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Retrospective Study

Adverse events in critical care: Search and active detection through the Trigger Tool

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Abstract**AIM**

To investigate the incidence of disadvantageous events by using the Global Trigger Tool in an intensive care unit (ICU).

METHODS

A retrospective descriptive study was performed in a 12-bed university ICU in the city of Medellín, Colombia. Clinical charts of hospitalized patients were reviewed, between January 1 and December 31, 2016, with the following inclusion criteria: subjects aged over 18 years, with at least 24 h of hospitalization and who had a complete medical history that could be accessed. Interventions: Trained reviewers conducted a retrospective examination of medical charts searching for clue events that elicit investigation, in order to detect an unfavorable event. Measurements: Information was processed through SPSS software

version 21; for numerical variables, the mean was reported with standard deviation (SD). Percentages were calculated for qualitative variables.

RESULTS

Two hundred and forty-four triggers occurred, with 82.4% of subjects having presented with at least one and an average of 3.37 (SD 3.47). A total of 178 adverse events (AEs) took place in 48 individuals, with an incidence of 52.1%. On average, four events per patient were recorded, and for each unfortunate event, 1.98 triggers were presented. The most frequent displeasing issues were: pressure ulcers (17.6%), followed by complications or reactions to medical devices (4.3%), and lacerations or skin defects (3.7%); the least frequent was delayed diagnosis or treatment (0.56%). Thirty-eight point four percent of mishap events caused temporary damage that required intervention, and 48.9% of AEs were preventable. Comparison between AEs and admission diagnoses found that hypertension and sepsis were the only diagnoses that had statistical significance ($P = 0.042$ and 0.022 , respectively).

CONCLUSION

Almost half of the unfavorable issues were classified as avoidable, which leaves a very wide field of work in terms of preventative activities.

Key words: Adverse events; Critical care; Trigger Tool; Complications; Security

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Core tip: The Global Trigger Tool is a type of active detection of adverse events (AEs). Three studies carried out in intensive care units (ICUs), which included only patients who died in the following 96 h or 7 d prior to ICU admission. The importance of our study is that it was performed during the entire hospital stay in the ICU. The incidence of AEs was 52.1%, and 48.9% of these were preventable. The most frequent were pressure ulcers (17.6%) and complications related to medical devices (4.3%). The three main triggers were skin defects, excitation or drowsiness, and unscheduled withdrawal of surgical catheter, probes, or drains.

Molina FJ, Rivera PT, Cardona A, Restrepo DC, Monroy O, Rodas D, Barrientos JG. Adverse events in critical care: Search and active detection through the Trigger Tool. *World J Crit Care Med* 2018; 7(1): 9-15 Available from: URL: <http://www.wjnet.com/2220-3141/full/v7/i1/9.htm> DOI: <http://dx.doi.org/10.5492/wjccm.v7.i1.9>

INTRODUCTION

In 2000, the publication of "To Err is Human: Building a Safer Health System" from the United States Institute

of Medicine marked a before and after in the awareness of this issue and has made security research become a fundamental pillar^[1]. In 2004, the World Health Organization (WHO) created the Global Alliance for Patient Safety, in order to coordinate, disseminate and accelerate improvements in patient safety worldwide.

Patient safety is defined as the absence of unnecessary or potential harm associated with health care. This damage is represented as a functional, structural or any detrimental effect derived from medical care. Adverse events (AEs) can be classified as preventable or nonpreventable. The causality model raises many factors that influence avoidable unfavorable event sequence. The system produces errors when several weaknesses occur momentarily, allowing the opportunity for accident. Risk management is a discipline the objective of which is study of unfavorable issues derived from assistance through its detection and analysis, with the ultimate goal of designing strategies for its prevention. Risk is defined as the combination of the probability of occurrence of an event and its consequences. In the United Kingdom, an organizational model of causation of errors and AEs, known as the London Protocol, was developed.

