Review

Medical errors in neonatal intensive care unit at Benha University Hospital, Egypt

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الأخطاء الطبية في وحدة الرعاية المركزة لحديثي الولادة في مستشفى بنها الجامعي، مصر

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الخلاصة: أجريت هذه الدراسة في وحدة الرعاية المركزة للأطفال حديثي الولادة في مستشفى بنها الجامعي، مصر، في الفترة من 1 أغسطس/ آب 2012 إلى 31 يناير/ كانون الثاني 2013 للتعرف على الأخطاء الطبية وتحديد عوامل الخطر وعواقب هذه الأخطاء. وتم الكشف عن الأخطاء عن طريق متابعة حديثي الولادة واستعراض التقارير، بما في ذلك أوراق متابعة طواقم التمريض وملاحظات الأطباء المقيمين حول التقدم المحرز وتقارير التحقيقات. ولقد اكتشفنا 3819 خطأً أثرت على 97٪ من حديثي الولادة. وقد تضمنت أنواع الأخطاء 403 خطأ في الأدوية (10.55٪ من إجمالي الأخطاء)، و652 خطأً في الإجراءات الروتينية اليومية (17.07٪)، و1042 خطأً في الإجراءات التي تتطلب اختراق الجلد (27.28٪)، و68 خطأً في التغذية (1.78٪)، و63 خطأً في المعدات (1.64٪)، و260 خطأً إدارياً (6.8٪)، و656 خطأً يتعلق بالعاملين (17.18٪)، و107 خطأً من الأخطاء البيئية (2.8٪)، و448 خطأً في مكافحة العدوى (11.73٪)، و120 خطأ في مكافحة العدوى التي تُكتَسب بالمستشفيات (3.14٪). كما وجد أن الأخطاء الطبية كانت عالية لدى حديثي الولادة المنخفضي الوزن عند الولادة، والمبتسرين، وتزداد مع مدة البقاء في المستشفى.

ABSTRACT This study was conducted in the neonatal intensive care unit of Benha University Hospital, Egypt from 1 August 2012 to the 31 January 2013 to identify medical errors and to determine the risk factors and consequences of these errors. Errors were detected by follow-up of neonates and review of reports including nursing follow-up sheets, resident progression notes and investigation reports. We detected 3819 errors that affected 97% of neonates. Types of errors included 403 medication errors (10.55% of total errors), 652 errors in daily routine procedures (17.07%), 1042 errors in invasive procedures (27.28%), 68 errors in nutrition (1.78%), 63 equipment errors (1.64%), 260 administration errors (6.8%), 656 staffing errors (17.18%), 107 environmental errors (2.8%), 448 infection control errors (11.73%) and 120 nosocomial infection errors (3.14%). Medical errors were high in low birth weight, low gestational age neonates and increased with duration of admission.

Erreurs médicales dans l'unité néonatale de soins intensifs du centre hospitalier universitaire de Banha, Égypte

RÉSUMÉ La présente étude a été conduite dans l'unité néonatale de soins intensifs du centre hospitalier universitaire de Banha, en Égypte, du 1er août 2012 au 31 janvier 2013, dans le but d'identifier les erreurs médicales et de déterminer les facteurs de risque et les conséquences associés. Des erreurs ont été détectées dans le suivi des nouveau-nés et l'analyse de rapports incluant des fiches de suivi des soins infirmiers, des notes sur la progression des internes, et des rapports d'enquête. Nous avons détecté 3 819 erreurs ayant affecté 97 % des nouveau-nés. Les types d'erreurs incluaient 403 erreurs de médication (10,55 % du nombre total d'erreurs), 652 erreurs dans les actes de routine journaliers (17,07 %), 1 042 erreurs dans les procédures invasives (27,28 %), 68 erreurs de nutrition (1,78 %), 63 erreurs d'équipement (1,64 %), 260 erreurs administratives (6,8 %), 656 erreurs au niveau du personnel (17,18 %), 107 erreurs en matière de pratiques environnementales (2,8 %), 448 erreurs liées à la lutte contre les infections (11,73 %) et 120 erreurs entraînant des infections nosocomiales (3,14 %). Les erreurs médicales étaient nombreuses dans les cas de nouveau-nés souffrant d'une insuffisance pondérale à la naissance ou étant nés prématurément, et elles augmentaient en fonction de la durée de l'hospitalisation.

