

Patient Safety Incidents in Operating Rooms Reported in the Past Five Years (2017-2021) in Korea

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Purpose: Patient safety incidents in the operating room require special attention because they can cause catastrophic and irreversible conditions in patients. Although patient safety incidents have different characteristics, there may be similarities and patterns of risk factors that may be common. Therefore, this study analyzed factors associated with the PSIs by analyzing data from the Korean Patient Safety Reports from 2017 to 2019.

Methods: The “Patient Safety Incidents Data from 2017 to 2021” systematically collected by the Korea Institute for Healthcare Accreditation, include patient safety incident reports from medical institutions. Data on 1140 patient safety incidents in the operating room were analyzed. They included patients’ gender and age, Hospital size, Incident seasons, incident time, Incident reporter, incident type, Medical department, and Incident severity. The Incident severity was analyzed by dividing it into three stages: near miss, adverse event, sentinel event, which are applied by domestic medical institutions.

Results: The highest number of OR patient safety incidents were related to surgery and anesthesia. On analyzing the probability of adverse events based on near misses, the significant variables were patient gender, incident reporter, incident type, and Medical department. Additionally, the factors that were likely to precipitate sentinel events based on near misses were patient gender, incident time, reporter, and incident type.

Conclusion: To prevent sentinel events in Patient safety incidents, female and during night shifts are required to pay close attention. Moreover, it is necessary to establish a patient safety reporting system in which not only all medical personnel, but also patients, generally, can actively participate in patient safety activities.

Keywords: patient safety, operating room, incident reporting, incident reporting system, hospital, risk management

Introduction

Patient safety is an important healthcare issue worldwide, defined as reducing the risk of unnecessary harm to patients associated with healthcare to the lowest acceptable level.¹ A patient safety incidents is an event or situation that unnecessarily harms a patient and is reported to be the third leading cause of death in the United States, and one patient harm is reported every 35 seconds in the United Kingdom.² Patient safety adverse events typically occur in 3–17% of hospitalized patients, and 50% of these are reported to be preventable.³ It also causes death in 14% of patients, permanent disability in 3% of patients, and temporary disability in 70% of patients.⁴

In particular, special caution is required in operating rooms (OR) because patient safety incidents can cause fatal and irreversible conditions in patients.⁵ Surgery-related incidents accounted for 43.1% of all medical dispute claims filed in Korea in 2021, the highest proportion of all medical dispute claims, and this proportion is gradually increasing.⁶ Types of patient safety incidents in ORs include surgery at an incorrect site or on the wrong patient, retained surgical items (RSIs) after surgery, surgical instrument reprocessing error, bed sores, fire, and hypothermia.⁷ Such patient safety incidents in the operating room can be fatal to patients and lead to a loss of trust in medical providers and prolonged patient

admission periods.^{2,4} This is a major concern and challenge for the healthcare industry as it can lead to poor quality of care and financial losses.⁸

In recent years, laws have been enacted globally to establish patient safety incident reporting systems and patient safety management systems to prevent the recurrence of patient safety incidents.⁹ In Korea, the Korea Patient Safety Reporting and Learning System (KOPS) has been systematically collecting and managing data related to patient safety incidents since 2016.¹⁰ This system gathers national data on patient safety incidents through voluntary reporting by medical institutions and patients.¹⁰ KOPS analyzes this data to identify the root causes of serious patient safety events and provides valuable insights into the causes and incidence of medical errors through case reviews. Additionally, multidimensional efforts have been made from the perspective of healthcare providers to prevent medical malpractice, medical errors, and adverse events by fostering a patient safety culture and implementing a patient safety reporting system.¹¹ Incident reporting in healthcare is known to play a crucial role in strengthening patient safety strategies, monitoring, prevention, and reducing the occurrence of patient safety incidents. Therefore, patient safety incident reporting is essential for the broader goal of error reduction.¹² Despite the importance of patient safety incidents in clinical settings, most medical institutions in Korea focus on acute care, leading to underreporting of patient safety incidents.¹³ Furthermore, the awareness of patient safety issues and the evidence for prevention remain low in the country, resulting in a lower frequency of reported patient safety incidents compared to other countries.¹³ To date, there have been few studies published on the frequency or rate of patient safety events in the operating room based on medical record reviews.^{14,15} Despite the high incidence of patient safety events in Korea and globally, there is a lack of national data on the characteristics of patient safety events in the operating room. Therefore, this study aims to analyze the trend of patient safety incidents and related factors in the operating room using data from the National Patient Safety Report from 2017 to 2021.