In a study by Resar *et al*^[2] conducted between 2001 and 2004 in 62 intensive care units (ICUs) of 54 hospitals, the authors described an incidence of 11.3 AEs. Rothschild *et al*^[3], for a year under direct observation, found 120 AEs in 79 subjects (20.2%), including 66 (55%) not avoidable and 54 (45%) avoidable; the rate per 1000 patient-days was 80.5. Forster *et al*^[4], in an academic ICU with 207 individuals being monitored daily, found AEs in 40 patients (19%), being preventable in 21 subjects (10%); these AEs were associated with an increase in hospital stay.

There are two types of AE detection: passive, where events are voluntarily reported; and active, where retrospectively or prospectively, a comprehensive assessment is performed to actively detect issues. The passives do not reach the absolute detection of the events, compared to the active review^[5]. As described previously, only between 10% to 30% of AEs are voluntarily reported^[6]. In one study, nurses were able to create a nonpunitive atmosphere which increased the spontaneous and voluntary reporting 10 to 20 times more^[2]. Another survey assessing different methods of notification in Hospital Monte Naraco, revealed that 30% of the events were reported by voluntary means^[6].

In the active methodology, there is a tool known as Global Trigger, which is based on a retrospective revision of the clinical chart performed by trained reviewers which seeks hints that will serve as indications for the evaluators to investigate the records in depth. This tool enables data acquisition and subsequent analysis and management through time of the causes of AEs^[7,8]. This tool has facilitated the detection of, at least, 10 times more events than those reported by passive search methods, such as voluntary reports^[2]. It has been reported that only between 10% to 20% of errors

Table 1 Triggers

Trigger	<i>n</i>	%
Skin defects or lacerations	36	14.75
Excitation or drowsiness of the patient	34	13.93
Unscheduled withdrawal of surgical catheter, probes, drains or other devices	34	13.93
Hypotension	33	13.52
Initiation of antibiotics after 48 h of admission	28	11.48
Abrupt fall in hemoglobin or hematocrit by more than 25%	24	9.84
Hypoglycemia	19	7.79
Pneumonia	9	3.69
Reintubation in less than 48 h	6	2.46
Unscheduled surgical reintervention	5	2.05
Chest tube insertion during ICU hospitalization	4	1.64
Initiation of dialysis during ICU hospitalization	4	1.64
Accidental extubation	3	1.23
Adverse drug reaction events	3	1.23
Cardiac arrest	1	0.41
Protamine use	1	0.41
Total	244	100.00

ICU: Intensive care unit.

are reported; and, of those, 90% to 95% do not cause harm to patients^[9]. We intend to establish the incidence of AEs by using the Global Trigger Tool (GTT) in a high-complexity academic ICU.

MATERIALS AND METHODS

A retrospective descriptive study was conducted in a 12-bed ICU, belonging to a university center in the city of Medellin, Colombia. This service is attended by intensivists, with a ratio of 6 patients per doctor at daytime and 12 patients per doctor at night. Nursing staff keeps a ratio of 6 patients per nurse during 24 h, and there is 1 nursing assistant for every 2 patients. There is an available respiratory therapist 24 h a day. Clinical charts of hospitalized patients were taken, between January 1 and December 31, 2016, with the following inclusion criteria: subjects aged over 18 years, with at least 24 h of hospitalization who had a complete medical history that could be accessed. This study was approved by the ethics committee of the Universidad Pontificia Bolivariana.

Techniques and data collection instruments

After the ethical and institutional endorsement, we proceeded to train the team of reviewers, constituted by nurses with expertise and experience in Quality of Health Services, and medical specialists in intensive care who were standardized in review(ing) criteria, established(ing) times and process(ing) order(s). Each team analyzed the medical records in the event of a trigger; the chart was sent to one of two intensive care specialists to define the presence of this AE. Sixteen triggers were used to detect AEs (Table 1). These triggers were initially extracted from the literature, and then corroborated by each of the service intensivists, and subsequently, a consensus was obtained at a group meeting.

In case of an AE, a consensus was reached between the two intensivists. If this was proven positive, the specialist analyzed the preventability and severity of the AE, which was carried out with the classification of the The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), which stipulates the following criteria on a scale from A to I. Criteria from A to D are considered incidents. From the E and on, they are considered events, as follows: E: Temporary harm requiring intervention; F: Temporary harm requiring prolonged hospitalization; G: Permanent harm; H: Injury that demands intervention to sustain life; Y: Harm that contributes to death.

