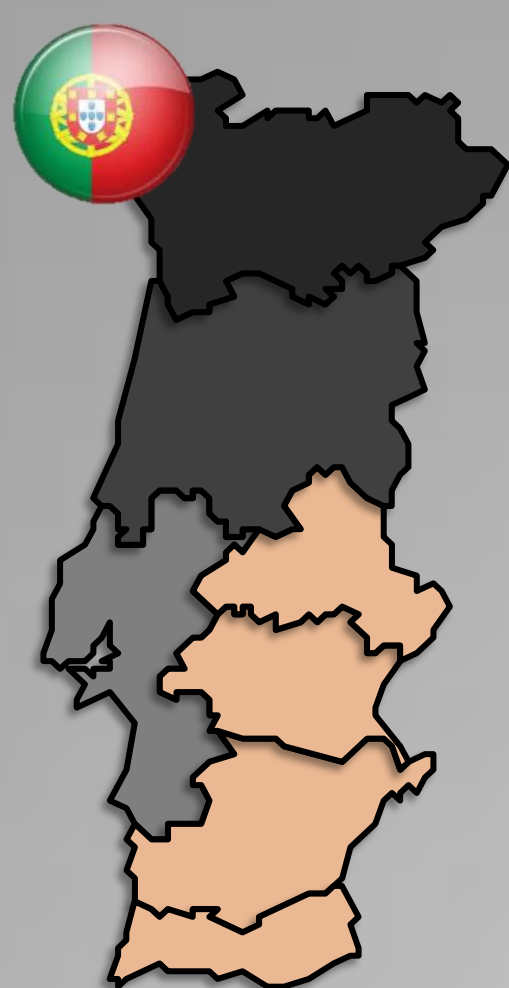


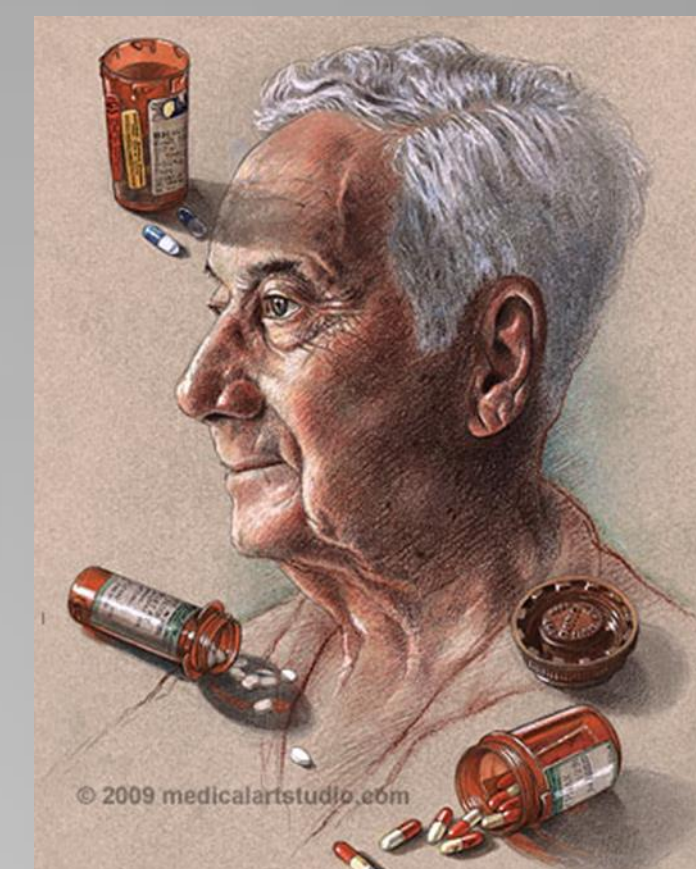
Pharmacists and suspected adverse drug reactions in old patients reported from 2009 to 2013



