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ORIGINAL ARTICLE

A prospective window into medical device-related pressure ulcers in intensive care

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Key words
Critical care; Cross-sectional study; Intensive care; Medical device-related pressure ulcer; Pressure ulcer; Prevalence; Prospective repeated measures

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Abstract

The aim of this study was to determine the prevalence, severity, location, aetiology, treatment and healing of medical device-related pressure ulcers (PUs) in intensive care patients for up to 7 days. A prospective repeated measures study design was used. Patients in six intensive care units of two major medical centres, one each in Australia and the USA, were screened 1 day per month for 6 months. Those with device-related ulcers were followed daily for up to 7 days. The outcome measures were device-related ulcer prevalence, pain, infection, treatment and healing. Fifteen of 483 patients had device-related ulcers and 9 of 15 with 11 ulcers were followed beyond screening. Their mean age was 60·5 years, and most were men, overweight and at increased risk of PU. Endotracheal (ET) and nasogastric (NG) tubes were the cause of most device-related ulcers. Repositioning was the most frequent treatment. Four of 11 ulcers healed within the 7-day observation period. In conclusion, device-related ulcer prevalence was 3·1%, similar to that reported in the limited literature available, indicating an ongoing problem. Systematic assessment and repositioning of devices are the mainstays of care. We recommend continued prevalence determination and that nurses remain vigilant to prevent device-related ulcers, especially in patients with NG and ET tubes.

Introduction

Pressure ulcers (PUs) are a serious complication of treatment in intensive care. They cause pain and suffering, impair quality of life, are expensive to treat and healing requires months to years of treatment after discharge from the intensive care unit (ICU) (1). To date, limited attention has been given to medical device-related (MDR) ulcers (2,3).

MDR ulcers differ from classic PUs in that they are caused by essential therapeutic equipment, occur on both the skin [skin medical device-related (MDR-S) ulcers] and mucous membranes [mucous membrane medical device-related (MDR-MM) ulcers] and do not usually lie over a bony prominence. Those MDR ulcers that are mucous ulcers are found on mucous membranes of the respiratory and gastrointestinal tract where a medical device has been located at the ulcer site (4). Furthermore, as identified by a recent National Pressure Ulcer Advisory Panel position statement (4), such MDR ulcers cannot be staged using the PU staging system for skin ulcers. Although these ulcers may be caused by pressure (from a medical device), similar descriptors of

Key Messages

- pressure ulcers are a continuing iatrogenic complication for critically ill patients in intensive care. Yet, little is known about medical device-related pressure ulcers in this patient population
- a prospective repeated measures design was used to sample 483 intensive care patients in two major medical centres, one each in Australia and the USA, to determine the prevalence, severity, location, aetiology, treatment and healing of medical device-related pressure ulcers in critical care patients
- medical device-related ulcer prevalence was 3·1%. Endotracheal and nasogastric tubes were the cause of most device-related ulcers. Most medical device-related ulcers were identified in men who were white, overweight, at increased risk of PU, at low risk of multi-organ failure and whose length of intensive care stay was long

skin and mucous membrane tissue cannot be used as mucous membrane ulcers are shallow, open and visually impossible to tell apart from deeper ulcers. Also, the coagulum formed in mucous membranes resembles slough seen in stage III PUs but is a soft blood clot (4).

MDR ulcers in adults are an important type of PU, with a reported prevalence of 0·85% (5) through 1·4% (3) to 34·0% (6). MDR ulcer prevalence has also been reported in 8·1% of hospitalised tracheostomy-dependent children (7) and 8·6% of Japanese neonatal intensive care babies (8). The proportion of MDR ulcers is high among the pressure ulcers identified in several reports, for example, 9·1% in a very large cluster of hospital prevalence studies (5), 34·5% in a large series of prevalence studies from a major mid-western US medical center (3) and 29% of serious ulcers that required reporting to the state (9). More data are needed to document the significance of the problem and provide the basis for appropriate prevention.

Devices causing MDR ulcers are quite variable. Respiratory equipment is often linked with these ulcers, including endotracheal (ET) tubes, tracheostomy tubes and oxygen masks/delivery systems (7,9,10). Nasogastric (NG) tubes frequently are implicated as are orthopaedic braces and collars, and continence management devices such as urinary catheters and faecal containment devices (3,5–7,9).

MDR ulcers are recognised as a negative iatrogenic outcome of intensive care (3) where the use of medical devices is high. Yet, the prevalence of these ulcers may be underestimated because systematic evaluation for MDR ulcer occurrence is not a part of routine skin assessment. Prospective data are needed to provide insights into MDR ulcer prevalence, aetiology, treatment and outcomes. Understanding the nature of MDR ulcers and the characteristics of the patients who develop them will aid clinicians to develop prevention strategies.

