

Evaluation of the Care Safety of Patients with Surgical Interventions from a High-Complexity Institution in Medellín, Colombia

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Objective. This work sought to evaluate care safety of patients with surgical interventions in the area of general surgery in terms of administrative problems in caring, incidents, and adverse events. **Methods.** This was an observational-type prospective descriptive study that followed up patients intervened surgically by the general surgery group of a tier IV hospital unit in the city of Medellín. **Results.** The study evaluated 182 patients who received complete follow up during the care process in the institution; of these, 59 (32.4%) received unsafe care (10 incidents, 9 problems with quality, and 40 adverse events); the remaining 123 (67.6%) had safe care of which, 28 developed complications in spite of not having had flaws in the care process. Regarding the health professionals responsible for patient care, we found that 57.4% of the adverse events was the responsibility of the treating physician and the remaining 42.6% was the responsibility of the nursing staff. **Conclusion.** The prevalence of adverse surgical events in this study was above that found in literature. Management

of nursing care focused on improving the healthcare system in the area of surgery could reduce substantially not only the occurrence of flaw in caring, but also the economic burden upon the healthcare system.

Key words: patient safety; health care facilities; health personnel; hospital units; patient care.

Seguridad de la atención de los pacientes con intervenciones quirúrgicas de una institución de alto nivel de complejidad en Medellín, Colombia

Objetivo. Evaluar la seguridad en la atención de los pacientes con intervenciones quirúrgicas en el área de cirugía general en términos de problemas administrativos para la atención, incidentes y eventos adversos. **Métodos.** Estudio descriptivo prospectivo de tipo observacional que realizó seguimiento a pacientes intervenidos quirúrgicamente por el grupo de cirugía general de una unidad hospitalaria de cuarto nivel de complejidad de la ciudad de Medellín (Colombia). **Resultados.** Se evaluaron 182 pacientes a quienes se les realizó el seguimiento completo durante proceso de atención

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en la institución, de ellos 59 (32.4%) tuvieron atención insegura (10 incidentes, 9 problemas con la calidad y 40 eventos adversos); los 123 restantes (67.6%), atención segura, de los cuales, 28 desarrollaron complicaciones a pesar de no haber tenido falla en el proceso de atención. Con relación al profesional de la salud responsable de la atención de los pacientes, encontramos que el 57.4% de los eventos adversos fue responsabilidad del médico tratante y el 42.6% restante fue responsabilidad del personal de enfermería. **Conclusión.** La prevalencia de evento adverso quirúrgico en este estudio fue superior a la encontrada en la literatura. La gestión del cuidado de enfermería enfocada a la mejora del sistema de atención en el área de cirugía podría reducir sustancialmente no solo la ocurrencia de la falla de la atención sino también la carga económica que ello conlleva al sistema de atención en salud.

Palabras clave: seguridad del paciente; instituciones de salud; personal de salud; unidades hospitalarias; atención al paciente.

Segurança da atenção dos pacientes com intervenções cirúrgicas de uma instituição de alto nível de complexidade em Medellín, Colômbia

Objetivo. Avaliar a segurança na atenção dos pacientes com intervenções cirúrgicas na área de cirurgia geral em

Introduction

Health interventions take place with the sole purpose of benefiting patients. Despite this, the work of professionals can end up causing damage or detriment, according to institutional, legal, or human conditions. The combination of multiple processes during care, joined to the use of technology and human intervention, leads to inevitable risk for adverse events to occur.¹

For over a century, surgical care has been an essential component of healthcare in the world, but the rapid growth it has experienced and the technology boom have had as consequences important outcomes that impact upon public health, not only to benefit the population, but which have also generated unfavorable results in health, denominated adverse events and widely studied

termos de problemas administrativos para a atenção, incidentes e eventos adversos. **Métodos.** Estudo descritivo prospectivo de tipo observacional que realizou seguimento a pacientes intervindos cirurgicamente pelo grupo de cirurgia geral de uma unidade hospitalar de quarto nível de complexidade da cidade de Medellín (Colômbia). **Resultados.** Se avaliaram 182 pacientes a quem se lhes realizou o seguimento completo durante processo de atenção na instituição, de estes 59 (32.4%) tiveram atenção insegura (10 incidentes, 9 problemas com a qualidade e 40 eventos adversos); os 123 restantes (67.6%), atenção segura, dos quais, 28 desenvolveram complicações a pesar de não haver tido falha no processo de atenção. Com relação ao profissional da saúde responsável da atenção dos pacientes, encontramos que 57.4% dos eventos adversos foi responsabilidade do médico tratante e 42.6% restante foi responsabilidade do pessoal de enfermagem. **Conclusão.** A prevalência de evento adverso cirúrgico neste estudo foi superior à encontrada na literatura. A gestão do cuidado de enfermagem enfocada à melhora do sistema de atenção na área de cirurgia poderia reduzir substancialmente não só a ocorrência da falha da atenção senão também a carga econômica que isto implica ao sistema de atenção em saúde.

