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Research Article

Study of Medical Errors Triggered by Medical Devices in Neonatal Intensive Care Unit

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Abstract

Background: Neonatal Intensive Care Units (NICU) depends heavily on biomedical devices and instruments for monitoring, diagnosis, and treatment. The objective of this study was to assess the impact of medical errors due to use of medical device in NICU.

Methods: This was prospective observational study to detect medical errors due to use of medical devices in NICU in one of the governmental hospital in Upper Egypt. It was carried out by monitoring devices related errors over six months. The information was collected using the data entry sheet of Egyptian Neonatal Safety Training network and designed check list. The number and types of monitored errors as well as contributing factors were recorded and causes were analyzed.

Results: The study included 275 newborn infants, 57.45% of them were exposed to medical device errors. The total number of recorded errors was 215. Intravenous invasive lines devices were associated with 47.44% of total devices errors, it was followed by respiratory equipment (26.97). The most common cause of devices errors was due to combined failure (active and latent) in 56.7% of total errors, followed by active failure and latent failure, P<0.001. The frequent error in the combined devices errors was fluid extravasation (21.3%), P<0.001, while the major cause in active failure errors was improper use of an infusion pump (23.4%). False monitor alarm was in 50% of latent failure errors. Majority of errors occurred during holidays and at night shift. 61.9% of errors caused harm, adverse events were 51.6% followed by sentinel events 10.2%. Near miss was in 38.1%.

Conclusions: Invasive intravenous lines devices and respiratory equipment were the common devices associated with errors. Adverse events were higher than near miss and increased during holidays and night shift. Majority of devices errors was related to combined/mixed failure.

Keywords: Medical device errors, Neonatal safety, Egyptian Neonatal Safety Training network (ENSTN), Active failure, Latent failure.

Abbreviations: NICU-Neonatal Intensive Care Units, GA-Gestational Age, ENSTN-Egyptian Neonatal Safety Training Network, FDA-Food and Drug Administration, BW-Birth Weight, RDS-Respiratory Distress Syndrome, SPSS-Statistical Program for Social Science, SD-Standard Deviation.

Introduction

Medical errors are a common occurrence in the Neonatal Intensive Care Unit (NICU). Medical error occurs due to active failure and or latent failure. Active failure includes errors related to individuals as doctors and nurses, while latent failure includes errors related to the system. Faulty information management, stressful environment, inadequate training of personnel and ineffective communication systems are some examples of latent failures [1]. A medical device is, simply defined, any item used to diagnose, treat, or prevent disease, injury, or any other condition that is not a drug, biologic, or food. Medical devices range from items as simple as tongue depressors to more complex devices, such as ventilators.

Neonatal intensive care units depend heavily on biomedical devices and instruments for monitoring, diagnosis, and treatment [2]. Although patient safety initiatives have focused mostly on medication errors but, medical devices also contribute significantly to patient injuries and deaths. For this reason, the Food and Drug Administration (FDA) put safe use of medical devices at the point of care. However, device/equipment related errors are not a regular component of medical education, and more researches have to carried out to understand the root causes, implications, to avoid device errors. The impact of safety issues related to use of devices in NICU is not entirely fully studied yet in Egyptian NICU as far as we know after searching the midline [3]. The objective of this study was to assess the impact of errors and adverse events due to use of medical device in NICU using the ENSTN reporting system. The objective of this study was to assess the impact of medical errors due to use of medical device in NICU [4].

Objectives

The aim of this study was to determine the active and latent failures related to devices use in NICU, and to recognize risk profile and causes of devices errors.

Methods

This prospective observational study was carried out to monitor the medical errors and incidents related to use medical devices in NICU. The study was performed in one of the NICUs of governmental hospital in Assiut governorate, Upper Egypt.

The study was carried out over six months. All the newborn infants admitted to NICU were included in the study. They had to be first time admission to ensure non-exposure to errors in other NICUs. The study involved 275 newborn infants, 117 (42.55%) newborn infants were not subjected to medical device error and the other 158 (57.45%) cases were exposed to medical device errors. The clinical characteristics are shown in **Table 1**.

