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Medical Device-Related Pressure Injuries in Critically Ill Patients

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Abstract: **Medical devices are integral part of patients care in intensive care units. These devices are used for diagnostic and therapeutic purposes. Pressure injuries resulting from medical devices deserved attention of the professionals in the health care system, studies investigating its frequency specifically among critically ill patients are limited. Therefore, the aim of this study was to determine the medical device-related pressure injuries in critically ill patients. Methods: A quantitative, observational, descriptive study design was used. Data were collected from A 134 newly admitted critically ill patients who stayed in three general ICUs; in a university hospital in Alexandria governorate for 24 hours or greater. Patients had a daily skin assessment from head to toe with special attention to the skin under, in contact with medical devices to detect the onset of the of pressure injuries. Other clinical variables were also assessed daily. Results: A 168 skin MDRPIs resulted from 17 medical device. The highest percent of the skin MDRPIs resulted from of pulse oximeter [23.2%], followed by ETT fixation [14.3%], FUC [11.9%], ETT [10.7%], and NGT [10.1%]. A83.3% of the injuries were Stage 1 injuries, 4.2% and 12.5 % of the developed injuries were Stage 2 and deep tissue pressure injuries respectively. Cheeks, fingers, and thighs are the most commonly affected sites by skin MDRPIs. The percent of skin MDRPIs at these sites are 27.9%, 23.2%, and 14.3% respectively. Presence of edema and moisture at MDRPIs site, poor selection of device size, tight securement, improper device use; poor alignment, pulling on the device, irregular repositioning, and prolonged external pressure over the device are factors associated with the development of skin MDRPIs. Conclusion: The MDRPIs are common among the studied critically ill patients. Presence of edema and moisture at MDRPIs site, poor selection of device size, tight securement, improper device use; poor alignment, pulling on the device, irregular repositioning are factors associated with the development of skin MDRPIs.**

Keywords: **Skin medical device related skin injuries (MDRPIs), critically ill patients, intensive care unit, factors associated.**

1. INTRODUCTION

Critically ill patients are patients who have an actual or potential life-threatening condition [1]. Being connected to a different machines or devices during Intensive Care Unit (ICU) stay is common [2]. Medical devices are integral part of patients care in ICU [3]. These devices are used for diagnostic and therapeutic purposes [4,5]. Patients' safety' is a fundamental component of health care quality. It is a global concern since studies revealed that between 3-16% of patients admitted to the hospital suffer from harms resulting from adverse events during patients' management [6]. Pressure injuries resulting from medical devices are clinical phenomena that deserve attention of health care specialists [7]. The National Pressure Ulcer Advisory Panel [NPUAP] has raised awareness of the medical devices induced pressure injuries. Medical device related pressure injuries [MDRPIs] may involve the skin or the mucous membrane. Skin MDRPIs has been defined as pressure injuries resulting from using medical devices. The developed injuries conform the device shape [4]. There are a variety of devices which may induce MDRPIs. These include but not limited to oxygen tubing, endotracheal tube [ETT], tracheotomy ties, ETT fixation devices, bite blocks, pulse oximeter probes, patients monitor cables, orogastric and nasogastric tubes, urinary catheters, fecal containment devices, neck collars, traction equipment, and elastic compression devices [7-9].

The MDRPIs may involve many anatomic locations including the head and face, the neck, the back, the chest, the lower extremity, and the upper extremity [7,9, 10,11]. Skin MDRPIs are staged using the revised NPUAP pressure injury staging system. Skin MDRSIs stages are Stage 1to 4, Unstageable full thickness pressure injury, and deep tissue injury [4]. Device production materials, inappropriate device size selection, and the securing method can concur in device related pressure injury occurrence [12]. Edema, local moisture [13], tight fixation of devices and the materials used to fixation, the friction force resulting from device movement are among the modifiable factors that may increase the risk for MDRPIs [14-16]. The MDRPIs are recognized as a significant recurrent iatrogenic problem in healthcare settings [15]. The frequency of MDRPIs varies from 0.6% to 19.2%[7,11,15]. The MDRPIs are challenging for ICU nursing staff [3]. Now, the MDRPIs are considered as a quality indicator especially in the acute care settings [15,17]. The concern about such injuries increased in clinical practice because of the negative impacts on patients and their families due to pain, delayed recovery and infections, prolonged hospital stays, higher cost, and high morbidity and mortality [18,19]. Studies investigating MDRPIs frequency specially in ICUs are limited [9,14,15,20]. Johnson and other researchers explored medical device-related pressure injuries in a tertiary hospital in Australia. They documented a 27.9% MDRPIs. The majority of injuries were recorded in ICU. The most common causes of a medical device-related pressure injury were the nasal cannula and endotracheal tubes. [9]

