



## Surveillance of adverse events in surgical department: An observational study

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### ABSTRACT

Adverse events (AEs) occur in health care and may result in harm to patients especially in the field of surgery. Our objective was to analyze AEs in surgical patient care from a nationwide perspective and to analyze the frequency of AEs that may be preventable. A total 98 patients were identified with AEs during April 2014 and March 2015. All AEs were categorized according to site, type, level of severity, and degree of preventability. We reviewed 532 patients' records and 98 (18.42%) were associated with AEs. A total of 93.87% of the AEs were considered probably preventable, over half contributed to prolonged hospital care or read-mission, and 4.7% to permanent harm. Healthcare acquired infections composed of more than one third of AEs. The majority of the most serious AEs composed of healthcare acquired infections and surgical or other invasive AEs. The incidence of AEs was 13% in patients 18 to 64 years old and 17% in > 60 years. Drug-related AEs were more common in patients being above 65 years. Urinary retention showed the highest degree of preventability. Patients with probably preventable AEs had in median 7.1 days longer hospital stay.

**Keywords:** Adverse events (AEs); preventability; Drug-related AEs; invasive AEs.

### INTRODUCTION

An Adverse Event (AE) can be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporarily associated with the use of a drug, without any judgment about causality or relationship to the drug. An adverse event can arise from any use of the drug (e.g., off-label use, use in combination with another drug) and from any route of administration, formulation, or dose, including an overdose. (Adverse Events, 2014)

Adverse events are unintended injuries or complications that are caused by health care management, rather than by the patient's underlying disease, which lead to death, disability at the time of hospital discharge or prolonged hospital stay. International retrospective case note review studies have demonstrated variable rates of AEs of between 3% and 17% among hospitalized patients. (DJ Williams, S Olsen, W Crichton, *et al.*, 2008)

Whilst some AEs are unavoidable, international studies have estimated that between 37% and 51% of adverse events are judged in retrospect to have been preventable. (Brennan T, Leape L, Laird N, *et al.*, 1991)

A recent study of 1006 admissions identified an ad-

verse event rate of 11% with only 5% of these incidents that resulted in patient harm being recorded by the routine reporting system. (Sari AB-A, Sheldon TA, Cracknell A, *et al.*, 2007)

As surgical healthcare seems to be more afflicted by AEs, and the number of surgical interventions is increasing, it was of interest to focus on the patients from the admissions that represented general surgical care.

The aim of the present study was to analyze the incidence and severity of AEs, to categorize and to evaluate if the AEs were preventable, and to analyze whether the panorama of AEs in patients above 65 years differed from those of younger age.

### METHODOLOGY

This study was conducted at Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa between April 2014 and March 2015. A total of 532 patients were screened of which 98 were identified with adverse events.

### Categorization of Adverse Events

An AE was categorized, as recommended in the Swedish National Manual for Record Review, according to type in 9 main groups; hospital-acquired infection, surgical and other invasive adverse event, urinary retention ( $\geq 500$  mL), failure in vital signs, drug-related adverse event, neurological injury, and others. The latter group included allergic reaction, hemorrhage not connected to surgery, thrombosis or emboli, skin or superficial vessel adverse event, anesthesia-related adverse event, postpartum or obstetric adverse event, and all

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other adverse event. An AE could only be categorized in 1 group. The choice was at the discretion of the review team. Severity of the AE was categorized in 5 groups based on the National Coordination Council for Medication Error Reporting and Prevention index.

- Category E: Contributed to or resulted in temporary harm and required intervention
- Category F: Contributed to or resulted in temporary harm requiring outpatient care, readmission or prolonged hospital care
- Category G: Contributed to or caused permanent patient harm
- Category H: Event that required lifesaving intervention required within 60 minutes
- Category I: Contributed to patient's death.

An AE was defined as being preventable or not using a 4-graded scale: the AE was "not preventable," "probably not preventable," "probably preventable," and "preventable."

#### Inclusion and Exclusions

An AE was defined as being preventable or not using a 4-graded scale: the AE was "not preventable," "probably not preventable," "probably preventable," and "preventable."

Records from patients of at least 20 years of age, with an in-hospital stay of at least 24 h throughout April 2014 and March 2015 were eligible for inclusion in a structured record review based on the GTT method.