	Newborn with medical error 158		**Newborn without medical error (117)**		**t*/x²**	**P**
	Mean ± SD	Range	Mean ± SD	Range		
GA (wks.)	35.4 ± 3.2	29-42	37.5 ± 3.2	29-41	5.496*	0.021 (S)
Postnatal age (day)	8 ± 7	**1-15**	5 ± 3	2-8	2.083*	0.041 (S)
BW (kg)	2.5 ± 0.9	0.9-4.4	2.7 ± 1	0.7-4.1	1.092*	0.083
Gender	Number	%	Number	%		
Male	99	62.66	62	53	4.147	0.037 (S)
Female	59	37.34	55	47		
Failure	Active		Latent		Combined/Mixed	
	N	%	N	%	N	%
	77	35.8	16	7.5	122	56.7
	X^2		35.901	P	<0.001	

Note: * Independent Sample t-test; x2-Chi-square test. This table shows that newborn infants with lower gestational age exposed significantly to device errors; the higher the postnatal age the more chance to expose to device errors. Male newborn infants were significantly higher than female newborn infants. Combined active and latent failure errors were significantly higher than other failures.

Table 1: Patients characteristics.

The non-errors group Gestational Age (GA) ranged from 29.0 to 41.0 weeks, their Birth Weight (BW) ranged from 0.7 to 4.1 kg and male to female ratio was 1.1:1. Their clinical diagnosis was jaundice, Respiratory Distress Syndrome (RDS), pneumonia, sepsis, extreme preterm infants, diaphragmatic hernia, postoperative meningomyelocele and hydrocephalus. The errors group GA ranged from 29.0 to 42.0 weeks, their BW ranged from 0.9 to 4.4 kg and ratio of male to female was 1.7:1. Their clinical diagnosis was jaundice, RDS, pneumonia, sepsis and prematurity.

Methods of Data Collection

This study involved direct monitoring of patients from time of admission till discharge, death or transfer, also review of medical records, procedures and progress notes was performed. The patient's history, clinical examination, laboratory results and procedures using any medical device of involved cases were recorded. The devices errors were collected daily through active monitoring, using the data entry sheet of ENSTN and the designed check list for device errors. Data collected included; type of device, nature and type of errors resulted from device use, related risk factors; environment, human errors or any other faults in the system that induced these errors. A structured approach to investigate the underlying causes was used to significantly examining the system and active causes of the resultant errors guided by Amoore approach [4,5]. The causes of devices failure were categorized into three types: active failure, latent failure according to Reason and mixed failure when both system and persons were responsible for the errors. Errors were classified according to harm into adverse, sentinel and near miss.

Statistical Analysis

Data were verified and validated then analyzed using Statistical Program for Social Science (SPSS) version 18.0. Quantitative data were expressed as mean ± Standard Deviation (SD). Qualitative data were expressed as frequency and percentage. Independent-samples t-test of significance was used to compare between two means, when data was uniformly distributed. Chi-square (X^2) test was used to compare proportions between two qualitative parameters. Multivariate post hoc test of significance was used to compare between multiple parameters. Probability (P-value) <0.05 was considered significant. P-value<0.001 was considered as highly significant and P-value>0.05 was considered insignificance.

Results

The newborn infants with lower gestational age exposed significantly to device errors. The higher the postnatal age the more chance to expose to device errors. Male newborn infants were significantly higher than female newborn infants. Combined/mixed active and latent failure errors were significantly higher than other failures, table 1. The most common errors were related to intravenous invasive lines and respiratory devices (The results are shown in **Table 1 to 5).**

