




## Short Communication

### Clinical Adverse Events in Elderly Hospitalized Patients in a Medical Ward - a Prospective Study

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## ABSTRACT

### Article history

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**Introduction:** Studies to date describe between 3% to 50% of patients experiencing one or more clinical adverse event (CAE) during their hospital admission and many preventable. The aim of this prospective study was to determine the frequency of medical CAEs in a medical ward. Also the study aimed to compare data between patient age groups and determine the effect on length of hospital stay and mortality.

**Methods:** This is a prospective study, consulting patients' electronic clinical notes over 6 months. Every week, all patient electronic processes were reviewed, and CAEs noted. The episode was only noted if the episode was clearly labeled as a CAEs by the medical team in the patient's notes. If confounding factors were present, this episode was excluded. Patients were grouped by age; compared in terms of demographics, comorbidities, diagnosis at admission and readmission rate. Primary outcomes included mean length of stay and mortality.

**Results:** 62 episodes were studied, 14.8% of those admitted to hospital experienced a CAE. The most frequent adverse events included analytical alterations, anemia and blood loss, infection and altered state of consciousness. The most commonly implicated therapies were anticoagulants (23%) which lead to episodes of bleeding, anti-hypertensive and diuretics (17%) immunosuppressive therapy (16%) beta blockers (1%) and insulin (1%). Mean length of stay in hospital was 17 days in all groups, longer than the average length of stay of this medical ward which is 11 days. Mortality rate within one year of hospitalization was 30% in total, again significantly higher than the 10% mortality rate calculated for the same period on the ward.

**Conclusion:** This study demonstrates that CAEs are still far too common, probably underestimated, cause serious harm to patients and strains healthcare services further.

**Keywords:** Clinical Adverse Effect, Inpatient, Complication, Side Effect

### Introduction

According to the Harvard Medical Practice Study, a clinical adverse event (CAE) is defined as: "an unintended injury or complication that results in disability, death or prolonged hospital stay caused by health care management rather than by the patient's underlying disease process" (1) Studies to date describe between 3% to 50% of patients

experiencing one or more CAEs during their hospital admission and a large proportion is preventable (2-5).

Acute admissions are rising especially of older patients with multiple diseases and multiple drug therapies. The elderly with multiple co-morbidities have longer lengths of stay (6-7).

Older patients are at particular risk of CAEs. Ageing is associated with various physiological changes, which lead to variations in volumes of drug distribution, metabolism and clearance (8, 9). Alterations in blood circulation along with changes in body composition are the main cause of this. A reduction in liver size and a decrease in hepatic blood occurs in normal ageing, resulting in reduced drug clearance (9, 10). There is also decreased renal function which naturally alters the clearance of drugs which are eliminated by the kidney. Drug distribution is affected by alterations in body composition which are a part of healthy ageing (10). Older adults are often poly-medicated and suffer from comorbidity and frailty which further increases their risk of CAEs. CAEs increase morbidity and mortality as well as length of hospital stay.

The basic principle of medicine, according to the Hippocratic Oath is “first, do no harm”, and as such it is imperative to understand this subject and prevent it. According to literature, CAEs are largely under reported, leaving a gap in knowledge that needs further research.

The aim of this prospective study was to determine the frequency of medical CAEs in a medical ward as they are described in clinical notes as many are not reported as clinical incidents. Studies demonstrate CAEs are unreported, so there is a gap in knowledge regarding their circumstances. We aim to compare data between patient age groups and determine the effect on length of hospital stay and mortality.

## Methods

This is a prospective study, consulting patients' electronic clinical notes over 6 months. Every week, all patient electronic processes of inpatients currently admitted to the internal medical unit were reviewed by an investigator, and CAEs noted. The episode was only noted if the episode was clearly labelled as a CAEs by the medical team in the patient's notes. If confounding factors were present, this episode was excluded. Patients were grouped by age; group A < 65, group B 65-80, group C > 80 years and compared in terms of demographics such sex, autonomy status, medical comorbidities, diagnosis at admission and readmission rate. Primary outcomes included mean length of stay and mortality. Simple statistical analysis was done.

This study complies with the ethical principles of the Declaration of Helsinki. Considering no intervention was performed extraordinary to current standard of care, no informed consent was required.