#### Record Review

Surgical care was defined as care on or initiated from the surgical ward. All surgical patients in the review did not undergo surgery. Some were, for example, admitted as emergency cases for observation or due to postoperative complications not requiring surgery. Whether or not the patient underwent a surgical procedure was not recorded in the study. The average length of stay (LOS) for patients with or without AEs was noted.

#### Statistical Analysis

Demographic data are presented as median (range). Comparison of proportions between groups was made using the Fisher Exact Test. Confidence intervals were calculated using normal distribution approximation. A P value <0.05 was considered significant. All statistical calculations were made using SPSS Version 22.

#### RESULTS

A total of 532 surgical patient records were reviewed in the hospital of which 98 were identified with AEs. A total of 37.75% of the patients were women and 62.24% men (**Figure 1**). The median (range) age for women was 19 (40 - 50) years and 11 (50 - 60) for men. (**Figure 2**).

#### Frequency of Adverse Events

One or more AEs were identified in 12 out of the 98 patients' records (12.24%). A total of 98 AEs were identified in these 532 records and 92 of the 98 (93.87%) were classified as "probably preventable" or "preventable". The incidence of AEs was 13% among patients 18 to 60 years and 17% among those aged above 60 years ( $P < 0.001$ ). Men were significantly more often affected by an AE than women, 62.24% and 37.75% respectively ( $P > 0.001$ ).

#### Type of Adverse Events

"Hospital-acquired infections" and "surgical and other invasive complications" were the most common AEs in surgical care accounting for more than half of the admission with AEs. Among the patients affected by AEs, patient's above 60 years of age were more often affected by drug-related AEs, and less often by surgical complications. There was no other difference in types of AEs between men and women.

Postoperative wound infections were the most common among hospital-acquired infections. Among these, patients above 60 years of age were more often affected by a postoperative wound infection, whereas urinary tract infections were more common in the older age group.

#### Severity and Preventability of Adverse Events

The least severe AEs (Categories E and F) accounted for 26.53% and 21.42%, respectively, of all AEs. The more severe AEs, (Categories G, H and I) accounted for 5.10%, 12.44%, and 0%, respectively, of AEs. (Table-1) Almost half of the AEs that contributed to outpatient care, readmission or prolonged hospital stay (Category F) were hospital-acquired infections. (Figure-3) The majority of AEs in Categories G and H were surgical AEs, and in Category I hospital-acquired infections or surgical AEs. There was no difference in distribution of AEs among the Categories E to I. The majority of AEs in all severity categories were regarded as "probably preventable" or "preventable".

#### Length of Stay (LOS)

Patients without any AE had an average hospital stay of 5.7 (7.1 SD) days. For patients with non-preventable AE and patients with "probably preventable" or "preventable" AE, the corresponding average LOS was 11.0 (11.2) and 12.8 (13.5) days. The same pattern was seen for the subgroup "hospital - acquired infection" where the mean LOS for patients with "non-preventable" AEs was 9.1 (7.5 SD) days and for "preventable" AEs 10.9 (9.4 SD) days. LOS was significantly increased in admissions of patients with an AE compared with admissions without an AE regardless of age group. Patients above 60 years of age without an AE had a longer LOS than younger patients, but there was no difference between the 2 age groups in admissions with AEs.