Statistical analysis

Data processing was done using SPSS version 21. Quantitative variables were analyzed by grouping (mean and median) and dispersion measures [standard deviation and interquartile range (IQR), according to their distribution type]. Categorical variables were analyzed as proportions. Bivariate analysis was performed to search for association between AE and admission diagnoses. χ^2 hypothesis tests were used for categorical variables and Student's *t*-test for continuous variables with normal distribution or Mann-Whitney *U*-test for those variables with a different distribution^[10]. A significant association was considered if a *P* value of less than 0.05 was obtained.

RESULTS

Data were collected from 134 patients. Forty patients were excluded for the following reasons: 12 subjects aged under 18 years and 28 patients remained less than 24 h in hospitalization; finally, 94 clinical charts were analyzed. General characteristics of the patients were: the mean age of the individuals was 56.77 years (standard deviation: 20.72; minimum: 10 and

Table 2 Adverse events

Adverse event	<i>n</i>	(%)
Pressure ulcers	62	17.6
Complications or reactions to medical devices	15	4.3
Lacerations	13	3.7
Drug-induced hypotension	10	2.8
Poor glycemic control	9	2.6
Nosocomial pneumonia	9	2.6
Injury during procedure	8	2.3
Phlebitis	7	2.0
Hemorrhage or hematoma related to surgery or procedure	7	2.0
Acute lung disease or respiratory failure	5	1.4
Operative site infection	5	1.4
Another event	5	1.4
Drug-induced neurological disorders	4	1.1
Sepsis and septic shock	4	1.1
Burns, erosion, bruises and fractures	3	0.9
Pneumothorax	2	0.6
Pruritus, rash or dermal lesions, reactive to drugs or dressings	2	0.6
Adhesion and functional alterations after surgical intervention	1	0.3
Bacteremia associated with device	1	0.3
Error in medication delivery	1	0.3
Events attributable to internal failures in timeliness or continuity of evaluation	1	0.3
Failures attributed to quality	1	0.3
Opportunistic infection by immunosuppressive treatment	1	0.3
Nosocomial urinary tract infection	1	0.3
Delay in diagnosis or treatment	1	0.3
Total	178	100

maximum: 87). Sixty-two point eight percent ($n = 59$) of patients were female, and 37.2% ($n = 35$) were male. Of the subjects who suffered AEs, 62.8% were women and 37.2% were men. APACHE II was 18 (IQR 14-24), and 12 of the 94 patients died (12.5%), with only one death related to an AE. The average patient stay was 8.05 d, with a standard deviation of 11.8 d (with a minimum of 1 d and a maximum of 66 d). The reasons for admission were: 22 (23.4%) patients were postsurgical, 18 (19.14%) came from the obstetric service, 14 (14.9%) from emergencies, 28 (29.78%) from hospitalization and 12 (12.76%) came from other institutions. Of the assessed patients, 43/94 (45.7%) had at least one comorbidity on admittance to the ICU; among the main ones were acute myocardial infarction (84%), sepsis (15%), cranioencephalic trauma (5%), pneumonia (5%) and cerebrovascular accident (4%). Other causes of lower frequency included: Urinary tract infection, heart failure and rheumatologic disease with 4%, 3% and 2%, respectively. Eighty-eight point three percent of the individuals had health system affiliation due to their job, and 11.7% were subsidized by the State.

Table 1 shows the triggers, totaling 248, concentrated in 69 subjects; the most frequent of which were: skin defects or lacerations (14.75%), excitation or somnolence of the patient through the RASS scale (+3 or -3) (13.93%) and hypotension (13.52%). The least frequent was the use of protamine (0.41%).

The Triggers found elicited further investigation into the medical records in order to look for unfavorable issues. This search yielded a total of 178 AEs in 49

subjects, with an incidence of 52.1%; on average, 3.6 events per patient were recorded, and 1.98 triggers for each AE.

