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**Should cognitive impairment be an exclusion criterion for hip fracture studies?**

Editor—As an anaesthetist with an interest in the management of patients with a proximal femoral fracture, I read the article by Bartha and colleagues with great interest. The authors should be congratulated on attempting to improve outcomes for this high-risk population.

I note, however, that the authors chose to exclude patients who were unable to give their own consent for inclusion in the study. This is a potential weakness of many studies examining proximal femoral fracture management and may be one explanation as to why so few interventions have been able to show meaningful decreases in postoperative morbidity and mortality.

The incidence of cognitive impairment in this population is around 40%, and this subset of patients may represent the population at the highest risk of complications. The Nottingham Hip Fracture Score demonstrated that a mini-mental test score of <7 was associated with a doubling of 30 day postoperative mortality [OR 2.42 (1.98–2.95)]. By excluding these patients, the authors may have excluded a population that had the potential for the greatest benefit from intervention.

Participants are commonly recruited to studies in which they cannot give their own consent (e.g. interventions given whilst sedated on intensive care), and assent is often sought from next-of-kin in the first instance, with formal consent subsequently sought if/when the participant is able to do so.

If investigators continue to ignore this high-risk population, it may be some time before we see a positive trial result in studies involving hip fracture patients.

**Declaration of interest**

None declared.

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**Reply from the authors**

Editor—We thank Dr Wiles for giving us an opportunity to discuss this important issue. The question he poses is important especially in this group of patients with a high prevalence of cognitive impairment. To totally exclude patients with dementia in a study like this would be a weakness.

According to the Swedish Medical Product Agency, the issuing organ of approval for clinical investigations and trials, only patients who are able to give their own consent could be included in clinical investigations. That is the reason why the inability to give informed consent was an exclusion criterion. Patients with impaired cognitive function can be included if they give informed consent. The condition for consent in these patients is that they are informed in a way that they can understand. Such consent has to be testified by a care giver who is not involved in the trial and the relatives of the patients have to be informed. Using this method, of the 282 patients who were assessed for eligibility, only four patients were excluded because of the lack of any communication (Figure 2 in the paper). In Table 2, we listed the co-morbidities of the included patients and it can be seen that we included 39 (26%) patients with diagnosed dementia. Besides these patients, there were also 21 patients with moderate or severe impaired cognitive function detected by the SPMSQ (Short Portable Mental Status Questionnaire). Consequently, the number of patients with impaired cognitive function was 60 (40%) in line with the literature that Dr Wiles cited.

Patients with impaired cognition and dementia were included in the study; so, it is reasonable to assume that we have studied a representative sample of these very fragile patients.

**Declaration of interest**

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