Materials and Methods

Design

This study used raw data from 2017 to 2021 collected for the Korea Patient Safety Reporting Survey, a nationally representative survey conducted by the Korea Institute for Healthcare Accreditation and conducted secondary data analysis to identify factors associated with the severity of patient safety incidents in the operating room.

Data Collection

The current study analyzed data on patient safety incidents in ORs from the “Patient Safety Incidents Data from 2017 to 2021”. The Korea Institute for Healthcare Accreditation systematically collected patient safety incident reports from medical institutions based on the Patient Safety Act implemented in 2016.

The Korea Institute for Healthcare Accreditation Evaluation and Accreditation Agency collects and analyzes information on patient safety incidents in medical institutions at the national level and discloses it through its website. There will be no penalties for reporting and strict confidentiality. Self-reporting may result in a reduction or waiver of administrative penalties; reporting is individualized and confidential; and feedback is provided to the entire healthcare organization.¹⁰

The number of patient safety incidents that occurred in ORs was 137 in 2017, 259 in 2018, 292 in 2019, 308 in 2020, and 317 in 2021, totaling to 1313 incidents over 5 years. Among these, we excluded 173 cases where the age and gender of the subject were unclear, categorized as inaccurate data. A total of 1140 patient safety incidents in ORs were analyzed.

The sample size was calculated using G* Power 3.1 version, and when performing a power analysis with a significance level (α) of 0.05, Odds ratio of 1.5, $\Pr(Y=1|X=1)$ of 0.4, and power ($1-\beta$) of 95%, the number of subjects required for logistic regression analysis is more than 350, so 1140 subjects can be considered an appropriate sample size (Critical $Z=1.96$, Actual power=0.95).

Variables

In the present study, the gender of the patient, age, Hospital size, Incident seasons, incident time, Incident reporter, incident type, Medical department, Incident severity were taken from the “Patient Safety Incidents Data”. The “Patient Safety Incidents Data” lists six categories: no risk, near-error (recovery without sequelae after treatment), mild (temporary harm or

Table 1 Classification of Analysis Variables

Analysis Variables	Category
Near miss	No harm
Adverse event	Recovery without sequelae after treatment Temporary damage or side effects
Sentinel event	Long-term damage or side effects Permanent damage or side effects Dead

side effects), moderate (long-term harm or side effects), severe (permanent harm or side effects), and death. In this study, the degree of risk was analyzed by classifying incidents into three categories: near-error (no risk and near-error), critical incident (mild and moderate), and red flag event (severe and death), which are applied in Korean medical institutions (Table 1).

Data Analysis

Data were analyzed using SPSS 25.0 (SPSS; IBM Armonk, NY, USA). Descriptive statistics, including frequency and percentage, were used to analyze the general characteristics of the patients. The difference in the risk of patient safety incidents according to the general characteristics of the patients was cross-analyzed using the chi-squared test. Multinomial logistic regression was used to identify factors associated with three categories of patient safety events: near miss, adverse, and sentinel events. The odds ratio (OR) of occurrence of adverse events and sentinel events were analyzed using near miss as the reference category. Results are presented as OR with 95% confidence intervals (CI), with a statistical significance level of $p < 0.05$.

Ethical Considerations

This study is a secondary analysis using raw data provided by the Korea Institute for Healthcare Accreditation, and because the raw data does not contain personally identifiable information of participants, the research protocol was submitted to the Institutional Review Board (IRB) of Konyang University and approved for exemption from review (IRB number: KYH: 2022–09-026).