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Received: 6/7/2015; accepted: 31/8/2016

Introduction

There is increasing interest worldwide in medical errors and their negative impact on health (*1*). Errors that are potentially harmful are 8 times more likely to occur in the neonatal intensive care unit (NICU) as compared with adult settings in the hospital (*2*). Neonates are at high risk for medication errors because of their low weight, physiological immaturity, limited compensatory abilities and extensive exposure to medication in the NICU (*3*). When a medical error occurs, whether it harms the patient (an adverse event) or not (a near miss), it should be investigated to determine the factors that led to its occurrence. An important part of such an investigation is analysis of the human factors that have contributed to the event. A systematic investigation should be carried out into the exact circumstances surrounding the event: lighting, environmental noise level, faulty equipment, the patients and the involved health professionals (*4*). Multi-institutional, voluntary, nonpunitive, error-reporting systems are likely to offer beneficial data on types, causes, results and preventability of errors in the NICU (*5*). This study was conducted in the NICU, Benha University Hospital, Egypt to identify medical errors and to determine the risk factors and consequences of these errors.

Methods

Study design and patients

This study had a prospective part that was done by observation of neonates from admission to discharge, and a retrospective part that involved reviewing the medical records of the same neonates. The study involved all neonates admitted to the NICU of Benha University Hospital from the 1 August 2012 to the 31 January 2013, at different times of day (morning, evening and night shifts) and weekends. The unit had a capacity of 12 incubators, 6 mechanical ventilators, 4 continuous positive airway pressure (CPAP) machines, 1 portable X ray apparatus and 2 resuscitators. There were no beds for phototherapy (all babies were inside incubators) and no isolation areas. Inclusion criteria: babies from birth to age 30 days and preterm and full-term neonates. Exclusion criteria: neonates with history or signs of iatrogenic complications before NICU admission and babies admitted solely for follow-up or observation for < 24 hours (such as feeding or minimal oxygen support after delivery).

A total of 178 neonates were admitted and 30 were excluded (23 with iatrogenic complications and referred to the NICU, e.g., calcium burn, pneumothorax or perforated oesophagus, and 7 were aged > 30 days at admission). This left a study group of 148 neonates, whose characteristics are shown in Table 1.

Data collection

Observations were made by 1 researcher who used a sheet with a list of possible medical errors. This list was developed by reviewing the related literature and under supervision of the authors. Observations were made 5–7 times weekly in the morning shift (08:00–14:00 hours), evening shift (14:00–20:00 hours) and night shift (20:00–08:00 hours). All the admitted neonates were subjected to the following: (*1*) complete history, including postnatal age, sex, gestational age, mode of delivery, cause of admission, history of admission to other NICUs, or history of any procedures such as endotracheal intubation, chest tube or umbilical catheterization; (*2*) thorough clinical examination for identification of any suggestive signs of iatrogenic origin, for example, ulcer, gangrene, burn or extravasation; (*3*) follow-up for all cases during NICU stay to detect medical errors and iatrogenic complications induced by therapeutic or diagnostic procedures; and (*4*) monitoring through reviewing of daily morning reports, nursing follow-up sheets, resident progression notes, radiographs and laboratory investigations (reviewing was done after baby discharge or death).

Errors

Errors included medication errors, errors in daily routine procedures, errors

Table 1 Patient characteristics

	n = 148	%
Gender		
Male	75	50.7
Female	73	49.3
Gestational age (wk)		
Preterm < 37	86	58.1
Full term ≥ 37	62	41.9
Gestational age, mean (SD), range	35.09 (3.73), 26–41 wks	
Admission weight, mean (SD), range (kg)	2.43 (0.9), 0.8–4.5 kg	
Gestation type		
Single baby	131	88.5
One of twins	10	6.8
One of triplets	7	4.7
Mode of delivery		
Normal vaginal delivery	59	39.9
Caesarean section	89	60.1
Duration of admission, mean (SD), range	12.59 (3.55), 1–140 d	
Age at admission, mean (SD), range	4.35 (5.74), 1–30 d	

SD = standard deviation.

in invasive procedures, errors in nutrition, equipment errors, administration errors, staffing errors, environmental errors, infection control errors and nosocomial infection errors. This classification of errors was made after a search of PubMed using the following terms: medical errors, adverse events, iatrogenic complications and hazards in neonatal intensive care unit. Medical errors were defined as any error in the delivery of medical care, regardless of whether it had the potential to cause harm or not (*1*). Medical errors were categorized using a modification of Leape's classification of medical errors (*6*) and *NICQ 2007: Improvement in Action* (*7*), as well as several other schemes described in the literature (*8–12*).