Device	**Errors**	**Total N**	**% of total errors**
Intravenous invasive lines devices	**Total**	**102**	**47.44**
	Phlebitis	14	6.511
	Infections	3	1.39
	Infiltrations	26	
	Abscess	9	4.18
	Tissue sloughing and necrosis	15	6.97
	Catheter occlusion	4	1.86
	Subcutaneous extravasation	4	1.86
	Prolonged umbilical catheter	7	3.25
	Accidental removal of catheter	4	1.86
	Malfunction of cannula	16	7.44
Respiratory devices	**Total**	**58**	**26.97**
	Pneumothorax	11	5.12
	CPAP nasal septum atrophy	10	4.65
	False monitor reading	8	3.72
	Airway trauma: Injury of mucosa from ETT intubation, bleeding, edema	6	2.79
	Failed ETT intubation	5	2.32
	Ventilator malfunction	4	1.86
	Air leak around ET tube	4	1.86
	Thermoregulation problem of incubator	4	1.86
	VAP	3	1.39
	Atelectasis during mechanical ventilation	3	1.39
Delivery room instruments	**Total**	**33**	**15.34**
	Cut injury of skin during CS	5	2.32
	Subconjunctival hemorrhage	13	6.05
	Caput-succedaneum and cephalhematoma	10	4.65
	Erbs palsy	3	1.39
	Fracture clavicle at birth	2	0.93
Infusion and syringe pump	**Total**	**18**	**8.37**
	Improper use	18	8.37
Nasogastric tube	Perforations of stomach from nasogastric tube	4	1.88
Total		**215**	**100**

Note: The most common errors were related to intravenous invasive lines and respiratory devices.

Table 2: Errors related to used devices.

Active failure 77	N	% of active failure	Latent failure 16	N	% of latent failure	Combined/Mixed failure 122	N	% of Combined failure
Improper use of an infusion pump	18	23.4	False monitor alarm	8	50	Extravasation from cannula	26	21.3
Subconjunctival hemorrhage	13	16.9	Thermoregulation and problem related to incubator	4	25	Malfunction of cannula	16	13.1
Caput-succedaneum and cephalhematoma	10	13	Ventilator malfunction	4	25	Tissue sloughing and necrosis from cannula	15	12.3
Prolonged umbilical catheter	7	9.1				Phlebitis	14	11.5
Injury of mucosa from ETT intubation	6	7.8				Pneumothorax	11	9
Cut injury of skin from scalpel during CS	5	6.5				CPAP nasal septum atrophy	10	8.2
Failed ETT intubation	5	6.5				Abscess due to cannula	9	7.4
Perforations of stomach from nasogastric tube	4	5.2				Subcutaneous extravasation	4	3.3
Accidental removal of catheter	4	5.2				Catheter occlusion	4	3.3
Erbs palsy	3	3.9				Air leak around ET tube	4	3.3
Fracture clavicle at birth	2	2.6				Catheter associated septicemia	3	2.5
						Atelectasis during mechanical ventilation	3	2.5
						Ventilator associated pneumonia	3	2.5
X2	28.475			8.3			12.86	
P	<0.001			0			<0.001	

Note: *x^2-Chi-square test, further multivariate post hoc test for active errors showed statistically significant highly increase of improper use of an infusion pump, subconjunctival hemorrhage, caput succedaneum and cephalhematoma, prolonged umbilical catheter in newborn infants with active errors. Multivariate post hoc test for latent device errors showed highly statistically significant increase of extravasation from cannula, malfunction of cannula, tissue sloughing and necrosis from cannula and phlebitis in newborn infants with combined failure errors.

Table 3: Distribution of errors in relation to origin of failure.

Risk factor Active failure (77)	N	%	Risk factor Latent failure (16)	N	%	Risk factor Combined/Mixed failure (122)	N	%
Inattention/distraction	18	23.4	Inadequate instructions for equipment	3	18.8	Lack of calibration and device misassembled	29	23.8
Lack of experience	16	20.8	Maintenance delay and technical support	3	18.8	unavailability of policies , procedures and guidelines	25	20.5
Communication problems/Miscommunication	14	18.2	Poor equipment design	2	12.5	flawed decision-making processes	24	19.7
Hard to read hand writing/Confusion	10	13	device failure	2	12.5	Lack of training and training program	24	19.7
Heavy workload/lapses	9	11.7	Lack of risk management	2	12.5	Loud working environment	20	16.4
Fatigue/Illness	5	6.5	Inadequate number of staff	2	12.5			
Nervousness	5	6.5	Lack of needed equipment or improper size	2	12.5			
X^2	6.109				7.078		12.872	
P	0.04				0.008		0.005	

Note: * x^2-Chi-square test. Multivariate post hoc test showed statistically significant increase of inattention/distraction, lack of experience and miscommunication in active errors, while inadequate instructions on equipment and maintenance delay and technical support were significant among the latent errors. Further multivariate post hoc test showed statistically significant increase of Lack of calibration and device misassembled and unavailability of policies, procedures and guidelines.