Palavras chave: segurança do paciente; instalações de saúde; pessoal de saúde; unidades hospitalares; assistência ao paciente.

around the planet.²⁻⁴ Globally, around 230-million major surgery procedures are practiced per year, which is equivalent to 1 for every 25 individuals. The number of surgical interventions almost duplicates the number of deliveries, although the risks involved are much higher. According to the setting, the rate of serious complications varies between 3 and 16%² and the rate of mortality between 0.2 and 10%.³ Consequently, surgical interventions produce at least seven-million incapacitating complications and one-million deaths each year and it is considered that at least half of these complications could have been avoided if basic care norms were applied more systematically, both in developed and developing countries.³ Organizations that place safety in first place and which urge their personnel to work together in implementing and complying with norms that diminish risks will provide a

safe operating room environment that fulfills the expectations of patients and their relatives.

The purpose of this research work was to assess the safety of caring for patients with surgical interventions performed in the area of general surgery at a tier-IV health institution in the city of Medellín, in terms of administrative problems in caring, incidents and adverse events, framed within guidelines from the World Health Organization for the surgical safety of patients and implementing the strategies of the initiative “safe surgical practices save lives”,³ to specifically identify flaws and errors in caring for surgical patients and find tools to reduce the growing frequency of deaths and complications caused by surgical interventions in these types of institutions.

Methods

This was an observational-type prospective descriptive study from 2010 to 2011 in a tier-IV complexity institution of the city of Medellín. Probabilistic sampling was performed with a sampling frame of almost 4000 users seen yearly in the hospital's general surgery unit, with 95% confidence index, 5% level of precision, expected proportion of 16%;² the minimum calculated sample was 182 users. The selection criteria used were: patients over 14 years of age who attended the general surgery service of the tier-IV institution in the city of Medellín with medical or traumatic pathology, requiring urgent elective therapeutic surgical intervention or if they had been programmed for surgery no more than 24 hours from the observation in emergency and who were monitored completely from the moment of admission until discharge from the institution.

Recruitment, evaluation, and filling out of the instrument with data from the patients admitted to the services and who complied with all the inclusion criteria to belong to the study was the responsibility of the medical residents from general surgery, who were on duty in the institution. It was guaranteed that one of them would remain for 24 hours in the emergency service and another in the surgical hospitalization

service. Once patients were transferred to the operating room, the resident physician in charge gave the data collection document to the Chief Nurse to control filling out the checklist. Direct observation and follow up of the patients took place in hospitalization wards (general, intensive, or special) by the group of researchers conformed by two general surgeons from the institution and two specialist nurses from the area patient quality and security. Data collection was conducted from admission until definite discharge, including the final evaluation through outpatient consultation.

To gather the information, direct observation and revision of patients' clinical charts were used, as well as the design of an instrument to consign all the necessary information, validated through a standard of processes, presented to all the researchers to unify criteria with respect to the instrument to collect data and avoid information bias. This instrument, described ahead, was filled out by the researchers and collaborators throughout the time the patient received care and, additionally, data was permanently controlled by the researchers.

The data collection instrument had three groups of information variables: a) demographic variables of the user: identification of the user; some socio-demographic variables: affiliation to the health insurance system, age, gender, among others; b) variables that measured the times of surgical care: hospitalization times, date and hour surgery was programmed, date and hour of admission, start and duration of the surgery; and c) variables that measured care safety: (i) administrative problems in caring for the users with: lack of supplies, problems with diagnostic aides, cancelation of surgery, inadequate prolonged stay; (ii) incidents like: problems with diagnostic aides, hemo-components, management of the airway, administration of medications, management of medical devices among others; and (iii) adverse events derived from patient care, like: infections, pressure ulcers, phlebitis, extravasation, reactions to medications, intraoperative events, among others.

A database was designed on the platform of the Faculty of Nursing at Universidad de Antioquia (<http://tone.udea.edu.co/CQP/#>), where the researchers and their collaborators permanently downloaded new research information. The descriptive analysis plan was carried out through frequency and percentages for the whole study variable. The variables were classified into four groups: 1) administrative problems for patient care, 2) incidents, 3) times of surgical care, and 4) adverse events.

According to article 11 of Resolution 8430 of 1993 from the Colombian Ministry of Health, this research is considered free of risk, given that no intentional intervention or modification was carried out of the biological or psychological variables of those who participated. The study only reviewed records and observed patient care, seeking to safeguard the anonymity of the personnel responsible for patient care. The Institutional Ethics Committee approved this study.