Subcategories of medication errors were as described by Kaushal *et al.* (*2*). The standards for drug dose, drug administration and invasive procedures were based on *Cloherty's Manual of Neonatal Care* 5th edition (*13*).

Severity of errors was graded according to the classification of the National Coordinating Council for Medication Error Reporting and Prevention (*14*). Each category of errors had a degree of severity as follows:

A: incidents that had the capability to cause errors;

B: an error happened but it did not reach the patient;

C: an error happened but did not harm the patient;

D: an error happened that needed monitoring and/or required intervention to prevent harm;

E: an error happened that resulted in temporary harm to the patient and required intervention;

F: an error happened that resulted in temporary harm to the patient and extension of stay in the NICU;

G: an error happened and resulted in permanent patient harm;

H: an error happened and needed intervention to sustain life;

I: an error happened that may have contributed to or resulted in patient death.

Ethical considerations

The entire medical and nursing staff of the NICU were notified about the study. Reports of medical errors were anonymous and we emphasized that reporting would not be used to apportion blame to any individual but to aid error detection with a view to system improvement. We directed medical personnel during information sessions about medical errors and how to avoid repeating these errors. The Ethics Committee of the hospital approved the study.

Statistical analysis

The variables analysed in our study were types of error, distribution of errors, admission weight, gestational age, age at admission, duration of admission, mode of delivery, presentation at admission and invasive procedures. We also analysed other variables that may have been related to risk factors for errors, such as experience of resident (senior was > 1 year and junior < 1 year experience), working days and holidays, and shifts. All data were revised for completeness and consistency. Precoded data were entered into the computer using Excel for Windows (2010). The data were summarized in terms of numbers and percentages for qualitative data, and mean (standard deviation; SD) and range for quantitative data. Comparisons between the different groups of the study sample were carried out using the Mann–Whitney test to compare 2 groups and Kruskal–Wallis test to compare ≥ 3 groups. Correlations between medical errors detected and some characteristics of the study group were assessed using the Spearman correlation coefficient (ρ). $P < 0.05$ was considered statistically significant and $P < 0.001$ was considered highly significant. The statistical analysis was conducted using SPSS version 19.

Results

Eighty-nine (60.2%) neonates were admitted to the NICU with respiratory distress, 24 (16.2%) with neonatal jaundice, 10 (6.8%) with lethargy, 7 (4.7%) with type 1 diabetes, 5 (3.4%) with intrauterine growth retardation (small for date), 4 (2.7%) with convulsion, 3 (2.0%) with coma (intracranial haemorrhage/hypoxic–ischaemic encephalopathy), 2 (1.4%) with birth trauma (skull/arm fracture), and 1 (.07%) each with bleeding tendency, choanal atresia, infected epiderma bullosa and multiple swelling in the body.

The invasive procedures carried out in the NICU are listed in Table 2. Peripheral venous catheterization was the most common procedure, in 256 (78.3%) neonates, followed by endotracheal intubation in 133 (39.8%). Venous cutdown and intraosseous needle insertion were the least common, with 1 (0.67%) patient each.

One hundred and forty-eight neonates were followed up in the NICU for 6 months, and 3819 medical errors were detected that affected 97% of the study population (Table 3). We found that the mean number of errors per patient was 25.8 (5.08), range 0–213. There were 403 medication errors, which comprised 10.55% of the total, 652 (17.07%) daily routine procedure errors, 1042 (27.28%) invasive procedure errors, 68 (1.78%) nutrition errors, 63 (1.64%) equipment errors, 260 (6.8%) administration errors, 656 (17.18%) staffing errors, 107 (2.8%) environmental errors, 120 (3.14%) nosocomial infection errors and 448 (11.73%) infection control errors.