Results

Difference in Patient Safety Incidents Severity by Research Variables

Male (47.0%) and female (53.0%) patients had similar rates of patient safety incidents, and 50.3% of all patients were aged 20–59 years. Hospital sizes of 500 beds or more accounted for 78% of the sample. Patient safety incidents were similar by season: 25.5% in spring, 26.1% in summer, 24.7% in fall, and 23.7% in winter. 56.8% of incidents occurred during the day. Most incidents were reported by patient safety officers (88.0%), and by Medical department, GS (23.5%) had the highest number of patient safety incidents. The most common type of patient safety incident was Surgery / Anesthesia / Procedure (49.9%). The Event severity of patient safety incidents was dominated by adverse events (51.1%), followed by near misses (41.9%) and sentinel events (7%). The Event severity of patient safety incidents was statistically different by patient gender ($\chi^2=17.81, p < 0.001$), time of incident ($\chi^2=40.59, p < 0.001$), incident reporter ($\chi^2=39.78, p < 0.001$), type of incident ($\chi^2=123.59, p < 0.001$), and medical department ($\chi^2=26.49, p = 0.022$) (Table 2).

Influence Factors Related to the Severity of Patient Safety Incidents

First, we calculated the OR of adverse events using near misses as the reference category. Patient gender, incident reporter, incident type, and medical department were significantly associated with adverse events. By gender, men (adjusted OR (aOR) = 0.68, 95% CI = 0.53–0.87) were significantly less likely to experience an adverse event than women. For incident reporters, the odds were significantly lower for patient safety officers (aOR = 0.26, 95% CI = 0.10–0.64) compared to heads of medical institutions. For patient safety Incident types, falls/burns (aOR = 5.27, 95% CI = 2.72–10.20), surgery/anesthesia/procedures

Table 2 Difference in Severity of Patient Safety Incidents by Research Variables. (N = 1140)

Variable	Category	Total N = 1140	Near Miss N = 478 (41.9%)	Adverse Event N = 582 (51.1%)	Sentinel Event N = 80 (7%)	$\chi^2(p)$
		n (%)	n (%)	n (%)	n (%)	
Patient gender	Male	536 (47.0)	255 (22.4)	256 (22.5)	25 (2.2)	17.81 (<0.001)
	Female	604 (53.0)	223 (19.6)	326 (28.6)	55 (4.8)	
Patient age (year)	0–19	70 (6.1)	25 (2.2)	43 (3.8)	2 (0.2)	6.12 (0.190)
	20–59	573 (50.3)	235 (20.6)	291 (25.5)	47 (4.1)	
	≥ 60	497 (43.6)	218 (19.1)	248 (21.8)	31 (2.7)	
Hospital size (Beds)	< 499	251 (22.0)	101 (8.9)	134 (11.8)	16 (1.4)	0.75 (0.686)
	≥ 500	889 (78.0)	377 (33.1)	448 (39.3)	64 (5.6)	
Incident time	Day (7:00–14:59)	648 (56.8)	287 (25.2)	338 (29.6)	23 (2.0)	40.59 (<0.001)
	Evening (15:00–22:59)	280 (24.6)	116 (10.2)	141 (12.4)	23 (2.0)	
	Night (23:00–06:59)	27 (2.4)	11 (1.0)	11 (1.0)	5 (0.4)	
	Unknown	185 (16.2)	64 (5.6)	92 (8.1)	29 (2.5)	
Incident reporter	Patient safety officer	1003 (88.0)	440 (38.6)	500 (43.9)	63 (5.5)	39.78 (<0.001)
	Health provider	93 (8.2)	32 (2.8)	56 (4.9)	5 (0.4)	
	Hospital Ledger	44 (3.9)	6 (0.5)	26 (2.3)	12 (1.1)	
Incident type	ICM	84 (7.4)	36 (3.2)	29 (2.5)	19 (1.7)	123.59 (<0.001)
	FB	76 (6.7)	20 (1.8)	52 (4.6)	4 (0.4)	
	SAP	569 (49.9)	261 (22.9)	273 (23.9)	35 (3.1)	
	MT	151 (13.2)	70 (6.1)	77 (6.8)	4 (0.4)	
	EE	106 (9.3)	69 (6.1)	34 (3.0)	3 (0.3)	
	Others	154 (13.5)	22 (1.9)	117 (10.3)	15 (1.3)	
Medical department	IM / PED	44 (3.9)	13 (1.1)	28 (2.5)	3 (0.3)	26.49 (0.022)
	GS	268 (23.5)	111 (9.7)	126 (11.1)	31 (2.7)	
	OBGY	133 (11.7)	48 (4.2)	77 (6.8)	8 (0.7)	
	NS/NEU	132 (11.6)	60 (5.3)	63 (5.5)	9 (0.8)	
	CS	60 (5.3)	26 (2.3)	27 (2.4)	7 (0.6)	
	OS	250 (21.9)	112 (9.8)	124 (10.9)	14 (1.2)	
	URO	39 (3.4)	20 (1.8)	17 (1.5)	2 (0.2)	
	Other	214 (18.8)	88 (7.7)	120 (10.5)	6 (0.5)	