The overall aim of this prospective study was to describe the characteristics of MDR ulcers in adult intensive care patients. The specific aims were to determine: (i) the prevalence, severity, location and aetiology of MDR ulcers in adult intensive care patients; (ii) the consequences of MDR ulcers for patients during their ICU stay, specifically pain and infection; (iii) the nature of MDR ulcer treatment in ICU patients and (iv) the healing trajectory of MDR ulcers in the first week after study enrolment or until hospital discharge, whichever occurs sooner.

Method

Study design

A prospective repeated measure design was used. Cross-sectional data were obtained 1 day per month for 6 months.

Study setting and sample

This study was conducted at two metropolitan medical centres that are large referral and teaching centres, one in Australia (AU) and one in the USA. The AU medical centre is located on the east coast and has a 36-bed ICU that admits patients with major trauma, burns, neurology diagnoses, neurotrauma and medical and surgical conditions, including cancer. The US site is a major west coast medical center with 77 critical care beds that are located in five ICUs, among which two are medical-surgical units, two are neurosurgical units and one is a cardiovascular unit. All adults (>16 years old in AU and ≥ 18 years in the USA) in the units who had been admitted prior to midnight on the day of the study were eligible for inclusion.

Measures

A screening form, developed by the investigators, included demographic information, clinical data and a list of therapeutic devices. Demographic variables were age, race and gender. Clinical variables were the admitting service, length of hospital stay and length of ICU stay on the day of the survey, PU risk (measured with Braden Scale for Pressure Sore Risk© – here after called the Braden Scale score), height and weight and presence of PU, and if a PU was present, whether hospital or community acquired, stage (for skin ulcers), location, date the ulcer was first documented and whether it was device-related. The list of devices was developed by recording the devices that were present on patients in AU and US ICUs. The screening form was pilot tested in both settings and modified to include the following: respiratory devices (ET tube, simple/non-rebreathing mask, non-invasive positive pressure ventilation, nasal oxygen cannula and tracheostomy); vascular lines (central venous catheter, peripheral intravenous catheter, continuous renal replacement therapy catheter, arterial line, peripherally inserted central catheter and epidural catheter); gastrointestinal/genitourinary devices (NG tube, orogastric tube, percutaneous endoscopic gastrostomy or jejunostomy tube, urinary catheter and faecal containment device); monitoring equipment (peripheral oxygen saturation probe, blood pressure cuff and electrocardiogram leads); and preventive devices (sequential compression device, thromboembolic deterrent stockings and restraints).

A MDR ulcer data collection form was developed by the investigators to record MDR ulcer data for both MDR-S and MDR-MM ulcers. Items on the instrument included the device causing the ulcer, when the device was inserted/applied, ulcer size, tissue type, stage for skin ulcers and blood clot/coagulum for mucous ulcers. MDR ulcer healing, pain, infection and treatment were also evaluated. PUs and MDR ulcers were evaluated using the US criteria from the NPUAP/EPUAP standards (2).

PU risk was evaluated using the Braden Scale. It is a six-item risk assessment instrument that evaluates dimensions of current PU risk: sensory perception, moisture, activity, mobility, nutrition and friction/shear. It is scored from 6 to 23 with scores of 18 or less indicating PU risk (11). It is the most frequently studied PU risk scale and has reported better sensitivity and specificity than the Waterlow scale, Norton scale or clinical judgment (12).

MDR ulcer pain was measured with a numeric rating scale (NRS). On a scale with a score of 0–10, patients are

asked to rate their MDR ulcer pain with 0 being no pain and 10 being the worst pain imaginable. When compared with the verbal rating scale and the visual analogue scale, the NRS is recommended for unidimensional assessment of pain intensity. Adequate psychometric properties have been established under varying conditions (13).

MDR infection was defined as a medical diagnosis of infection with supporting progress notes implicating a MDR ulcer.

PU healing for skin ulcers was measured by examining ulcer size (length × width), tissue type and drainage over time. Mucous ulcer healing over time was evaluated by their size (length × width) and whether there was a blood clot or coagulum present (2).

Severity of illness was evaluated using the Sequential Organ Failure Assessment (SOFA) system. It is a six-organ score measuring multiple organ failure. Organ categories are respiratory, coagulation, hepatic, cardiovascular, nervous system and renal. Each organ is graded from 0 (normal) to 4 (the most abnormal), providing a score of 0–24. A higher score indicates greater organ failure and serial measures can be used to predict outcomes (14,15).

Procedures

Researchers at the two international sites had two face-to-face meetings during the project where they tested and edited the screening tool and data collection form, established inter-rater reliability in use of the study instruments, visited and were introduced to the culture of the other's intensive care setting. Prior to initiation of data collection, research nurses appointed and paid to collect data were trained in clinical assessment techniques and use of the data collection form. The bedside nurses at both sites were oriented to the purpose of the study.

Research nurses identified and screened all patients in the ICUs that met the inclusion criteria. On the 1-day prevalence study each month, the research nurses talked with the registered nurse at the bedside, reviewed the medical record, conducted a head-to-toe skin examination for PUs and recorded all patient care devices attached to the patient. When a PU was identified, it was determined whether it was present at admission and therefore a community-acquired pressure ulcer (CAPU). For those PUs that were hospital acquired (HAPUs), MDR ulcers were differentiated from classic PUs. Skin assessment was coordinated with routine nursing assessment to reduce study participant burden. Data to calculate SOFA scores on the screening day were obtained on all patients with MDR ulcers.

