Adverse events in a Tunisian hospital: results of a retrospective cohort study

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Abstract

**Background.** Despite the worldwide growing attention to patient safety, Tunisia has no data on the magnitude and consequences of hospital adverse events (AEs).

**Objective.** To estimate the incidence, nature and consequences of AEs and preventable AEs in a university hospital in Tunisia.

**Design and setting.** We opted for a two-stage retrospective medical record review of 620 inpatients admitted during 2005 based on the use of 18 screening criteria. Records were reviewed by a trained medical student, then by an expert physician when one or more criteria were identified.

**Main outcomes measures.** We determine the incidence, preventability and consequences of the AEs. Patients and admissions characteristics were also recorded.

**Results.** Among 620 inpatients, 62 inpatients experienced an AE with an incidence of 10% (95% CI [7.6–12.3]). Surgical/invasive procedures and therapeutic errors were the most common AEs (55 and 21%, respectively). Among the confirmed events 60% were judged to be highly preventable and 21% led to patient death. All ages and both genders experienced equal rates of AEs. However, patients who experienced these events were significantly more exposed to extrinsic risk factors (all surgical interventions and invasive procedures that were listed in the review form 2 of the questionnaire). Physician reviewers estimated that a total of 570 additional hospital days were associated with AEs.

**Conclusion.** This study confirms that preventable AEs were not rare in our context. They caused human harm and consumed a significant part of hospital resources. Thus, targeted interventions are needed.

**Keywords:** adverse events, medical errors, Tunisia

Introduction

Patient safety is receiving attention worldwide growing and is now being considered as a human rights issue. One important indicator of patient safety is the rate of adverse events (AEs) among hospital patients. AEs are defined as unintended injuries or complications caused by health care management, rather than by the patient’s underlying disease and that lead to death, disability at the time of discharge or prolonged hospital stay [1]. In some cases AEs can be considered as an unavoidable complication of the inpatient care. However, between 35 and 70% of AEs have been judged to be preventable [2–4]. These events cause death, disability or prolonged hospital stays and impose large financial costs on the healthcare systems [5].

In a variety of countries, hospital record reviews have revealed that between 2 and 21% of inpatients experienced one or more AEs [6]. These studies have offered important data on a critical aspect of hospital performance and provided impetus for the development of patient safety initiatives.

In Tunisia, there are few data on the prevalence of AEs. Some studies have focused on certain aspects, especially healthcare associated infections [7]. However, studying these infections does not provide an accurate estimate of the magnitude of the problem of AEs in hospitals.

This study was designed to describe the frequency, type and preventability of AEs for patients admitted in the university hospital of Monastir. It is part of a larger effort undertaken by the Eastern Mediterranean Regional Office of the
World Health Organization to Hospitals assess the problem of patient safety in six countries of the region.

Materials and methods

Definitions

In our study, we used the following definitions:

(i) *Adverse event*: injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. AEs may be preventable or non-preventable. Events were considered preventable if they occurred because recommendations for care were not followed.

(ii) *Intrinsic risk factors*: are the co-morbidities selected from the established list in the review form 1.

(iii) *Extrinsic risk factors*: they included the following:

- Surgical interventions;
- Endoscopy;
- Cardiac catheterization;
- Central line catheterization;
- Urinary catheterization;
- Mechanical ventilation.

Setting and sampling

The goal of our study was to estimate the prevalence of AEs in Tunisian hospitals. However, since the methodology has not been tested in this country, the study also had to assess the feasibility of medical record review as a tool to measure AE rates.

The study was carried out in the university hospital of Monastir (Tunisia). It is a general public university hospital, including 18 clinical departments. The total number of admissions was 20,000/year with a mean length of stay about 6 days [8].

We conducted a retrospective cohort study. The necessary data were retrieved from the medical records for hospital admissions that occurred during the year 2005. Medical records were selected by using stratified random sampling strategy. The sample size was proportional to the number of admissions in each of the 18 clinical departments. Assuming a rate of AE of 15% based on prior literature, we calculated that the study would require a sample of 544 patients to achieve a precision of ±2% (based on a 0.05 probability of a type 1 error) [1, 6]. In order to avoid the problem of incomplete records, we selected 620 medical files to ensure that we end up with 544 complete records.

