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Hot topic in geriatric medicine

Are old patients not fit for clinical trials, or do clinical trials not fit to old patients? A survey in 35 pharmaceutical companies



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ARTICLE INFO

Article history:

Received 18 December 2014

Accepted 8 April 2015

Available online 29 April 2015

Keywords:

Clinical studies

Older patients

Geriatric assessment

ABSTRACT

Clinical data and evidence-based guidelines for prescriptions for older patients are rare, and older patients are often excluded from clinical trials. The aim of this study was to use a questionnaire to assess the interest of pharmaceutical companies in including patients over 70 years of age in relevant pharmaceutical clinical trials. Additionally, the use of geriatric assessment tools was assessed. Overall, 35 international pharmaceutical companies were selected to report all studies performed over a 10-year period (1999 to 2009), and a total of 26 studies reported by eight companies were evaluated. In 19.2% of the studies, older patients were included but not analyzed separately. In 53.9% of the studies, age was either considered as a covariate or analyzed in a subgroup analysis. Seven studies included only patients aged 70 years and older. However, geriatric assessment tools were only utilized in four studies. Older patients were sufficiently included and analyzed in only a minority of company-initiated pharmaceutical studies. Given current demographic changes, there is an urgent need to address this situation.

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1. Background

Older patients are generally underrepresented or even excluded [1–3] from clinical trials, especially in pharmaceutical studies. However, older patients often represent the most significant group of consumers of investigated drugs [2,4]. So even in their geriatric medicines strategy the European Medicines Agency (EMA) pointed out, that “older people are the main users of medications – not a minority or special population. . . therefore, legislative and regulatory frameworks must be designed to ensure that the use of newly approved medicines in the intended population is supported by relevant data on the benefit-risk balance” [5]. But, in the reality, clinical data and evidence-based guidelines for prescriptions for older patients are rare. Furthermore, the results from clinical trials in younger patients are not directly applicable to the treatment of older patients [6,7]. The prescription of drugs that have not been tested in older people may endanger the health of patients, as solid evidence with regard to drug efficacy and toxicity within the patient age group may be unavailable [6–9]. This statement is also true for over-the-counter drugs, as package leaflets normally do not state whether the drug was tested in older patients.

For various reasons, age is the most significant barrier to subject recruitment for clinical trials [4,6,8,10]. Older patients show a high prevalence of comorbidities, especially when they have chronic diseases, and tend to require continuous and extensive drug therapy [4,11]. This increases the risk of side effects, and complications should be expected. The higher prevalence of cognitive impairments further aggravates the recruitment of appropriate study participants. Other exclusion criteria that have been reported in previous studies include frailty, communication barriers, transportation difficulties due to physical disabilities, visual or hearing deficits (sensory deficits), low income, and a lack of social support [8,10,12].

Little information is available regarding how many older people have participated in clinical research. Even if older individuals are involved, a separate evaluation of the results in the older population or an analysis of age as a covariate is anything but standard.

Therefore, only small developments in the understanding of the need to include older patients in clinical studies have been seen, and there is significant room for improvement. To achieve the goals of an effective geriatric drug therapy, the drug and the study design need to be accurately tested [4,13].

The aim of this survey was to use a questionnaire to assess the interest of pharmaceutical companies in including patients older than 70 years in relevant pharmaceutical clinical trials; in cases in which older patients were specifically excluded, the survey aimed

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to identify the reasons for their exclusion. The survey also assessed the use of geriatric assessment tools.

2. Materials and methods

The major suppliers of drugs (95% of all drugs delivered) in our hospital consortium were selected for inclusion in this study. All but one of the 35 identified pharmaceutical companies are international companies. Questionnaires in English and German (Appendix 1) were sent to the national headquarters of the companies.

The companies were asked to report all studies worldwide performed over a 10-year period (1999–2009) and to identify each study by its study code, study phase (I–IV) and investigated chemical substance/drug. Patients aged 70 years and older were not generally excluded, but the companies were asked if the final eligibility for the study was based on the results of one or more geriatric assessments or solely on the patient's numerical age.

The questionnaires were sent to the companies in January 2009. One reminder was sent in April 2009, and a second reminder was sent in August 2009 (Fig. 1).

The survey was carried out on behalf of the German umbrella organization of the gerontological and geriatric

societies (Dachverband der Gerontologischen und Geriatischen Gesellschaften Deutschlands e. V. – DVGG).

3. Results

Of the 35 companies that were contacted, eight did not reply even after the second reminder. Four companies reported that they did not have the capacity to complete the questionnaire or were bound by confidentiality. Thirteen manufacturers reported that they did not perform relevant clinical trials during the period (1999 until 2009). The replies of two companies were inconsistent and therefore excluded from the evaluation.