All AU and consenting US patients with an identified MDR ulcer were followed for up to 7 days. Each MDR ulcer was examined daily to evaluate its healing trajectory. Patients were queried as to the level of their MDR ulcer pain and nursing care for the MDR ulcer was recorded. The medical record was also reviewed to identify data on the presence of MDR ulcer infection. This procedure was repeated for each of the six study months at both institutions.

Ethical considerations

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in approval to conduct this study from the participating universities and hospitals' respective human research ethics committee and internal review board. Despite differences in the approval processes, permission was granted at both sites to screen all patients for all devices in use and prevalence of PUs and MDR ulcers. In AU, patients were recruited on an 'opt-out' basis. There is good evidence that, for studies where the risk to participants is low, an 'opt-in' approach results in selection bias and poor recruitment rates (16). Informed consent can be especially problematic where the patient population is critically ill. In this study, complete patient numbers were crucial to address the study aims. In particular, failure to include patients may result in underestimation or overestimation of MDR ulcer prevalence and result in a biased assessment of the magnitude of the problem. In the USA, screening of all patients was permitted as a component of routine quality screening. However, written informed consent was required for all patients who were followed for the 7-day observational research protocol.

Analysis

All data were de-identified, subjects assigned a study number and data entered into the Statistical Packages for Social Sciences (SPSS) (Version 15, Chicago, IL). Ten per cent of the data were double entered at each site and all extreme values were evaluated by the investigators to ensure accurate data entry. Separate data files were created at each site and merged after cleaning.

Descriptive statistics were calculated for all variables (means and standard deviations for continuous variables; frequencies and percentages for categorical variables). First, the data were analysed to describe all subjects whom were screened. HAPU MDR prevalence was calculated by the total number of MDR ulcers present on 1 day per month for 6 months divided by the total number of ICU patients screened over the same 1 day per month for 6 months. The demographic and clinical profile of the sample of patients that developed MDR ulcers was then described. The small sample with MDR ulcers precluded examining the relationship between MDR ulcers and age, gender, PU risk, BMI, length of stay (LOS) and total number of devices as the basis for developing a predictive model. Descriptive-correlational statistics were used to address the study aims.

Results

Screening sample

The mean age of the screening sample was 56·0 years and most of them were men. Most patients were white, at increased risk of PU and admitted to a surgical service (Table 1). The mean number of devices per person in those screened was 7·6 (Table 2). The devices used in more than half of the patients included peripheral intravenous lines, sequential compression devices, blood pressure cuffs, urinary catheters,

Table 1 Demographic and clinical characteristics of patients whom were screened for device-related pressure ulcers

	Australian site ($n=132$)	US site ($n=351$)	Total ($n=483$)
Age, mean (SD)	53·6 (18·7)	56·8 (16·1)	56·0 (16·9)
Gender, number (%)*			
Men	79 (58·9)	172 (49·0)	251 (52)
Women	53 (40·2)	179 (51·0)	232 (48)
Race, number (%)*			
White	124 (93·9)	262 (74·6)	386 (79·9)
Black	1 (0·8)	49 (14·0)	50 (10·4)
Asian	4 (3·0)	33 (9·4)	37 (7·7)
Native Hawaiian/Pacific Islander	1 (0·8)	5 (1·4)	6 (1·2)
American Indian	0 (0)	2 (0·6)	2 (0·4)
Aboriginal/Torres Straight Islander	2 (1·5)	0 (0)	2 (0·4)
ICU days,†mean (SD)	7·6 (9·6)	8·4 (13·2)	8·2 (12·4)
Hospital days,†mean (SD)	12·7 (16·8)	11·3 (15·4)	11·7 (15·8)
Type of service, number (%)			
Medical	48 (36·4)	132 (37·6)	180 (37·3)
Surgical	84 (63·6)	219 (62·4)	303 (62·7)
Braden Scale score			
Mean (SD)*	16·5 (2·8)	15·3 (3·5)	15·6 (3·4)
Mode	15	15	15
MAP, mean (SD)	88·4 (13·5)	86·8 (18·9)	87·3 (15·2)
Temperature, mean (SD)*	37·3 (0·8)	37·1 (0·7)	37·1 (0·7)
Body mass index, mean (SD)	27·7 (6·4)	28·1 (7·8)	28·0 (7·4)

ICU, intensive care unit; MAP, mean arterial pressure.
*$P < 0{\cdot}05$ difference between AU and US sites.
†Number of days at the time of screening.

