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Handling of informed consent and patient inclusion in research with geriatric trauma patients - a matter of protection or disrespect?

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Despite the aging of numerous societies and future health care challenges, clinical research in the elderly is underrepresented. The aim of this review was to analyze the current practice exemplary in gerontotraumatology and to discuss potential improvements.; A literature review was performed in 2016 based on a PubMed search for gerontotraumatologic studies published between 2005 and 2015. Trials were evaluated for methodology and ethical and age-related aspects.; The search revealed 649 articles, 183 of which met the inclusion criteria. The age range for inclusion was heterogeneous; one-third of trials included patients <65 years and only 11% excluded very elderly. Seventy-four trials excluded patients with typical comorbidities, with 55% of these without stating scientific reasons. Frailty was assessed in 94 trials and defined as the exclusion criterion in 66 of them. Informed consent (IC) was reportedly obtained in 144 trials; descriptions of the IC process mostly remained vague. Substitute decision making was described in 19 trials; the consenting party remained unclear in 45 articles. Diagnosed dementia was a primary exclusion criterion in 31% of the trials. Seventeen trials assessed decisional capacity before inclusion, with six using specific assessments.; Many trials in gerontotraumatology exclude relevant subgroups of patients, and thus risk presenting biased estimates of the relevant treatment effects. Exclusion based on age, cognitive impairment, or other exhaustive exclusion criteria impedes specific scientific progress in the treatment of elderly patients. Meaningful trials could profit from a staged, transparent approach that fosters shared decision making. Rethinking current policies is indispensable to improve treatment and care of elderly trauma patients and to protect study participants and researchers alike.
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