Chung et al.[14] studied the application of care bundles to reduce medical device related pressure injury incidence in the coronary care unit. In this study the medical devices accounted for 73.1%. of pressure injuries. Inadequate decompressing surface, and restrain equipment reported as the top ranked causes of MDRPIs. Mehta et al.[15] examined the prevalence and risk factors of MDRPU in critically patients. They recorded 19.2% MDRPU. Non-invasive ventilation mask and nasogastric tube resulted in the highest percent of injuries. In Egypt, Ismail and her associates [20] examined the effect of evidence based nursing, and preventive measures to minimize the incident of ETT pressure injury. Their study revealed that, ETT pressure injury occurred in [9/48] and [42/52] in experimental and control group respectively. The MDRPI are a continuing clinical issue needs further investigations. In the clinical settings where the current study was implemented, there is no specific policies for prevention, regular assessment, detection, management and document of MDRPIs. The earliest deviation from the normal skin conditions specifically at the sites of medical devices are not regularly detected.

2. AIM OF THE STUDY

To determine the medical device-related pressure injuries in critically ill patients.

3. RESEARCH QUESTION:

Is there medical device-related pressure injuries in critically ill patients?

4. MATERIALS AND METHOD

Materials

Research design and sampling

A prospective, observational, descriptive study design was used to conducted this study in three ICUs in a University hospital in Alexandria, Egypt. The three general ICUs namely unit I, unit II, and III. The bed capacity of these units is 17, 9, 8 beds respectively. The units are equipped to provide care for patients who have possibility of a sudden respiratory function deterioration necessitating advanced respiratory support. Patients have circulatory instability and in need for hemodynamic monitoring and circulatory support. Patients may have central nervous system depression and need neurological monitoring and support. The use of medical devices for diagnostic and therapeutic purposes is essential at these ICUs. All critically ill patients [155 patients] who were newly admitted to the previously mentioned ICUs from November 2017 to January 2018, and above 18 years, free from any skin injuries at the application, insertion, or fixation site of medical devices were included in this study. Patients who met the previously mentioned criteria and stayed in the ICUs for 24 hours or greater after the day of ICU admission completed the study [134 critically ill patients]. Patients died, discharged, or transferred from the ICUs before 24 hours were excluded from this study. Patients who were received from other ICUs or were attached to an invasive device before ICU admission and patients who had skin breakdown at the insertion sites before device insertion were also excluded from this study [21 patients]. The final sample size is 134 critically ill patients.

Instrument

Two tools were used in this study. Tool [I] "Medical device related pressure injuries assessment tool" is developed by the researcher after reviewing the related literature [21-24]. It is composed of 3 parts. Part I includes demographic data; sex, age, diagnosis, history of smoking. Part II includes patients' clinical data; level of consciousness; conscious or disturbed level of consciousness, presence of mechanical ventilator, medications [dichotomous scale], perfusion variables; mean arterial blood pressure, status of fluid balance, temperature and comorbidity variables; blood protein level, blood glucose level are scored as high, normal or low. Status of fluid balance are scored as normal or positive or negative fluid balance. Part III includes data related to the medical devices and skin condition at its site; device type, presence of local edema, local moisture, appropriateness of the selected device size, device fixation and device use in addition to, the presence of external pressure. These were scored using dichotomous scale. This tool was used to record patients' general assessment and medical device related data. Tool [II][4] is an adopted tool namely the "Revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System". It was developed by National Pressure Ulcer Advisory Panel in 1987 and updated in 2016.This tool was used to assess the stage of developed pressure injuries. This staging system classify the stages of skin pressure injuries as follows; stage 1 to stage 4, unstageable full thickness pressure injury, deep tissue pressure injury.