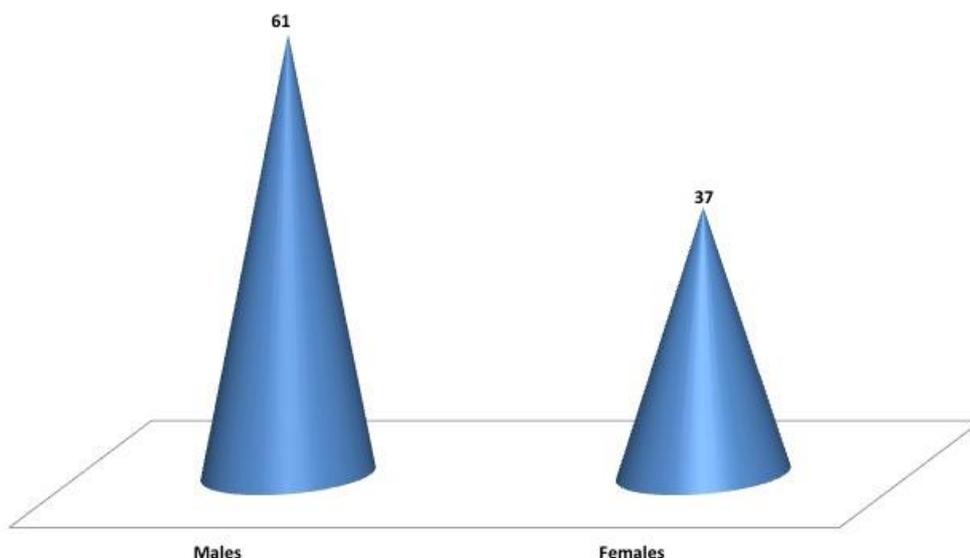


Figure 1: Gender Wise Distribution

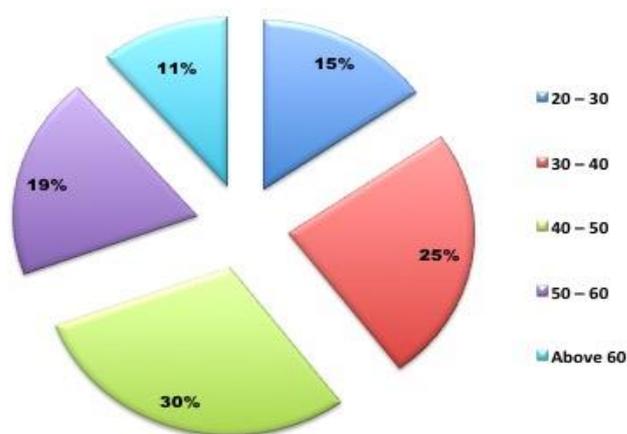


Figure 2: Age Wise Categorization

**DISCUSSION**

This is a survey describing the panorama of AEs in surgical department of RIMS, Kadapa. 18.42% (98) of all 532 patients included were affected by an AE. Of the AEs, 62.5% were regarded as “probably preventable” or “preventable”. More than 50% of the AEs contributed to readmission or prolonged hospital care, 4.7% contributed to permanent harm. The most common AE was hospital-acquired infection, affecting more than 40% of admissions with an AE. Urinary retention was the AEs with the highest degree of preventability. The incidence of AEs was 13% in patients 20–50 years old and 17% in above 65 years, and drug-related AEs being more common in the elderly.

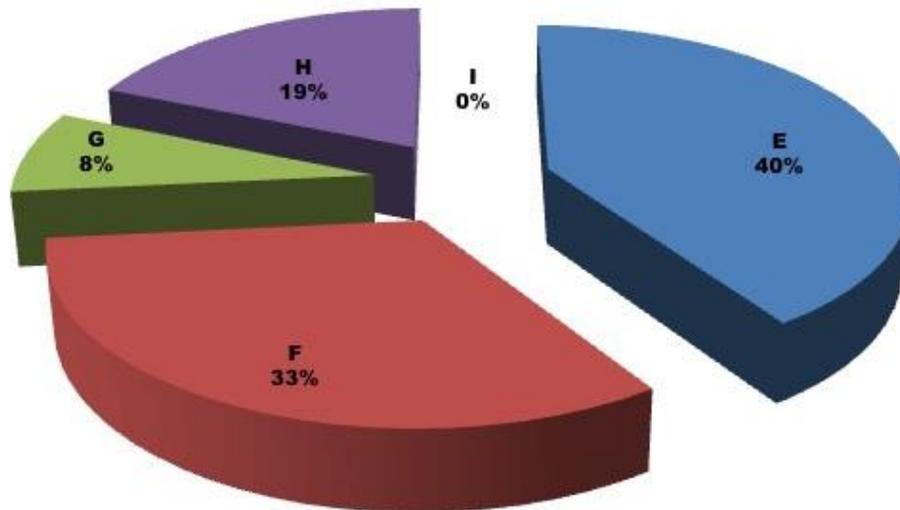
Comparisons between studies dealing with AEs after surgery must be made carefully, as there are often differences in definitions, methods used to compile data, and classification of AEs. Our review was based on the Global Trigger Tool methodology, and included triggers specific for surgical and intensive care. We

found an AE incidence of 15.4%, which is similar to other studies. (Anderson O, Davis R, Hanna GB, et al., 2013) found comparable numbers of minor and fatal outcomes, 52.5% and 3.6%, respectively. Similar figures were reported by (Griffin FA, Classen DC, 2008) with 14.6% of patients having an AE of which 44% caused temporary harm (Category E) and 2.9% death (Category I).

