

Importance of quality assurance methods in the pharmacotherapy of arterial hypertension

Abstract of the PhD Thesis

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Background and introduction

Arterial hypertension represents in our days a major epidemiological problem worldwide, because of the high number of implicated persons. Worldwide, raised blood pressure is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths. This accounts for 57 million disability adjusted life years (DALYS) or 3.7% of total DALYS. The control rate of HBP is very low: lower than 50% of the treated patients. This is a very significant problem, because blood pressure lowering to the goal levels could not only increase lifetime expectancy, but also has impact on the national health status and public health economy.

Aims and objectives

The objective of this study is to evaluate the characteristics of pharmacotherapy in the current everyday practice and to analyze the therapeutical chain in aim to identify the weak links and to propose quality assurance methods to improve it. Pharmaco-therapeutic methods are evaluated in a novel way: upon the appearance of adverse drug reactions and from the point of view of quality assurance.

Design and methods

We have performed two consecutive cross-sectional, non-interventional pharmaco-epidemiological studies, in concordance with current guidance and legislation. The methodologies of these studies were compiled as study protocols. The statistical analysis was performed using Excel Statistical Package, GraphPad Prism 5 and EpiInfo statistical software.

Results

The first study was performed including 112 adults, while the second study included 301 adult subjects. The results of our first study revealed a high frequency of hypertension (66.07%), with a relatively high awareness (81.08%); but a very low control rate and unsatisfactory compliance

(27.5%). As well we could analyze the frequency of use of different medicines, the appearance of polypragmasy; observing this way several weak links in the chain of the treatment of hypertension. Based on the results of our first study, which are comparable to the results of the national SEPHAR II survey, we have planned our second study. During the second study our purpose was to evaluate the pharmacotherapy from the point of view of eventual adverse drug reactions and the methods of quality assurance. Therefore we have chosen hyperkalemia as a parametric factor. The frequency of hyperkalemia in the studied population was very high (82.1%), and the evaluation of its relationship with the different illnesses respectively therapeutical algorithms returned statistically significant correlation in case of chronic renal failure and five drug associations. These drug associations and the statically significance level of each are: ACEI and diuretics ($p=0.01$), ACEI and NSAID ($p=0.07$), diuretics and spironolactone ($p=0.07$), diuretics and ACEI and spironolactone ($p=0.008$), diuretics and ACEI and spironolactone and NSAID ($p=0.05$). The adverse reaction scaling was performed on a total of 121 cases and we could observe that more than 45% of these cases were situated in the probable range of the scale.

Conclusions

In both the first and the second study we observed a high frequency of hypertension and the analysis of the pharmacotherapy was possible. The first study revealed a lack of compliance to the treatment, polypragmasy and low control rate while during the second study we observed a decreased health status of the studied population, a high frequency of polypragmasy and high incidence of adverse drug reactions. During the whole evaluation the absence of quality assurance methods was noticeable.

Discussion

We should accomplish that quality assurance is a professional concept, initiated and controlled by the profession itself. In medicine quality assurance is already widely used, but until now most only in controlled clinical trials. The challenge is to take over these well established methods and personalized implement them in the current everyday practice, building this way a quality assurance process.

Key words: pharmacological therapy, hypertension, quality assurance, adverse drug reaction