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Background

Aging is associated with physiological, pharmacokinetics and pharmacodynamics changes as well as to co-morbidities, polypharmacy and the risk of potentially inappropriate medication prescription, making this population more vulnerable to the emergence of adverse drug reactions (ADR). Spontaneous reporting allows safety drug monitoring through their whole life cycle, in large populations and in the real world. It enables safety early signs detection despite underreporting, according to Mittmann *et al* about 94% of the serious ADR are not reported to the authorities. Generally, among health professionals, the pharmacists are not the main reporters, particularly in Portugal. During the studied period Pharmacists were responsible, in average, for 42% of the ADR reports. However South region of the country, having pharmacists as pharmacovigilance delegates, presents greater involvement of these health professionals.

Study Purpose

To study pharmacist's suspected adverse drug reactions reports regarding old population, in the South Region of Portugal, during 2009-2013.

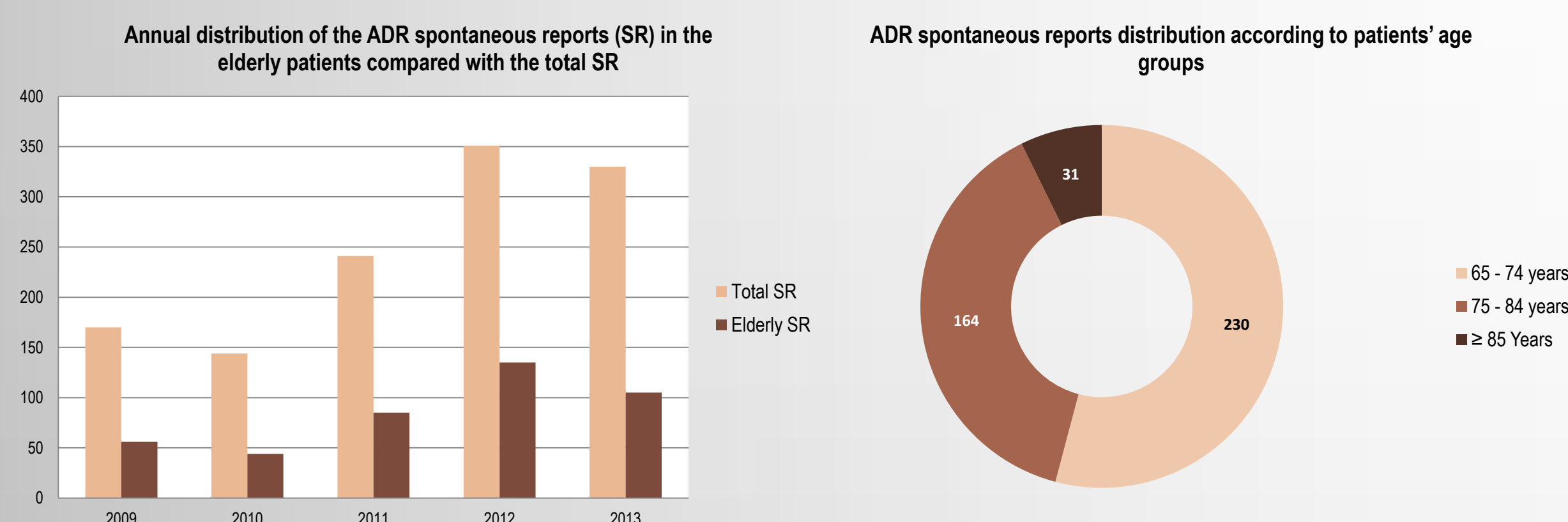
Study Design and Methods

Cross sectional study performed in the Pharmacovigilance South Center based on its spontaneous reports database concerning suspected ADR occurred in old patients (≥ 65 years old), reported during 2009-2013. A descriptive analysis with EPI INFO 2007 system was done. Medicines were classified by Anatomic Therapeutic Chemical (ATC) and ADR by MedDRA dictionary.