Table 4: Risk factors of devices errors.

Distribution of errors in relation to origin of failure showed that active errors failure had statistically significant highly increase of improper use of an infusion pump, subconjunctival hemorrhage, caput succedaneum and cephalhematoma, prolonged umbilical catheter in newborn infants with active errors. Latent device errors showed highly statistically significant increase of extravasation from cannula, malfunction of cannula, tissue sloughing and necrosis from cannula and phlebitis in newborn infants with combined failure errors.

Regarding the risk factors, post hoc test showed statistically significant increase of inattention/distraction, lack of experience and miscommunication in active errors, while inadequate instructions on equipment and maintenance delay and technical support were significant among the latent errors. Further multivariate post hoc test showed statistically significant increase of Lack of calibration and device misassembled and unavailability of policies, procedures and guidelines, Table 4**.** Devices errors significantly increased during holidays and during night shift, table 5. Errors with harm (adverse and sentinel events) resulted in 61.9% of total errors, while errors without harm (near miss) occurred in 38.1%.

Discussion

The errors that cause injuries to patient resulting from the management by the medical staff is defined as adverse event. Active or person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness. The system or latent approach concentrates on the conditions under which individuals work and tries to build defenses to avert errors or mitigate their effects [1].

This study was prospective observational study to identify medical device errors. Confidentiality, non-punitive, anonymous, and voluntary reporting system was used.

Type of event	Number	% of total errors
Harm	133	61.9
Adverse	111	51.6
Sentinel/Never	22	10.2
Near miss	82	38.1
X^2	69.958	
P	0.001	

Note: * x^2-Chi-square test. This table shows that adverse events had the highest percent. Multivariate post hoc test revealed statistically significant increase of adverse events and near miss in newborn infants with total errors.

Table 5: Classification of devices errors in relation to type of event.

Voluntary, nonpunitive systems are thought to yield the best estimate of iatrogenic events, the error rate was much higher in studies using voluntary reporting than in those based on mandatory reporting [4,6]. The current study included 275 newborn infants, 57.45% of them were subjected to medical device errors. The most common devices associated with errors was related to intravenous invasive lines devices (47.44%) followed by respiratory devices (26.97%) then delivery room instruments (15.34%), infusion and syringe pump (8.37%) and nasogastric tube (1.88%). These findings were comparative to other studies; Bergon-Sendin, et al., found that the rate of appropriate use of the monitors and respiratory support equipment was 33.68%, which mean that 66.32% was inappropriate use; Snijders, et al., reported that 41% of incidents were due to mechanical ventilation and intravascular catheters.

In report from ENSTN equipment errors were 31.34% from the total reported errors. The higher percentage in the current study may be due to involvement of errors from all medical devices including simple devices as peripheral catheters, infusion pump, endotracheal tube as well as complicated equipment as monitors and ventilators [7-9]. The variations in incidence between different studies were due to inconsistency of definitions, type of involved devices as well as discrepancy in type of the studies and the nature of reported errors. In this study all incidents were reported weather lead to harm as adverse event or no harm as near miss. This study showed that significant increase in errors related to combined active and latent failure than errors of latent or active failure P<0.001. This finding denotes that jointly system and personal approach are important in preventing devices related errors.