Data collection:

Patients' demographic data; sex, age, diagnosis, history of smoking was recorded on inclusion to the study. Presence of mechanical ventilator, medications, perfusion variables; mean values of mean arterial blood pressure [calculated from 24hours recorded readings in patient charts], status of fluid balance, temperature, and comorbidity variables; blood protein level, blood glucose level were obtained from the medical records daily from inclusion in the study till the onset of the pressure injuries.

The included patients were assessed by the researcher for level of consciousness daily. Patients had a daily skin assessment from head to toe by inspection with special attention to the tissue under and around all medical devices to detect the onset of the of pressure injuries. Device type and appropriateness of the selected device size was recorded on inclusion to this study. Appropriateness of device fixation and device use regarding the presence of poor alignment of device, pulling/ traction on the device, irregular repositioning of device, presence of external pressure over the device and presence of external pressure, and skin condition at medical device site; presence of local edema, moisture, were assessed and recorded daily by the researcher. Medical device fixation [for fixed ones] were removed by nurses assigned to the included patients, assessment of skin at the medical device site for the development of pressure injury was done by the researcher daily. Refixation of medical devices was done by the assigned nurses after finalization of assessment. At the onset of medical device pressure related injuries, the detection was confirmed by nurses responsible for surveillance of safety events in ICUs. The stage of Skin MDRPI was recorded using the NPUAP Pressure Injury Staging System. The duration for development of MDRPI was calculated from device insertion time; on admission till the development of pressure injury.

Statistical analysis

Descriptive statistical analysis for all study variables was conducted. Binary logistic regression analysis was used for determining the specific factors associated with the top five skin MDRPIs. Statistics were conducted using SPSS version

Ethical consideration

The current study was approved by the research ethics committee of the faculty of nursing, Alexandria University, Egypt. Participation in this study was voluntary. Participants were informed of their right to withdraw from the study at any time. An informed consent was obtained from each of the included nurses after explaining the aim of the study. Nurses' confidentiality, anonymity, and privacy were ensured during the study

5. RESULTS

Table I and figure 1 shows the distribution of the studied patients according to their biodemographic data. A 53.7% of the studied patients are males and 35.8% of them their age is ranging from 40 to less than 60 years. Cardiovascular, respiratory, and renal system alterations are the most common alteration among the studied patients [45.5%, 32.1%, 19.4% respectively].

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Table I: Distribution of the studied patients according to their biodemographic data

Demographic data			No N= 134	%
Sex	Male		72	53.7
	Female		62	46.3
** Body system alterations	Cardiovascular		61	45.5
	Respiratory		43	32.1
	Renal		26	19.4
	Neurological		4	3.0
	Hepatic		14	10.4
	Others	Trauma	2	1.5
		Poisoning	20	14.9

