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ER and medications adverce events: An active pharmacovigilance study at the A.O. G. Rummo of Benevento

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Abstract

The Emergency Division represents a strategic hospital headquarter to implement pharmacovigilance activities. The ease of access, the care availability of 24 hours to 24 and the patient's multidisciplinary approach make Emergency Division is the ideal access to health care. The data reported in this paper are from the year 2011 the project MEREAFaPS.

It is clear that the presence of the hospital pharmacist in Emergency Division is an important resource for the spontaneous reporting system. A pharmacist infact, reports and supports physician to identify ADR/ADE in Emergency Division, increasing the number of ADR/ADE report forms.

In addition, the professional role of hospital pharmacist is an useful tool to create an important network of hospital pharmacovigilance and to increase the number of ADR report forms, their quality and the awareness in safety pharmacology.

Keywords: Emergency Division, MEREAFaPS Project, Epidemiological, pharmacology, hospital pharmacist, ADR/ADE, 2011 report

Introduction

The Emergency Division represents a strategic hospital headquarter to implement pharmacovigilance activities. In this study, the drugs mainly involved were: non steroidal antiinflammatory (NSAIDs), platelet inhibitors, anticoagulants and antibiotics. The data reported in this paper are from the year 2011 the project MEREAFaPS. It is clear that the presence of the hospital pharmacist in Emergency Division is an important resource for the spontaneous reporting system. A pharmacist infact, reports and supports physician to identify ADR/ADE in Emergency Division, increasing the number of ADR/ADE report forms.

The presence of pharmacist contributes so to establish a mechanism to ensure that adverse drug reactions or events are systematically reported and reviewed. Several studies confirms the importance of hospital pharmacist's figure as a pharmacovigilance monitor in Emergency Divisions including MEREAFaPS project too. [1,2]. The aim of this study is to confirm that a pharmacist who supports medical staff and nurses to signalling ADR, should be improve the national system of Pharmacovigilance involving (where possible) the patient in order to understand better the dynamics of suspected drugs use. "Gaetano Rummo" Benevento Hospital direct care staff, in cooperation with the pharmacist, has the responsibility of reporting, documenting and monitoring adverse drug reactions that occur within the ED population.

In all hospital divisions, the monitoring activities in response to signals provided by reports of Emergency Division were determinant. The Emergency Division is infact an important center of immediate hospitalization of all patients with more or less serious pathological phenomena. Some specific targets (indicators) were considered: the percentage of ED visits due to ADR (adverse drug reaction) or ADE (adverse drug event), the percentage of hospital admissions due to acute ADR and ADE, suspected drugs which caused reaction and other drugs took in association, the type and frequency of observed adverse drug reactions and events, the type of population involved (age, sex, comorbidities), how many of these ADRs and ADEs are predictable and therefore preventable and their classification in severe, non severe and lifethreating.

In addition, the professional role of hospital pharmacist is an useful tool to create an important network of hospital pharmacovigilance and to increase the number of ADR report forms, their quality and the awareness in safety pharmacology.

Materials and methods

Indicated the hospital pharmacists / monitor officers and medical staff of the health-PS participated in an intensive course for learning both the theoretical aspects related to the recognition and reporting of suspected ADE / ADR, as well as those related to the project technical and operational.

Following the work of monitoring and continuous working relationship with the medical and nursing staff of pharmacists at the hospital emergency room, the recording of ADR / ADE (coded according to MedDRA: Medical Dictionary for Drug Regulatory Activities) in PS was conducted using a single card (image ins) have been reported in which the patient demographic data (initial and last name, date of birth and gender), ethnicity, medications in therapy, the duration and dosage of same, the reasons for therapy, the type of pathological changes observed (clinical and / or laboratory) and its degree of severity (according to the criteria of the EMEA), if the treatment has been prescribed by a doctor and if there is a history personal or family for previous adverse reactions to drugs.

The board also provided an indication of alternative causes (if any) to the drug / the suspect / s for the onset of the ADR / ADE, of previous reactions to medications and any comorbidities in progress, the data relating to smoking and alcohol have shown signs of clinically important for the recognition and reporting of the incident. The survey was finally completed with the recording of blood tests, when performed and available, follow-up was scheduled

for more severe cases and / or requiring hospitalization, through consultations (where permitted) of medical records and detailed informational interviews with Patients (and / or their family members) and the doctors who had evaluated the clinical course. The cards have been filled by the pharmacist in charge is regularly present in PS or promptly warned by the staff of the Unit (in particular the one on duty at the triage) if he had presented a suspected ADR / ADE, either by doctors or nurses of the PS if the pharmacist had not been reached (evening shifts, night or holidays), and properly stored in a special folder in each local frame attached with the respective minutes of discharge (or admission) of the patient in question.