Study Findings

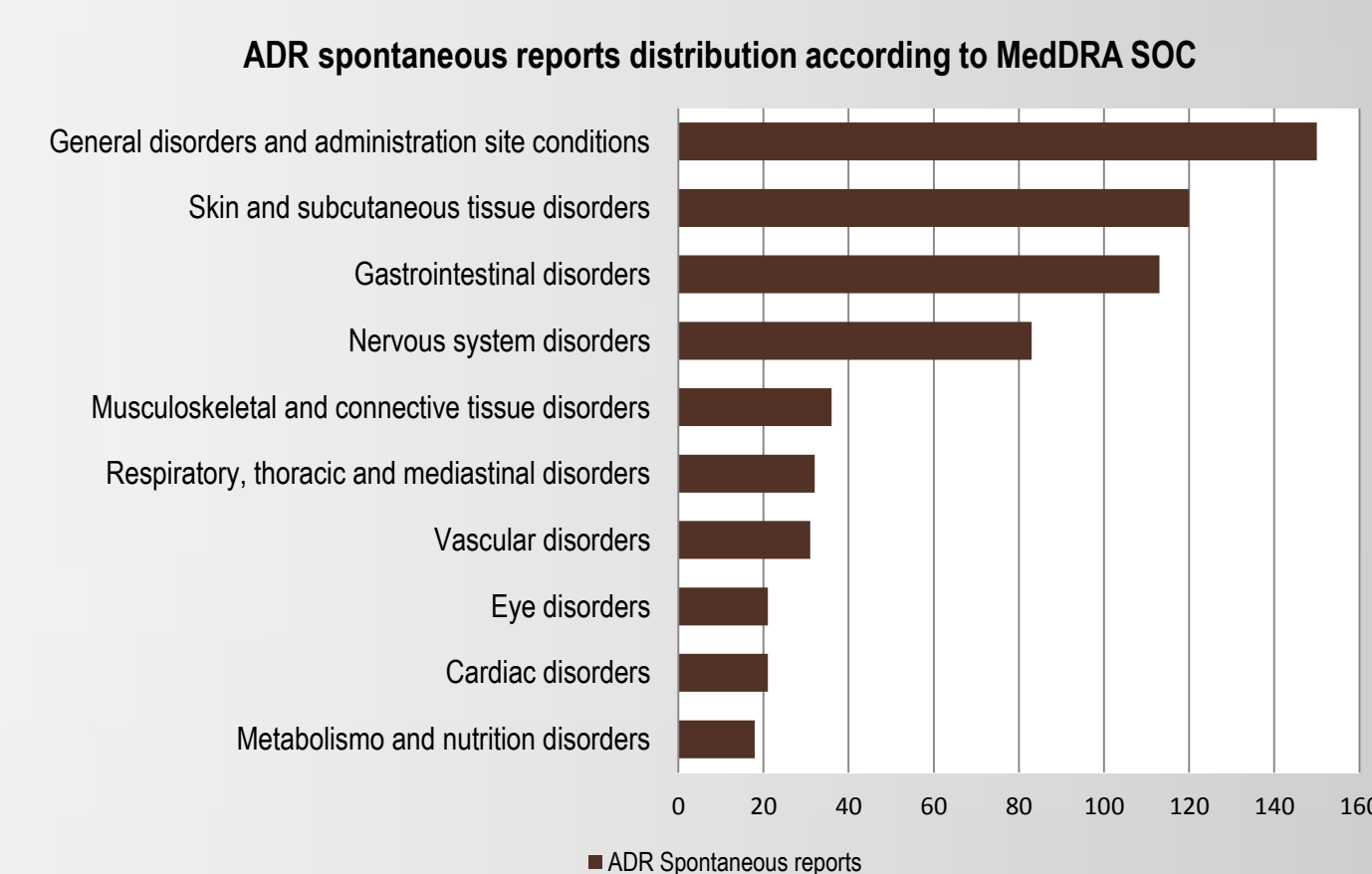
Patient profile

Among 1,236 spontaneous ADR reports, received during the studied period, 425 (34.4%) ADR occurred in old patients (≥ 65 years old) and were analyzed. Patients' mean age was 74 years (65 – 99) with higher frequency of ADR (65.4%) in female gender.



