

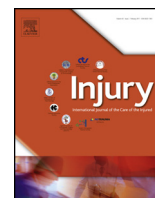


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Postoperative continuous-flow cryocompression therapy in the acute recovery phase of hip fracture surgery—A randomized controlled clinical trial

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ABSTRACT

Background: The acute recovery phase after hip fracture surgery is often complicated by severe pain, postoperative blood loss with subsequent transfusion, and delirium. Prevalent comorbidity in hip fracture patients limit the use of opioid-based analgesic therapies, yielding a high risk for inferior pain treatment. Postoperative cryotherapy is suggested to provide an analgesic effect, and to reduce postoperative blood loss. In this prospective, open-label, parallel, multicentre, randomized controlled, clinical trial, we aimed to determine the efficacy of continuous-flow cryocompression therapy (CFCT) in the acute recovery phase after hip fracture surgery.

Methods: Patients with an intra or extracapsular hip fracture scheduled for surgery were included. Subjects were allocated to receive postoperative CFCT or usual care. The primary endpoint was numeric rating scale (NRS) pain the first 72 postoperative hours. Secondly, analgesic use; postoperative haemoglobin change and transfusion incidence; functional outcome; length of stay; delirium incidence; location of rehabilitation; patient-reported health outcome; complications and feasibility were assessed.

Results: Sixty-one subjects in the control group, and 64 subjects in the CFCT group were analysed. Within the CFCT group, post treatment NRS pain declined 0.31 ($p=0.07$) at 24 h, 0.28 ($p=0.07$) at 48 h, and 0.47 ($p=0.002$) at 72 h relative to pre treatment NRS pain. Sensitivity analysis at 72 h showed that NRS pain was 0.92 lower in the CFCT group when compared to the control group (1.50 vs. 2.42; $p=0.03$). Postoperative analgesic use was comparable between groups. Between postoperative day one and three haemoglobin declined 0.29 mmol/l in the CFCT group and 0.51 mmol/l in controls ($p=0.06$), and transfusion incidence was comparable. The timed up and go test and length of stay were also comparable between both groups. Complications, amongst delirium and cryotherapy-related adverse events were not statistically significantly different. Discharge locations did not differ between groups. At outpatient follow-up subjects did not differ in patient-reported health outcome scores. Subjects rated CFCT satisfaction with an average of 7.1 out of 10 points.

Conclusions: No evidence was recorded to suggest that CFCT has an added value in the acute recovery phase after hip fracture surgery. If patients complete the CFCT treatment schedule, a mild analgesic effect is observed at 72 h.

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Introduction

Hip fractures frequently occur in the elder population, and global incidence is steadily rising [1]. Mainly due to aging of the population, global incidence figures are projected to increase by 1–3% annually the coming decades [1]. Early surgical fixation with direct postoperative mobilization remains the cornerstone of hip fracture treatment in nearly all cases, and targets preservation of pre-fracture functional status.

The severe postoperative pain hip fracture patients experience has led to various treatment options ranging from nerve blockades, loco-regional opioid administration, and to systemic (opioid) analgesia therapy [2,3]. The multitude of treatment options illustrates that adequate pain control continues to be a challenge in this condition. Most elderly patients experience physiological decline in organ function (such as renal or hepatic function) that can alter the pharmacology of analgesics [4]. In addition, comorbidities and polypharmacy render elderly susceptible to drug interactions and adverse events, which puts them at risk for inferior pain treatment [4,5]. The need for adequate pain relief is evident, as inferior pain treatment has been associated with delayed ambulation, which leads to an extended hospital admission, to poorer short and mid-term functional outcome, and development of postoperative delirium [6,7]. Taken together, these altered pharmacodynamics and kinetics narrow the therapeutic window, and combined with the painful nature of a hip fracture this leads to increased difficulty in providing adequate analgesia to hip fracture patients [2].

The injury sustained during a hip fracture causes fracture site bleeding that render 40% of admitted hip fracture patients anaemic [8]. The additional blood loss that fracture repair encompasses increases this figure to 93% [8]. This high incidence of anaemia is problematic since it negatively impacts length of stay (LOS), readmission rates, and odds of death [8]. However, erythrocyte transfusion delays wound healing and increases risk of infection, hence the need for transfusion should be carefully considered, or

avoided completely if feasible [9]. Continuous-flow cryocompression therapy (CFCT) combines the flow of ice-cold water with a dynamic intermittent compression adjunct aiming to result in haemostasis as well as providing analgesia in a non-pharmacological manner. It is mostly applied after musculoskeletal soft tissue trauma or after semi-elective musculoskeletal surgery such as arthroplasty, with ambiguous results. In two studies with total knee arthroplasty (TKA) patients, CFCT reduces postoperative pain and postoperative blood loss, while others found no apparent effect [10–13]. In total hip arthroplasty (THA) patients CFCT reduces morphine consumption and mitigates postoperative haemoglobin decline, while others demonstrated a shortening of admission time [14–16]. A hip fracture is generally accompanied by soft tissue trauma that is aggravated by subsequent surgical fixation [17]. As hip fracture patients have duplicate trauma (the fracture and the surgical fixation), experience severe pain, and have fracture site bleeding with related inflammation, these patients are expected to benefit most from CFCT.

To date no studies have researched the efficacy of CFCT in the acute postoperative recovery phase of hip fracture surgery. We aimed to determine the analgesic efficacy of CFCT in the acute postoperative recovery phase of hip fracture surgery. Secondly, we aimed to determine the effect on postoperative blood loss, short-term functional outcome parameters, and assess feasibility. We hypothesized that: 1) CFCT will lower perceived pain levels and analgesic use; and 2) will reduce postoperative blood loss and transfusion incidence; and 3) reduced pain by CFCT will lead to lower delirium incidence, and 4) will enhance functional recovery, leading to shorter LOS.

Methods

The Medical Ethical Committee 'METC Noord-Holland', Alkmaar, The Netherlands (date: September 29, 2014; reference no: M014-013) approved the study and after written informed consent was obtained, 126 subjects were enrolled in this open-

Table 1
Subject criteria.

Inclusion criteria	Exclusion criteria
* Intra or extracapsular hip fracture	* Fractures at multiple foci
* Age ≥ 18 years	* Open fracture/wounds ^a
* Informed consent or proxy consent	* Acetabular fracture
	* (Suspicion of) concomitant malignancy
	* BMI > 40
	* Unwilling to give (proxy) consent
	* Preoperative osteosynthesis materials in situ in the ipsilateral leg above knee level
	* Morphine allergy or dependence
	* ASA ≥ 4
	* Cryoglobulinemia
	* M. Raynaud
	* Central neuromuscular disorder
	* Absent ADP/ATP pulsations in the injured extremity
	* Active deep vein thrombosis
	* Suspected pulmonary embolism
	* Patient delay > 24 h
	* NYHA-class ≥ 3
	* IQ-CODE score $\geq 4.6^b$
	* Long-acting femoral blocks
	* Use of local infiltration anaesthesia
	* Postoperative haemodynamic instability

^a Open wounds unable to close per primam.

^b The IQ-CODE is only administered if the clinician has doubts about the cognitive status of the subject. BMI: body mass index; ASA: American Society of Anesthesiologists; ADP: dorsal pedal artery; ATP: posterior tibial artery; NYHA: New York Heart Association; IQ-CODE: Informant Questionnaire for the Cognitive Decline in the Elderly.

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