Table 2 shows the AEs detected; the most predominant were pressure ulcers (17.6%), followed by complications or reactions to medical devices (4.3%), lacerations or skin defects (3.7%). The least presented was delayed diagnosis or treatment (0.56%).

One part of the analysis of displeasing events is prevention; almost half of the AEs were preventable (48.9%), 28% were incidents, 1.2% were nonpreventable and 21.9% were a complication of the underlying disease.

The 38.4% of severity of AEs were classified in category E (temporary harm that required intervention), 10.8% classified in category H (harm that required an intervention to sustain life), 0.9% were rated in category F (temporary harm demanding prolonged hospitalization), and finally, categories Y (harm that contributed to death) and G (permanent harm), accounted for 0.3%.

Another comparison between AEs and admission diagnoses found that hypertension and sepsis were the only diagnoses that had statistical significance ($P = 0.042$ and 0.022 , respectively).

When reviewing the patient's age and preventability, the most striking findings indicated that 172 patients had preventable AEs, who were at least 17 years of age and had a maximum age of 87 years, with a median of 69 years and a 75th percentile of 77 years. On the contrary, 6 patients developed nonpreventable AEs, with a minimum age of 64 and a maximum of 87 years; the median was 69 and the 75th percentile was 75 years.

Table 3 Comparison between the different studies in ICU using the Trigger Tool methodology

Ref.	Patients	No. of ICUs	Sample	Incidence or prevalence of AEs
Resar <i>et al</i> ^[2]	During ICU stay	62	12074	11.3/100 patient d
Nilsson <i>et al</i> ^[12]	Those who die in less than 96 h of ICU admission	1	128	32/100 ICU admissions 19.5%
PREVENT ^[13]	Within 7 d prior to ICU admission	5	280	27.1% (80% related to reason for admission)
UPB (Molina <i>et al</i>)	During ICU stay	1	94	52.1% 3.6 AEs per patient

AEs: Adverse events; ICU: Intensive care unit.

The statistical significance was a Kruskal-Wallis *P* value of 0.012.

DISCUSSION

The main finding of our study is that the incidence of AEs in the ICU is 52.1%. The most frequent triggers were skin defects or lacerations (14.7%), excitation or somnolence of the patient according to the RASS scale (+3 or -3) (13.9%), and hypotension (13.5%). The most predominant AEs were pressure ulcers (17.6%), followed by complications or reactions to medical devices (4.3%), and lacerations or skin defects (3.7%). On average, 3.6 events per patient were recorded, and 1.98 triggers for each AE.

The largest study to identify the occurrence of displeasing issues was conducted by the Institute for Healthcare Improvement in 62 ICUs from 54 hospitals, between 2001-2004. The prevalence of AEs observed in 12,074 admissions in the ICU was 11.3 AEs/100 patient d; in a subgroup of 1,294 charts of 13 ICUs, which were reviewed in detail, 1,450 unpleasant events were identified, with a prevalence of 16.4 events/100 ICU d^[2]. The Institute used, for the first time as a method of detecting AEs in ICU, records related to medications linked to pharmacy, finding 120 AEs in 79 patients (20.2%), with a rate of 8.05 AEs/100 patient d. This incidence is lower than ours, but with two differences: the Institute did not use the Tool, and it was prospective for a year, through continuous direct observation. Forster *et al*^[4] also monitored patients daily by a multidisciplinary team; they evaluated 207 critical patients, with AEs in 40 patients (19%).

In a systematic review of the GTT by the end of 2016, in the different specialties, only three studies carried out in ICUs were found. Apart from the aforementioned^[11], which shares similarity to ours, investigating triggers in subjects during hospital stay, the other two studies differ in their admission criteria. The first, Nilsson *et al*^[12], included only patients who upon admission to the hospital's ICU or in the following 96 h died. The second, the PREVENT trial^[13], reviewed clinical charts 7 d prior to ICU admission. Table 3 shows the methodological characteristics of these surveys, including our own. Table 4 shows the most frequent triggers and AEs in the different studies performed with GTT in ICU.