** the total is more than 100%

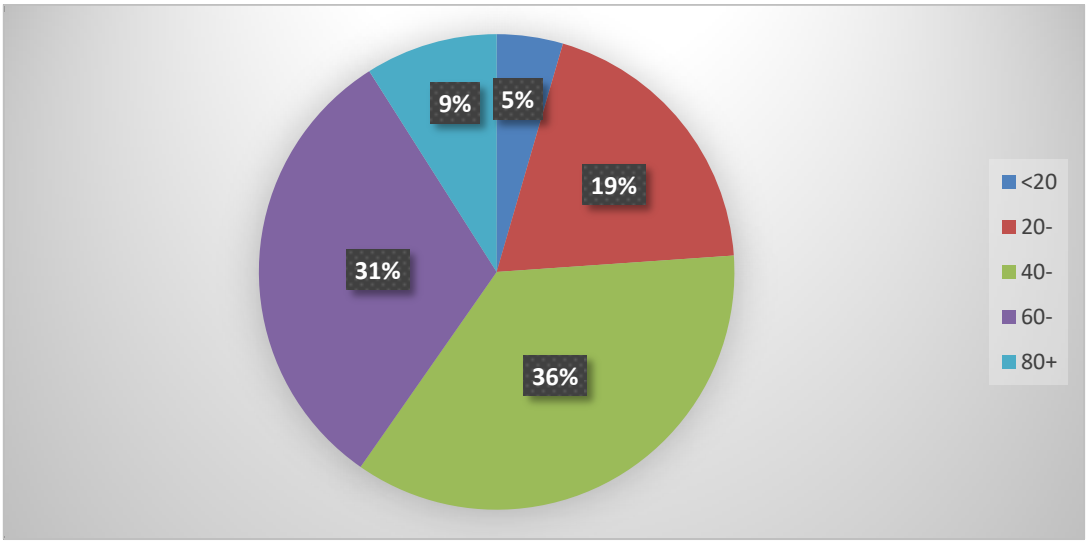

Figure 1: Distribution of the studied patients according to their age

Table II shows the clinical data of the studied patients. A66.4% of the studied patients were suffering from sensory perceptual alteration. A 58.2% of them were normothermic. A 68.7% had normal mean arterial blood pressure. A 59.7% had positive fluid balance. A59.4% had hypoalbuminemia. A 68.5% were normoglycemic. A 64.9% had generalized edema. A70.9% had skin dryness. A86.6% were mechanically ventilated. A19.4% of patients were receiving vasoactive medications.

Table II: Distribution of the studied patients according to their clinical data

Patients' clinical data	No N= 134	%	Patients' clinical data	No N= 134	%
Sensory perceptual alteration			**Random blood glucose ** **		
No	45	33.6 %	Hypoglycemia	1	0.8%
yes	89	66.4%	Normoglycemia	89	68.4%
Body temperature			Hyperglycemia	40	30.8%
Hypothermia	12	9.0%	**Skin dryness**		
Normothermia	78	58.2%	No	39	29.1%
Hyperthermia	44	32.8%	yes	95	70.9%
Mean arterial pressure			**Presence of MV**		
Normal	92	68.7%	No	18	13.4%
Low	42	31.3%	Yes	116	86.6%

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Fluid balance			**Medications**			
Balanced	2	1.5%	Vasoactive	yes	26	19.4%
Positive balance	80	59.7%		No	108	80.6%
Negative balance	52	38.8%	Corticosteroid	yes	29	21.6%
Serum protein *				No	105	80.6%
Normal	39	40.6%	Sedative	yes	12	9.0%
Hypo proteinemia	57	59.4%		No	122	91%
Generalized edema			Dobutrex	yes	18	13.4%
No	47	35.1%		No	86.6	116%
Yes	87	64.9%				

*n= 96 ** n= 130 MV mechanical ventilator

Table III demonstrates that 168 skin MDRPIs resulted from 17 medical device. The highest percent of the skin MDRPIs [23.2%] resulted from of pulse oximeter, followed by ETT fixation [14.3%], FUC [11.9%], ETT [10.7%], and NGT [10.1%]. The highest percent of skin MDRPIs resulted from pulse oximeter, ETT fixation, FUC, ETT, and NGT were stage I pressure injuries [19.0%, 10.1, 11.9, 9.5, and 7.1 % respectively]. The mean duration for development of skin MDRPIs is 2.3± 0.9 days.

Table III: Distribution of the developed skin MDRPIs according to source and stage of injury