Table 2 Total number and percent of devices present in the screening sample of intensive care patients

Device	Australian site ($n=132$)	US site ($n=351$)	Total ($n=483$)
Respiratory			
ET tube†	54 (40·9)	72 (20·5)	126 (26·1)
Face mask*	8 (6·1)	13 (3·7)	21 (4·3)
Nasal oxygen†	36 (27·3)	134 (38·2)	170 (35·2)
Tracheostomy	24 (18·2)	42 (12·0)	66 (13·7)
Vascular lines			
Central†	77 (58·3)	149 (42·5)	226 (46·8)
Peripheral†	59 (44·7)	228 (65·0)	287 (59·4)
CRRT	7 (5·3)	14 (4·0)	21 (4·3)
Arterial†	112 (84·8)	110 (31·3)	222 (46·0)
PICC†	12 (9·1)	86 (24·5)	98 (20·3)
Epidural	5 (3·8)	13 (3·7)	18 (3·7)
GI/GU			
Nasogastric†	77 (58·3)	124 (35·3)	201 (41·6)
Orogastric†	18 (13·6)	4 (1·1)	22 (4·6)
PEG/PEJ†	1 (0·8)	17 (4·8)	18 (3·7)
Foley†	127 (96·2)	256 (72·9)	383 (79·3)
Faecal drain	11 (8·3)	31 (8·8)	42 (8·7)
Monitoring			
BP cuff†	40 (30·3)	310 (88·3)	350 (72·5)
ECG leads†	132 (100·0)	338 (96·3)	470 (97·3)
SpO_2 probe†	132 (100·0)	311 (88·6)	443 (91·7)
Preventive devices			
SCDs	80 (60·6)	237 (67·5)	317 (65·6)
TEDs†	110 (83·3)	4 (1·1)	114 (23·8)
Restraints	10 (7·6)	49 (14·0)	59 (12·2)
Mean devices per patient (SD)	8·6 (1·2)	7·2 (2·0)	7·6 (1·9)

BP, blood pressure; CRRT, continuous renal replacement therapies; ECG, electrocardiograph; ET, endotracheal; GI/GU, gastrointestinal/genitourinary; PEG, percutaneous endoscopic gastrostomy; PEJ, percutaneous endoscopic jejunostomy; PICC, peripherally inserted central catheter; SCDs, sequential compression device SpO_2, peripheral oxygen saturation of hemoglobin; TEDs, thrombo-embolism deterrent.
*Includes non-rebreathing mask and non-invasive ventilation.
†$P < 0{\cdot}05$ difference between AU and US sites.

oxygen saturation probes and electrocardiogram leads.* There are some differences in how often various devices are used between the AU and US sites as shown in Table 2.

Thirty-eight CAPUs were present on 27 patients. The overall prevalence of CAPUs in the sample screened was 5·6% (27/483) with 3·0% (4/132) in the AU sample and 6·6% (23/351) in the US sample. Sixty-one ICU HAPUs occurred in 48 patients. The overall prevalence of ICU HAPUs was 9·9% (48/483) with 12·8% (17/132) in the AU sample and 8·8% (31/351) in the US sample ($P < 0{\cdot}05$). HAPUs included the MDR ulcers.

MDR ulcer sample

Following screening, nine patients with 11 ulcers were followed for up to a week, eight were AU patients and one was a US patient. Six US patients could not be observed beyond screening as one patient declined participation and five could not be consented because of their condition and the lack of a surrogate who could be contacted. In addition, two AU patients died during data collection, unrelated to their MDR ulcer, and one was transferred from the AU study site to another facility.

*A number of devices not included in the screening form were incidentally noted, including external ventricular drains, intracranial pressure monitors, chest tubes, Jackson-Pratt drains, nephrostomy tubes, nasal and rectal temperature probes, colostomy appliances, nasal trumpets, extracorporeal membrane oxygenators and vascular assist devices. Because these were not systematically assessed for all patients, they were not included in the total number of devices or in our analyses.

The mean age of the MDR ulcer sample ($n = 15$) was 60·5 years and most participants were men, white and at increased risk of PU (Table 3). On an average, they had 8·7 devices per person, were overweight, had an ICU stay and hospital stay of about 2 weeks at the time of their screening and were at low risk of multisystem organ failure. The time from device insertion to detection of a MDR ulcer ranged from 3 to 13 days.

When the AU and US samples were compared on age, BMI, PU risk, LOS (ICU and hospital) and number of devices at screening, data showed that the US sample had higher BMI ($P = 0{\cdot}035$) and were at greater PU risk ($P = 0{\cdot}012$). As little data have been published describing the clinical and demographic characteristics of ICU patients with MDR ulcers, individual data on all 15 patients with MDR ulcers are shown in Tables 4 and 5. Data on all 15 patients were used to address study aim 1, whereas the nine subjects who were followed for further observation provide the data to address aims 2–4.