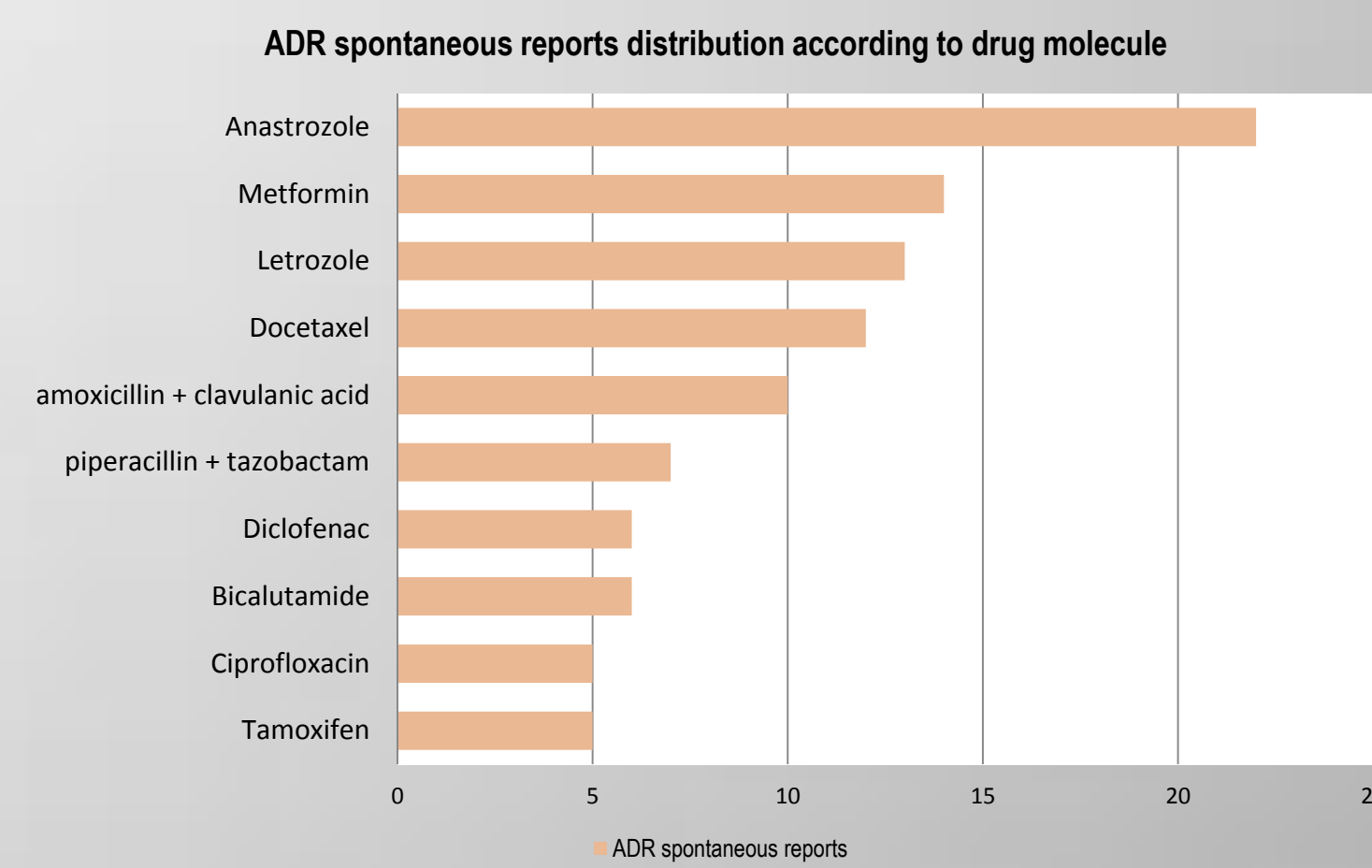