Devices/ injury sources	**Total**		**Stages of skin MDRPIs**						**Mean +SD**
			Stage 1		**Stage 2**		**Deep Tissue Pressure Injury**		
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	
Pulse oximeter	39	23.2%	32	19.0%	0.0	0.0%	7	4.2%	2.4±1.5
ETT fixation	24	14.3%	17	10.1%	4	24%	3	1.8%	2.2± 0.8
FUC	20	11.9%	20	11.9%	0.0	0.0%	0.0	0.0%	2.2± 0.8
ETT	18	10.7%	16	9.5%	0.0	0.0%	2	1.2%	2.6 ± 1.2
NGT	17	10.1%	12	7.1%	2	1.2%	3	1.8%	2.1 ± 0.9
Cardiac monitor	14	8.3%	14	8.3%	0.0	0.0%	0.0	0.0%	2.1±0.8
Face mask	9	5.4%	8	4.8%	0.0	0.0%	1	0.6%	1.8 ± 0.8
Oropharyngeal airway	5	3%	4	2.4%	0.0	0.0%	1	0.6%	2.8 ± 0.8
Restraint	5	3%	2	1.2%	0.0	0.0%	3	1.8%	2.2 ±1.3
Nasal cannula	4	2.4%	4	2.4%	0.0	0.0%	0.0	0.0%	2.4± 0.9
Dialysis catheter	3	1.7%	3	1.8%	0.0	0.0%	0.0	0.0%	--
Elastic stocking	2	1.2%	1	0.6%	0.0	0.0%	1	0.6%	--
Ventilator tubing	2	1.2%	2	1.2%	0.0	0.0%	0.0	0.0%	--
Blood pressure cuff	2	1.2%	1	0.6%	1	0.6%	0.0	0.0%	--
CVC	1	0.6%	1	0.6%	0.0	0.0%	0.0	0.0	--
Identification band	2	0.6%	1	0.6%	0.0	0.0%	0.0	0.0	--
Infusion set	1	0.6%	1	0.6%	0.0	0.0%	0.0	0.0	--
ECG limb leads	1	0.6%	1	0.6%%	0.0	0.0%	0.0	0.0	--
Total	168	100.0%	140	83.3%	7	4.2%	21	12.5%	3±0.9

ETT endotracheal tube **FUC** Foley's urethral catheter **NGT** nasogastric tube **CVC** central venous catheter

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Figure 2 depicts that, 83.3% of the injuries were Stage 1 injuries, 4.2% and 12.5 % of the developed injuries were Stage 2 and deep tissue pressure injuries respectively.

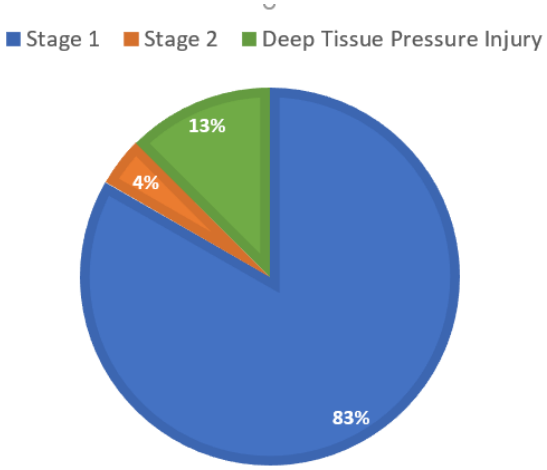

Figure 2: Distribution of the developed skin MDRPIs according to injury stage

Figure 3 illustrates that cheeks, fingers, and thighs are the most commonly affected sites by skin MDRPIs. The percent of skin MDRPIs at these sites are 27.9%, 23.2%, and 14.3% respectively.