Table 3 Demographic and clinical characteristics of patients with device-related pressure ulcers

	Australian site ($n=8$)	US site ($n=7$)	Total ($N=15$)
Age, mean (SD)	56·4 (16·9)	65·1 (24·7)	60·5 (20·6)
Gender, number (%)			
Men	6	4	10 (67%)
Women	2	3	5 (33%)
Race, number (%)			
White	8 (100%)	6 (86%)	14 (93%)
Non white	0	1 (14%)	1 (7%)
ICU days,*mean (SD)	10·1 (6·3)	17·3 (16·5)	13·5 (12·2)
Hospital days,*mean (SD)	11·6 (5·0)	17·6 (16·6)	14·4 (11·8)
Type of service, number (%)			
Medical	3 (38)	4 (57)	7 (47)
Surgical	5 (63)	3 (43)	8 (53)
Number of devices, mean (SD)	8·7 (1·2)	8·6 (1·1)	8·7 (1·1)
Braden Scale score			
Mean (SD)	15·5 (2·3)	12·3 (2·0)	14 (2·6)**
Mode	16	10	15
SOFA score, mean (SD)	4·3 (2·9)	4·6 (2·3)	4·4 (2·6)
MAP, mean (SD)	85·5 (13·2)	83·4 (15·6)	84·5 (13·9)
Body mass index, mean (SD)	26·8 (7·0)	37·8 (10·3)	31·8 (10·1)***

ICU, intensive care unit; SOFA, Sequential Organ Failure Assessment.
*At the time of screening.
**$P=0·035$; ***$P=0·012$.

Aim 1: To determine the prevalence, severity, location and aetiology of MDR ulcers

Prevalence

The overall prevalence of MDR ulcers was 3·1% (15/483) with 6·1% (8/132) in the AU sample and 2·0% (7/351) in the US sample. There were 20 MDR ulcers in 15 subjects and slightly more were MDR-S ulcers (11/20) than MDR-MM ulcers (9/20). Ten patients developed one MDR ulcer and five patients developed two MDR ulcers.

Severity

The MDR-S ulcers ($n=11$) depth was described by stage (2). There were two stage I ulcers, eight stage II ulcers and one stage III ulcer. MDR-MM ulcer severity was *not* evaluated by depth (2). MDR ulcer size ranged from 0·06 to 2·0 cm^2. Tissue of open MDR skin ulcers was granulation or epithelial tissue. The surface of the MDR-MM ulcers was covered in slough or coagulum.

Location and aetiology

Most MDR ulcers occurred on the head and neck. Ten were located in the nose, five on the mouth/lip, two on the neck, two on the ear and one on the posterior thigh. Eight of the MDR ulcers were due to nasogastric (NG) tubes, seven were caused by ET tubes, two were due to damage from oxygen tubing, two were caused by tracheostomy tubes and one was due to lying on a rectal thermometer probe. The ET and NG tubes both were used more frequently in the AU sample than in the US sample ($P < 0·05$ for each). The small sample precluded analysing the data to determine whether there was a relationship between severity of MDR ulcers and location.

Aim 2: To determine the consequences of an MDR ulcer for patients during their ICU stay, specifically pain and infection

There were 11 MDR ulcers among the nine patients followed for up to 7 days. Eight were from the AU site and one from the US site (Table 4). When queried daily, only two of nine patients reported MDR ulcer-related pain, each on 1 day. One patient reported pain of two of ten on an NRS (nose ulcer) and another pain of one of ten (mouth/lip ulcer) at the MDR ulcer site. No MDR ulcer-related infection was present in any of the ulcers.

Aim 3: To determine the nature of MDR ulcer treatment in ICU patients

For the nine patients followed for up to 1 week or until discharge, there were 58 MDR ulcer assessments of the 11 MDR ulcers. Treatment was categorised as device repositioning, device padding, cleansing and moisturising. The most frequent treatment was repositioning (22/58), followed by padding (14/58), cleansing (12/58) and moisturising (11/58). There was no patient treatment with some observations and some patients received more than one treatment in a single day (data not shown). Moisturising agents included paraffin, melonin and petroleum jelly. Cleansing agents were normal saline and chlorhexidine. No MDR ulcer was debrided.

Aim 4: To determine the healing trajectory of MDR ulcers in the first week after study enrolment or until hospital discharge, whichever occurs sooner

Skin MDR ulcer healing based on size is shown in Table 5. In summary, over the observation period, of the 11 ulcers,

- 4 healed (1 healed day 2, 1 healed day 7 and 2 healed day 6);
- 4 remained the same size (2 observed 2 days; 1 observed 5 days and 1 observed 7 days),
- 3 became smaller (1 observed 5 days and 2 observed 7 days).

It should be noted that one patient with one MDR ulcer and one patient with two MDR ulcers died, unrelated to their ulcers. In addition, one patient was transferred to another facility. These events limited the duration of observation.

Figure 1 illustrates the size of the 11 ulcers in the nine patients who were followed beyond the screening observation. Most of the MDR ulcers had either no drainage or a small amount of drainage. One ulcer from a tracheostomy tube had continued moderate drainage for the entire period. Drainage did not increase for any ulcer over the observation period.