Abbreviations: ICM, Infection / contamination of Medical material; FB, Falls / Burns; SAP, Surgery / Anesthesia / Procedure; MT, Medication & Transfusion; EE, equipment error and Examination; IM, Internal medicine; PED, Pediatrics; GS, General surgery; OBGY, Obstetrics and gynecology; NS, Neurosurgery; CS, Thoracic and cardiac surgery; OS, Orthopedics; URO, Urology.

(aOR = 2.12, 95% CI = 1.36–3.31), and medications/transfusions (aOR = 2.23, 95% CI = 1.32–3.76) had higher odds ratios compared to medical equipment errors/ examination. By Medical department, the odds of adverse events were higher in internal medicine/pediatrics (aOR = 2.53, 95% CI = 1.01–6.37) than in urology.

Second, we analyzed the probability of sentinel events using near misses as the baseline category. Sentinel events were significantly associated with gender, time of incident, incident reporter, and incident type.

The probability that males would experience a sentinel event was lower than that for females (aOR = 0.39, 95% CI = 0.24–0.65). Regarding the time when Patient safety incidents occurred, compared to those in Day, the incidents occurring in Evening (aOR = 5.67, 95% CI = 1.81–17.72), Night (aOR = 2.47, 95% CI = 1.33–4.58) were significantly more likely to be classified as adverse events. Patient safety officers (aOR = 0.07, 95% CI = 0.02–0.19) and medical provider (aOR = 0.07, 95% CI = 0.02–0.30) were significantly less likely to report a sentinel event than the head of the medical institutions. Among the types of incidents, infection/contamination of medical materials (aOR = 12.13, 95% CI = 3.36–43.77) was 12.13 times more likely to contain a sentinel event than medical equipment error/examination (Table 3).

Table 3 Multinomial Logistic Regression Analysis for Predicting Patient Safety Incidents (N=1140)

Variables (Reference)	Categories	Adverse Event (Reference = Near Miss)			Sentinel Event (Reference = Near Miss)		
		Adjusted OR	95% CI	p	Adjusted OR	95% CI	p
Gender (Female)	Male	0.68	0.53–0.87	0.002	0.39	0.24–0.65	0.000
Age (≥ 60)	0–19	1.51	0.89–2.55	0.123	0.56	0.12–2.49	0.449
	20–59	1.08	0.84–1.39	0.507	1.40	0.86–2.29	1.40
Hospital size (<500 beds)	> 500 beds	0.89	0.66–1.20	0.462	0.90	0.49–1.65	0.749
Incident time (Day)	Evening	0.84	0.36–1.98	0.706	5.67	1.81–17.72	0.003
	Night	1.03	0.77–1.38	0.832	2.47	1.33–4.58	0.004
Incident Reporter (Head of the medical institutions)	Patient safety officer	0.26	0.10–0.64	0.003	0.07	0.02–0.19	0.000
	Health provider	0.40	0.15–1.08	0.072	0.07	0.02–0.30	0.000
Incident type (EE)	ICM	1.63	0.86–3.09	0.131	12.13	3.36–43.77	0.000
	FB	5.27	2.72–10.20	0.000	4.60	0.95–22.27	0.058
	SAP	2.12	1.36–3.31	0.001	3.08	0.92–10.32	0.068
	MT	2.23	1.32–3.76	0.003	1.31	0.28–6.09	0.727
Medical Department (URO)	IM / PED	2.53	1.00–6.37	0.048	2.30	0.33–15.75	0.393
	GS	1.33	0.66–2.67	0.415	2.79	0.61–12.60	0.182
	OBY	1.88	0.90–3.95	0.093	1.66	0.32–8.54	0.540
	NS/NEU	1.23	0.59–2.58	0.574	1.50	0.29–7.53	0.622
	CS	1.22	0.52–2.83	0.641	2.69	0.50–14.39	0.247
	OS	1.30	0.65–2.61	0.456	1.25	0.26–5.92	0.779

