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Identification of adverse events in orthopaedic practice : A step towards quality care

Mir SADAT-ALI, Abdallah S. AL-OMRAN, Mohammed Q. AZAM

Fom King Fahd University Hospital, AlKhobar, Saudi Arabia

Adverse Events (AE's) are unintended injuries or complications resulting in death, disability or prolonged hospital stay, that arise from deficiency in the health care management. The objective of this retrospective study is to assess the incidence of AE's, its impact on patients in terms of morbidity and mortality. All orthopaedic patients admitted to the male orthopaedic ward between 1st August 2010 to 31st July 2011, were included. Any such event that occurred in the index admission or within 30 days of discharge was included in the present study. Identification of AE's was based on the written records in case-sheet and analysis of the computer data. When clarification was required, the issue was discussed with involved physicians and nursing staff and the patient was contacted by telephone. Presence of one or more of the 12 predefined screening criteria constituted the screening process.

Fifty three (10.83%) of 489 patients studied during the study period experienced a total of 101 AE's (20.65%). Majority of AE's occurred in trauma patients admitted from the emergency room – 35 (66%) – and from the outpatient department (OPD) – 30 (56.6%) –. Of the 101 AE's, 74 (73.1%) were estimated to have a high degree of preventability. On assessing the impact on patients, residual morbidity was noted in 1 (1.88%) patient. There was no mortality as a result of AE.

AE's occurred due to non-adherence to existing protocols in totality. AE's resulted in increased morbidity of the patients, longer hospital stay, multiple surgeries and economic burden to the hospital. Identifying AE's provides the foundation and driving force for initiative to reduce morbidity. It also helps to evolve specific risk reduction strategies and self auditing and thereby improve quality care of patients.

Keywords : adverse events ; orthopaedic surgery ; quality care.

INTRODUCTION

Adverse events are unintended injuries or complications that are caused by health care management, rather than patients' underlying diseases, which lead to disability, impairment and prolonged hospital stay. Determining the true burden of AE's are important so that safety measures are planned to prevent frequently occurring unwanted and undesirable events. In a historic report "To Err is Human"

■ Mir Sadat-Ali, MBBS, MS, FRCS, D Orth., Professor of Orthopaedic Surgery.
■ Abdallah S. Al-Omran, MBBS, SSC (Ortho), Associate Professor of Orthopaedic Surgery.
■ Mohammed Q. Azam, MBBS, MS, Assistant Professor of Orthopaedic Surgery.
Department of Orthopaedic Surgery College of Medicine, University of Dammam, Dammam and King Fahd Hospital of the University, Al-Khobar, Saudi Arabia.
Correspondence : Prof. Mir Sadat-Ali, PO BOX 40071, King Fahd Hospital of the University, AlKhobar 31952, Saudi Arabia. E-mail : drsadat@hotmail.com

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from the Institute of Medicine (IOM) in the USA the authors observed that 44,000 to 98,000 people die each year as a result of preventable medical errors (*10*). Following this there were landmark studies conducted in many developed countries in an attempt to identify adverse events and their impact. Studies have reported substantial rates of AE's in the United States and Australia, ranging from 3.7% to 16.6% (*4,7,9,13,21*). Neale *et al* (*13*) further reported 705 of AEs lead to short-term disability but in 7% disability was permanent and in another 14% the AE contributed to death. Patient safety is receiving growing attention worldwide, thanks to numerous legal cases and media stories that have highlighted the consequences of undesired events.

Adverse events cost hospitals billions of dollars yearly. Bates *et al* (*5*) reported that AEs cost up to $5.6 million each year per hospital. Studies from Australia have reported that direct hospital cost of AEs is $483 million and $900 million per annum (*15*). The figures recently jumped to an estimated cost of $17 billion to $29 billion per year (*20*). Health care services in Saudi Arabia has increased to phenomenal heights in the last few decades but the assessment of quality of care was not given its due importance. However, a review of English language literature did not yield any concrete reports on AEs in Saudi Arabia and in the Gulf countries. The objective of this study is to assess the incidence of AE, the place of its occurrence, its impact on patients in terms of morbidity and mortality, and recommend ways to improve quality care and formulate safety measures.

MATERIAL AND METHODS

In this retrospective study all orthopaedic patients admitted between 1st August 2010 to 31st July 2011 were included. Identification of AE's was based on the written records in case-sheet and analysis of the computer data. When clarification was required, the issue was discussed with the involved physicians and nursing staff and the patient was contacted by telephone. Presence of one or more of the 12 predefined screening criteria given in Table IA constituted Stage 1 screening process. This stage of screening process was completed by all the authors separately. The place of occurrence of this AE was recorded and designated to either of the three following stages : A. Patient admission to shifting to ward or operation theatre. This included any delay due to missed or improper diagnosis, lack of proper planning and its execution, delayed consultation, operation theatre unavailability, lack of ICU bed or inability to arrange blood or blood products). B. occurrence of AE in the ward up to discharge. This included bedsore, delayed consultations, pin-track infections etc. C any AE happening in the operation theatre. This category recorded whether per-op complications were due to lack of pre-op planning, compromise in implant selection, not using image intensifier or part of the surgical procedure.