The data reported on paper ballots were then loaded on computer, specially prepared for this project by the "Business Information Service" of the AO Niguarda Ca 'Granda. The web-based software (image ins) was shared on the Internet, without the need for loading on site, and has been used by all the companies that participated in the project, which enabled both the knowledge and the sharing of data previously recorded by part of all AO Database security was guaranteed by assigning a different password for each access code (password was sent through a text message on your mobile phone the pharmacist previously authorized and registered) in accordance with the laws on patient privacy and confidentiality of sensitive data, in addition, this software has enabled real-time statistical analysis of the collected data, allowing both a global analysis of the data that a separate analysis for each AO, So as to highlight the homologies and / or the discrepancies between the different AO.

The hospital pharmacist in charge, finally, has provided monthly to exhibit at the premises of the PS, special paper reports that highlight the number of reports made during the month, the description of ADR / ADE with its triage color (red, yellow, green or white) and the suspected drugs in order to provide the medical and paramedical staff of the unit constant updates about the progress of the study and keep the attention on the subject of reports regimens.

Results

Taking into consideration the following graph (**Fig. 1**), allowing for a reporting period from January to December 2011 we see a large number of reports (177) carried out, which stood on an average of about 15 reports per month. Comparing the month of May 2010 when the project began MEREAFaPs (**Fig. 2**) with the same month of May 2011 we see an increase of 60% compared to the signals and May alone, equal to the same 60%, this exponential increase is shown as a function of the fact that the operator has made known adverse reactions with a frequency and greater attention.

see FIg. 1

see Fig. 2

Epidemiological data show that 47% of reports made were aimed at adults under the age of 65 years, 52% for adults over the age of 65 years and 1% interested in pediatric subjects. (**Fig. 3**) latter in number markedly low probably due to an emergency room decentralized and therefore not monitored. Data pertaining to 2011 are in contrast to 2010 as you can see (**Fig. 4**) where there has been a 'turnaround likely also due to the fact that during the year 2010 was given the reports carried out only by May 2010, the month in which the project MEREAFaPs has been activated.

see Fig. 3

see Fig. 4

Population of which were analyzed adverse reactions in the year 2011, 54% belonged to the male and 46% female in the also in this case is seen in the data obtained (**Fig. 5**).

see Fig. 5

To recognize what are the active ingredients in the top ten most involved in reported adverse reactions is observed that acetylsalicylic acid and warfarin are more susceptible to adverse reactions establish fact of 98 adverse reactions produced it is recognized that only 29 are borne by 'acetylsalicylic acid resulted in a percentage of 29.6% (**Fig. 6**)

see Fig. 6

Through the classification System Organ Class (SOC) shows that out of 289 cases observed, 22.1% (64 cases) undergoes gastrointestinal disorders, 18% (52 cases) reported diseases of the skin and subcutaneous tissue, 12.5% (36 cases), instead manifests respiratory, thoracic and mediastinal disorders, 12.1% (35 cases) has systemic diseases and conditions relating to the administration site, then 8, 7% reported diseases related to the central nervous system. (**Fig. 7**)

see Fig. 7

The number of reactions per ADR (Preferred Term) in detail, we found 19 cases that have influenced the vascular-hematopoietic system (epistaxis) 13 cases in which the drug is ineffective, 10 have shown fatigue, 10 hematuria, 10 hives and finally 9 cases complained of headache (**Fig. 8**).

see Fig. 8

The severity of the reactions are shown as non-serious (39%) in which the symptoms resolved without any consequence, 61% had severe reactions but without interfering with vital signs while 38% put in life-threatening patient requiring hospitalization. In one case, death occurred as a result of impairment of the clinical parameters (**Fig. 9**)

see Fig. 9

Observing the data related to medication suspected of causing the onset of ADR / ADE can be seen as the majority of reports concern polytherapies; fact patients who use more drugs in the therapy appears to be equal to 54% of reports (95 cases) while the 46% of reactions reported (70 cases), is attributable to a single agent (**Fig. 10**).

see Fig. 10

In detail, it relates the number of drugs involved in suspected polypharmacy with the number of ADR / ADE associated with them. In particular are 30 cases of signals attributable to polytherapies carried out with two drugs and 12 cases attributable to association of three, while 2 cases are attributable to the concomitant use of four drugs. (**Fig. 11**)

see Fig. 11

Discussion

All drugs, including those administered for the treatment of generic trivial (common cold, pain of various types, etc..) present a risk to cause adverse reactions [3]. It's important to use all drugs considering their risk/benefit ratio, starting from a correct understanding of the potential adverse events and the severity of the condition for which each drug is used. It must, therefore, make a balance on the true incidence of adverse drug reactions/events that may occur in the course of drug therapy, particularly in Emergency Division: its ease of access, its availability and the patient's multidisciplinary approach are necessary to implement the strategic drug surveillance [4].

