BALTIC FRACTURE COMPETENCE CENTRE
O5.4 Diagnostics Pilot Report

Authors:

Janne Karjalainen, Bone Index Finland, Kuopio, Finland;
Sarunas Tarasevicius, Lithuanian University of Health Sciences, Kaunas, Lithuania

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1. Management Summary

This document describes the pilot study regarding the use of the BFCC Fracture Registry in the diagnosis of osteoporosis in patients treated for fracture in a hospital. The study plan has been created and ethical approvals for the study and measurements have been completed in the participating hospitals, which were equipped with the Bindex® (Bone Index Finland Ltd, Kuopio, Finland) bone density measurement device. The results reported here were also presented on the Bone Innovation Summit in Lübeck on 13-14th February 2019.

In this pilot, we could show that Bindex® measurements were feasible before surgery without additional delay of treatment. More detailed analyses were conducted on patients with trochanteric fractures treated with DHS or Gamma nail in order to examine linkages between Bindex® measured bone density and migration (femoral neck shortening) of the implant. We observed that patients with complications had a lower Density Index measured by Bindex®, which warrants further examinations. Given the small number of subjects (n=77), contribution of other factors in complications, such as Tip Apex Distance and Cleveland Zones during installation of implant, should be controlled for in future analyses.

The hospitals that participated in this pilot study will continue using the technology, and additional research topics have been raised in dialogue with other hospitals. In longer term, the output can contribute to new applications of bone density measurements, and provide improved fracture management, treatment and eventually reduce fracture related costs.

2. Rationale of the pilot project

The BFCC established a transnational collaboration platform between hospitals and industry, which was tested in three transnational pilots, with five hospitals and three companies involved. Hospitals generally store a large amount of clinical data for each treatment case. For this pilot, diagnostic parameters provided by Bindex® were also recorded in the fracture registry developed during the project.

Patients with a fragility fracture are almost twice as likely to suffer another fragility fracture compared to their age-matched peers with no previous fractures[1,2]. Hip fracture is the most serious outcome of osteoporosis when considering mortality and morbidity[3,4]. During the first year after a hip fracture, over 24 % of the patients at 65 years of age or over will die[4]. Approximately 50 % of patients who have suffered a hip fracture had a previous fragility fracture[5]. A large study in Spain showed that 18 % of patients with a hip fracture had received treatment for osteoporosis and only 26 % were receiving pharmacological treatment after being discharged from the hospital[6].

Orthopedic surgeons routinely encounter patients with low energy fractures. That has led to more interest on prevention of secondary fractures among orthopedists. Previous fractures are known as a significant predictor for future fractures, and thus it would be valuable to detect and manage osteoporosis in this population. Knowing the degree of osteoporosis during surgery could also alter the treatment and post-operative care strategy in ways that could lead to less complications and a better outcome for the patient. Furthermore, early surgical intervention without any unnecessary delay is imperative for minimizing the postoperative morbidity and mortality in hip fracture treatment.

Aim of the study was to evaluate the clinical use of the Bindex® device in patients with an acute fracture, showing that peri-operative bone mass index evaluation is possible without delaying the time to surgery and giving the surgeon useful information during surgery and post-operative period management. The benefits of Bindex® are the easy and rapid use in comparison to other bone mineral density measurements. It can give reliable information directly before surgery whether the patient is an osteoporosis risk patient and if the surgery and post-operative care procedures should be adapted respectively. The combination of bone mineral density diagnostics before surgery and its possible impact in treatment and immediate rehabilitation decisions is a unique approach and the data and results can be very valuable for clinics.

3. The diagnostics pilot study

This chapter summarises the scientific pilot study conducted during the BFCC project. The investigation is titled "Modes of hardware migration after trochanteric fracture fixation using DHS (dynamic hip screw) of PFN (proximal femoral nailing) in relation to bone density assessed with pulse-echo ultrasound". The results reported here combine data focused on cases with trochanteric fractures collected in two participating hospitals.

3.1. Introduction

Osteoporosis is characterised by reduced bone mass and disruption of bone architecture, resulting in increased risk of fragility fractures which represent the main clinical consequence of the disease. Hip fractures are the most frequent and the most serious outcome of osteoporosis in terms of mortality and morbidity.

