Surgical Never Events: A Retrospective Study in Iranian Hospitals

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Abstract

Background: A never event is an unintentional injury or complication that increases the length of hospital stay, disability at the time of discharge, or death due to improper health care management. Adverse events are potentially preventable in terms of patient injury, increasing the length of hospital stay, and increasing health care costs. Due to the importance of the subject, the present study was conducted to investigate the factors related to adverse surgical events in Iranian hospitals in 2020.

Methods: This cross-sectional study (descriptive-analytical) was conducted to determine the factors associated with adverse events related to surgery in Iranian hospitals. All reports entered in the unwanted events registration system related to codes 1, 2, 3, and 4 of unwanted surgical events from March 2018 to March 2021 were included in the study.

Results: The results showed that the rate of surgical never events in Iranian hospitals is about 0.006%. The highest incidence of unwanted surgical events was in error code 4 (leaving any device including gauze, scissors, pliers, etc., in the patient's body) with 63.7%, and the lowest incidence of adverse surgical events was in error code 2 (performing surgery incorrectly on another patient) at 4%.

Conclusions: The findings of the present study show that the rate of unwanted surgical events in Iranian hospitals is lower than the global average. Lack of a precise framework for job descriptions and responsibilities, failure to use instructions, and lack of decision support systems are all factors in the occurrence of adverse surgical events.

Keywords: Never Events, Surgical, Unwanted Events, Hospitals

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Introduction

Never events are a combination of salient concepts and preventable hospital accidents that were first named in 2001 by the National Quality Forum (NQF) [1]. According to the World Quality Committee, adverse events are considered severe, preventable side effects related to health care providers, aiming at public accountability in health care centers [2].

According to research reports, adverse events occur in 5 to 10 percent of health care providers, and almost half of these cases are preventable. Not all unwanted events are the result of medical error. The data show that at least half of all surgical complications are avoidable [3, 4]. Patients expect to receive quality medical care through evidence-based medicine. This safe care will be accompanied by a reduction in patients' costs, some of which will be reduced by preventing the side effects of surgery [4].

Medical errors lead to 100,000 deaths annually and approximately $30 billion in financial losses. Therefore, this issue has made patient safety an important priority of health care systems since

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1999. Elimination of injuries to patients should be considered a major concern of the health system [5].

The outcome of surgery is closely related to the quality of intraoperative care. The surgeon's skill, the physical condition of the operating room, the relationship between the surgical team, and the standardization of patient care are some of the factors that indirectly affect the rate of complications after surgery [6].

Studies show that using a safe surgical checklist designed by the WHO reduced the rate of surgical site infection from 6.2% to 3.4%. The effectiveness of safe surgical checklists shows that the checklist helps the surgical team to avoid simple mistakes during surgery or reduce distractions in the operating room [3].

The Ministry of Health of the Islamic Republic of Iran has set up an error reporting system as part of the clinical governance system [7].

In 1996, the Deputy Ministry of Health communicated the procedure for registering never events, 28 adverse events, and the unwanted event reporting form to universities of medical sciences throughout the country. The present study was conducted to investigate the factors associated with surgical never events in hospitals throughout Iran in 2020.

Materials and Methods

This is a cross-sectional (descriptive-analytical) study that was performed to determine the factors associated with never events related to surgery in Iranian hospitals. From the total number of 980 reports registered in the unwanted events registration system, related to codes 1, 2, 3, and 4 of surgical unwanted events from March 2018 to March 2021, 22 errors were recorded with the wrong code, which were removed from the samples. A total of 958 surgical adverse events were included in the study.

Sampling was done by census of all errors with codes 1, 2, 3, and 4 of unwanted events related to surgeries listed in the Never Events registration system. First, reports of error codes 1, 2, 3, and 4 of adverse events related to surgery were received through the Never Events registration system. Reports of any error codes were then reviewed by a patient safety expert, and the patient's personal details and information related to the university and hospital were recorded in the checklist.

