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Skin complications associated with vascular access devices: A secondary analysis of 13 studies involving 10,859 devices

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ABSTRACT

Background: Vascular access devices are widely used in healthcare settings worldwide. The insertion of a vascular access device creates a wound, vulnerable to irritation, injury and infection. Vascular access-associated skin complications are frequently reported in the literature, however very little evidence is available regarding the incidence and risk factors of these conditions to inform practice and technology development.
Objectives: To estimate the incidence of vascular access-associated skin complications, and to identify patient, catheter and healthcare-related characteristics associated with skin complication development.
Design: Secondary data analysis from 13 multi-centre randomised controlled trials and observational studies evaluating technologies and performance of vascular access devices in clinical settings between 2008 and 2017.
Settings: Six hospitals (metropolitan and regional) in Queensland, Australia.
Participants: The 13 studies involved paediatric and adult participants, across oncology, emergency, intensive care, and general hospital settings. A total of 7669 participants with 10,859 devices were included, involving peripheral venous (n = 9933), peripheral arterial (n = 341), and central venous access (n = 585) devices.
Analysis: Standardised study data were extracted into a single database. Clinical and demographic data were descriptively reported. Cox proportional hazards regression models (stratified by peripheral vs central) were used for time-to-event, per-device analyses to examine risk factors. Univariate associations were undertaken due to complexities with missing data in both outcomes and covariates, with $p < 0.01$ to reduce the effect of multiple comparisons.
Results: Over 12% of devices were associated with skin complication, at 46.2 per 1000 catheter days for peripheral venous and arterial devices (95% confidence interval, CI 42.1–50.7), and 22.5 per 1000 catheter days for central devices (95% CI 16.5–306). The most common skin complications were bruising (peripheral n = 134, 3.7%; central n = 33, 6.8%), and swelling due to infiltration for peripheral devices (n = 296; 2.9%), and dermatitis for central devices (n = 13; 2.2%). The significant risk factors for these complications were predominantly related to device (e.g., skin tears associated with peripheral arterial catheters [hazard ratio, HR 16.0], radial insertion [HR 18.0] basilic insertion [HR 26.0])) and patient characteristics (e.g., poor skin integrity associated with increased risk of peripheral device bruising [HR 4.12], infiltration [HR 1.98], and skin tear [HR 48.4]), rather than management approaches.
Conclusions: Significant skin complications can develop during the life of peripheral and central vascular access devices, and these are associated with several modifiable and non-modifiable risk factors. Further research is needed to evaluate effectiveness technologies to prevent and treat skin complications associated with vascular access devices.

Abbreviations: BMI, body mass index; CVAD, central venous access device; IQR, Interquartile range; HR, hazard ratio; MARSI, medical adhesive related skin injury; RCT, randomised controlled trial; VA, vascular access; IR, incidence rate; CI, confidence interval.

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What is already known about this topic?

The skin surrounding vascular access devices is exposed to irritation and trauma, associated with device management, resulting in complications such as bruising and dermatitis.

The incidence of these complications, and the risks associated with their development, have not previously been clearly estimated.

What this paper adds

Significant skin complications frequently develop around peripheral and central vascular access devices, with bruising, infiltration and dermatitis the most common.

Risk factors were mostly associated with device (e.g., peripheral device placement) and patient (e.g., increasing age, co-morbidities) characteristics, rather than management (e.g., dressings).

1. Background

Worldwide, vascular access devices play a vital function within healthcare. Almost all patients admitted to hospital require some form of vascular access to facilitate the administration of short and long-term treatments (Ullman et al., 2015c). However patients relying on vascular access can be complex, and are often at extremes of age, or have chronic health conditions such as cancer or renal failure (Broadhurst et al., 2017; Thayer, 2012).

Clinicians are focussed on the prevention of harm associated with vascular access devices. The prevention of local and systemic infections associated with these devices are of high priority, and strategies such as skin decontamination using solvents and detergents (e.g., chlorhexidine gluconate) are used to prevent extra-luminal colonisation by bacteria (e.g., *Staphylococcus aureus*) (Mimoz et al., 2015). Dressing and securement technologies, such as sutures, medical adhesives and manufactured devices, are applied to prevent vascular access dislodgement and skin contamination (Marsh et al., 2015b; Ullman et al., 2015a,b). While these strategies reduce systemic infections and promote device performance, they also expose the vascular access site to repeated potential irritation and trauma.

Skin complications associated with vascular access devices are distressing, disfiguring to the skin (i.e., scarring) and frequently result in device failure (Broadhurst et al., 2017). These complications involve a range of conditions including bruising, venous infiltration and extravasation, local site infections, pressure injuries, moisture-associated skin damage (e.g., maceration), contact dermatitis, and mechanical skin injuries, such as skin tears and blisters (Broadhurst et al., 2017; McNichol et al., 2013; Thayer, 2012). Signs and symptoms include itch, erythema, and pain, (McNichol et al., 2013; Thayer, 2012). While these conditions and symptoms are significant, and frequently reported in the literature (Kutzscher, 2012; LeBlanc and Baranoski, 2011; McNichol et al., 2013; Thayer, 2012; Ullman et al., 2015b; Wall et al., 2014), robust, systematic evidence concerning vascular access-associated skin complication incidence and modifiable risk factors, are sparse.