Numerous treatment methods and implants are available for the management of trochanteric hip fractures, such as dynamic hip screws, locking Gamma nails or prosthetic replacement. Dynamic hip screw (DHS), the most representative implant of extramedullary fixation, has been considered as a "gold standard" for treatment of stable trochanteric fractures. While Gamma nail as intramedullary fixation method has been widely used for many years as safe method with a low complication rate, one of the most common hardware failure modes is dynamic screw migration and following limb shortening is reported in both (DHS and Gamma nail) devices. Dynamic screw migration might be related to stability of fixation, postoperative load on operated leg or osteoporosis level. One might suspect that higher osteoporosis level and related bone weakening could result in greater dynamic screw sinking and following shortening of the femoral neck. Some shortening of the femoral neck is part of the healing process if a dynamic screw was used, however, excessive shortening resulting in changes of hip joint biomechanics and limb shortening is considered as an adverse event.

We found no reports in the literature investigating femoral neck shortening due to screw migration in relation to osteoporosis level and comparing DHS and Gamma nail used for trochanteric fracture fixation. We hypothesise that greater osteoporosis level should result in greater dynamic screw migration. The aim of this study was to compare femoral neck shortening in patients with trochanteric fractures treated with DHS or Gamma nail in relation to their osteoporosis level.

3.2. Methods

A total number of 77 consecutive trochanteric fracture patients treated in Lithuania and Germany meeting the inclusion criteria were investigated. Inclusion criteria were the following: patients older than 55 years with non-pathological fresh two of three parts trochanteric fracture treated with DHS or Gamma nail.

Before surgery, patients were investigated in respect to their osteoporosis level using Bindex® device, which defines osteoporosis with Density Index (DI) parameter, for which 90 % sensitivity and specificity thresholds have been validated in accordance to the guidelines of the International Society for Clinical Densitometry (ISCD) [7,8]. Ultrasound (US) measurements were

conducted at 1/3 of the length of the tibia from the proximal head by trained study nurses (Figure 1). The device consists of a hand piece connected into the USB port of a laptop and an ultrasound probe. Two parameters were collected including cortical thickness at the proximal (Ct. Thprox) tibia and the DI. The method for cortical thickness measurement has been validated and can be considered as accurate method of osteoporosis assessment as comparing to axial DXA[9].

Figure 1: *Ultrasound measurement (Bindex®) at proximal tibia. Tibial cortical thickness is measured, and a diagnostic parameter, Density Index, is calculated based on the cortical thickness and patient age, weight and height. Results sheet (on the right) shows the Density Index on a color scale, with classification with diagnostic thresholds as required by the International Society for Clinical Densitometry guidelines (ISCD).*

After the osteoporosis level assessment, patients were operated either with DHS or Gamma nail. The surgeon was blinded to Bindex® measurements results and the choice of the devise used for fracture fixation was based only on his own preference. After surgery, the same postoperative care regime was applied for all patients which included full weight bearing up to the sustainable pain level on the operated leg. Radiological assessment included the AP x-ray performed immediately after surgery and at 2-4 month postoperatively (Figure 2.).

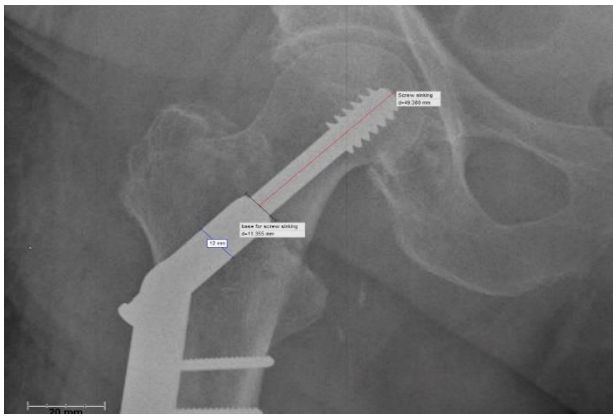

Figure 2: *Post-operative native X-ray at the proximal femur on a patient treated with Dynamic Hip Screw (DHS) for trochanteric fracture.*

3.3. Results

Patients' demographic data in respect to the device used for fracture fixation is presented in Table 1.