Table IA. — Screening criteria for the identification of AE

1	Unplanned Admission / Readmission
2	Delay in referral (to other dept, or other specialist hospital)
3	Incorrect / missed diagnosis causing return to operation theatre within a week
4	Complication during surgery (including anaesthesia related)
5	Hospital complication (infection, bed sore etc)
6	Surgery related complication
7	Missed metabolic problem causing delayed surgery
8	Inability to stop anti-platelet drugs leading to postponement of cases
9	Postponement of case due to improper time/ space management/ blood arrangement etc
10	Inadequate assessment from OPD
11	Drug reaction/ related
12	Death

Table IB. — Scale to judge causation, preventability and severity of Adverse Events

Scale of Causation	i. Little or no evidence ii. Slight to moderate evidence iii. Not likely (less than 50/50, but close call) iv. More likely (more than 50/50, but close call) v. Moderate to strong evidence vi. Certain evidence
Scale of Preventability	i. Virtually no evidence of preventability ii. Slight to moderate evidence of preventability iii. Preventability not quite likely (less than 50/50, but close call) iv. Preventability more than likely (more than 50/50, but close call) v. Strong evidence of preventability vi. Certain evidence of preventability
Scale to assess physical disability / Impairment	i. No impairment ii. Minimal impairment or recovery in one month iii. Moderate impairment or recovery in 1-6 month iv. Moderate impairment or recovery in 6-12 month v. Permanent impairment, degree of disability < 50% vi. Permanent impairment, degree of disability > 50% vii. Death

In Stage 2 screening, the authors together re-analyzed the data to understand if the AE recorded falls within the predefined definition. The severity of damage occurred was evaluated using a six point scale of causation suggested by Brennan *et al* (*6*) (Table IB). This recommends that a score of 4 or higher will be regarded as AE. Now to assess preventability of AE irrespective of the cause, the scale suggested by Wilson *et al* (*20*) is used, in which any score of 4 or more means highly preventable. Finally, the severity of AE were graded on a 7 point scale in which a score of three point or more will indicate a major AE (*8,21*).

RESULTS

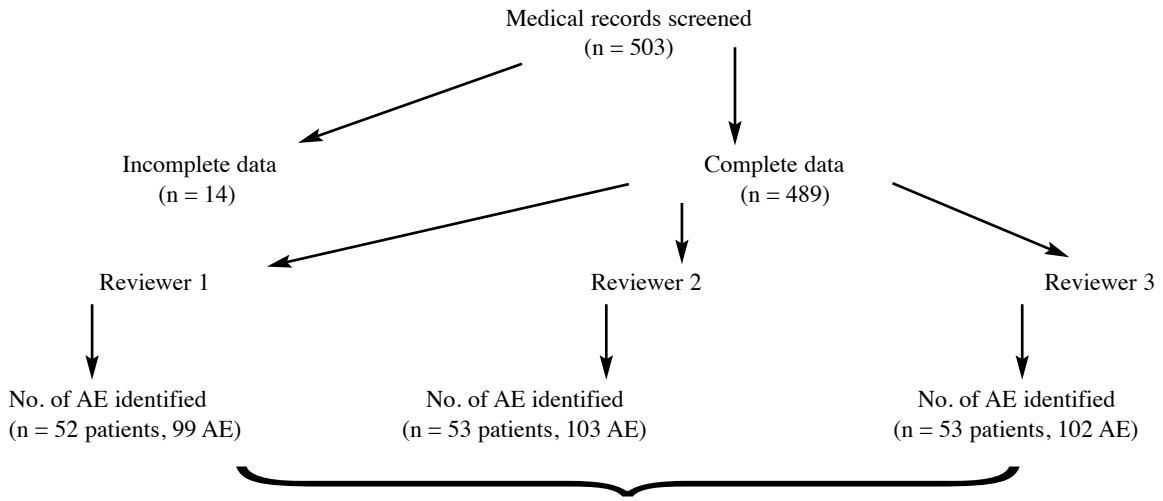
Fifty three (10.83%) of 489 patients studied during the study period experienced a total of 101 AEs (20.65%) (Table II). Majority of AEs occurred in trauma patients admitted from emergency room 35 (66%) and from outpatient (OPD) 30 (56.6%). AE in elective trauma patients were 7 (13.2%)%, in spinal surgery patients were 5 (9.4%), in arthroplasty patients were 3(5.6%) and in sports injury cases were 1 (1.88%) respectively Of the 101 AEs, 74 (73.1%) were estimated to have a high degree of preventability. Majority of adverse events occurred in Operation theatre 69 (68.3%), followed by Emergency ward 27(26.7%). On assessing the impact on patient, residual morbidity was noted in 1 (1.88%) patients, disability more than 50% was seen in 1 (1.88%) and rest of the patients recovered well without any morbidity (Table III). There was no mortality as a result of AE. Figure 1 gives the flow chart and the screening process and final results.