MEREAFaPS project showed the validity and importance of hospital pharmacist's professionalism for realization of pharmacovigilance system and as a valuable source of information and support to medical and paramedical staff. The problem of awareness the medical and paramedical staff in ED was in this way, immediately solved thanks to the constant presence of the hospital pharmacist: a part of this task force. However there is an "old" problem about all spontaneous reporting systems: the under-reporting or the failure to report

is a more or less significant fraction of all adverse drug reactions or events that are manifested in patients during a drug treatment.The causes of failure to report ADR or ADE are numerous and very heterogeneous. The experience of MEREAFaPS project shows infact that for a lot of time ADR/ADEs are considered of little clinical significance, causing underreporting and some time medical and paramedical staff were uncertain about the causal relationship with the drug and suspected advents events or reactions they noted [5].

In addition, the frenetic rhythm of emergency department is another obstacle for capturing the interest of operators on the reporting practice.

Following the example of MEREAFaPS project and thanks to his/her cultural background on medication, the hospital pharmacist is identified not only as a reference in the legislative practices of drugs dispensation (in discharge or departments) but as a consummate professional for prescribing appropriateness, for the interactions and toxicity of drugs, for pharmacovigilance practices and active medical device-vigilance too. These dynamics have been favored by specific guidelines of the hospital pharmacist with the aim to involve medical and paramedical staff in the ED and highlight how good and beneficial work the hospital pharmacist had undertaken in the perspective to improve the quality of patient's care.

Hospital pharmacist supports medical and paramedical staff with recent scientific literature, EMEA and AIFA updates that could resolve all suspected cases of ADR/ADEs. Adverse drug reactions don't only affect the health of population but also have an high economic costs. In light of the obtained results from MEREAFaPS project, it's possible to conclude that the implementation of an efficient structure of pharmacovigilance and the cultural and professional competence of in the hospital pharmacist can open and encourage many future scenarios. In fact, creating a dense monitoring network, we can improve the appropriateness of drugs' use in all the italian territory to protect population's life and to save hospital costs related to ADR/ADEs. Pharmacovigilance is a crucial source for reporting the inadequacies of pharmacokinetic/pharmacodynamic characteristics of all drugs that are on the market but that aren't observed during the previous phases of clinical trials.

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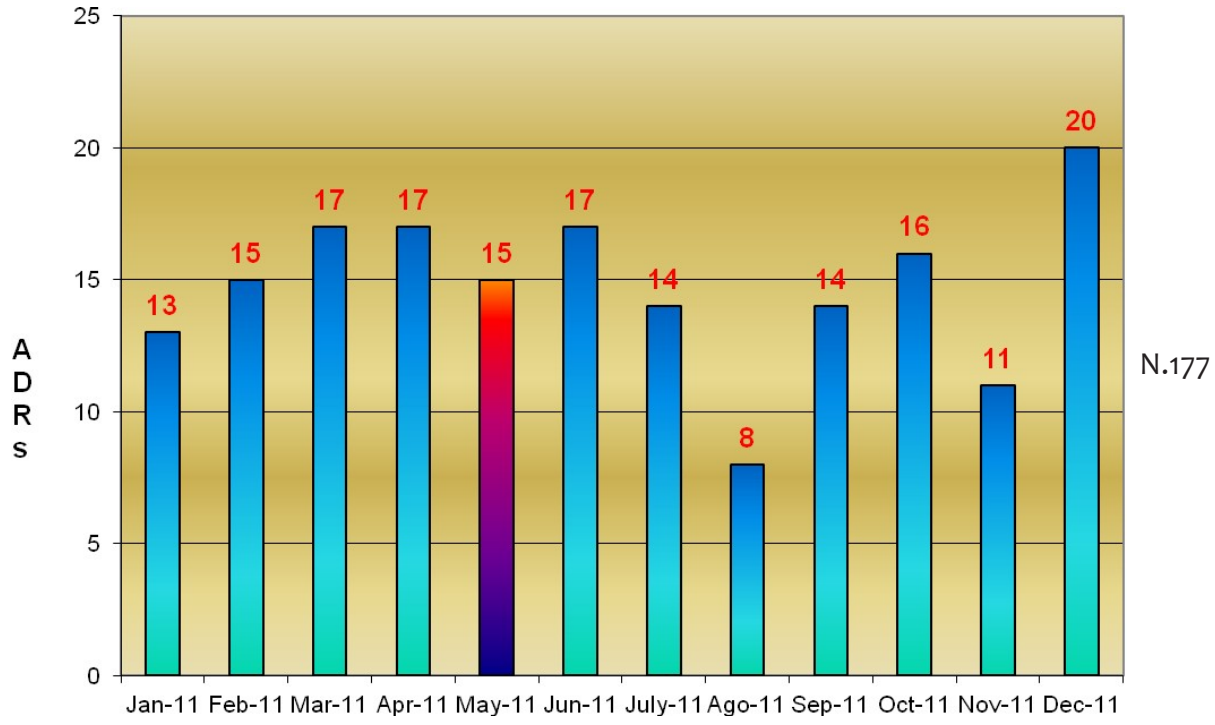

