

External validity of a randomized controlled trial in patients with femoral neck fracture

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Background: Randomized clinical trials (RCT) are the most reliable way to evaluate the effect of treatments by comparing them to previously accepted treatment regimes. The results obtained from a RCT are extrapolated from the study environment to the general health care system. This parameter is called external validity. In the present study, we sought to evaluate the external validity of an RCT comparing the results of total hip arthroplasty to hemiarthroplasty in displaced femoral neck fracture in patients 80 years of age and above.

Methods: In a prospective cohort study, 963 patients (999 hips, 72% females, mean age 87 [range 80-102]) were included in the cohort study. All were screened according to the inclusion and exclusion criteria for the RCT. The patients were divided into two groups: 1) Those who gave their informed consent (IC) and were randomized (IC group, 118 patients) and 2) those that were asked to participate in the RCT but would not give their informed consent (non-consenters group, NC, 63 patients). The outcome variables were hip function evaluated with Harris hip score at 1 year, mortality and baseline data. Follow up was performed at 1 year postoperatively by a mailed survey including patient reported outcome.

Results: Non-consenters had a higher 1 year mortality than those included when adjusting for sex, age, ASA category (1-2 or 3-4) and surgical treatment (IC 3.4% vs 19.4% in the NC group, odds-ratio 5.9, 1.5 – 23, $p=0.01$). The differences in baseline data were significant regarding age (87 vs 85.5, $p=0.01$) and surgical treatment with more total hip arthroplasty in IC ($p<0.01$). There were no difference regarding Harris hip score also when adjusting for confounders.

Discussion and Conclusion: This cohort study indicates a higher mortality rate, slightly higher age but comparable hip function in eligible non-consenters compared to eligible consenters when evaluating the external validity of a RCT patients with femoral neck fracture age 80 and above.

Conflicts of interest: None.