Abbreviations: ICM, Infection / contamination of Medical material; FB, Falls / Burns; SAP, Surgery / Anesthesia / Procedure; MT, Medication & Transfusion; EE, equipment error and Examination; IM, Internal medicine; PED, Pediatrics; GS, General surgery; OBY, Obstetrics and gynecology; NS, Neurosurgery; CS, Thoracic and cardiac surgery; OS, Orthopedics; URO, Urology.

Discussion

The present study examined the data on patient safety incidents in ORs in the last five years (2017 to 2021) based on the “Patient Safety Incidents Data” published by the Korea Institute for Healthcare Accreditation in 2022. Reporting and analyzing patient safety incidents can help you understand patient safety, which is an essential part of being a healthcare provider.

Patient safety incidents, especially in the operating room, require special attention because they can cause catastrophic and irreversible conditions for patients.

The most common types of patient safety incidents in ORs were surgery and anesthesia-related incidents. Previous studies have shown that 1 in 10 patients have experienced adverse events such as surgery (39.6%) or medication (15.1%).¹⁶ These Results indicate that patient safety incidents related to surgery are high. The study found that among accident types, near misses, adverse events, and sentinel events were all high in surgery and anesthesia-related incidents. In addition, the OR for adverse events was 2.12 times higher than the OR for equipment errors/examination. Types of patient safety incidents related to surgery include surgery on the wrong site or wrong patient, residual surgical items (RSIs) after surgery.⁷ The most critical factor in preventing surgery and anesthesia at the wrong site or wrong patient is accurate patient sign-in. Education and training are needed to accurately perform safety procedures, such as patient sign-in before anesthesia induction, patient time-out before incision, and patient sign-out after suture. In response to recent reports of related red-flag events in Korea, the Korea Institute for Healthcare Accreditation issued a cautionary warning related to patient identification for surgery and anesthesia and provided recommendations for preventing recurrences in medical institutions.¹⁷ A practical method for identifying patients should be devised and announced, such as installing a tablet PC at surgical scrub stations to allow repeated viewing of training videos for accurate patient identification whenever hand hygiene is performed, having the staff check each item on a time-out monitoring sheet, and notifying the department of the implementation rate.¹⁷ Regarding the management strategy for preventing postoperative RSIs, it is

necessary to improve counts accuracy by integrating automated systems, such as barcode tracking systems, data matrix labels, and radio-frequency identification (RFID) tag devices, rather than manually counting surgical instruments and gauze.¹⁸ Additionally, regarding the retention of small surgical instruments or needles which cannot be remedied by an automated system, using ultraviolet fluoroscopy by applying a fluorescent coating to small instruments and needles to enable their easy retrieval can prevent RSIs in the patient's body.¹⁹

Sentinel events were higher in the evening (5.67 times) and night (2.47 times) than during the day. This is likely related to the fact that most surgeries are performed during daytime hours and nursing staffing is relatively deployed during the day.²⁰ Thus, it is necessary to analyze nursing activities by working hours in calculating the nursing workforce and to apply an industrial engineering method that analyzes the flow of nursing activities by measuring the duration of each nursing practice.