Fig. 1 Reports made in A.O Rummo throughout the year 2011

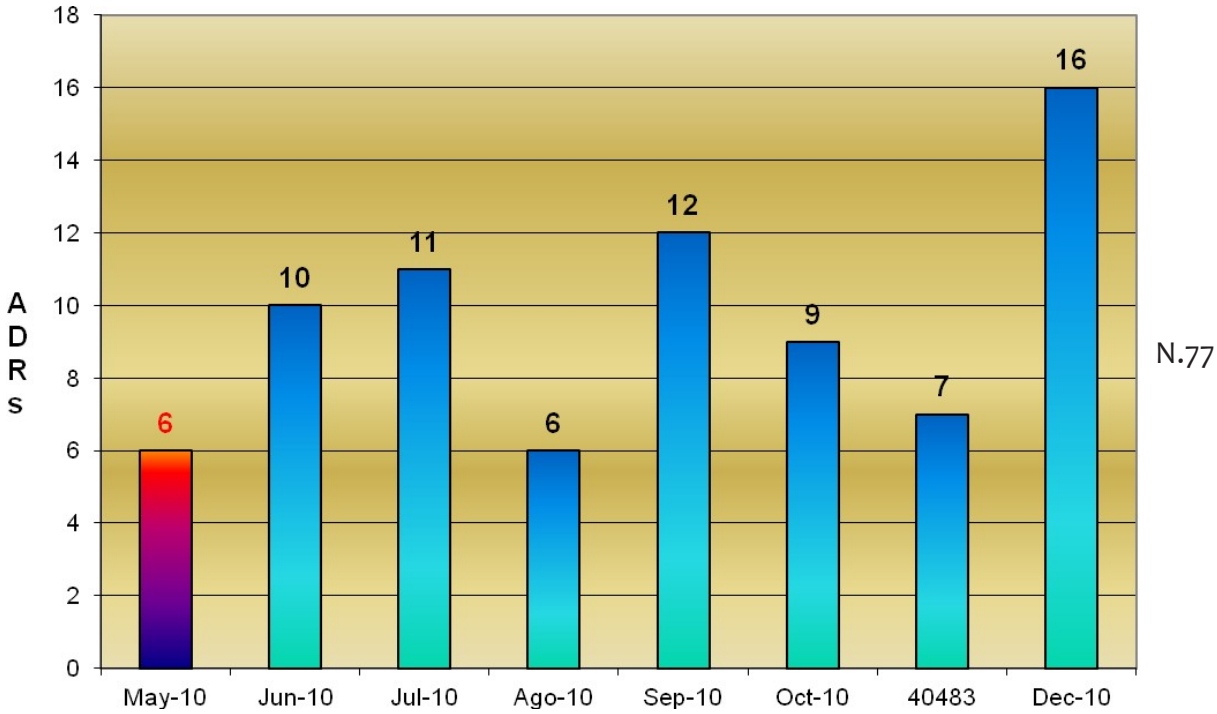

Fig. 2 Reports carried out from May 2010 to December 2010

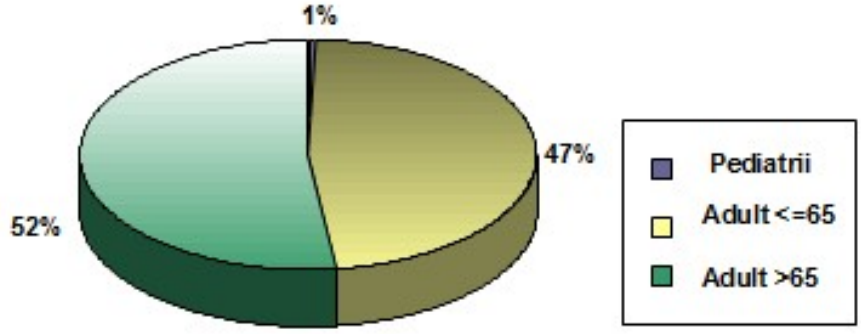