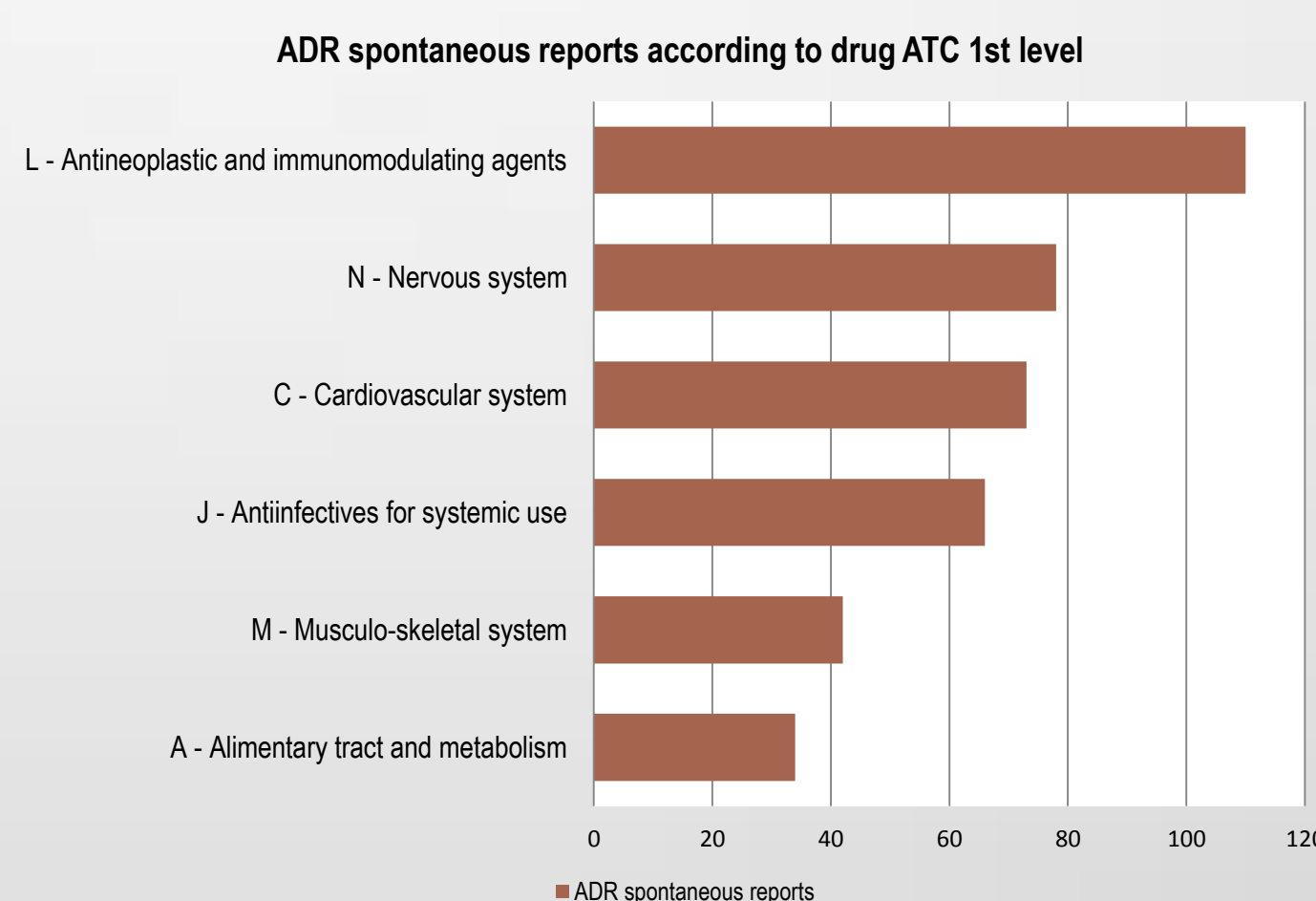
ARD profile