Of the findings of these investigations, we can highlight the following. Firstly, that AEs are preventable

in a high proportion (between 48.9% and 77% of cases). Secondly, in all studies, except PREVENT, AEs in their severity were more temporal (E or F). Thirdly, in spite of using the GGT methodology, only Resar *et al*^[2] and ours describe the most conventional triggers. And, lastly, the most common AEs in the different studies are distinct, perhaps they do resemble in that they are related to skin care.

In our study, the most extensive trigger was skin laceration, which is consistent with the most prevalent AE: pressure ulcer; this event is consistent with other studies, such as IBEAS^[14] in hospitalization, which considers it as the most common in Latin America. This event is largely associated with the presence of patients' comorbidities, such as physical dependence, poor nutritional status, high hospital stay and the need to be in bed, distinctive of subjects hospitalized in an ICU.

In terms of severity and age, it was evident that as the patient was older, the likelihood of developing an AE increased, a fact that is consistent with a study conducted in Spain, where it was observed that age over 65 years was associated with the presence of AE^[15]. Our knowledge indicates a higher frequency of unpleasant issues in females, in contrast to a survey performed in an ICU in Sao Paulo, which revealed a higher incidence of AE in males 52.3%. Sex differences could be attributed to the fact that the institution included in this research serves primarily maternal patients^[16].

This study had several limitations. First, it was performed in a single center. Second, since it is retrospective, there may be bias in the lack of information from medical and nursing records. The third limitation was the inclusion of the unit's own intensivists within the research team; however, this fact strengthened their competencies in the use of the methodology and facilitated that they self-evaluated the AEs presented. The fourth limitation was the difficulty that existed in our environment for the unification in the administrative criteria of hospitalization in intensive care; that is to say, there may be special care patients. The fifth limitation was selection bias for interobserver variability, despite treatment and use of the same tool.

In the future, it will be worthwhile to carry out a multicenter study, given the shortage of these, and with the clearance of the most frequent triggers found in this study and Resar *et al*^[2]. In addition, a prospective cohort study, after identifying the triggers, can be done to see how many AEs are prevented.

Table 4 Triggers and adverse events among the different studies in ICU using the Trigger Tool methodology

Ref.	Most frequent triggers	Adverse event	Severity	Preventability
Resar <i>et al</i> ^[2]	1 Proceeding 2 Hemoglobin fall 3 Intubation or reintubation 4 Pneumonia 5 Positive blood cultures	Triggers led to an AE in: 1 17.8% 2 65% 3 54% 4 67% 5 83%	E = 58.2% F = 24.3% G = 2% H = 11.4% Y = 4.1%	Not reported
Nilson <i>et al</i> ^[12]	Not reported	1 Nosocomial infection (22%) 2 Hypoglycemia (19%) 3 Pressure ulcer (17%) 4 Complication by procedure (15%)	E = 49% F = 10% G = 2.4% H = 4.8% Y = 33.8%	54%
PREVENT ^[13]	149 triggers. Does not report frequencies	1 Delay/failure in medical management (14.4%) 2 Surgical tissue damage (11.5%) 3 Failure to monitor scales by nursing (96%) 4 Error in medication prescription (8.6%)	E = 5.5% F = 31% G = 32% H = 21% Y = 10.5%	77%
UPB (Molina <i>et al</i>)	248 triggers 1 Skin defects or lacerations (14.7%) 2 Excitation or drowsiness of the patient (13.9%) 3 Hypotension (13.5%) 4 Unscheduled removal of surgery catheter, probes, drains or other devices (13.9%) 5 Initiation of antibiotics after 48 h of admission (11.5%)	1 Pressure ulcers (17.6%) 2 Complications or reactions to medical devices (4.3%) 3 Lacerations (3.7%) 4 Drug-induced hypotension (2.8%) 5 Poor glycemic control (2.6%)	E = 38.4% F = 0.9% G = 0.3% H = 10.8% Y = 0.3%	48.9%

The main conclusions of our study were: we had an incidence of 52.1%; on average, 3.6 events per patient were recorded, and for each AE we had 1.98 triggers; and, the main AEs were related to skin lesions (pressure ulcers, lacerations) and the use of medical devices. Almost half of the AEs were classified as preventable, which leaves a very broad field of work in terms of preventing the occurrence of such events. We propose that each ICU identify its triggers, so that it can actively prevent the AEs.

