LETTERS

Inclusion and Analysis of Older Adults in RCTs

To the Editor:—We read with interest the paper of Zulman et al. regarding the inclusion and analysis of older adults in randomized controlled trials[1]. In a detailed cohort study of over 1500 breast cancer patients aged 65 years and older, we applied the inclusion and exclusion criteria of the clinical trials upon which the national breast cancer guidelines in The Netherlands are founded. Based on age, 43% of the patients would be excluded. Of the remaining patients, 25% would be ineligible due to comorbid conditions and 12% because of a history of cancer. After exclusion criteria regarding breast cancer stage, a maximum of 12% of elderly patients could enter the trials. Consequently, studies which do include elderly are likely to suffer from selection bias; only elderly patients considered 'healthy enough' will enter[2]. Extrapolation of results of many clinical trials to the elderly population therefore is at least questionable.

We agree with the authors that it is of high priority to achieve evidence in this substantial population. We doubt, however, whether the suggestions made by the authors to increase enrollment in clinical trials will be sufficient to fill the 'evidence gap'. The great heterogeneity in the elderly population stretches the possibilities to construct randomized controlled clinical trials. Clinical trials might not be equally applicable in the setting of the multiple morbidities often seen in elderly patients: even with inclusion of very large numbers, it remains a challenge to create homogeneous, comparable study arms. Therefore we stress the importance of exploring different study designs in this ever growing population. Restriction in research topics, design, and analysis may give observational research the chance to be as credible as randomized evidence[3]. Large, quality assured prospective cohort studies generate a large amount of reliable data. Moreover, these data are a representative selection of the general population, including the substantial heterogeneity within the elderly. International prospective registration studies (EURECCA; European Registration of Cancer Care[4]) and cancer registry collaborations (EUROCARE, a European cancer registry based study on survival and care of cancer patients) may fulfill an important role in data generation and obtaining evidence. Recently, we initiated a detailed cohort study to study characteristics, treatment strategies and outcome in over 2000 elderly breast cancer patients (FOCUS: female breast cancer in the elderly, optimizing clinical guidelines using clinicopathological & molecular data). Our joint efforts will hopefully result in evidence-based medicine for elderly (cancer) patients.

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REFERENCES

1. **Zulman DM, Sussman JB, Chen X, Cigolle CT, Blaum CS, Hayward RA.** Examining the evidence: a systematic review of the inclusion and analysis of older adults in randomized controlled trials. J Gen Intern Med. 2011.
2. **Pallis AG, Fortpied C, Wedding U, Van Nes MC, Penninckx B, Ring A, et al.** EORTC elderly task force position paper: approach to the older cancer patient. Eur J Cancer. 2010;46(9):1502–13.
3. **Vandenbroucke JP.** When are observational studies as credible as randomised trials? Lancet. 2004;363(9422):1728–31.
4. **van Gijn W, van de Velde CJ.** Improving quality of cancer care through surgical audit. Eur J Surg Oncol. 2010;36(Suppl 1):S23–6.

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