It was found that 27.5% (n=117) of the reported ADR were severe. From all cases, 56% evolved to cure and were registered 4 deaths in the study period. "General disorders and administration site conditions", "Skin and subcutaneous tissue disorders", "Gastrointestinal disorders" and "Nervous system disorders" were the most frequently affected MedDRA systems.



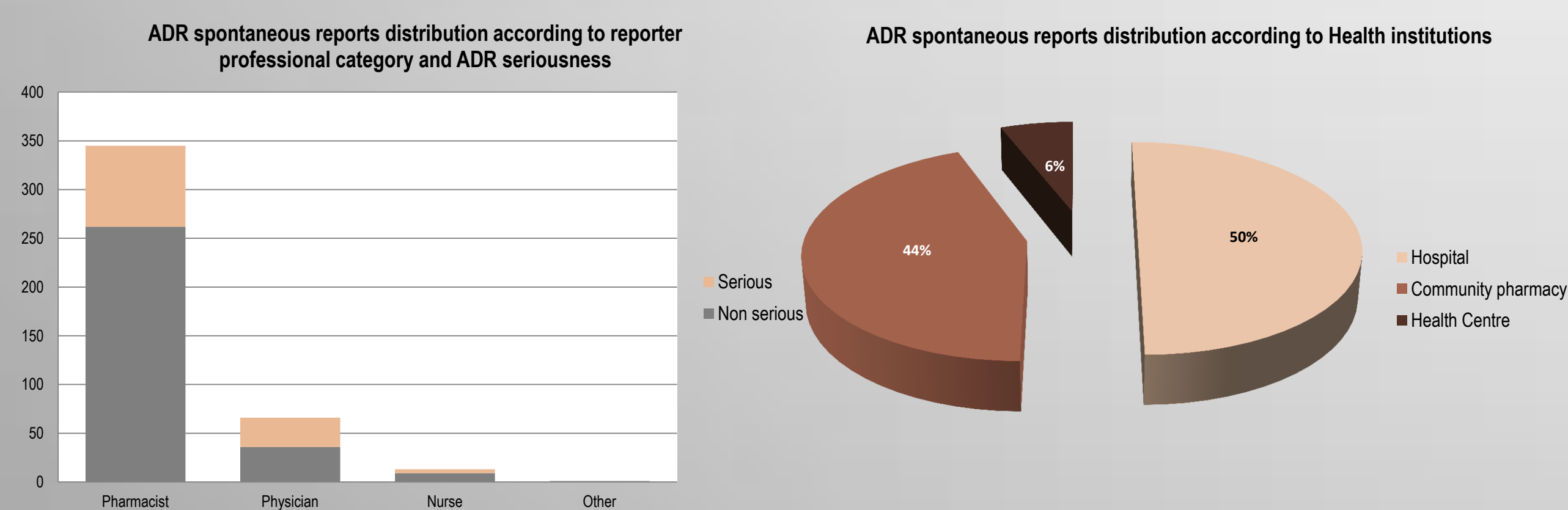
Drug profile

The ATC groups L (antineoplastic and immunomodulators agents), N (nervous system), C (cardiovascular system), J (general anti-infective for system use) and M (musculoskeletal system) were the most frequent groups related to ADR reports in old patients.