Medication errors are described in more detail in Table 4. Dispensing errors were the most common (167, 41.43%), followed by administration errors (124, 30.76%), prescription errors (81, 20.1%) and ordering errors (31, 7.7%).

Table 2 Invasive procedures performed on neonates

Invasive procedures	No. of procedures	No. of affected neonates	% of neonates
Peripheral venous catheter	256	116	78.3
Endotracheal intubation	133	59	39.8
Mechanical ventilation	59	59	39.8
Continuous positive airway pressure	67	46	31
Ambulatory ventilation	91	55	37.1
Venous cutdown	1	1	0.67
Intraosseous needle	1	1	0.67
Surgically placed central venous catheter	35	35	23.6
Umbilical venous catheter	40	40	27
Exchange transfusion	7	7	4.7
Chest tube	10	9	6.7
Blood and blood product transfusion	118	54	36.4
Urinary catheter	18	18	12.1

Table 3 Types of medical errors *(continued)*

Type of medical errors	No. of errors	% of total errors
1 Medication errors	403	10.55
2 Errors related to daily routine procedures	652	17.07
3 Errors related to invasive procedures	1042	27.28
A. Vascular procedures (catheters) (468)		12.25
1. Error in peripheral venous catheter	282	
2. Errors in peripheral inserted central venous catheters	137	
3. Error in umbilical catheter	49	
B. Respiratory procedures errors (406)		10.3
1. Error in intubation	164	
2. Error inmMechanical ventilation (MV)	149	
3. Errors in chest tube	9	
4. Error in continuous positive air way pressure (CPAP)	33	
5. Error in nasal prong	51	
C. Errors in blood sampling	82	
D. Urinary tract catheters errors	18	
E. Phototherapy errors	41	
F. Errors in blood transfusion	27	
4 Nutrition errors	68	1.78
A. Poor milk bottle storage	38	
B. Abdominal distension and vomiting (overfeeding of crying babies)	16	
C. Delayed initiation of trophic feeding as ordered	6	
D. Increased caloric intake (amount of milk)	8	
5 Equipment Errors	63	1.64
A. Nonworking equipment (X-ray and portable suction)	25	
B. Processing errors (incubators, laryngoscope, ventilators)	23	
C. Necessary equipment unavailable (monitors, pulse oximeter and blood pressure cuff)	14	
D. Not easy to use (unfamiliar new apparatus)	1	
6 Administration errors	260	6.8
A. Decrease in resources (syringe pump, IV lines, betadine, scalpels different sizes of ETT, umbilical catheters)	211	
B. Medication not available	49	
7 Staffing errors	656	17.18
A. Lack of supervision (mislabelling drugs, IV fluid preparation, storage of medication and milk bottles storage)	260	
B. Shortage of nurses	121	
C. Handoff and documentation errors including laboratory investigations, invasive manoeuvres and radiographs not registered in nursing sheets	120	
D. Error in collection of laboratory reports and X-rays in patient files	68	

Table 3 **Types of medical errors** *(concluded)*

Type of medical errors	No. of errors	% of total errors
E. Inability to contact resident in short time	63	
F. Poor team work (during resuscitation)	21	
G. Inability to contact needed staff	3	
8 Environmental errors	107	2.8
A. Noise (work interruption)	53	
B. Poor use of floor space	33	
C. Lack of space and overcrowding of equipment	21	
9 Nosocomial infection errors	120	3.14
A. Sepsis	91	
B. Conjunctivitis	16	
C. Omphalitis	9	
D. Pneumonia	4	
10 Infection control errors	448	11.73
A. Inappropriate medical supply towels and 50 cm syringe for IV fluid infusion	265	
B. Hand washing, gloves and gown not used in invasive procedures	56	
C. Using common bag of saline without labelling	55	
D. Poor infection control measures in IV fluid preparation	40	
E. Inappropriate sharp waste management	32	
Total errors	3819	100.00

ETT = endotracheal tube; IV = intravenous.

Table 4 **Distribution of medication errors**

Type of medication errors	n = 403	%
A. Errors in ordering	31	7.7
B. Errors in prescription	81	20.1
1. Calculation	45	11.2
2. Illegible prescription	36	8.9
C. Errors in dispensing	167	41.43
1. Labelling errors	96	23.8
2. Poor drug storage	71	17.6
D. Errors in administration	124	30.76
1. Wrong time	63	15.6
2. Incorrect speed of IV fluid	30	7.4
3. Written communication error	17	4.2
4. Solution set used instead of syringe pump	9	2.2
5. Local skin injury or chemical burn	5	1.2

IV = intravenous.