Table II. — Site, type and number of AEs

N° of records reviewed	489
N° of Patients with AE	53 (10.8%)
N° adverse events detected	101
Preventable (% of events)	74 (73.1%)
Elective	23 (43.4%)
Emergency	30 (56.6%)
Trauma	35 (66%)
Spine	5 (9.4%)
Arthroplasty	3 (5.6%)
Elective Trauma	7 (13.2%)
Delay in Surgery	6 (11.3%)
Admitted and Discharge	9 (16.9%)

Table III. — Impairment/Disability, Causative Factors of AEs

Degree of physical disability/ impairment	Number of adverse events	Adverse events due to negligence
None	59	32
Minimal impairment, or recovery in one month	21	7
Moderate impairment, recovery in 1-6 months	10	3
Moderate impairment, recovery in 6-12 months	6	1
Permanent impairment, degree of disability < 50%	1	1
Permanent Impairment, degree of disability >50%	0	–
Death	0	0
Unable to determine	4	0



Notes : a. preventable AE 74 (73.1%)
b. 72 AE occurred in trauma patients, 5 in spine surgery, 3 in arthroplasty cases and 1 in a sports injury patient
c. 51 patients recovered without any residual disability within 6 months, 1 patient had disability < 50% and 1 had disability > 50%.

Fig. 1. — Flow Chart of the final result

DISCUSSION

The prevalence of adverse events (AE) in our study was 10.83%. Of these 73.1% were preventable. Most of AE in trauma patients occurred in the emergency room where either life threatening injuries delayed identification of orthopaedic injury or decisions based on inappropriate and inadequate views proved the culprit. Standard protocols already exist like second-look physical examination after optimizing patient's condition within 24 hours. However available records showed these rules were not adhered to in totality. Other major causes of AE were in the operation theatre in the form of protruding intramedullary nails, placement of locking bolts outside the designed hole, compromise in implant selection or arranging implants. All were preventable by appropriate use of image intensifier and

preoperative planning. On reviewing literature on incidence of AE, a Swedish study reported AE in 15% of all orthopaedic admissions (*19*). Neale *et al* (*13*) observed that in medical wards the incidence was lower in comparison to surgical units like orthopaedic surgery, where it was 9.7% AEs. A recent report of Zegers *et al* (*22*) found that surgical AEs occurred in 3.6% of Dutch hospital admissions and represented 65% of all AEs. Schilling *et al* (*17*) reviewed the data from the American College of Surgeons National Surgical Quality Improvement Program and found that only ten procedures accounted for 70% of the adverse events and in post trauma hip surgery AEs were 19%, followed by knee (18%) and hip arthroplasty (11%), making some AEs which could be prevented easily if enough attention was given for the patient safety. Authors firmly believe the comparison may be difficult because of difference in inclusion and exclusion criteria, difference in defininig AE and finally difference in design of other studies. Michel *et al* (*12*) reported that AEs per 1000 hospital days in University hospitals was 8.6% compared to 7% in the private hospitals. Baker *et al* (*4*) found higher numbers of patients with AEs in teaching hospitals than in small or large community hospitals. We have no comparative data of private hospitals in the region hence comments on this issue would be incorrect. Wrong site surgery is a major AE in any patient's life causing psychological, physical and economic loss to the hospitals. Robinson and Muir (*16*) reported that in the year 2006 to 2007, the number of wrong-site surgeries in England and Wales was 292 cases and orthopaedic surgery accounted for 87 (29.8%) of these cases. In our review we did not encounter any wrong site surgeries.

Identifying risk factors for AE's constitute a crucial first step towards their prevention, an important goal of improving quality assurances. In United States and Australia these findings / analysis have provided the foundation and driving force for initiative to reduce harm to patients and to make more efficient use of expensive hospital resources. In US there are organizations which have taken the front seat in improvement of patient safety and prevention of AEs. The Surgical Care Improvement Project (SCIP) as well as the American College of Surgeons Surgical Quality Alliance and National Surgical Quality Improvement Program (ACSNSQIP) have played important roles in highlighting the issue of patient safety and in turn the AEs (*1-3,18*).

Being a retrospective study it has inherent weakness of hindsight bias and possibility of not recording of all such events. However in the absence of published literature from this region and paucity of literature in general the study is an attempt to convince the health care providers that it is time to be self critical to our own work to minimize any such AE and thereby reduce suffering of patients and curtail preventable hospital expenditure. We conclude that more prospective study on the subject is required that would provide more reliable information on the numbers, types and costs of adverse events in our system. This would allow the administration to realize the high incidence of AEs, their risk factors and preventability, so as to evolve specific risk reduction strategies and self auditing, and possible joining a national organization for patient safety guidelines.

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