Active failure includes errors related to individuals as doctors and nurses, while latent failure includes errors related to the system. Faulty information management, stressful environment, inadequate training of personnel and ineffective communication systems are some examples of latent failures [1]. Combined/Mixed failure errors resulted in several harm included peripheral catheter related lesions as extravasation from cannula in 21.3%, multivariate post hoc analysis showed also that malfunction of cannula (13.1%), tissue sloughing and necrosis (12.3%) and phlebitis of grade 1to III (11.5%) were highly significant too, P<0.001. Abscess was detected in 7.4%, umbilical catheter occlusion in 3.3%, and umbilical catheter associated septicemia occurred in 2.5% of the reported errors. Other studies reported infiltration/extravasation in 45.6% of peripheral venous catheters inserted into newborns and incidence of contracting extravasation harm producing skin necrosis in 38/1000 babies admitted to tertiary NICUs.

Reichembach, et al., found the incidence of complications related to use of intravenous peripheral catheters in 63.15% of neonates, being infiltration /extravasation (69.89%), phlebitis (17.84%) and obstruction (12.27%) [10-12]. The significant risk factors of combined/mixed errors were lack of calibration and device misassembled (23.8%) and unavailability of policies, procedures and guidelines (20.5%), it was followed by flawed decision-making processes (19.7%), Lack of training and training program (19.7%) and loud working environment (16.4%), P=0.005. Several contributing factors include; inattention, improper cannulation, poor quality of used catheters, use of fluids containing calcium and hypertonic fluids, absence of flushing before and after administration of medications, unavailability of policy, procedures and guidelines, prolonged use of the cannula in same vein, use of incorrect cannula gauge, and trauma to vein during insertion. These risk factors were comparable to others. Thus, even simple device as peripheral intravenous cannula/ catheter can predispose to several medical errors and harm from simple extravasation to tissue necrosis [12,13]. Pneumothorax was detected in 5.12% of total errors in ventilated newborn infants; the root causes were related to improper intubation, high peak inspiratory pressure, high volume, and inadequate monitoring and follows up.

Air leak around endotracheal tube happened in 1.86% of errors and related to the incorrect position or improper size of tube. Atelectasis during mechanical ventilation also occurred in 1.39%, and was due to mucous plug, poor suctioning, and right main stem intubation. Ventilator associated pneumonia was 1.39% of errors with combined failure which related to unavailability of antiseptic guidelines, prolonged mechanical ventilation, frequent re-intubation, prematurity, and low birth weight. Nasal septum atrophy due to CPAP was 4.65% of combined/mixed failure errors, and was related to prematurity, improper prong placement/size and long duration of use. Schuman et al found that incidence of pharyngoesophageal injury was 0.10% and increased with decreasing gestational age and weight being 0.38% at less than 27 weeks' gestation [14].

Several studies depicted the complications related with mechanical ventilation. It was recognized that prolonged mechanical ventilation was related to BPD, pneumothorax, errors related to endotracheal intubations as malpositioning, trauma to the vocal cords, larynx, and esophagus, subglottic stenosis and palatal grove, and ventilator-associated pneumonias [6,15]. This study showed the magnitude of the combined failure errors that occurred due to both active and latent failure. Latent conditions additionally dispose to the happening of numerous active failures including slips, lapses, mistakes and violations that ensue in patient harm. Latent disorders reduce the barriers of defense against error [16].

Majority of errors caused by active failure were improper use of an infusion pump in 23.4%, followed by sub conjunctival hemorrhage in 16.9%, caput succedaneum and cephalhematoma in 13.0% and prolonged use of umbilical catheter in 13.0% of errors due to active failure, P<0.001. Errors of use of infusion pump were related to incorrect settings, calculation error in rate. Theses might be due to inattention/distraction, poor communication between staff, lack of expertise, heavy workload, fatigue or more often poor documentation of administration and unavailability of guidelines. It was also reported that infusion pump programming errors is most common cause as well as improper use of an infusion pump [17].

Other active failure errors were prolonged use of umbilical catheter>14 days (3.25%), mucosal injury due to ETT (2.79%), failed ETT (2.32%), cut injury of skin during cesarean section (2.32%), perforation of stomach from nasogastric tube (1.86%), accidental removal of umbilical catheter occurred (1.86%), Erbs palsy (1.39%), and fracture of clavicle at birth (0.93%). Birth trauma was reported by other studies and reported as 3.1% in labor room admissions [18,19]. The related causes to active failure were inattention/distraction, lack of experience, miscommunication, confusion, heavy workload/lapses, fatigue/illness, and nervousness.