Results

The study evaluated 182 patients subjected to surgical interventions in the general surgery service, who received complete follow up. Table 1 shows that the patients were mostly under 50 years of age (81.8%, mean age was 39 ± 19 years) and males predominated (71.4%). In all, 98.9% of the surgical interventions were classified as urgent, with the most frequent admissions due to trauma (81.3%). Regarding times of care measured since the patient's admission to the emergency operating room, in operating room, to the immediate surgical recovery ward, it was found that 73.7% of the patients were defined surgical conduct, were surgically intervened, and had immediate post-surgical recovery in less than four hours. It should be clarified, however, that most of the surgeries were classified as urgent and the response time was consistent and appropriate, which could be explained by the characteristics of the hospital that has a vast historical trajectory in caring for trauma patients, demonstrated by the high level of training of the

physician surgeons and the surgical care staff. The process of surgical care of patients with poly-trauma lasted between 4 and 6 h, with 16.4% (30) of the surgical interventions object of investigation. For surgical safety in healthcare, a checklist is available, which permits verifying minimum safety conditions at the moment of the surgical intervention. Within this context, it was observed that 60.7% of the patients with surgical intervention had verification of this list, and the 38.8% that did not have verification of their checklist mostly presented poly-trauma and were admitted with vital emergency, which due to severity condition required immediate surgical intervention.

In providing health services, patient safety is measured by the number of safe and unsafe care situations (incidents and adverse events). The results of this research show that 67.5% of the patients received care classified as safe during their healthcare process, which comprised from admission through emergency to the discharge process through general surgery. Of this percentage, 28 presented medical complications inherent to the health status and their pathological process. Another 32.4% received unsafe care, finding 87 errors in healthcare, distributed among problems of administrative nature, incidents in care, and adverse events (Table 2). Besides, it is worth indicating that in the distribution in the frequency of flaws identified in patient care, it was found that 57.8% (34) presented a flaw or error in care; 32.2% (19) presented two flaws in their care processes, and 10% (6) presented three or more flaws in their care process.

Table 2 also shows that 4.9% of the patients reported administrative errors. These corresponded to delays in scheduling diagnostic aides, evaluations through inter-consultation, or on the initiation of the surgery. In addition, 5.4% presented incidents in the care process, understood as an error or flaw by the health staff that did not cause harm to the patient and which were related to the diagnostic aides and administration of medications.

Table 1. General characteristics of the 182 patients with surgical interventions from a high-complexity institution in Medellín, Colombia

Variable	Frequency	Percentage
Gender		
Male	130	71.4
Female	52	28.5
Age		
14-24 years	69	37.9
25-50 years	80	43.9
> 50 years	33	18.1
Admission		
Urgent	180	98.9
Trauma	148	81.3
Thorax	89	48.9
Abdominal	36	19.7
Neck and limbs	23	12.6
Medical emergency	33	18.1
Elective surgery	2	1.0
Surgical time in hours		
0-2	57	31.1
3-4	78	42.6
5-6	30	16.4
>6	7	3.8
Without data	10	5.5
Checklist		
Yes	111	60.7
No	71	38.8

Table 2. Distribution according to type of care in the safety of 182 patients with surgical interventions from a high-complexity institution in Medellín, Colombia

Variable	Frequency	Percentage
Type of care		
Safe care	123	67.5
Without complications	95	52.1
With complications	28	15.3
Unsafe care	59	32.4
Administrative problems	9	4.9
Incident in the care	10	5.4
Adverse event	40	21.9
Number of errors in the care		
Patients with one error	34	57.8
Patients with two errors	19	32.2
Patients with three and more errors	6	10.0

Of all the patients seen, 40 (21.9%) presented one or more adverse events – understood as the care error or flaw that causes them harm or detriment and which occurs due to the healthcare process, and not because of their inherent conditions or because of their illness process.

The study found 61 adverse events of which the most frequent were infections associated to care (27.8%), readmissions before 20 days for the same diagnosis or related to the care process (13.1), and hemorrhages and hematomas (11.4%) (Table 3).

Table 3. Distribution of the 61 adverse events presented by 40 patients with surgical interventions from a high-complexity institution in Medellín, Colombia

Adverse event	Frecuency	Percentage
Infections associated to healthcare	17*	27.8
Readmission before 20 days for the same diagnosis	8	13.1
Hemorrhages or hematomas	7	11.4
Problems with management of airway	7	11.4
Pressure ulcers	5	8.1
Removal of catheter or probe	2	3.2
Chemical phlebitis	1	1.6
Transfusion reaction	1	1.6
Reaction to medication	1	1.6
Other	12	19.6

*10 Infections of the operation site (5 superficial, 3 deep, and 2 of the organ space related), 4 sepsis, 2 infection of the urinary tract associated to vesical probe, and 1 pneumonia.