## Results

Sixty-two episodes (equivalent to 61 different patients) CAEs were studied in the 6 months involved in 2017. A total of 411 patients were admitted to the medical ward studied in that period of time; which means 14.8% of those admitted to hospital experienced a CAE. Of those studied 34 were female patients, 28 were male patients with mean age of 74 years. Autonomy decreased with increasing age (100% independent of activities of daily living in group A vs 65% in group B and 47% in group C). Of the comorbidities studied, 30% of patients had arterial hypertension, 30% atrial fibrillation, 18% diabetes mellitus II, 17% ischemic heart disease and 17% cerebral vascular accident

An average of 54% of patients were readmitted within one year (61% A, 61% B, 47% C), with an average number of readmissions of 2.1 (1.8 A, 2.1 B, 2.2 C). In 56% of the cases, the adverse event was the cause of admission, for the remainder, the clinical adverse effect occurred after the admission to hospital for other reasons.

The most frequent adverse events included analytical alterations including acute renal failure and electrolyte imbalances (30% total, 30% A, 23% B, 39% C), anemia and blood loss (28% total 23% A, 23% B, 34% C), infection (18% total 38% A, 19% B, 0.5% C) and altered state of consciousness (15% total, 0% A, 19% B, 17% C).

The most commonly implicated therapies were anticoagulants (23%) which lead to episodes of bleeding, anti-hypertensive and diuretics (17%) which accounted for altered blood results such as acute kidney injury of electrolyte disturbances, immunosuppressive therapy (16%) leading to infection, beta blockers (1%) and insulin (1%) lead to episodes of altered consciousness, due to bradycardia and hypoglycemia.

Mean length of stay in hospital was 17 days in all groups (16 days A, 17.5 B, 18.3 C), which is considerably longer than the average length of stay of this medical ward which is 11 days. Furthermore, mortality rate within one year of hospitalization was 30% in total, again significantly higher than the 10% mortality rate calculated for the same period on the ward (10% A, 27% B, 43% C).

## Discussion

The patient's safety is imperative and therapeutic review is a medical obligation. Pharmacovigilance is increasingly important in view of the elderly and polymedicated population present in hospital settings, as they are particularly prone to side effects of therapies prescribed for them. This study highlights the extreme importance of regular medication review and adaptation to the needs of the patient with close monitorization of possible side effects of therapies instituted. In our small study the most commonly encountered CAE were bleeding episodes related to anticoagulation. Anticoagulants are prone to side effects due to their expectable risk of hemorrhage. However, the context in which they are used is very important to note, most of the episodes noted in this study occurred in elderly patients anticoagulated due to atrial fibrillation, which translates into a higher risk of stroke many fold, therefore these patients are medicated with anticoagulants long term. The difficulty of medicating a susceptible population, indefinitely with a potentially dangerous medication must be carefully pondered in a multidisciplinary team using available evidence and risk scores to make this complex decision (12). Many times, this may be a situation in which “you are damned if you do and damned if you don't”. Another commonly encountered CAE was acute renal failure and electrolyte imbalances that were attributed to antihypertensive medication and diuretics; this finding is understandably related to the high prevalence of cardiovascular disease in the aging population care for in inpatient units. The patients are medicated with antihypertensive medication and as their physiology changes with age, these are not reviewed. Studies show that a significant proportion of elderly patients remain on the same blood pressure medication despite signs of

hypotension. Common consequences of hypotension in older people include falls, syncope and fear of falling (13-15). However these episodes were not included in this study as they were not described in the patients notes as a direct side effect of a specific therapy, which is a clear limitation of this study, the same was the case with delirium. Immunosuppression is commonly used in this hospital's inpatient unit as it is linked to the hospital's autoimmune diseases and is a center for biological therapies. Beta-blockers and insulin lead to episodes of altered state of consciousness due to bradycardia and hypoglycemia respectively. Interestingly, no nosocomial or hospital acquired infections were included in this study although one could argue that they are CAEs linked to poor antibiotic stewardship. This is due to the inclusion criteria of this study, which required the description of the CAE in the patient's notes. The length of stay and mortality is increased in patients who suffer from adverse drug events, particularly with increasing age (16, 17) as was demonstrated in our small sample. This small study has many limitations, which include small study size, data that is limited to the description of adverse events in the clinical notes, and thus it is likely that this study will significantly underestimate the prevalence of adverse events. The data was analyzed by a single investigator, which raises the risk of potential bias. The strength of this study is highlighting that clinical adverse effects are still far too common, probably underestimated, cause serious harm to patients and strains healthcare services further. As CAEs are underreported, studies, which bring them to light, are necessary.

## Conclusion

This study demonstrates that CAEs are still far too common, probably underestimated, cause serious harm to patients and strains healthcare services further.

## Conflicts of interest

No conflict of interest reported.

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## Author's contribution

First author designed study, collected data and wrote article. Co-authors collected the data on patients, helped with data processing and reviewed and corrected the article.

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