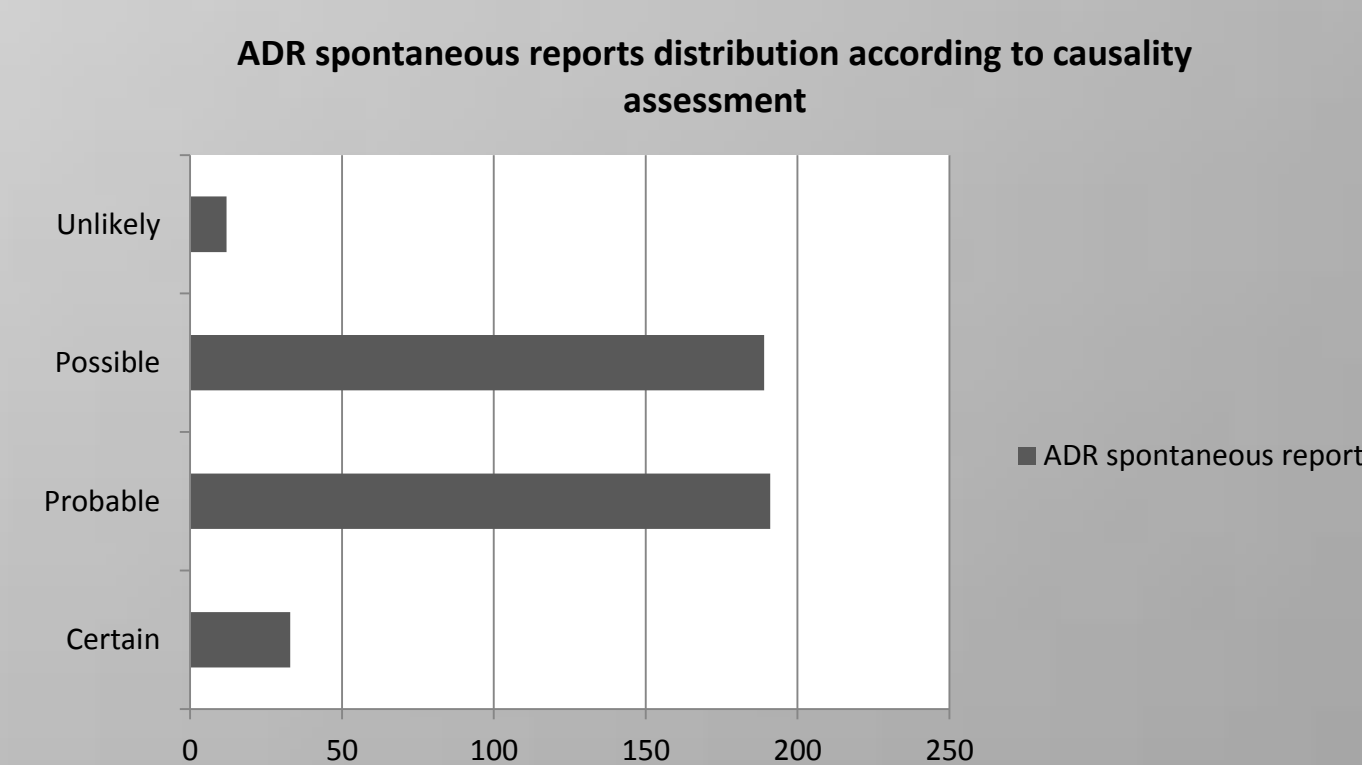


Reporter profile

Pharmacists were the main reporters with 81.2% (n=345). The hospital was the most active health institution, being responsible for 50.0% (n=212) of the SR, followed closely by the community pharmacy with 44.0% (n=187).



The causality assessment between suspected drugs and reported adverse reactions were classified, for 97.2% of the cases, as certain, probable or possible.



Conclusions

This study showed high frequency of ADR in old patients and allowed a more complete understanding of its profile, leading to the conclusion of the need to increase knowledge in this area in order to promote safe and rational use of medicines in this age group. Pharmacists, by patient's proximity, can provide a great reinforcement to the Pharmacovigilance system in compliance with their place as main reporter in this region of the country. Pharmacovigilance can constitute an opportunity for the pharmacists to provide a better centered patient's care, to increase medicines knowledge and confidence and, to conquer, through their professional empowerment, a stronger role in the health systems and society.