Due to the use of the checklist, there was no need to assess reliability, and only its validity was assessed. The content validity method was used to assess the validity of the questionnaire. According to the results, the range of CVR values was from 0.31 to 0.71, and this range was calculated for the CVI index from 0.79 to 0.95.

We examined biographical variables such as age, length of hospital stay, type of admission, and variables related to the location of the accident and the factors affecting the occurrence of adverse events. All factors related to adverse events were calculated in total and compared between different years (2018, 2019, and 2020).

SPSS software version 26 was used for statistical analysis. Descriptive statistics methods were used to calculate the number and frequency of variables, and to investigate the factors related to errors in codes 1, 2, 3, and 4 of adverse events related to surgery, a significant calculation of one variable against another variable (Chi-square test) was used.

Results

The highest age group for surgical adverse events in the samples was between 18-35 years, comprising 37.4% of the study population, while 26.2% were over 55 years old. Regarding gender, 39% of the study population were men and 61% were women. The incidence of adverse surgical events was 25.2% in 2018, 48.2% in 2019, and 26.6% in 2020.

The incidence of adverse surgical events in hospitals was 99.6%, and in restricted surgery centers, it was 0.3%. The highest incidence of errors occurred during the morning shift at 19.5%, while the lowest incidence was during the night shift at 9.6%.

Among the unwanted surgical events registered in the system, 9.6% occurred in private hospitals, 78.3% in academic (governmental) hospitals[1], 9.3% in non-governmental public hospitals, and 2.8% in charity hospitals.

Regarding the type of patient admission in hospitals, 47.9% of cases were emergency admissions, and 50.8% were elective admissions. The highest incidence of adverse surgical events was in academic hospitals at 78.5%, compared to 21.5% in non-academic hospitals. The highest incidence of adverse surgical events occurred in the surgical ward at 53.8%, and the lowest in the internal ward at 4.2%.

The most common external devices left in the patient's body were sponges or gauze, accounting for 46.5% of cases, while the least common were forceps at 1.2%. The most frequent outcome due to adverse surgical events was an increased hospital stay with reoperation in 69.6% of patients. Unwanted surgical events were associated with death in 2.4% of cases.

The most common complications following surgical never events included fever, pain, redness, and swelling of the operation area, accounting

1. hospitals of affiliated to organizations and institutions except Ministry of Health (including: Education, Radio and television, Social Security, Martyr Foundation, Sepah, Nazaja, Army, Municipalities, University Jihad, Banks, Ministry of Oil, Mostazafan Foundation, Relief Committee, Ministry of industry ...)

for 46.3% of the recorded errors, while the least common complication was embolism at 0.4%. In terms of root cause analysis, the highest factor in the occurrence of adverse surgical events was treatment error at 60.4%, and the lowest factor was decision error at 0.5%.

The incidence of adverse surgical events during 2018, 2019, and 2020 was significantly different according to the patient's age (Table 1). However, there was no significant difference according to the patient's gender (P = 0.223), the educational nature of hospitals (P = 0.135), and the location of the error (P = 0.097). There was also a significant difference between the type of physician specialty (Table 2) and the incidence of adverse surgical events in different years.

The main cause of surgical error (P = 0.097), the type of outcome due to the error (P = 0.165), and the type of root cause analysis (P = 0.241) did not show a significant difference in the incidence of adverse surgical events during 2018, 2019, and 2020. However, in terms of factors affecting the error (Table 3), a significant difference was observed between 2018, 2019, and 2020.

The incidence of adverse surgical events during 2018, 2019, and 2020, according to the type of hospital affiliation (P = 0.038), type of hospital ward (P = 0.039), type of surgical error code (P = 0.039), and type of retained device in the body (P = 0.018) showed a significant difference, but there was no significant difference when comparing different years.