The percentage of adverse events and sentinel events reported by head of the medical institutions was higher than those reported by providers and patient safety officers. Currently, Korea requires hospital-level healthcare organizations with 200 beds or more to have a patient safety committee and dedicated patient safety staff.²¹ However, given the size of the hospital the number of dedicated staff responsible for patient safety and executing overall patient safety activities is small. Therefore, there is a need to create a culture of voluntary reporting, and active participation in patient safety activities by all healthcare providers in healthcare organizations. In addition, the best way to reduce medical errors is for patients and caregivers to be active participants in patient safety activities,²² and patients and caregivers should take the initiative to ensure and maintain their own safety. Among the types of patient safety incidents, sentinel events due to surgical site infections (SSI) and medical material contamination were 12.13 times higher than equipment errors/examinations. A previous study found that infections accounted for 40% of adverse events in the operating room,²³ similar to our findings. SSIs are reported to be related to surgical skin preparation, use of preoperative antibiotics, maintenance of normal body temperature, surgical hand hygiene, personnel participating in surgery, and the number of door openings during surgery.^{19,24} Preoperative showers using chlorhexidine gluconate 4%,²⁵ hair removal using clippers, skin disinfection using chlorhexidine gluconate and povidone iodine, and surgical hand disinfection using products containing alcohol and chlorhexidine are recommended.²⁶ Appropriate use of preoperative antibiotics prophylaxis is required, as multiple studies have reported that using appropriate preoperative antibiotics reduces surgical site infections.²⁷ Since intraoperative door openings are associated with high levels of microbial air contamination in the OR, all necessary materials should be placed in the OR before surgery to avoid frequent opening of the door during surgery.²⁸ It is recommended that fewer than five people participate in an operation and to not have many people entering and exiting the OR during the operation.²⁸ Material-appropriate cleaning (eg, ultrasonic cleaning and machine washing²⁹ and high-level sterilization methods³⁰ should be used to clean and sterilize surgical instruments and materials. Moreover, the sterilization status and effective dates must be checked and care must be taken to avoid contamination during surgery. These findings are consistent with previous studies that have shown that incidents of surgical site infections and medical material contamination in the OR are related to human factors.²³ Therefore, interventions targeting human causes are recommended and specific strategies are required.

This study analyzed data on safety incidents related to the operating room from the Korean Patient Safety Report Data Survey but, it was challenging to identify specific patient safety incident types, such as RSIs, and error rates of surgical and anesthetic errors due to the limited categories of safety incident types. It was also difficult to integrate organizational factors related to patient safety incidents, such as the working environment and organizational culture.

Regarding patient safety reporting systems outside Korea, specific data are collected by merging structured and free text-based data collection; the completeness of the information is ensured by providing review notifications and references in the system when data is missing.³¹ The Korean patient safety reporting system should be revised to ensure the provision of detailed data (Length of stay, presence of endogenous and exogenous risk factors, communication, gait, comorbidities, etc.) to enable research. Moreover, data research on organizational factors, such as working environment and patient-centered data, needs to be conducted in future. They also suggest tracking changes over time after implementing a particular policy or education program to determine its impact on patient safety incidents. An integration of hospital information systems and patient safety reporting systems is needed to identify patient safety risks, prioritize

resource allocation, develop interventions to mitigate risks, and systematically operate a feedback system that evaluates whether risks have been reduced through interventions.

Conclusion

The study analyzed “Patient Safety Incident Data from 2017 to 2021” to determine the factors associated with patient safety incidents in operating rooms in Korea. Based on near misses, the factors that were more likely to cause an adverse event were patient gender, reporter, type of incidents, and medical department, and the factors that were more likely to cause a sentinel event were patient gender, incident time, reporter, and the type of incidents.

As a result of these findings, to prevent sentinel events in patient safety incidents, close attention should be paid to female patients, surgeries performed during night shifts. Furthermore, compared to equipment errors/examination, infections and contamination of medical materials can have devastating consequences, requiring the active involvement of medical staff and patient safety managers. Finally, a patient safety reporting system should be in place to enable patients and guardians to take ownership of, participate in, and report on patient safety activities.

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Disclosure

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