The identification of AEs was made by adopting a 2-stage review process. First, a medical student reviewed the medical records to check for the presence of at least 1 of 18 screening criteria using the Review form 1 (Appendix 1). The 18 criteria were previously validated in the Australian study of AEs [1]. The criteria were not mutually exclusive and each patient could qualify for more than one criterion. Second, if one or more criteria were identified as present in the record by the medical student, the corresponding medical record was then reviewed independently by two expert physicians to judge whether an adverse event had occurred. The severity and preventability of each event was then assessed using Review Form 2. The preventability of an adverse event was assessed using a scale from one to six indicating the likelihood that an event could have been prevented. At ratings of at least four (i.e. more than 50% likelihood), AEs were classified as preventable [1].

Statistical analysis

The analysis of factors associated with AEs was based on appropriate statistical tests (Student’s t-test to compare means, non-parametric test when normality is not assumed and $\chi^2$ for the comparison of percentages). A P-value of ≤0.05 was considered to be statistically significant and Confidence Intervals were calculated at the 95% level. Relative risk for an AE was calculated to give the positive screening criterion. The value of the relative risks gives the best predictors for determining an AE.

The level of agreement between the two medical students was estimated by calculating a Kappa coefficient. On the basis of a sample of 60 medical records (1 of 10 of all study records) the Kappa score was 0.67 for the medical student review. The Kappa score for the level of agreement between the expert physicians was 0.82 and it was also calculated based on 1 of 10 of all positive screened records (10 medical records). In case of disagreement concerning the presence of an adverse event, the two physicians discussed the case in order to judge.

Results

Rate of AEs

All clinical departments ($n = 18$) in the university hospital of Monastir agreed to take part in the study. In the first stage of the study, 73 (11.7%) patients were assessed as positive for one or more screening criteria and were sent for detailed review by the physician reviewers. Table 1 reveals that the most common AE screening criteria identified were ‘Unplanned admission within 12 months’ (25.8%, RR = 11.8 95% CI [8.4–16.6]) and ‘Hospital acquired infection/sepsis’ (23.6%, RR = 13.9 95% CI [10.1–8.9]). Among patients with positive criteria, two patients out of three had only one criterion and a maximum of three criteria were registered during the hospital stay resulting in a total of 93 positive criteria.

The physician reviewers confirmed the occurrence of an AE for 62 of the 73 inpatients who had screened positive for a potential AE in the first stage yielding an AE rate of 10% (95% CI [7.6–12.3]) with an incidence of 4 events/1000 hospitalization-days.

AEs were more likely to occur in the intensive care unit than the medical and surgical units ($P<0.01$). Sixteen patients experienced an AE in medical units (2 events/1000
hospitalization-days) compared with 30 patients experiencing an AE in surgical units (5 events/1000 hospitalization-days). In Intensive Care Units, 30 patients were judged to have at least one AE by the physician reviewers (6.9 events/1000 hospitalization-days). Table 2 shows that 34 of the 62 patients (55%) had AEs associated with surgical and invasive procedures. Thirteen of the 62 patients with AE (21%) had therapeutic errors.

Table 3 shows examples including the development of a wound infection after surgical intervention (a surgical and invasive procedure event) and an example of complications occurring after use of a non-indicated treatment (therapeutic error).

Factors associated with the occurrence of AEs

The age and sex of patients with AEs did not differ from the age and sex of other patients (Table 4). The intrinsic risk factors (comorbid conditions) of patients showed no relationship with the occurrence of an AE ($P = 0.52$), but, the rate of AEs was significantly higher for patients with extrinsic risk factors ($P < 0.001$).

Among the 62 patients who experienced AEs, 47 (75.8%) were judged to have a prolonged hospital stay. This period was estimated on average as an additional 8 days in 60% of cases (Fig. 1). Overall, 570 additional hospital days were associated with the AEs in this study. Death was significantly higher in the group of patients with AEs compared with other patients (21 versus 8%, $P < 0.01$).

The experts considered 60% of the AEs to be preventable and preventability was statistically significantly different among specialities (45% in medical departments, 50% in...

