpatient ACL reconstruction is a safe option and whether comparable results can be achieved. We designed a randomized controlled trial (RCT) to answer this question and hypothesized that outpatient ACL reconstruction leads to similar outcomes as inpatient ACL reconstruction, with regard to postoperative pain and functionality.

2. Materials and methods

2.1. Study design

This study was designed and reported according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines [22]. Our respective Institutional Review Board approved the study and patients gave a written informed consent. The trial was registered under the reference number M08-018. This was a single-center, stratified (outpatient versus inpatient care with balanced randomization [1:1]), nonblinded, controlled, parallel-group study conducted in the Netherlands.

The sample size was calculated on a maximum change of the Lysholm score of 10 points between the two groups. For this power analysis based on non-inferiority, we used a Lysholm standard deviation (SD) of 12.7 resulting from a previous study [23]. It was determined that a sample size of 18 patients per group would be necessary to detect the maximal 10 point difference with 80% power when alpha was set equal to 5%. Anticipating that we would lose 20% of the participants enrolled at long-term follow-up, we planned to enroll 23 patients in each group.

2.2. Participants, eligibility criteria and randomization

Patients with instability of the knee due to a torn ACL were included if they could give informed consent and if they were able to complete the questionnaires. The patients were excluded if they had open growth plates, previous injury or operation to their knee, simultaneous fracture, concomitant injury to the posterior cruciate ligament, injury to the posterolateral corner or lateral collateral ligament, a grade II or III medial collateral ligament tear, evidence of osteoarthritis on radiograph, or articular cartilage lesions with exposed bone as observed during arthroscopy. The patients with meniscal tears that required repair were excluded, whereas those with mild tears of the menisci that required no treatment and those who required partial meniscectomy were included. The patients with serious health issues requiring in-hospital supervision were excluded.

After the patient was fully informed about the study and agreed to participate, informed consent was signed. A simple fully balanced randomization was used by means of identical sealed opaque envelopes assigning the patient to outpatient or inpatient care. The envelopes were prepared by the first author. The patient was asked to select one envelope. Regardless of treatment allocation, all study patients were scheduled for operation as the first or second case of the day. All authors of this study cooperated in the enrollment and assignment of the participants to the study groups.

2.3. ACL reconstruction technique and perioperative care

After standard arthroscopic examination of the joint, followed by the removal of irreparable fragments of torn menisci, the semitendinosus-gracilis graft was obtained from the patient's ipsilateral side. Anatomical landmarks were used to create the bone tunnels, and a poly-L-lactic acid (PLLA) interference screw (Bio-Interference screw, Arthrex Inc., Naples, FL) was used in the femoral tunnel to fix the graft. The knee was then taken to 20° of flexion and the graft pulled in a distal direction using the sutures within the tendons with a force of 60 N [24]. Isometric positioning of the graft could be judged while the knee was moved through a full range of motion. The quadruple hamstring graft was then fixed within the tibial tunnel using a second PLLA interference screw, which was advanced until it was flushed with the tibia. Correct placement of the screw could be confirmed arthroscopically. Wounds were closed in layers to complete the procedure.

All patients in the study were supplied with a Cryocuff (AirCast Inc., Summit, NJ) knee icing system for use in hospital and at home for the first 2 weeks. A physiotherapist supported all patients when they practiced with crutches and assisted all inpatients with their daily exercises. Inpatients were discharged from the hospital on day 2 after their ACL reconstruction. Outpatients were discharged on the day of surgery. Discharge criteria were identical for all patients. The patients should be alert and oriented, feel well without nausea or vomiting and have a subjective acceptable pain level (visual analogue scale (VAS) <4). Furthermore, they were able to void, walk with crutches and the wounds were without excessive drainage. After discharge, all patients continued with the same rehabilitation program (Table 1).

2.4. Analgesic medication

Premedication consisted of a combination of midazolam 7.5 mg, acetaminophen 1000 mg and diclofenac 50 mg. After surgery, the patients were provided with analgesics in the recovery room. A VAS pain score of less than 4 was considered acceptable and was a discharge criterion. A VAS pain score between 4 and 7 was preferably

Table 1
Rehabilitation protocol.

Phase	Goals	Specific exercises
Immediately postoperative phase: First week	Full extension, 90° of flexion; limited effusion; ambulation with normal gait (crutches)	Prone hangs, heel props; straight leg raises; heel slides; muscle setting exercises (quadriceps/hamstrings); and Cryocuff, compression stocking
Immediately postoperative phase: Second week	Full extension, 90° of flexion; limited effusion; ambulation with normal gait; increased weight bearing to 100% guided by effusion	Prone hangs, heel props; straight leg raises; heel slides; active flexion; muscle setting exercises (quadriceps/hamstrings); Cryocuff, compression stocking; and closed kinetic chain exercises (balance on stable and unstable ground (pillow), wall slides, isokinetic hamstring training)
Intermediate phase: Weeks 3–6	5° of hyperextension, 130° of flexion; limited effusion; ambulation with normal gait; full weight bearing	Prone hangs, heel props; heel slides; active flexion/extension; and closed kinetic chain exercises (balance on stable and unstable ground (pillow), wall slides, isokinetic hamstring training)
Advanced strengthening phase Weeks 6–24	Full motion and symmetrical strength in both knees	Closed kinetic chain exercises (rowing, bike, cross trainer); balance on unstable ground (pillow, wobble board); single leg stance; open kinetic chain (side shuffles, cariosas, jumping rope, swimming, running, lunges, stair climbing (forward, backward), trampoline)
Return to competition Week 24+	Symmetrical; normal knees; full competition	Sports-specific exercise, functional progression, return to competition