ARTICLE HIGHLIGHTS

Research background

The Global Trigger Tool (GTT) enables data acquisition and subsequent analysis and management through time of the causes of adverse events (AEs). This tool has facilitated the detection of, at least, 10 times more events than those reported by passive search methods. GTT is a type of active detection of AEs. Just three studies carried out in intensive care units (ICUs), which included only patients who in the following 96 h died or 7 d prior to ICU admission. The importance of our survey is that it was performed during the entire hospital stay in ICU.

Research motivation

The main motivations for the study were the low amount of reports on AEs and the issue that the search and report systems do not detect all events that could present in our institution. Although there is a high incidence of AEs in hospitalized patients in the ICU, current search and report systems fail to detect them all. For this reason, we are inclined to the GTT methodology. One of the problems was that these triggers were initially extracted from the literature, and then corroborated by each of the service intensivists, and subsequently, a consensus was obtained at a group meeting. Therefore, it is essential that the medical team of each ICU in the world defines which would be the most useful triggers. Another difficulty we had was the review of all the patients' records to identify the triggers. One solution is to carry out prospective studies that include data for the detection of triggers in each patient's evolution chart. In the future, it will be worthwhile to carry out a multicenter study in this sense.

Research objectives

The authors intended to establish the incidence of AEs by using the GTT in a high-complexity academic ICU. The authors determined which were the most frequent triggers and AEs, along with their severity, which was carried out with the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) classification, that stipulates criteria on a scale from A to I, and from A to D. In addition, analysis was performed to explore the association between AEs and admission diagnoses. For future prospective multicenter research, the association of triggers with AEs should be evaluated.

Research methods

A retrospective descriptive study was conducted in a 12-bed ICU. The inclusion criteria were subjects aged over 18 years, with at least 24 h of hospitalization, and who had a complete medical history that could be accessed. A training team of reviewers (nurses and intensivists) were standardized in review criteria, established times and process order. Each team analyzed the medical records in the event of a trigger. Sixteen triggers were used to detect AEs. These triggers were initially extracted from the literature, and then corroborated by each of the service intensivists; subsequently, a consensus was obtained at a group meeting.

Research results

The main finding of this study was that the incidence of AEs in the ICU is 52.1%. The most frequent triggers were skin defects or lacerations (14.7%), excitation or somnolence of the patient according to the RASS scale (+3 or -3) (13.9%), and hypotension (13.5%). The most predominant AEs were pressure ulcers (17.6%), followed by complications or reactions to medical devices (4.3%), and lacerations or skin defects (3.7%). This search yielded a total of 178 AEs in 49 subjects, with an incidence of 52.1%; on average, 3.6 events per patient were recorded, and 1.98 triggers for each AE. One of the problems of this retrospective study was the detection of the severity of AEs. For this reason, the authors sent the data to two intensivists to agree on the severity of these AEs; we think that this aspect could be better solved in a prospective research study.

Research conclusions

The Global Trigger Detection Tool is a useful instrument to detect AEs in an ICU. As a descriptive study, no theory could be generated from our findings. In this survey, the clinical chart review methodology, suggested by the IHI,

was taken as a reference, although the research team made variations in the manner of selecting patients (systematic randomized sampling), along with the review time of clinical records (review all charts), which allowed the detection of more triggers and AEs that could be useful for future investigations. Including GTT methodology to the study implies an increase in the frequency of AEs, and thus adopts measures that reduce their incidence in the future.

Research perspectives

The authors suggest the adoption of the methodology in the institution with a trained team in this tool. In future investigations, it is recommended to determine the effectiveness of the tool through analytical studies (cases and controls) that show statistically significant differences between passive and active methods of AE detection. The authors suggest prospective projects that validate the methodology to verify that they could anticipate the presentation of AEs.

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