Fig 3 Reporting year 2011 classified by age

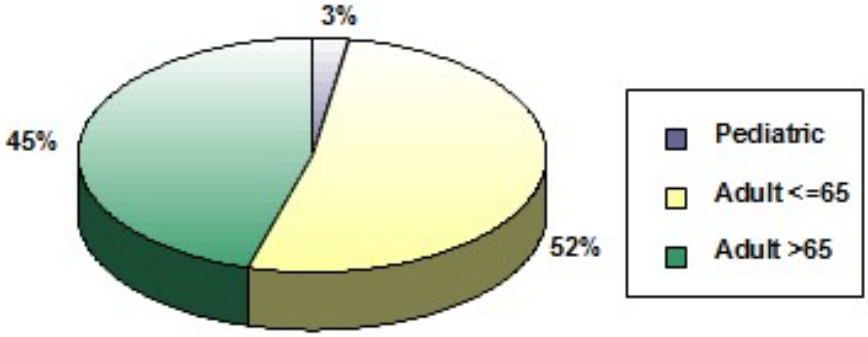

Fig.4 Reporting year 2010 classified by age

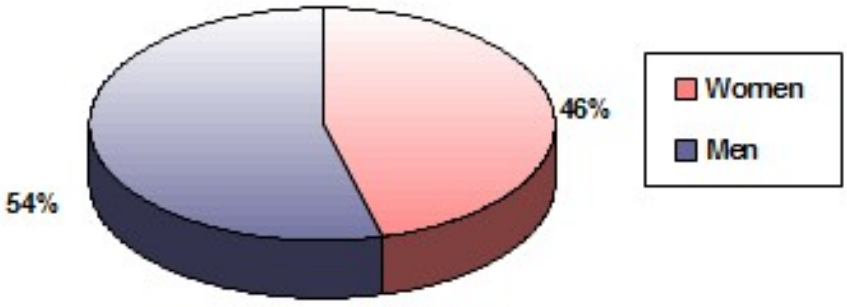

Fig 5 Distribution of reports based on gender