We analysed the correlations between patients' risk factors and different types of errors. Medical errors showed a significant positive correlation with duration of admission (Figure 1A) and a significant negative correlation with weight at admission (Figure 1B) and gestational age. The maximum length of stay in the NICU was 140 days and the maximum number of errors was 213, which appeared as extreme outliers. This neonate had congenital heart disease and was waiting for surgical correction and exposed to multiple iatrogenic complications.

There were no significant differences in errors between different shifts, except for a significant increase in administration errors in the evening and night shifts compared with the morning shift (Figure 1C). Also, we found a highly significant increase in staffing and environmental errors in the evening and night shifts compared with the morning shift (Figure 1D). There was no significant difference in errors between holidays and working days, but there was a significant increase in errors in junior residents compared with senior residents (data not shown).

Severity of errors was graded according to the classification of the National Coordinating Council for Medication Error Reporting and Prevention (*14*). The number (% of total) of errors in each group was as follow: A, 1296 (33.94%); B, 36 (0.94%); C, 442 (11.57%); D, 486 (12.73%); E, 1465 (38.36%); F, 78 (2.04%); G, 0; H, 16 (0.42%) and I, 0.

Discussion

In this study, we reported different types of medical errors that affected 97% of neonates, which is considered a high percentage, which agreed with a study in an NICU in the United States of America where medication errors occurred in 91% of admitted cases (*2*). In a study in India, medical errors were detected in 76.6% of neonates admitted to the NICU (*15*). Our number of errors was considerably higher than that in a prospective observational interventional study performed in 4 tertiary, university-affiliated NICUs in Israel, where the prevalence rate of iatrogenic events was only 18.8% of hospitalized infants (*16*). So, there is wide variation between our results and others and this