Discussion

This is the first study to report prospective data on patient characteristics, treatment and healing of MDR ulcers. The

Table 4 Individual demographic and clinical characteristics of each patient with a medical device-related ulcer

Subject ID*	Age	Sex	Diagnosis	Service	ICU days†	Hospital days†	Braden Scale score	SOFA score	Body mass index	Total number of devices
A	56	Male	Multiple trauma	Surgical	15	15	15	3	36·9	7
B	48	Female	Subarachnoid haemorrhage	Surgical	12	12	20	5	21·2	8
C	62	Female	Septic shock	Medical	4	6	16	11	24·1	8
D	44	Male	Burns	Surgical	8	8	12	3	38·7	8
E	76	Male	Subdural haematoma	Surgical	7	7	15	2	24·7	9
F	70	Male	Cardiac arrest	Medical	14	14	16	4	26·3	10
G	25	Male	Pneumonia	Medical	1	10	14	2	22·2	10
H	70	Male	Abdominal aortic aneurysm	Surgical	20	21	16	4	20·5	10
I	60	Female	Sepsis	Medical	22	24	10	3	37·5	8
J	21	Male	Necrotising pancreatitis	Medical	11	11	11	7	38·3	3
K	79	Male	Sepsis	Surgical	13	13	10	6	35·5	8
L	90	Male	Sepsis	Medical	12	12	13	3	30·5	10
M	92	Female	Myocardial infarction	Medical	1	1	15	1	22·9	7
N	54	Female	Oesophageal fistula	Surgical	10	10	14	5	44·8	9
O	60	Male	Perforated duodenal ulcer	Surgical	52	52	13	7	55·3	10

ICU, intensive care unit; SOFA, Sequential Organ Failure Assessment.
*A–I = Followed up for up to 7 days.
†At the time of screening.

Table 5 Medical device-related ulcer description, days observed, treatments and healing status at the end of observation by subject

					Number of treatments				Healing status	
Subject ID*	Type of ulcer	Location	Device causing ulcer	Days observed	R	C	M	P	Size (cm^2), day 1	Size (cm^2), final observation
A	Mucous	Mouth/lip	Endotracheal tube	7	1	0	4	1	1·0	Healed
B	Mucous	Nose	Nasogastric tube	7	2	0	0	0	0·5	Healed
C†	Mucous	Mouth/lip	Endotracheal tube	5	5	0	4	2	1·0	1·0
D	Mucous	Mouth/lip	Endotracheal tube	7	2	4	0	0	2·0	1·0
E‡	Mucous	Mouth/lip	Endotracheal tube	5	2	0	3	2	1·0	0·5
F†	Mucous	Nose – L nare	Nasogastric tube	2	2	0	0	0	1·0	1·0
	Mucous	Nose – R nare	Endotracheal tube	2	2	0	0	2	1·0	1·0
G	Mucous	Nose	Endotracheal tube	7	3	7	0	0	1·0	Healed
H	Skin – stage III	Tracheostomy plate	Tracheostomy tube	7	0	0	0	7	2·0	2·0
I	Skin – stage II	Nose – L nare	Nasogastric tube	7	3	1	0	0	0·01	Healed
	Skin – stage II	Nose – R nare	Nasogastric tube	2	0	0	0	0	0·125	0.09
J	Skin – stage II	Neck	Tracheostomy	X	X				X	X
	Skin – stage II	Nose – R nare	Nasogastric tube							
K	Skin – stage I	Nose – L nare	Nasogastric tube	X	X				X	X
	Skin – stage I	Nose – R nare	Nasogastric tube							
L	Skin – stage II	Ear	Oxygen tubing	X	X				X	X
	Skin – stage II	Ear	Oxygen tubing							
M	Mucous	Mouth/lip	Endotracheal tube	X	X				X	X
N	Skin – stage II	Nose	Nasogastric tube	X	X				X	X
O	Skin – stage III	Posterior thigh	Rectal thermometer probe	X	X				X	X

R, repositioning; C, cleansing; M, moisturising; P, padding.
*A–I = followed up for up to 7 days.
†Died.
‡Transferred.
X = screened only – not able to consent and so unable to follow.

prevalence of MDR ulcers was low in this sample of patients from six ICUs in two large medical centres in AU and the USA, and similar to that reported by others (3,5). Specifically, we found that most MDR ulcers developed in men who were white, at increased overall PU risk, were overweight, at low risk of multi-organ failure and who had a long ICU stay. Most patients did not report MDR ulcer-related pain and there was no MDR ulcer infection. MDR ulcers were quite small ($\leq$2 cm^2) and about half of them were mucous ulcers, a finding not previously reported in relevant literature (3,5,9). Treatment of the MDR ulcers was limited and yet some of the ulcers (4/11) healed within 1 week of study enrolment.