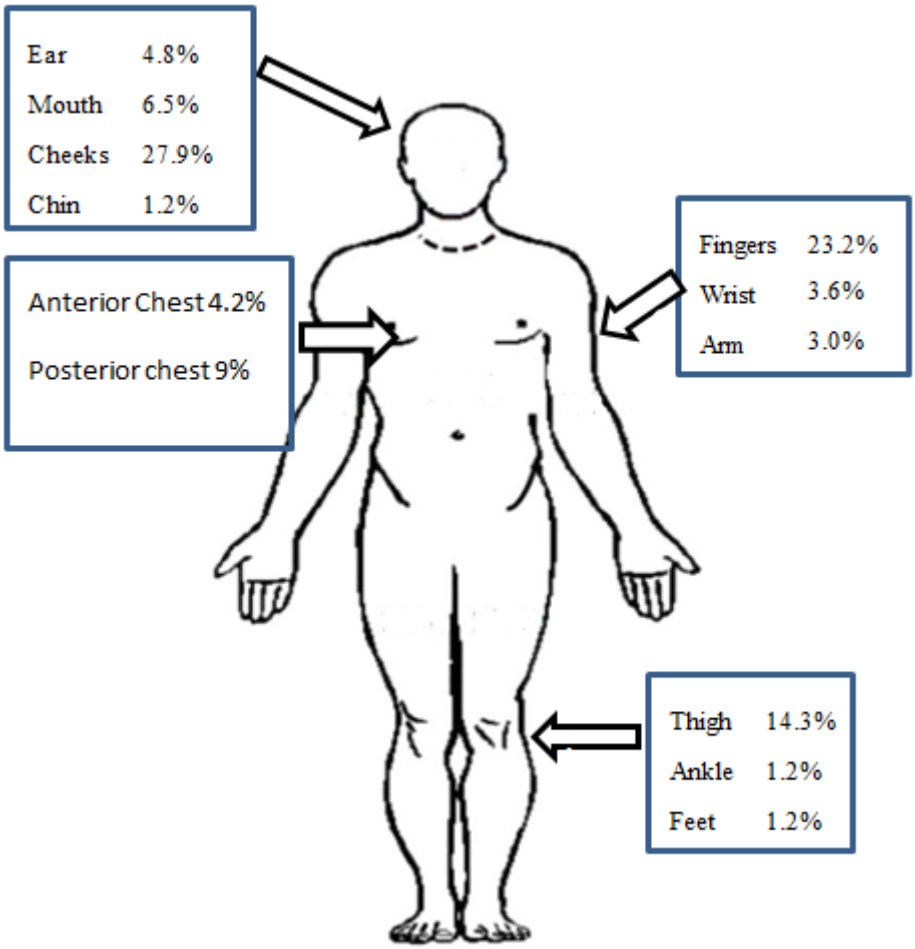

Figure 3: Distribution of the developed skin MDRPIs according to the site of injury

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Table IV shows the specific factors associated with the top five skin MDRPIs using binary logistic regression analysis [Enter method]. Presence of edema and moisture at MDRPIs site, poor selection of device size, tight securement, improper device use; poor alignment, pulling on the device, irregular repositioning, and prolonged external pressure over the device are factors associated with the development of skin MDRPIs. [R^2 value is 0.514 and $P \leq 0.05$]

Table IV: Specific factors associated with the top five skin MDRPIs using binary logistic regression analysis [Enter method]

Specific factors associated with the top five skin MDRPIs	B	S.E.	Wald	P
Local Edema [yes/no]	4.28	1.57	2.12	0.051*
Local Moisture [yes/no]	2.94	1.44	1.25	0.048*
Poor device size selection [yes/no]	1.97	1.12	3.20	0.005*
Device rigidity [yes/no]	0.33	0.45	0.53	0.465
Tight securement of device [yes/no]	3.97	2.17	5.61	0.053*
Improper device use [yes/no]	3.45	0.78	4.39	0.051*
Constant	-23.80	3.61	43.39	0.001*

Model X2 =152.85, P< 0.0001* Cox & Snell R2=0.514 *Significant at $P \leq 0.05$

6. DISCUSSION

Skin injuries create a significant burden in the health care system [21]. Skin injuries due to medical devices use is an unfortunate reality of the vulnerable critically ill patients [11]. Development of pressure injuries increase nurses' work load and can lead to changing the plan of patients care and prolong hospital stay [25]. The current study aims to determine skin medical device related pressure injuries in critically ill patients. This study reveals 168 skin MDRPIs resulted from 17 medical device. The highest percent of skin MDRPIs are Stage 1 followed by stage 2 injuries, and deep tissue pressure injuries. The highest percent of the skin MDRPIs resulted from of pulse oximeter, followed by ETT fixation, FUC, ETT, and NGT. This finding may be attributed to the prolonged pressure secondary to the lack of regular changing device fixation site, prolonged pressure over the device secondary patients position[right or left side position], traction/ pulling over the device resulting from in adequate support of the connected system like mechanical ventilator tubing and urinary bag, tommy syringe or pulling on the medical device as a result of patients' agitation. Cheeks, fingers, and thighs are the most commonly affected sites by skin MDRPIs. This finding may be attributed to the increased fragility of skin as a result of generalized edema.