Table 1*: Patient Demographics, treatment DHS vs PFN.*

	Implant		p value
	DHS	NAIL	
Female	28	21	p=1
Male	16	12	
	Age		
Mean ± SD	79,0 ± 14,1	77,5 ± 14,0	p=0,668
	Density Index		
Mean ± SD	0,83 ± 0,1	0,81 ± 0,1	p=0,459
	Fracture type		
2 fragments	19	7	p=0,131
3 fragments	23	19	

There was a significant difference in age of the healthy (70.2 ± 17.8 years) and osteoporotic subjects (82.9 ± 8.8 years). Femoral neck shortening showed no statistically significant difference between the healthy and osteoporotic groups. However, the mean neck shortening was higher in the non-osteoporotic group (Table 2). Three reoperations were required due to cut-out/through complications (3.9 %). All of the complication cases had density index at osteoporotic zone by Bindex®.

Table 2*: The results for femoral neck shortening, Caput-collum-diaphyseal (CCD) angle, TAD, in patient groups with different treatment.*

	Osteoporotic		p value	Non-osteoporotic		p value
	DHS	Nail		DHS	Nail	
	Femoral neck shortening					
Mean ± SD	9,95 ± 12,37	13,11 ± 10,05	p=0,5191	16,65 ± 7,81	12,47 ± 8,01	p=0,3356
	CCD					
Mean ± SD	5,25 ± 3,62	6,72 ± 5,52	p=0,4974	1,68 ± 1,71	5,50 ± 4,40	p=0,1143
	TAD					
Mean ± SD	4,82 ± 2,65	5,65 ± 3,27	p=0,5469	3,92 ± 4,03	13,88 ± 12,86	p=0,1414

3.4. Discussion

We hypothesised that DHS, which is considered as not that stable construct as PFN, should result in bigger femoral neck shortening especially in more osteoporotic patients. However, osteoporotic patients had significantly lower hardware migration and related femoral neck shortening than those who were classified as non-osteoporotic. Further, the age of patients in osteoporotic and non-osteoporotic groups were different. Typically, younger subjects can be assumed to be more physically active and laying more load to the implant. This would suggest higher contribution of post-operative loading schemes and patient activity to the femoral neck shortening, than bone density. Future analyses should take this point in consideration.

Interestingly, all complication subjects had an osteoporotic value from Bindex®, which would suggest for potential of bone density assessment with Bindex® to predict complications such as cut-throughs or cut outs. The number of subjects in the study is too low to reliably assess this, as also other known factors such as TAD and Cleveland zone affects the rate of complications.

To conclude, Bindex® was feasible for pre-operative measurement of trochanteric fracture subjects, without delay in treatment. The Bindex® assessment of bone density may be useful for predicting complications in DHS and PFN treated fractures and may help assessing femoral neck shortening if activity and age are controlled for. The results show promise for pre-operative bone density assessment, however, given the low number of subjects in this pilot study, extension and future studies with higher number of patients are warranted.

4. Output evaluation

In the BFCC diagnostics pilot, the application of Bindex® method was piloted in a transnational hospital setting for trochanteric hip fracture cases. We aimed at investigating the innovative application of Bindex® diagnostics for the prediction of surgery outcomes, implant migration, subsequent fractures or to aid in design of rehabilitation procedures. The novel aims in the pilot address the interests of involved companies and university hospitals in commercial and scientific sense. The network around the registry has the potential to provide a good platform initiating/innovating and implementing industry originated product/business development, validation of novel products for clinical use or as a test platform for new applications simultaneously or separately at different Baltic Sea Region countries. On the other hand, the network could act as a platform for continuous two-way dialogue, where demands/needs are detected and may be conveniently communicated to both either party.

Participated organisations and institutions will continue using the technology and additional research topics have been raised by other participating hospitals. In longer term, the output can contribute in new applications of bone density measurements, and provide improved fracture management, treatment and eventually reducing fracture related costs.

5. References

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