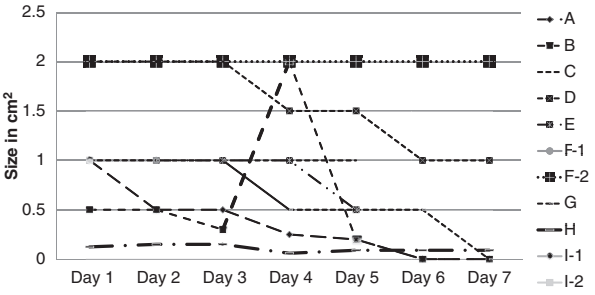

Figure 1 Medical device-related ulcer size for 11 ulcers for up to 7 days.

Patients in this study who developed MDR ulcers had an average of 8·6 devices, suggesting that the potential risk of device-related tissue injury was high, yet MDR prevalence was only 3·1%. Considering the large number of devices present on each patient and the complexity of care for these extremely sick ICU patients, nurses did an excellent job of MDR ulcer prevention. While the frequency of use of many devices differed between the two settings, ET and NG tubes were the greatest offender in both settings. There were many similarities between the AU and US sites related to equipment, patient/staff ratios and general patient management. The ICUs at both sites used the same equipment for mechanical ventilation, patient monitoring and providing fluids by infusion pumps. Notably, the patient/staff ratio across both sites was one registered nurse per one mechanically ventilated patient; although there were many other ($P < 0{\cdot}05$) non-intubated patients in the US site, where one registered nurse was often responsible for two patients. Patients with MDR ulcers at both sites were similar in age, gender and LOS ($P > 0{\cdot}05$); those in the US units were at greater PU risk (lower Braden Scale score) and had a greater body mass index ($P < 0{\cdot}05$). The Braden Scale score was not related to MDR ulcer development.

Comparison of our data with that of other studies is difficult. Only three studies were identified that addressed MDR ulcers in a general population of hospitalised adults (3,5,9). VanGilder *et al.* (5) reported an observational, cross-sectional cohort study as part of the International Pressure Ulcer Prevalence Survey™. Data from the USA from 2008 to 2009 were compared with previously collected data from 2006 to 2007. Given this large study, we considered the most recent 2009 data provided by the researchers. In 2009, the total US sample was 86 932 acute care patients across multiple settings. MDR ulcers comprised 9·1% (1631/17 811) of the ulcers and 785 of 1631 ulcers were facility acquired. Prevalence of MDR ulcers calculated from the VanGilder *et al.*'s report (5) shows that acute care MDR ulcer prevalence was only 0·85% (740/86 932). Across the hospital, the most common sites for MDR ulcers were the ears (20%), the sacrum/coccyx (17%), the heel (12%) and the buttocks (10%). When ICU prevalence of MDR ulcers is calculated from VanGilder *et al.*'s (5) data, the prevalence of facility-acquired MDR ulcers in adult surgical ICU (44/1842), general ICU (132/4830), medical ICU (22/1940) and general coronary care unit (CCU) (42/2199) is 2·2% (240/10 811). Specific medical devices that caused the ICU ulcers were not reported.

VanGilder *et al.*'s (5) robust dataset sheds light into the breadth of the MDR problem and indicates that even when classic PUs were the focus of prevalence studies, MDR ulcers were identified. Reporting of data by the number of ulcers shows that MDR ulcers comprise a large proportion of facility-acquired ulcers. However, lack of reporting of the prevalence of MDR ulcers in this article makes comparison of the data challenging. Although understandable given the extent of data reported, the authors provided limited information about the MDR ICU ulcers and patients. This paucity of data limits nurses' ability to formulate and implement appropriate prevention interventions in this population whose treatment routinely requires multiple devices.

In a retrospective study using existing data collected by the Nebraska Medical Centre on PU quality improvement initiatives and outcomes, Black *et al.* (3) sought to determine the extent of MDR ulcers in hospitalised patients and identify possible risk factors for these ulcers. A total of 2178 patients were included in analyses and excluding patients with CAPUs ($n = 99$), the prevalence of hospital-acquired MDR ulcers was 1·3%. The number of ICU patients screened is not reported, precluding calculation of ICU MDR ulcer prevalence rate. However, the authors do report that MDR ulcers comprise 34·5% (39/113) of hospital-acquired ulcers. Data also indicate that if a patient had a medical device, they were significantly more likely to develop a PU ($P = 0{\cdot}008$). Approaching significance is the finding that when a medical device is present, patients were 2·4 times more likely to develop a PU of any kind ($P = 0{\cdot}10$). The most common locations for MDR ulcers in these hospitalised patients were the ears (35%), lower leg (11%) and heels (8%). Black *et al.* (3) highlighted numerous risk factors for PU development; however, none differentiated between those with MDR ulcers and classic PUs. They concluded that the key risk factor for developing a MDR ulcer was placement of the device itself.

There is no question that the placement of the device is implicated in these ulcers; yet we question whether this conclusion can be reached as the retrospective nature of their data did not allow Black *et al.* (3) to evaluate whether medical devices were present that did *not* result in an ulcer. In contrast, our data showed that of the medical devices monitored, only five devices caused MDR ulcers. While patients screened had nearly eight devices per patient, the majority did *not* develop MDR ulcers. It is important that more than a third of the HAPUs in the Black *et al.*'s study (3) were MDR ulcers, findings that are consistent with our sample where of 62 HAPUs, 20 were MDR ulcers (32·8%). These data indicate how important it is to assess, identify and initiate early prevention for potential MDR ulcers. However, reporting of the ICU data by ulcer rather than by patient precludes calculation of the prevalence and therefore limits comparison across sites and studies.