Black et al.[11] conducted a retrospective study in the United States. Their study revealed a less frequent medical devices related pressure ulcers [39 of 113]. Most medical device related hospital acquired pressure ulcers [MDR HAPUs] were stage I. However; they also reported unstageable and stage III pressure ulcers among their studied patients. Concerning pressure injury site, they reported different findings of that in the current study. Additionally, Black et al. documented that the most common locations of MDR HAPU were the ears, lower leg and heels. Apold and colleagues [13] analyzed 255 pressure injuries; Stage 3, Stage 4, or unstageable injuries. They reported that under one-third of the serious pressure injuries were device related injuries. The most common devices involved in the development of MDRPIs were cervical collars or braces, other types of immobilizers, oxygen tubing. Their study also depicted MDRPIs staged from stage I to stage 4 in addition to unstageable injuries. More than half of the recorded pressure injuries were unstageable and located most commonly on the face [13].

Faisal and other colleagues [26] studied 431 adult ICU patients in Saudi Arabia. Their study revealed that 32.4% of the total number of all pressure injuries were medical device related. The devices caused the pressure injuries were the endotracheal tubes, Foley catheters, neck collars, nasogastric tubes, traction equipment. Kayser et al. [7] examined MDRPIs prevalence and characteristics from the international survey of pressure ulcer prevalence. Result of this study revealed that the prevalence of MDRPIs was 0.60% including both mucosal and non-mucosal MDRPIs. Most MDRPIs were superficial; Stage 1 or 2 injuries. Stage 3 or 4 or unstageable and deep-tissue pressure injuries were less frequent. The most common anatomic locations for MDRPIs were the ears and the feet. Nasal oxygen tubes, cast or splints, and

continuous positive airway pressure masks were the most common devices associated with MDRPIs. Johnson et al. study revealed 27.9% MDRPIs. The highest percent of injuries developed in ICU. Nasal cannula for oxygen therapy and endotracheal tubes were the most common causes of MDRPIs [9]. Mehta et al.[15] study revealed 19.2% MDRPU in intensive care unit. The highest percent of injuries resulted from Non-invasive ventilation mask and nasogastric tube. Jackson et al. [17] carried out a systematic review and meta-analysis to determine medical device commonly associated with pressure injuries. This study revealed that respiratory devices, neck collars, tubing devices, splints and vascular access devices are devices commonly associated with MDRPIs. Hanonu and Karadag [27] determined the rate, characteristics of and risk factors for development of MDRPIs in critically ill patients. Their study revealed that two fifth of studied patients developed hospital acquired MDRPIs. The highest percent of these injuries resulted from ETTs and the most frequent pressure injury stage is stage II.

This study result shows that, the presence of edema and moisture at MDRPIs site, poor selection of device size, tight securement, improper device use; poor alignment, pulling on the device, irregular repositioning are factors associated with the development of skin MDRPIs. Edema leads to over stretching of skin and over fragility. It also compresses blood vessels and impairs oxygen transport from capillaries to cells. Humidity at the skin–device interface secondary to presence of secretions, discharges, sweating change the microclimate of the skin leading to decreased pressure tolerance and liability for pressure injuries [11,15,16,27]. Poor selection of device size may lead to protrusion of device from its site and continuous pressure. Tight securement of device for the purpose of preventing accidental removal may lead to tourniquet like effect; specially in the presence of device fixation site edema resulting in poor blood supply to the underling tissue and skin injuries. Poor alignment resulting from patient positioning and turning or agitation and irregular repositioning of the device lead to prolonged pressure and compromised blood supply. Pulling on the device specially in the absence of device site padding also lead to shearing force and prolonged pressure.

7. CONCLUSION AND RECOMMENDATIONS

The MDRPIs are common among the studied critically ill patients. Stage one and two were more frequent than other stages pressure injuries. The highest percent of the skin MDRPI resulted from pulse oximeter, ETT fixation, FUC, ETT, and nasogastric tube. The most commonly affected sites are cheeks, fingers, and thighs. Presence of edema and moisture at MDRPIs site, poor selection of device size, tight securement, improper device use; poor alignment, pulling on the device, irregular repositioning are factors associated with the development of skin MDRPIs. There is an urgent need for establishing policies and procedures, continuous audits and structured training programs for critical care nurses to prevent and early detect MDRPIs in critically ill patients. Considering MDRPIs as a key indicator of patient s' safety and quality of nursing care in ICU. Nurses must pay special attention to the specific/local risk factors leading to skin MDRPIs.

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