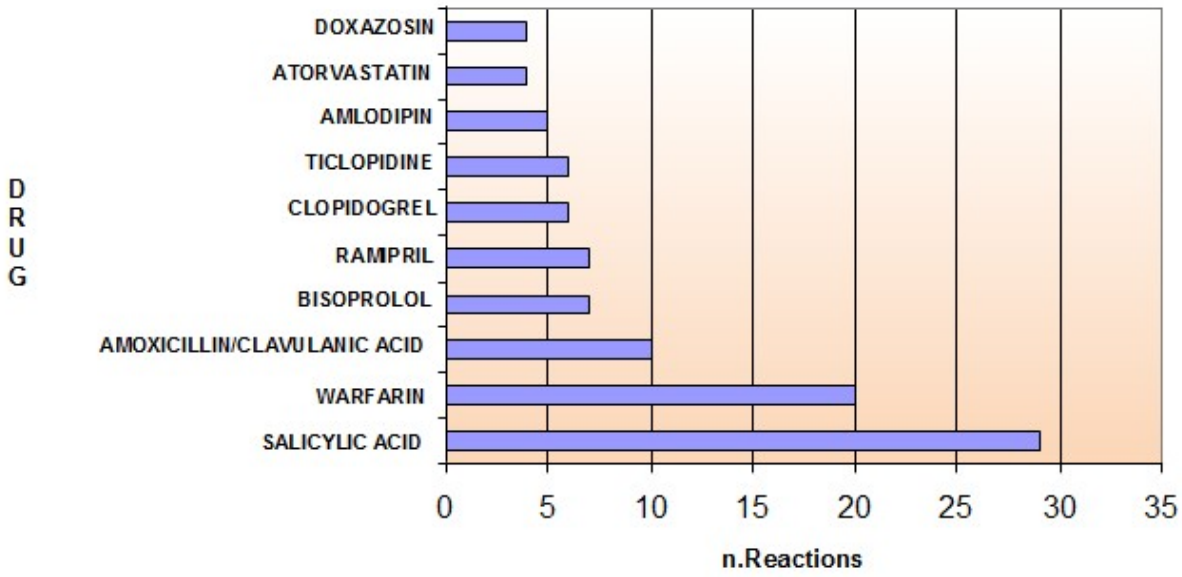

Fig.6 *Top ten active ingredients involved in ADRs*

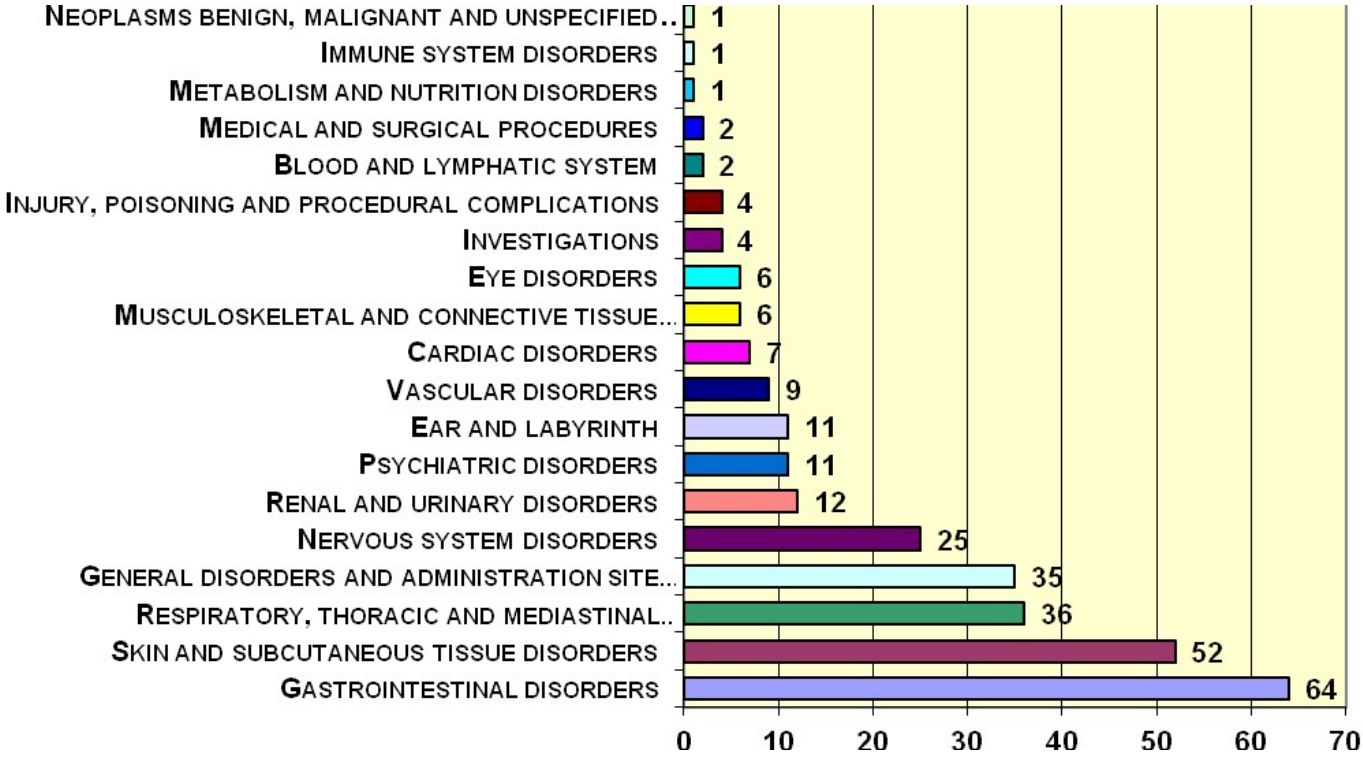

Fig.7 *Type of ADR / ADE reported classified according to the terminology System Organ Class (SOC)*