The study by Apold and Rydrych (9) examined Minnesota's mandatory state reporting data to identify trends in common root causes for MDR ulcers that were reported across the state and develop best practices for prevention related to cervical collars and respiratory equipment. Serious PUs (stages III, IV and unstageable) that were not present at hospital admission were reported. Over the period between 2003 and 2007, 146

ulcers were reported, an average of 37 per year. In 2009, the state called together experts, revised their reporting form to refine their root cause analysis and include MDR ulcers. Since that time, 255 serious hospital-acquired ulcers were reported by 34 hospitals with 113 other hospitals not reporting any serious ulcers. Root cause analysis was performed for each ulcer and findings show 29% of these ulcers were device-related. Types of devices implicated were cervical collars or braces (22%), other immobilisers (17%), stockings or boots (12%) and NG tubes (8%). Most of the MDR ulcers were on the head or neck. In this study, the number of patients screened was not reported, so prevalence could not be calculated. Also, because state reporting was required only for the serious ulcers, the number of less-severe ulcers was not included. In contrast, only 5% of ulcers (1/20) in our dataset were severe, and so the number of MDR ulcers would be significantly underestimated if only severe ulcers were considered. In addition, the Apold and Rydrych's report (9) does not address ICU and so comparison with our sample is not possible. However, they do provide a set of prevention strategies for cervical collars and respiratory devices, an item that has been under-addressed in the literature. It is not possible from this study to determine what proportion of the recommended prevention strategies is evidence-based.

Congruent with the three previous studies, data from this study showed no relationship between PU risk assessment and development of MDR ulcers. In addition, findings from this study show different location sites for device-related ulcers than other published data by Black *et al.* (3) and VanGilder *et al.* (5) where the ears were the most frequent location of MDRs, and Watts *et al.* (10) and Apold and Rydrych (9) where cervical collars were the most common sites. Findings in this study identified the nose and lips or mouth as the most common MDR sites, specifically related to NG and ET tubes, devices commonly used in intensive care. Also important is the finding from this study of the large number of mucous ulcers in contrast with only skin ulcers in the other articles (3,5,9,10), suggesting the need to include mucous membrane assessment with skin assessment when a medical device such as a NG or ET tube is in use.

This study is subject to the limitations of cross-sectional repeated measure designed prevalence studies. Time of the day each prevalence study was conducted also may have affected the number of devices identified as patients being discharged from the unit had many devices removed and those admitted directly from surgery may have had more devices present. Timing variations could not be controlled because of the limitations in the available research personnel and funding. SOFA scores were calculated only for patients with ulcers, so it cannot be known if the SOFA has a predictive value for determining risk of MDR ulcers. No effort was made in this study to evaluate the mechanisms by which devices caused ulcers in this intensive care patient sample.

Conclusion

This is the first study to prospectively and systematically evaluate adult intensive care patients for MDR ulcers over time. It provides a baseline understanding of common, but preventable threats to skin integrity, thus contributing significantly to new knowledge in this area.

Data showed that the prevalence of MDR ulcers was 3·1%, indicating that MDR ulcers are a continuing problem in intensive care. Most ulcers were identified in men who were white, overweight, at increased risk of PU, at low risk of multi-organ failure and who had a long (2 weeks) ICU stay. Nearly half of the MDR ulcers were mucous ulcers rather than skin ulcers, a finding not previously reported. PU risk as determined by the Braden Scale was not related to the development of MDR ulcers. Furthermore, the time from device initiation to detection of an MDR ulcer ranged from 3 to 13 days, suggesting a need for more systematic daily assessment of high-risk areas (nares and lips) in order to detect PU injury earlier and reduce or mitigate skin and mucus membrane damage.

Treatment of MDR ulcers in this sample was not systematic, perhaps with the exception of daily repositioning of devices to relieve pressure on the ulcer. Implementation of procedures that address systematic assessment, treatment and treatment timeframes is needed. Healing occurred with 1 week of observation in 4 of 11 ulcers, even with inconsistent treatment.

Further work is needed in the intensive care population to document the extent of the problem of MDR ulcers and evaluate treatments. A larger sample is needed to develop and test a predictive model. In addition, MDR ulcers are appropriate for further research using a comparitive effectiveness research approach where assessment and interventions could be evaluated within the context of the complex, high acuity arena of intensive care.

We recommend continued evaluation of the prevalence of MDR ulcers in routine prevalence studies in intensive care to monitor their rate and cause. Both skin and mucous membranes sites adjacent to devices require ongoing assessment. Nurses need to be vigilant in prevention of MDR ulcers in ICU patients, especially in those with NG and ET tubes.

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