There was a significant difference in the incidence of adverse surgical events according to the type of complication caused by the error (Table 4). There was also a significant difference between 2018 and 2019, as well as between 2019 and 2020.

Table 1: Unwanted surgical events according to the patient's age in different years

Age	2018 No (%)	2019 No (%)	2020 No (%)	P-value
< 1	3 (%1.3)	15 (%3.2)	6 (%2.4)	
1 – 18	18 (%7.5)	38 (%8.2)	22 (%8.7)	
18 – 35	93 (%38.9)	174 (%37.7)	90 (%35.4)	
35 - 55	67 (%28)	107 (%23.2)	72 (%28.3)	0/015
>55	58 (%24.3)	128 (%27.7)	64 (%25.2)	
Total	239 (%100)	462 (%100)	254 (%100)	
P-value	0/043			
		0/043		

Table 2: Unwanted surgical events according to Type of physician specialization in different years

Physician specialty	2018 No (%)	2019 No (%)	2020 No (%)	P-value
Gynecologist	93 (%42.1)	153(%35.3)	75(%31.8)	
Gastroenterologist	3 (%1.4)	5 (%1.2)	4 (%1.7)	
Surgeon	49 (%22.2)	124 (%28.7)	73 (%30.9)	
Cardiologist	16 (%7.2)	19 (%4.4)	10 (%4.2)	
Orthopedics	21 (%9.5)	45 (%10.4)	21 (%8.9)	
Ophthalmologist	7 (%3.2)	12 (%2.8)	16 (%608)	
Anesthesiologist	6 (%2.7)	12 (%2.8)	4 (%1.7)	
MD	4(%1.8)	1(%0/2)	0	
Urologist	11(%5)	16(%3.7)	14(%5.9)	
ENT	1(%0.5)	11(%2.5)	3(%1.3)	
Internal specialist	3(%1.4)	2(%0.5)	1(%0.4)	
Neurosurgeon	4(%1.8)	7(%1.6)	7(%3)	
Radiologist	2(%0.9)	3(%0.7)	1(%0.4)	
Pediatrician	0	5(%1.2)	3(%1.3)	
Lung specialist	0	2(%0.5)	1(%0.4)	
Neurologist	1(%0.5)	5(%1.2)	0	<0/001
Dermatologist	0	2(%0.5)	0	
Emergency specialist	0	7(%1.6)	3(%1.3)	
Maxillofacial surgeon	0	1(%0.2)	0	
Unknown	20(%8.3)	30(%605)	19(%7.5)	
Total	241 (%100)	462 (%100)	255 (%100)	
P-value	<0/001			
		<0/001		

Table 3: Unwanted surgical events according to factors affecting the error in different years

Factors Affecting Error	2018 No (%)	2019 No (%)	2020 No (%)	P-value
surgery	52 (%21.8)	124 (%26.9)	119 (%46.7)	
drug	0	2 (%0.4)	0	
Nursing-midwifery	70 (%29.4)	125 (%29.3)	51 (%20)	
Treatment method	14 (%5.9)	42 (%9.1)	17 (%6.7)	
Diagnostic	6 (%2.5)	10 (%2.2)	11 (%4.3)	
Wrong count	11 (%4.6)	10 (%2.2)	7 (%2.7)	
Op-room staff	15 (%6.3)	36 (%7.8)	28 (%11)	
Incorrect Documentation	3 (%1.3)	11 (%2.4)	1 (%0.3)	
Op-room conditions	1 (%0.4)	6 (%1.3)	1 (%0.4)	
Three factors(count, staff, document)	66 (%27.7)	85 (%18.4)	20 (%7.8)	0/006
Total	238 (%100)	462 (%100)	255 (%100)	
P-value	0/007			
	0/007			

Table 4: Unwanted surgical events according to Complication caused by error in different years