Regarding the frequency of adverse events, according to the patient care or hospitalization service, 42.3% were from general hospitalization wards, 28.8% from the intensive care unit, 15.2% from the intermediate or special care unit, and only 11.8% were seen in the emergency service. With relation to the health professional responsible for patient care, the findings show that 57.4% of adverse events was the responsibility of the treating physician and the 42.6% remaining was the responsibility of the nursing staff

Discussion

To address growing healthcare costs derived from adverse events, it is indispensable to determine their rate of occurrence and perform contextualized analysis, according to the type of institution, region or country it is in, so that effective correction and prevention actions can be established adjusted

to the institutional reality and, thus, agree on policies aimed at reducing complications, hospital readmissions, and adverse events.

This study reported an incidence of 21.9% of adverse events occurring in the 182 patients attended with surgical intervention in a tier-IV institution, which is above the incidence in the ENEAS study⁵ (8.4%) and in other studies reported in the scientific literature.^{2,6,7} The moment patient care takes place in surgical services diverse factors converge, turning these types of services into units of high risk for the occurrence de adverse events.⁸ Upon analyzing the results with the existing bibliography, we found limitations in the comparisons with other studies because a unified taxonomy still does not exist for the patient's surgical safety. Some authors, like Rebollo *et al.*,⁹ recommend that the treatment given to the analysis and comparisons of adverse events must be assumed with caution

and referred to the context of the patient and type of flaw or error (incident or adverse event), but also focused on the context of the health services provider institution, its level of care complexity, and the methodologies used in classifying and analyzing adverse events.

Differences observed in the occurrence of adverse events in the surgical area in this study, compared to those in other countries including those reported in Colombia, must be attributed probably to the types of patients cared for by this institution that in the vast majority of cases were urgent patients with poly-trauma, some with multiple wounds due to firearm, victims of violence, with vital emergency, and where the severity of the wounds increased the possibility of adverse events. In contrast, this situation is not contextualized in studies consulted, which report incidences of adverse events of elective, obstetric, and ambulatory type in surgical patients; that is, comparison with existing literature does not obey to equal patients characterized. These population characteristics causes the morbidity of the adverse events in this study to be higher than the data reported by others.^{10,11} In spite of all the limitations in comparing the rates of occurrence of adverse events, similarities can be noted in the types of adverse events of patients surgically intervened with those reported in scientific literature.^{9,12}

The adverse events appearing in the first place were the infections associated to care, with 27.8%, similar to the results reported in other studies.^{9,13,14} Secondly, hemorrhages and hematomas were present with 11.4% and which also appear reported in literature; problems with the airway also appear in equal proportion to this last. Although the literature on adverse events associated to care of the airway is not specific for the care of surgically intervened adults, reports are available in studies on prevalence of adverse events in intensive care and pediatric units.^{11,15} Errors in care related to the airway are the responsibility of nursing professionals. The care plan for surgical patients should focus on establishing prevention measures on the occurrence of adverse events,

given that it becomes an added cost in patient care because it is related to increased days of hospital stay, besides the risks of infections of the respiratory system.

A study conducted by a group of nurses in California found a relationship between the increased standard of nurses and the decrease of adverse events associated to the airway.¹⁶ It is worth emphasizing that the population studied corresponded to surgical patients who required start of early respiratory therapy. Occurrence of this adverse event may be explained in this institution because respiratory therapists perform respiratory therapy during the day shift and not at night or on weekends. This permits concluding that the existence of nursing professionals empowered of respiratory care could favor the decrease of complications and incidents associated to the airway.¹¹ Pressure ulcers presented the same behavior as other similar studies.^{11,13,17} This study found no significant data related to adverse events related by invasive devices or by medications, as reported in existing literature.^{11,17}

In conclusion, the information obtained and analyzed accounts for the importance of measuring, studying, and monitoring adverse events to characterize needs, according to the particular context of each country or region, and propose correction and prevention actions to diminish the incidence of adverse events and unfavorable outcomes, as consequence of these. Knowing specifically where to locate the flaws in caring for surgical patients, along with which services impact most upon their frequency and what types of flaws or errors are committed by the professionals responsible for the care,¹⁸ will permit health institutions to be more effective in controlling and diminishing their occurrence to project effective programs incidental on the prevention of adverse events and, thus, offer safe and quality care for surgical patients.¹⁹⁻²²

This study reported the prevalence of adverse surgical events above that found in the scientific bibliography; however, prudence and caution is recommended when comparing with other studies,

given that the institutional context – added to the type of admissions diagnosis and the characteristics of patients differ from those reported and analyzed is such. Improvement of the healthcare system in the surgery area could reduce substantially not only the occurrence of flaws, but also the economic burden said flaws cause in healthcare.

In managing nursing care, it is necessary to ensure quality, which is why it is indispensable to have early identification of flaws or errors in care that are the responsibility of nursing professionals to adequately establish risk management through clinical and administrative activities that permit evidencing the effectiveness of actions in processes and in the results of patient care.

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