The root causes included unavailability local guidelines and training that were augmented by lack of experience of the newly hired residents and nurses and inadequate supervision by senior staff. Lack of training and experience was found in 10.5% of cases. Also there was misinterpretation of medical orders. Sometimes patient related factors

as large for gestational age and prematurity. These factors may amplify the incorrect thought processes, reasoning or analysis among stressed and extreme cognitive loaded staff and lead to lack of concentration slips, lapses or fixation that lead to mistakes [19].

Regarding the latent errors, this study showed that false interpretation of alarm and monitor reading (50%) was significantly higher than other causes of latent failure errors. The alarm problems were studied in other NICU and reported to be very significant. In our study, the other causes of latent failure included ventilator malfunction which was recorded in 25% of errors related to latent failure. These results agreed with others. Parihar reported equipment failures or inadequacy in 14.8% of the errors. Thermoregulation and problem related to incubator was detected in 25% of errors, other study focused on errors related to incubator, showed that 40% of incubators showed output temperature higher or lower than specified limits for each measurement point [8,9,20,21].

Causes related to latent failure included inadequate instructions for equipment that lead to inappropriately use, delay maintenance, technical support, device failure; incorrect connection, occlusion, incorrect usage and material damage, lack of needed equipment or improper size, poor equipment design. Root causes were related to insufficient or incorrect training related to procedures, machine and teamwork that lead to lack of skills to operate medical devices, also lack of proper suppliers, purchasing poor quality catheters, and inadequate policies, procedures and guidelines as well as constant communication methods. Lacking of calibration and organization maintenance affect precision of monitor displays and alarm failure triggered staff misread of records or overlook it with subsequent unsuitable clinical judgments [3].

The gestational age was significantly lower among newborn infants subjected to device errors than non-device errors newborn infants. These results were in coincidence with the data of others. The increased liability to device errors in preterm infants may be due to their need for assisted ventilation and use of medication and intravenous fluid than other newborn infants. The rate of incident per neonate was 1.27. Our results showed that the device errors occurred more in males than females as percent of male to female was 1.7:1. This reflect the increase of admission of male newborn infants than female newborn infants in the studied NICU, this is similar to Hoffmeister, et al., who reported 52.9% male gender in their study and frequency of 1.6 incidents per newborn [22-24].

There was significant increase in devices errors during holidays (63.3%) than workdays (36.7%). Also significant higher errors occurred at night shift (50.7%) than morning (19.5%). Work overload time shift potentiate to more medication errors [23]. Concerning to type of event, our study showed that majority of errors were adverse events, it resembled 51.6% of events. The literature showed variable data due to different definition, methods of evaluation of errors, gestational age and methodology. One study reported adverse events in 57% at gestational ages of 24 to 27 weeks compared with term gestation (3%). Adverse events occurred in 39% intubations with non-severe and severe events in 35% and 8.8% intubations, respectively. The overall adverse event reported by ENSTN was 43.2% while close call or near miss was 50.16%, 5.9% was sentinel events and 0.222% considered as unsafe act [6,9,25].

Conclusion

This study was an attempt to brief the healthcare personnel to the importance of medical device errors. Invasive lines devices and respiratory equipment were the common devices associated with errors. The errors were either due to user or equipment malfunctions. Identifying technical failure/equipment malfunctions from user errors is an important to inhibit adverse events. Adverse events were higher than near miss and increased during holidays and night shift. Majority of devices errors was related to combined/mixed failure. It means that system errors predispose to active errors and from this perspective, improvement of safety issues related to devices need system and personal approach.

Ethical Considerations

The study was approved by Faculty of Medicine of Girls, Al-Azhar University council. According to the ENSTN reporting system, confidentiality was ensured. Parents' consent was obtained after explaining the nature of the study.

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