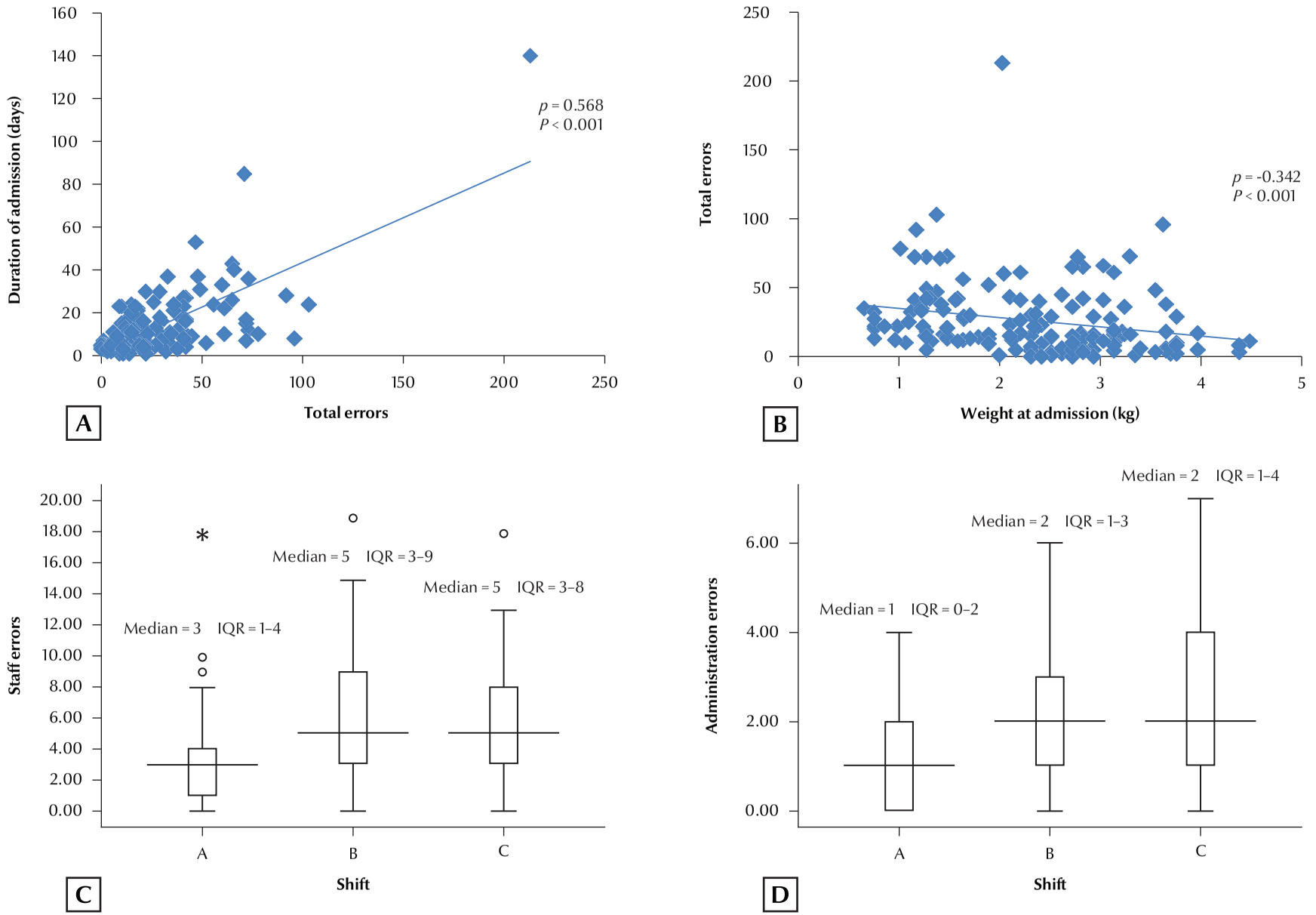

Figure 1 (A) Scatter plot for correlation between total errors and duration of admission. (B) Scatter plot for correlation between total errors and weight at admission. (C) Box plots for median and interquartile range of staff errors in different shifts. *Not significant; °errors in Shifts B and C were more significant than in Shift A. (D) Box plots for median and interquartile range of administration errors in different shifts.

may have resulted from differences in the classification of errors and the methods used to identify them.

The high rate of medical errors detected in our study may have been because it was conducted in a developing country where there is under-financing of essential health services, poor infrastructure and poor performance of personnel because of low motivation and insufficient technical skills. All these factors make the probability of medical errors higher than in developed countries. Another explanation for our high rate of medical errors is the use of two methods for error detection, the follow-up method and the method of review of medical records.

Errors in invasive procedures were the most frequent type, comprising 27.28% of the total number of medical errors. Within that group, catheterization errors (peripheral venous, peripheral inserted central venous and umbilical catheters) were the most common type of error, constituting 12.2% of the total number of medical errors. This was followed by respiratory procedure errors (intubation, mechanical ventilation, CPAP and nasal Prong), which comprised 10.3% of the total number of medical errors. These results are consistent with a study in which catheter errors were the most common iatrogenic events (20% of total), followed by respiratory procedure errors (16%) (*16*). Another study reported that cutaneous injuries (peripheral catheter-related lesions) were the most common iatrogenic event (*10*). Thus, it is clear that high numbers of errors in invasive procedures result mainly from catheter and respiratory procedure errors.

In our study, medication errors were low and represented 10.55% of total errors. This agrees with a previous report that medication errors comprised 13% of total iatrogenic events (*16*), whereas other studies have reported that medication errors represented 68.5% of total errors (*15*). Another study found that half of the iatrogenic complications in the NICU were related to medication errors (*9*). Thus, we found wide variation between our own and other results. Such variation was confirmed by Chedoe *et al.*, who suggested that the differences were due to variation in the definition of errors and the accuracy of the method used to identify them (*17*). Also, it is reported that studies of errors in the NICU are rare and most focus on medication errors (*5*).

With regard to nosocomial infection, neonatal sepsis affected 91 neonates (61.4%) in our study, which agrees with a study in Southern Brazil that reported a 45.8% incidence of nosocomial infection in neonates (*18*). Garland and Uhing have reported that hospital-acquired infections, which can result from medical procedure errors, continue to be common in the NICU, often resulting in significant morbidity, mortality and increased length of stay (*19*). However, this disagrees with other studies that have reported that nosocomial infection represented only 15% of iatrogenic events (*16*) and an incidence of up to 20% in the NICU (*20*). The high rate of nosocomial infection in our study can be explained by the fact that most comparable studies were conducted in more developed countries. This agrees with a study in which rates of neonatal infection were 3–20 times higher in developing countries than in developed countries (*21*).