The rapid development of surgical techniques has stretched indications for surgery, and surgical interventions are increasing also in older and fragile patients. In a recent large study (Adams PD, Ritz J, Kather R, et al., 2014), the frequency of harmful AEs increased with age and the AEs were predominantly infection, renal failure, and deep vein thrombosis. Our study also indicates that older patients are more often affected by AEs, although we did not find any increase in infection rate with age. Postoperative wound infections were even lower in the older age group. Instead, at age above 65 years the incidence of drug-related AEs increased. Patients over 65 years admitted to hospital for

**Table 1: Severity and Preventability of Adverse Events**

S.No	Category	Number of events	Percentage
1.	E	26	26.53%
2.	F	21	21.42%
3.	G	5	05.10%
4.	H	12	12.44%
5.	I	0	0%

**Figure 3: Frequency of Adverse Events**

any reason, have a 4 times higher risk of drug-related AEs than the general adult population. (Beijer HJ, de Blaey CJ, 2002) From our results, there seems to be an increased risk also among surgical patients. Our results indicate a lower incidence of surgical complications for those aged above 65 years. This might be explained by the fact that a lower proportion of these patients underwent a surgical procedure in connection with hospitalization.

The most effective strategies to reduce surgical harm identified in a systematic review were the employment of surgical safety checklists and the adherence to care pathways. (Howell A-M, Panesar SS, Burns EM, et al., 2014) The World Health Organization "safe surgery checklist" used in the operating theatre can reduce mortality and morbidity after surgery. (Haynes AB, Weiser TG, Berry WR, et al., 2009, Bliss LA, Ross-Richardsson CB, Sanzari LJ, et al., 2012) It was introduced in Sweden 2009 and has become widely spread. SURPASS (SURgical Patient Safety System), a comprehensive checklist that includes the time from decision to operate until outpatient visit after surgery, almost halved the incidence of complications and mortality after surgery. (De Vries EN, Prins HA, Crolla PM, et al., 2010) The translation, adaption, and pilot testing to Swedish conditions started in 2013.

The principles of enhanced recovery after surgery (ERAS) can reduce overall complications (Spanjersberg WR, Reurings J, Keus F, et al., 2011) and are embedded in the safe abdominal surgery project. Initiatives to

stop smoking before surgery (Grønkjær M, Eliassen M, Skrubbeltrang Skov-Etterup L, et al., 2014, Thomsen T, Villebro N, Møller AM, 2014) are ongoing and the effects of alcohol cessation (Eliassen M, Grønkjær M, Skrubbeltrang Skov-Etterup L, et al., 2013) are gaining interest.

Surgical AEs have a significant negative effect on post-operative quality-of-life and in some cases this effect persists for several years. (Bouras G, Burns EM, Howell A-M, et al., 2014) Efforts to improve patient safety must be intensified and target the leading causes of patient harm.

Hospital-acquired infections were those most common in our study. Another recent study identified almost 40% of surgical AEs as being infections. (Zegers M, de Bruijne MC, de Keizer B, et al., 2011) According to our protocol an infection with onset after 48 hours hospitalization was characterized as a hospital-acquired infection. Anderson et al found that non-operative errors were more frequent than errors in surgical technique. (Anderson O, Davis R, Hanna GB, et al., 2013) Non-operative AEs included errors in monitoring, treatment, and diagnostic procedures. In another study; focusing on risk assessment on the surgical ward. (Anderson O, Brodie A, Vincent CA, et al., 2012)

We estimated that more than 60% of AEs were "probably preventable" or "preventable", which is high. This was also found in other recent studies indicating 30% to 40% of AEs as being "preventable". (Anderson O, Davis R, Hanna GB, et al., 2013; Zegers M, de Bruijne

MC, de Keizer B, *et al.*, 2011) Seventy percent of the AEs in our study, however, were graded as “probably preventable” or “probably not preventable”, which illustrates the difficulties in strict assessing AEs in a retrospective survey of patients notes.

AEs are associated with an increase in LOS and thereby cost. (Andrews LB, Stocking C, Krizek T, *et al.*, 1997; Thomas EJ, Studdert DM, Newhouse JP, *et al.*, 1999) We found no difference in the increase in LOS in patients affected by an AE between the two age groups.

## CONCLUSION

In one of the largest recent nationwide studies covering all surgical departments, we have found that AEs are common in surgical care and the majority of events are probably preventable. Older patients seem more vulnerable and preventing drug-related adverse events is important among these patients.

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