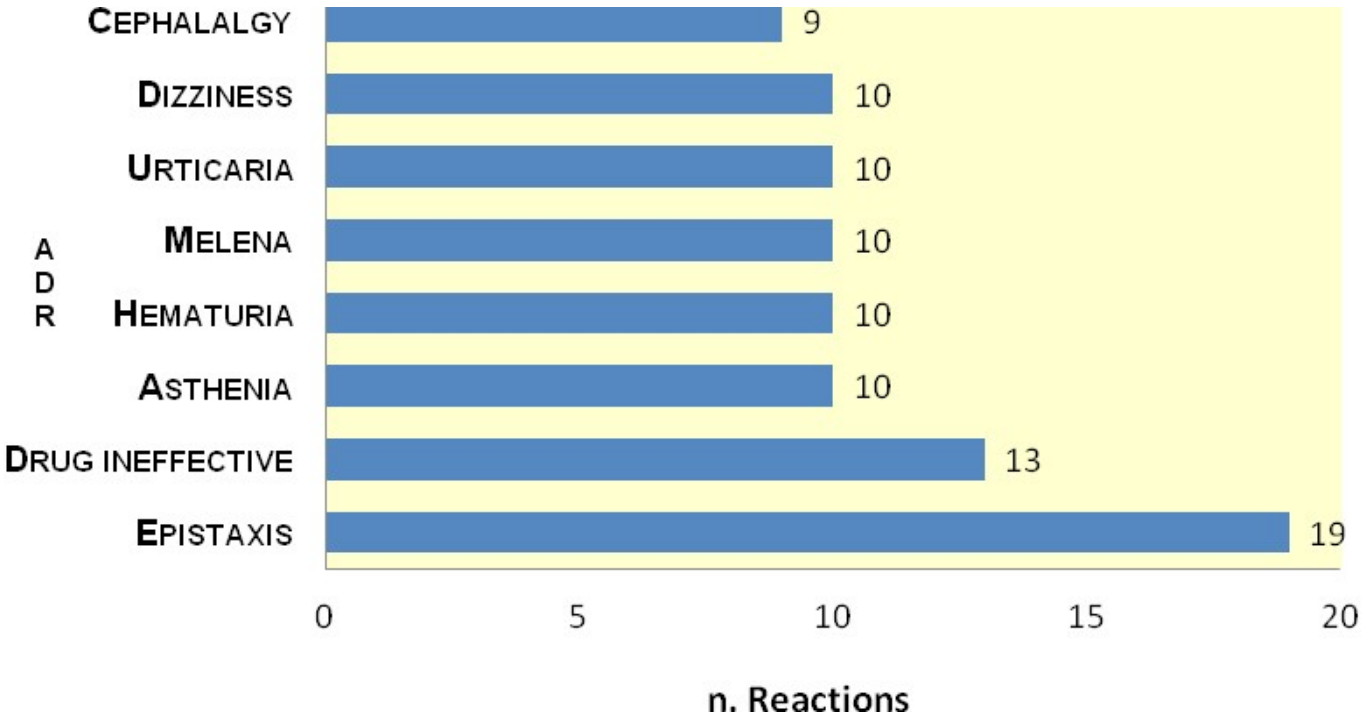

Fig.8 *Analysis of ADR through the Preferred Term*

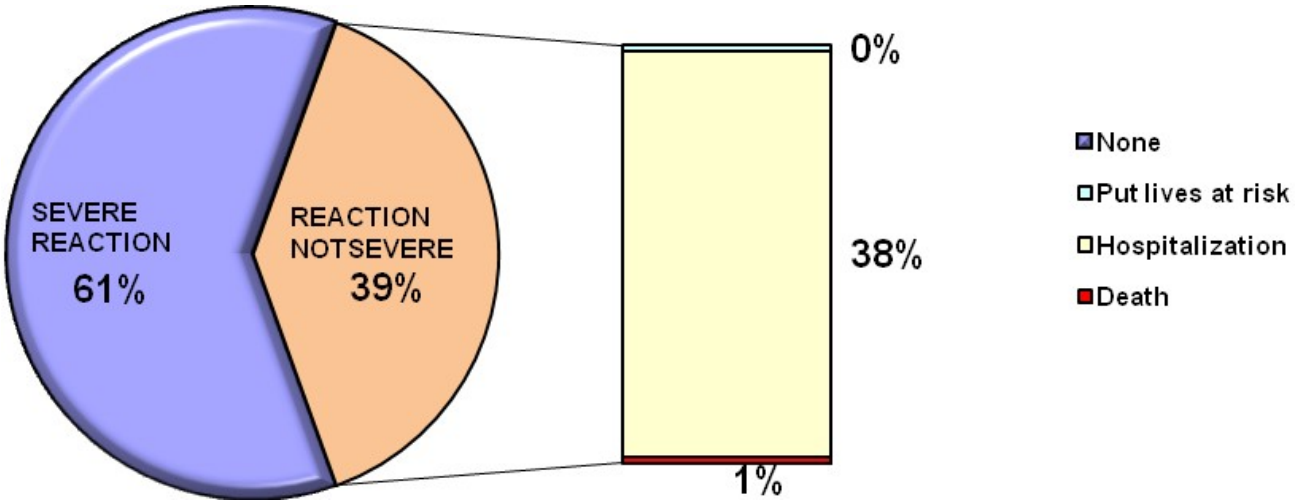

Fig.9 *Analysis of the severity of adverse reactions obtained*

