Can Patients with Cognitive Impairment Be Included in a Randomized Controlled Trial on Hip Fractures: A Feasibility Study

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Purpose: One in 3 patients with a hip fracture is known to have a degree of cognitive impairment. A recent systematic review has shown that patients with cognitive impairment are rarely included in randomized controlled trials (RCTs) and as a result a significant subpopulation of the patients with hip fractures may be overlooked. The purpose of this study was to evaluate the recruitment, retention, and completion of patients with and without cognitive impairment in a high-quality clinical trial.

Methods: This was a prospective, single-center RCT approved by the local research ethics committee. Patients aged between 55 and 95 years with a low-energy intertrochanteric unstable proximal femoral fracture (OTA/AO 31A2) were randomized to either a dynamic hip screw (DHS) or a short intramedullary nail (EBA2; Citieffe). Permuted block randomization was stratified by Abbreviated Mental Test Score (AMTS). Patients were asked to perform the timed "Up and Go" (TUG) test, the proposed primary efficacy assessment measure at each follow- up (FU) visit (2, 4, and 12 weeks).

Results: 60 patients were recruited and randomized in the study. The average age was 84.9 years (range, 56-95). 48 were females and 12 males. 31 patients were randomized to a nail and 29 to a DHS. 22 (37%) patients had AMTSs <8. From the 38 patients with AMTS ≥8, 35 (92%) completed the study (2 were withdrawn by the research team and 1 was lost to FU). From the 22 patients with AMTS <8, 14 (64%) completed the study (6 died, 1 withdrew consent, and 1 was withdrawn by the research team). Attendance in each FU visit was lower for patients with AMTS 8 (2-week FU: 82% vs 89%, 4-week FU: 73% vs 89%, 12-week FU: 59% vs 87%). Patients with AMTS <8 were less likely to be able to perform the TUG test at each FU visit (TUG test was performed by 33%, 80%, and 75% of the patients with AMTS <8 and by 76%, 85%, and 94% of the patients with AMTS ≥8 at 2, 4, and 12 weeks of FU, respectively).

Conclusion: This study showed that patients with cognitive impairment are less likely to complete an RCT and they are less likely to be able to perform the clinical outcome assessments than patients with normal cognition. This differentiates them from the normal population and may mean that they should be considered a separate subpopulation, unless suitable surrogate outcomes can be identified that can be captured early in the treatment process in both groups. Including patients with cognitive impairment in clinical trials, although they may require separate assessment and tailored outcomes, will ensure that the results are applicable to this sizeable subpopulation.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.