Complication due to error	2018 No (%)	2019 No (%)	2020 No (%)	P-value
Wound problems	4 (%1.7)	3 (%0.6)	1 (%0.4)	
Urogenital	36 (%15.3)	66 (%14.3)	19 (%7.5)	
Gastrointestinal	24 (%10.2)	51 (%11)	18 (%7.1)	
Cardiovascular	30 (%12.8)	88 (%19)	6 (%2.4)	
Respiratory	6 (%2.6)	31 (%6.7)	10 (%3.9)	
Anesthesia	1 (%0.4)	4 (%0.9)	1 (%0.4)	
Bleeding	7 (%3)	15 (%3.2)	9 (%3.5)	
Infection	21 (%8.9)	32 (%6.9)	24 (%9.4)	
Embolism	2 (%0.9)	2 (%0.4)	0	0/003
Others (Fever, pain, redness, swelling…)	104 (%44.3)	170 (%36.8)	167 (%65.5)	
Total	235 (%100)	462 (%100)	255 (%100)	
P-value	0/011			
	0/005			

Discussion

From 2018 to 2020, 14,636,613 surgeries were performed in Iranian hospitals, of which 958 cases of surgical adverse events occurred. In other words, one case of adverse surgical events was reported for every 15,278 surgeries in all Iranian hospitals (0.006%).

In Bohnen's study, out of 9,288 surgical cases, 183 had surgical adverse events [6]. Cornelus et al. reported the rate of adverse surgical events as one case in 22,000 surgeries [8]. Mohseni Saravi's research showed that out of 317,996 hospital admissions, 182 (0.06%) medical errors occurred [9]. Halfon reported an overall prevalence of surgical side effects in hospitals of 14.1% [10]. Of the 3,020 surgeries performed, Baines reported 240 adverse events, with an overall rate of about 8% [11]. In the study by Moppett et al., the risk of surgical side effects was one in 16,423 surgeries [12].

It seems that the rate of surgical side effects in the present study is lower than in other studies. This factor can be partly due to the lack of accurate and timely recording of unwanted events in the system and definitely due to the proper observance of patient safety standards and completing the safe surgery checklist in the country's hospitals.

Similarly, in 2018, there was one error per 2,013 surgical cases (0.004%); in 2019, one case of error for 11,143 surgeries (0.008%); and in 2020, one error occurred for 16,403 surgical cases (0.006%).

According to Baines' research, the rate of adverse reactions increased from 4.1% in 2004 to 6.2% in 2008 [11]. In the present study, this rate is much lower than the findings of research conducted in other countries.

The highest age group for surgical adverse events in the samples was between 18-35 years, comprising 37.4% of the study population, followed by 26.2% in the age group over 55 years. The mean age of patients in the present study was 40.5 years, while in Baines

and Bohnen's studies, the mean age of the samples was about 56 years [6, 11]. The mean age of patients with surgical side effects in Batista's study was 44.5 years [13]. Considering the highest incidence of errors in young people in the present study, it seems necessary to consider strategies to prevent it.

In the present study, 39% of the population were men and 61% were women. In Baines' study, 49% of the samples were men [11]. In the study by Zare Nejad et al., 58% of patients were men and 42% were women [14]. Thus, special attention to the occurrence of errors in women's wards seems necessary.

Among the unwanted surgical events registered in the system, 9.6% occurred in private hospitals, 78.3% in public hospitals, 9.3% in non-governmental public hospitals, and 2.8% in charitable hospitals. The highest incidence of adverse surgical events was 78.5% in university hospitals and 21.5% in non-university hospitals. In Baines's study, the risk of adverse events in academic hospitals was 1.72 [11]. According to the study by Mohseni-Saravi et al., 51.6% of medical errors occurred in non-teaching hospitals [9]. According to Attenello et al., the risk of adverse events in teaching hospitals was 1.29 times higher than in non-teaching hospitals [1].

Considering the high number of surgeries in public hospitals, it seems reasonable to expect an increase in the number of unwanted events in those hospitals. However, it is necessary to consider more factors affecting errors in public hospitals. In teaching hospitals, the number of surgeries is higher due to low medical service tariffs, and consequently, the number of unwanted events increases. However, how students provide services and care should be considered.