To identify risk factors associated with the development of medical errors, we explored the role of factors related to patients as well as staffing, administration, equipment, environment and infection control practices. Considering the patient factors, there was a significant inverse correlation between gestational age, birth weight and different types of medical errors, which agrees with many studies that found a significant inverse correlation between birth weight and medical errors (*3*). It is also reported that higher rates of adverse events occurred in infants with low gestational age (*16, 22*).

There was a significant positive correlation between medical errors and duration of admission, which was not unexpected because extremely premature infants are prone to various diseases during long hospital stays and exposed to more invasive procedures. This is consistent with studies in which neonates with low birth weight had longer length of stay and required complex invasive manoeuvres, so they had more frequent medical errors (*10, 16*).

We found that staffing errors represented 17.18% of the total errors and lack of supervision, shortage of nurses and poor communication between residents and nurses were important risk factors. The number of medical errors was increased by work overload and fatigue. This agrees with a study in which a decrease in the number of nurses correlated with an increase in human errors and led to adverse events (*23*). It has also been shown that poor communication among healthcare providers leads to poor teamwork and potentially increases unsafe practices (*24*).

We found that administration errors accounted for 6.8% of total errors. There was a lack of some medications due to unavailability in the hospital pharmacy. Also, there were deficiencies in some medical supplies, such as blood sugar strips, and different sizes of endotracheal tubes, umbilical catheters, suction tubes and scalpels. These factors had a negative impact on the performance of the healthcare system and health outcomes. This agrees with a study in 4 hospitals in Southeast Asia where cost of neonatal care, hospital infrastructure and access to medication are important barriers to neonatal care in developing countries (*25*).

Equipment errors represented 1.64% of total errors in our study and we reported defects in essential equipment such as monitors, pulse oximeters, X-ray apparatus, portable suction equipment,

and monitors. This agrees with other studies that reported that failure in medical devices was one of the causes of near misses in the NICU (*26*, *27*).

Environmental errors comprised 2.8% of total errors in our study. We found that poor use of floor space, noise and lack of space were common environmental problems, which may be attributed to overcrowding by staff and lack of organization, especially in morning shifts. Similarly, Brown reported that premature infants in the NICU are often exposed to continuous loud noise (*28*). Therefore, it is recommended that reducing noise in the NICU should be a top priority because medically fragile, vulnerable preterm infants need a more developmentally friendly auditory environment. NICU caregivers, especially nurses can do much to create a friendly and less noisy environment (*29*).

We found a significant increase in medical errors in junior residents compared with senior residents, which may have been due to lack of training and experience in the former. This agrees with a study that found an increase in errors when new doctors joined the rotation or when there was change to junior medical staff (*30*).

With regard to the severity of medical errors, our study revealed that Groups A–D were minor errors (59.18%) and included the majority of errors. Group E errors (38.36%) resulted in temporary harm to the patients and required intervention. Group F errors (2.04%) resulted in temporary harm to the patient and required initial or prolonged hospitalization. These latter 2 groups were moderate errors. Group H errors (0.42%) required life-saving intervention and were considered severe errors. In our study, minor errors were the most common, followed by moderate and severe errors. This agrees with a study that reported 61% minor errors, 26% moderate errors and 13% major errors (*11*). However, our results disagree with another study that reported 30% major errors (death or need for ICU-specific intervention), 25% moderate errors (requiring routine therapy available outside the ICU) and 45% minor errors (no intervention required) (*27*).

There were some limitations to our study. First, it was conducted in 1 hospital, in which, the medical errors may have differed from those in other hospitals. Thus, further research is needed, including university and Ministry of Health hospitals, to detect and report different types of errors. Second, classification of errors was made by only 1 reviewer, so it was not possible to determine the reliability of this reviewer.

Conclusion

Medical errors were high in low birth weight, low gestational age neonates and increased with longer NICU stay. Most errors resulted in minor problems but some were serious and needed intervention or extended hospitalization.

Funding: None.

Competing interests: None declared.

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