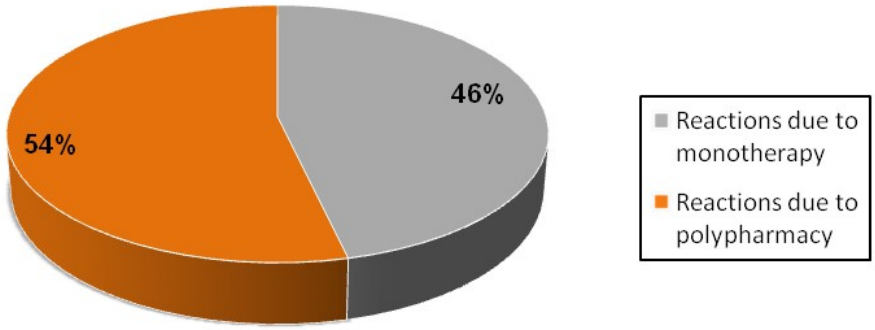

Fig.10 *Distribution adverse reactions mono-polypharmacy*

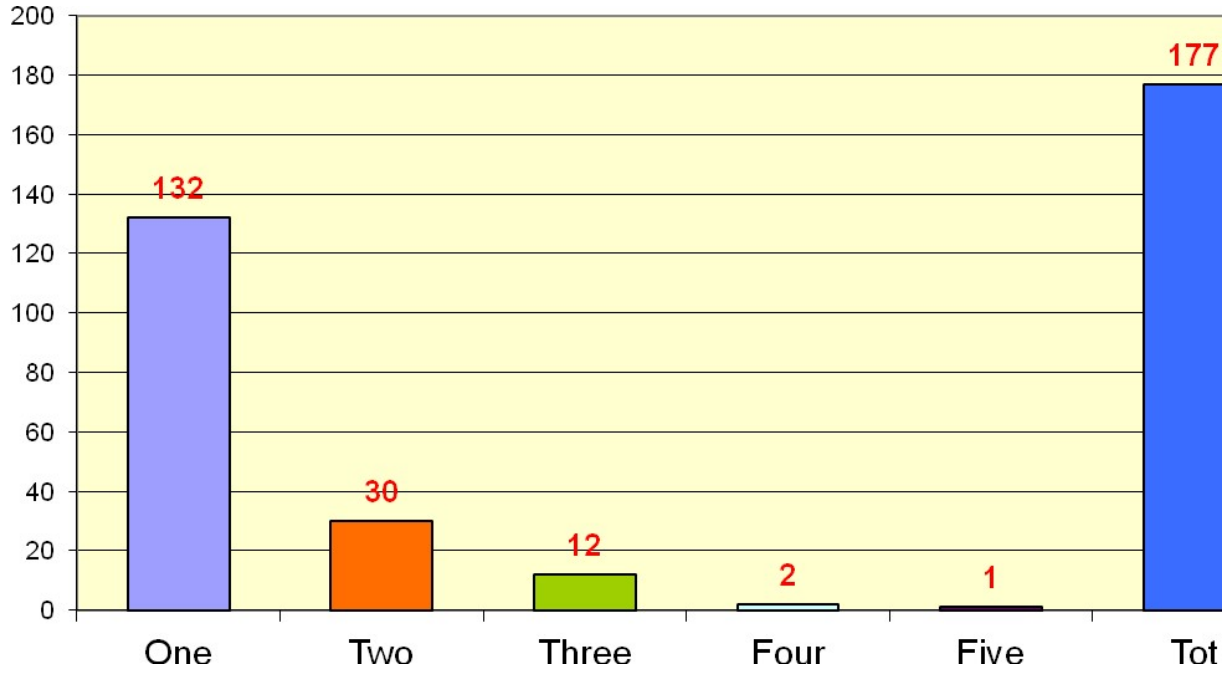

Fig.11 *Distribution for number of reactions suspected drugs*