Regarding the type of patient admission in hospitals, 47.9% of cases were emergency admissions, and 50.8% were elective admissions. In Attenello's study, the risk of adverse events in emergency admissions was 2.09 [1]. Although the incidence of errors appears to be higher in emergencies, the results of our study do not show this, whereas in elective cases, errors can be easily prevented.

The highest incidence of surgical never events was in the surgical ward at 53.8%, and the lowest incidence was in the internal medicine ward at 4.2%. Of the total number of nursing errors, 52 cases (27.6%) occurred in the women's ward. In the Gitlow study, adverse events were twice as common in surgical ward patients [2]. Baines also showed that more than 50% of therapeutic side effects are related to surgery [11]. In the study by Zarenejad et al., 47% of adverse events occurred in general surgery and 34% in gynecological surgery [14]. Mohseni Saravi's study showed that the highest number of medical errors was observed in the surgical ward (42.3%) [7]. Training of personnel in various departments, especially surgery, as well as operating room personnel in the field of accuracy in providing medical services, is necessary.

In our study, the most common cause of adverse surgical events in hospitals was surgery, accounting for 27.6%, followed by causes related to nursing and midwifery at 25.5%. According to Chung's study, most unwanted events (72.3%) occur due to human factors [3]. To reduce the incidence of surgical errors, accuracy in surgical procedures and the provision of nursing care are essential.

In the present study, the incidence of adverse surgical events by gynecologists was 33.5%, and by general surgeons was 25.7%. Due to the high error rate by gynecologists and general surgeons, it seems necessary to pay more attention to how relevant services and care are provided, as well as periodic training of physicians and treatment staff.

The most effective factor in the incidence of error was the surgical method at 30.9%, followed by factors related to nursing and midwifery at 26.8%, with the drug-related factor having the least effect at 0.2%. In the study by Adibi et al., factors related to tasks (20%), education (16%), communication (14%), and teamwork (13%) contributed to the occurrence of adverse events [5].

Mohseni Saravi's study showed that the highest frequency of medical errors was related to improper care or lack of care (37%) and medication errors (28%) [9]. More accuracy by physicians in the field of surgery, more precise care by the treatment staff, and increasing the number of nurses relative to the number of patients significantly reduces the error rate.

The highest amount of residual devices in the patient's body was gauze, accounting for 46.5% of cases, while the lowest amount was forceps at 1.2%. The study by Zarenejad et al. showed that 73% of the remaining body objects were gauze, and 27% were other objects [14]. Hariharan's review article showed that the overall prevalence of foreign body retention in the body is low but is more common in open abdominal surgeries, with gauze being the most common residual object compared to needles and other objects [15].

In the present study, the highest outcome due to adverse surgical events was an increase in the length of hospital stay with reoperation in 69.6% of patients, and the lowest outcome was death at 2.4%. According to the Rafter study, the patient's hospital stay increased by an average of 6.1 days per adverse event, which cost $5,550 per adverse event [4]. In Haukland et al.'s study, adverse events leading to death accounted for 1.3% of total hospital admissions, and 64% of patients who died experienced one or more adverse events [16]. Reoperation, in addition to increasing the bed occupancy rate and employing medical staff, imposes a huge financial burden on the health system.

After analyzing the root causes of the error, the most important factor in the occurrence of surgical errors in 60.4% of cases is the error in the patient's treatment process (by a physician or medical staff). In 27.7% of cases, there was an error in team communication in the operating room between the doctor and the operating room staff. In the study by Kevin et al., the most adverse events (72.3%) occur due to human factors. In the study by Adibi et al., communication in 14% and teamwork in 13% of cases contributed to the occurrence of adverse events. In the research by Kumar et al., the factors affecting medical error are classified into human error, communication error, system failure, and equipment failure [17].