Overall, 26 studies reported by eight companies were evaluated (Fig. 1). Two studies were still in the recruitment phase, 24 studies were already completed. In six cases the number of subjects included was not revealed, the remaining 18 studies comprised a total of 29,487 patients (mean 1638, min 12, max 5385). The study types reported are listed in Table 1. Five of the studies (19.2%) reported that older patients were included but not separately analyzed. Ten studies (38.5%) included a subgroup analysis of patients aged 65 to 75 years, and four studies (15.4%) treated age as a covariate. In seven studies (26.9%), no age distinction was needed because the trials focused primarily on a population aged 70 years and older. However, only two of the studies answered the question,

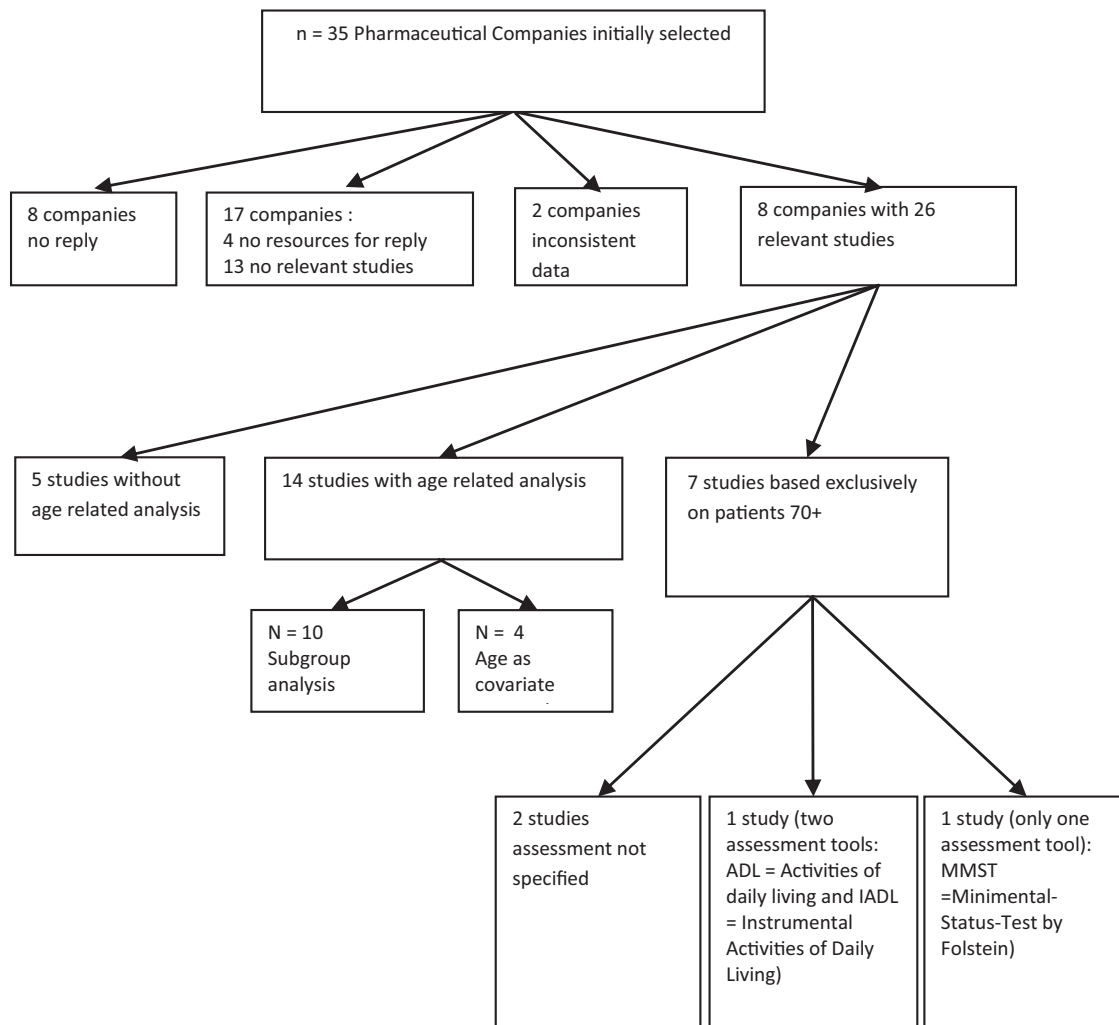


Fig. 1. Flowchart of the survey.

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