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Table 1  Proportion of Review Form 1 records in which criteria indicative of AEs were identified

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Positive</th>
<th>Positive with AE (%)</th>
<th>Relative risk (RR)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unplanned admission</td>
<td>24</td>
<td>83.3</td>
<td>11.8</td>
<td>[8.43–16.62]</td>
</tr>
<tr>
<td>Hospital acquired infection/sepsis</td>
<td>22</td>
<td>95</td>
<td>13.9</td>
<td>[10.11–18.92]</td>
</tr>
<tr>
<td>Hospital incurred patient injury</td>
<td>10</td>
<td>90</td>
<td>10.3</td>
<td>[7.46–14.32]</td>
</tr>
<tr>
<td>Unexpected death</td>
<td>9</td>
<td>77.8</td>
<td>8.6</td>
<td>[5.61–13.34]</td>
</tr>
<tr>
<td>Unplanned transfer to intensive care unit</td>
<td>8</td>
<td>66.7</td>
<td>6.8</td>
<td>[2.95–15.71]</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>11.7</td>
<td>8.6</td>
<td>[6.61–11.09]</td>
</tr>
</tbody>
</table>

AEs, Adverse events.

Table 2  Classification of the AEs

<table>
<thead>
<tr>
<th>Type of AEs</th>
<th>Number of patients</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical and invasive procedures</td>
<td>34</td>
<td>54.8</td>
</tr>
<tr>
<td>Therapeutic errors</td>
<td>13</td>
<td>20.9</td>
</tr>
<tr>
<td>Diagnostic errors</td>
<td>8</td>
<td>12.9</td>
</tr>
<tr>
<td>Drug related AEs</td>
<td>4</td>
<td>6.5</td>
</tr>
<tr>
<td>Others</td>
<td>3</td>
<td>4.9</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 3  Selected examples of AEs

Preventable surgical event
A 15-year-old adolescent admitted in the surgical department for abdominal pain and fever. The diagnosis of acute appendicitis was admitted and the patient was urgently underwent surgical operation. Forty-eight hours after surgery patient developed a surgical site infection
A 20-year-old pedestrian injured in transport accident and hospitalized in intensive care unit. Patient developed a traumatic pneumothorax as a complication of a central line catheter

Non-preventable surgical event
A 70 year patient with a history of type 2 diabetes was admitted for gangrene in the left big toe. Ten days after surgery the evolution was unfavorable and patient was re-operated with foot amputation

Preventable therapeutic errors
A 34-year-old woman was admitted for a pelvic pain with 10 weeks amenorrhea. She was previously treated by antispasmodic drugs. Then, after admission a tubal pregnancy with rupture of (fallopian) tube was diagnosed

Non-preventable therapeutic errors
A 38-year-old carrier with antecedent of persistent allergic asthma is treated for respiratory infection for a correct duration. Patient readmitted for severe asthma
Occurrence of enterocolitis in a premature newborn 1 month despite the transition to enteral nutrition in accordance with protocols

382
surgical departments and 70% in intensive care unit; $P < 0.01$). An example of a preventable event was the development of pulmonary embolism after hip fracture (Table 3).

Most of the AEs (54%) led to impairment or disability, which was resolved within 6 months from discharge (Table 5). The main factors contributing to the occurrence of AEs were inadequate training and reporting (50 and 36%, respectively). Areas of attention were dominated by communication (66%) and education (37%).

### Discussion

The validity of screening AEs by the medical record review, and the validity of calculating the sensitivity and specificity have been analyzed in previous studies on retrospective reviews of medical records conducted in many countries [9]. These studies concluded that AEs can be detected with higher degree of accuracy when adequate information is available in medical records [9].

Our study showed that an estimated 10% of patients admitted to University Hospital of Monastir in 2005 experienced one or more AEs during the index admission, or during the preceding 12 months. In order to facilitate comparisons with previous studies, we followed a well-established protocol [1]. Even though the rate of AEs in our study was similar to studies using the same methodology [10, 11], it is likely that retrospective medical record review provides an underestimate of the true rate of AEs. Some events, e.g. adverse drug reaction, may be difficult to detect, as side effects from drugs may be very similar to the symptoms of diseases. Furthermore, in this study, some AEs occurred after the index admission and are not likely to have been detected using this method of review [12]. In addition to the above-mentioned reasons, our culture emphasizes verbal rather than written communication. Thus, some events may have occurred with out being recorded in the medical records.

With regard to the nature of AEs, several studies have noted that surgical procedures account for the most common types of AEs. Nearly half of these were considered preventable [11, 13, 14]. Indeed, surgical procedures are becoming more specialized and complex, exposing patients to considerable risk of complications and death [15]. In our study, we have also noted that the majority of AEs were related to surgical procedures (55%). Surgical care and its attendant complications represent a substantial burden of AEs worthy of attention from the public health community. The World Health Organization ‘safe surgery checklist’ led to a significant reduction in surgical mortality and morbidity rate in many countries and may be an important tool to reduce AEs in our context [16].