Cuschieri's review study showed that important components of safe surgery include organizational structure with strategic control over health care delivery, teamwork and leadership, evidence-based performance, physician proficiency, continuous improvement of all employees, access to health information technology, and accident reporting and adverse event reporting systems [18]. Therefore, proper and accurate use of safe surgery checklists and annual training of operating room staff in reducing unwanted surgical events is essential.

The findings of Anderson et al.'s systematic review of 40 articles and 16,424 surgical patients showed that the rate of adverse events was observed in 14.4% of patients and preventable adverse events in 5.2% of cases [19].

Chen et al.'s research on the information related to surgical events during 2015 and 2016 from the Adverse Event Registration System in Boston, USA showed that out of 3020 surgical cases, 142 medical errors and 103 adverse events were reported, which is constituted a total of 8% of cases [20].

The research findings of Fujita showed that the mortality rate was higher in hospitals with special departments with more than 500 beds and in psychiatric hospitals [21].

In Perotti et al.'s study, two-thirds of the reports had RCA information and defects in the reporting policy were observed in most of the RCA forms [22].

According to the research of Stahel et al., using the analysis of the data registered in the Colorado Physicians Insurance Institute from 2002 to 2008, significant injuries were observed in 5 wrong patients (20%) and 38 wrong operation sites (35.5%). [23].

Considering that the registration of unwanted events in the system was done by experts from different universities of medical sciences in Iran, the way of completing the forms may be different. The lack of inclusion of time and error occurrence shift in most reports or RCA can be one of the limitations of the present research.

Conclusion

Incident reporting is an essential component of promoting patient safety. Incident reporting alone does not improve patient safety, but learning from mistakes is essential to prevent similar incidents in the future. Efforts to improve hospital safety depend on systemic reforms aimed at greater patient safety.

Not paying attention to clinical guidelines and instructions in the process of academic education of medical sciences, as well as negligence in the design and implementation of training courses upon arrival or during service, has caused doctors not to be familiar with the clinical guidelines. As a result, they do not use them and diagnose and treat according to their own preferences. This issue has caused hospital management to lack attention to the issue of guides and instructions, removing it from the scope of priority activities.

Failure to define the mechanism for monitoring the performance of health service providers in the use of guidelines, especially in teaching hospitals, has caused a lack of effective communication between medical science graduates and other health service providers with clinical guidelines and implementation instructions.

Creating a learning error reporting system in the organization, while creating a suitable platform and culture, and besides creating a suitable mechanism, encourages employees to report incidents that may occur in the future. The report of unwanted events has been actively and effectively analyzed with the participation of employees, and the results are used to eliminate the causes of errors and correct related processes.

The lack of training in effective communication between the treatment staff and the patient, the presence of obstacles to the patient's access to the necessary care services such as speaking in a different language, the lack of training for nurses, and the lack of nursing staff are also effective in the occurrence of errors.

Annual training courses on patient safety standards are necessary for the treatment staff (including doctors, operating room personnel, and nursing staff) in order to properly identify the patient during surgery, use the safe surgery checklist accurately and completely, and have proper team communication in the operating room.

Emphasizing interprofessional teamwork is important in improving coordination and increasing patient safety. One of the benefits of improving teamwork at the patient's bedside, in addition to reducing errors and stress, is sharing experiences and learning from each other, which will have a major impact on improving patient safety.

The coherent functioning of treatment teams can result in better clinical outcomes and greater patient satisfaction, so its promotion is necessary to improve patient safety outcomes. Due to the lack of accurate recording of error causes and RCA in the adverse event registration system (including the type of doctor's specialty, hospitalization department, duration of hospitalization, exact date and time of incident, patient's contact number, etc.), annual training of patient safety experts in hospitals is necessary.

Conflict of Interest

The authors of this article state that there were no financial, personal or professional interests that may affect the method of research or writing of the article.

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