In several studies, the preventability rate ranges from 35 to 70% [2, 3]. In our study 60% of the confirmed AEs were judged to be preventable. The differences in rates of preventability may reflect variations in patient safety level and policies of the countries involved in these studies. However, rates of preventability may also be sensitive to the reviewer’s knowledge and the information available to the reviewer [17].

Previous and more extensive studies have compared the rate of AEs and preventable AEs among different types of hospitals and specialties [18]. In our study, we have found a significant correlation in AEs and their preventability according to specialties. Patients in ICU experienced AEs more than others specialties. This was probably related to the critical conditions and vulnerability of these patients and their exposure to many invasive procedures. However, this study was carried out in only one university hospital and does not allow subgroup analysis of the occurrence of AEs. Thus, this should be considered as a preliminary result and a starting point for understanding the incidence of AEs and the burden of injury resulting from AEs in Tunisian hospitals. More research is needed to establish the rate and consequences of AEs across the Tunisian healthcare system.

### Table 4 Patient’s characteristics and occurrence of AEs ($n = 62$)

<table>
<thead>
<tr>
<th>Patient’s characteristics</th>
<th>Total number</th>
<th>Number of adverse events</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 2 years</td>
<td>46</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>3–15 years</td>
<td>70</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>16–45 years</td>
<td>268</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>46–64 years</td>
<td>124</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>65 years and more</td>
<td>112</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>331</td>
<td>27</td>
<td>NS</td>
</tr>
<tr>
<td>Male</td>
<td>289</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Length of stay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$&lt; 7$ days</td>
<td>360</td>
<td>22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>$\geq 7$ days</td>
<td>260</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Extrinsic risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>173</td>
<td>44</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>No</td>
<td>447</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Intrinsic risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>207</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>No</td>
<td>413</td>
<td>51</td>
<td></td>
</tr>
</tbody>
</table>

### Figure 1 Relationship between the proportion of Review Form 1 positive and the length of stay (truncated to 25+ days).
AEs led to prolonged hospital stay, disability and death [6, 18]. In fact, most other studies have also revealed an increase in the length of stay as consequence of the occurrence of an AE [13]. Some studies reported high rates of AEs based on a forensic autopsy [19]. In our study most of the patients who experienced an AE recovered without permanent disability, but their AEs contributed to longer hospital stay or temporary disability. Indeed, a prolonged hospital stay may expose inpatients to the occurrence of an AE and conversely the occurrence of an AE may lead to prolonged hospital stay. It is difficult to attribute a cause and effect relationship between prolonged lengths of stay and the occurrence of AEs in this study. Although the permanent disability rate was low, the death rate was significantly higher in patients experiencing an AE.

The main gaps identified in our study by reference to the AEs contributory factors were the inadequate communication and training. In fact, several studies have confirmed the role of communication in reducing inpatient harm [20]. The part of training in the improvement of patient safety was also well known for both nursing and medical staff. In fact adequate training was associated with improvements in patient outcomes [21, 22]. In view of the substantial human and economic burden of AEs, hospitals should consider adopting a safety-oriented culture in daily practice.

**Conclusion**

This study is the first step to determine the magnitude of AEs and their consequences in our context. The results need to be integrated in a comprehensive patient safety program. The latter will address the priorities and translate them into a concrete patient safety action plan. The patient safety culture should be given a high priority as it represents an important cornerstone of any success and will facilitate positive benchmarking among teams in other hospitals and settings.

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**Appendix 1. The 18 review form 1 criteria**

1. Unplanned admission within 12 months prior to index admission.
2. Unplanned admission after discharge.
3. Hospital incurred patient injury.
4. Adverse drug reaction.
5. Unplanned transfer from general to intensive care.
6. Unplanned transfer to another acute care hospital.
7. Unplanned return to the operating room.
8. Unplanned removal, injury or repair of organ during surgery.
9. Other patient complications: (AMI, CVA, PE etc.).
10. Development of neurological deficit not present on admission.
11. Unexpected death.
12. Inappropriate discharge.
13. Cardiac/respiratory arrest, low Apgar score.
14. Injury related to abortion or delivery or neonatal complications.
15. Hospital acquired infection/sepsis.
16. Dissatisfaction with care documented in the medical record.
17. Documentation or correspondence indicating litigation.
18. Any other undesirable outcomes not covered above.

**References**