Single site, observational studies in mixed settings (Farris et al., 2015; Konya et al., 2010) have reported overall medical adhesive-related skin injury prevalence (across all types of exposure to medical adhesive) of 3–25%, with the highest risk in elderly patients (Farris et al., 2015), and those with vascular access devices (Konya et al., 2010). A recent Australian point prevalence study (Ullman et al., 2017b) demonstrated 10% of paediatric central vascular access devices were associated with a skin complication, such as dermatitis and/or bruising. A Cochrane Systematic review (Ullman et al., 2016a; Ullman et al., 2015b) examining the effects of central vascular access device dressing and securement reported only 5 of the 22 trials (n = 1159) collected skin irritation and damage, and within these there was no clear evidence of differences in skin complications for a variety of dressing and securement devices.

Vascular access-associated skin complications are a significant and potentially avoidable burden on the healthcare system. However, greater evidence describing the associated risk factors is required in order to guide best practice policies, and focus expensive interventions appropriately. Risk factors associated with other types of vascular access complications have focussed on the examination of patient- (e.g., age, co-morbidities, nutrition status, pre-existing skin conditions), device- (e.g., device type, insertion location) and healthcare- (e.g., dressing and securement products, antisepsis, inserter clinicians) related characteristics (Chopra et al., 2012). A similar approach is evident in studies examining other forms of skin complications, including incontinence-associated dermatitis (Kottner et al., 2014) and pressure injuries (Webster et al., 2015). Thereby, this study aimed to estimate the incidence of vascular access-associated skin complications, and to identify patient-, device- and healthcare-related characteristics that are associated with an increased or decreased risk for vascular access-associated skin complications. The identification of risk factors can then be used to support the development of innovative interventions for appropriate patient groups, to prevent and treat these complications and ensure the efficient use of health resources.

2. Method

2.1. Design

A secondary data analysis of 13 multi-centre randomised controlled trials and observational studies evaluating technologies and performance of vascular access devices undertaken in clinical settings between 2008 and 2017. Together these studies involved 10,859 devices inserted in 7669 participants. This combined data set was analysed to examine the effect of pre-specified potential patient-, device- and healthcare-related risk factors on the development of vascular access associated skin complications and associated symptoms.

2.2. Types of studies

Data were extracted from 12 randomised controlled trials (Bugden et al., 2016; Chan et al., 2017; Edwards et al., 2014; Kleidon et al., 2017; Marsh et al., 2018a Marsh et al., 2015a; Reynolds et al., 2015; Rickard et al., 2016,2015; Rickard et al., 2012; Ullman et al., 2017a, Webster et al., 2017) and one prospective cohort study (Marsh et al., 2018b) completed by the Alliance for Vascular Access Teaching and Research group, and combined into a single database for analysis. The individual studies examined the efficacy of vascular access dressing and securement products (Bugden et al., 2016; Chan et al., 2017; Edwards et al., 2014; Kleidon et al., 2017; Marsh et al., 2018a; Marsh et al., 2015a; Reynolds et al., 2015; Rickard et al., 2016, 2015; Ullman et al., 2017a; Webster et al., 2017), evaluated the effectiveness of routine peripheral vascular access device replacement (Rickard et al., 2012), and observed vascular access-associated management and outcomes (Marsh et al., 2018b). Each study included prospectively collected data, including standardised terms surrounding patient-, device- and healthcare- characteristics of study participants, and skin complications. Data were collected on peripheral arterial, peripheral venous and central venous access devices across six hospitals in Queensland, Australia between 2008 and 2017. All six hospitals involved in the trials were large metropolitan or regional hospitals, with one specialising in paediatrics, managing a combined total of 480,000 admissions per year.

Ethical approval for each trial was obtained from the appropriate health service and Griffith University human research ethics committee, including an approval to reanalyse data in future research. Additional approval was received to undertake this secondary analysis via Griffith University human research ethics committee (GU Ref No. 2017/538).

2.3. Types of participants

The original studies included paediatric and adult participants, across oncology, emergency, intensive care, and general hospital settings. No studies included outpatients. While inclusion and exclusion criteria varied between studies, all dressing and securement randomised controlled trials specifically excluded patients with pre-existing skin complications surrounding the vascular access site, and known allergies/sensitivities to any of the study products (i.e., polyurethane dressings, tissue adhesive, sutureless securement devices). All participants and/or legal guardians provided written, informed consent prior to participation in the original trials.

2.4. Data collection

Trained research nurses were employed on each project and were responsible for data collection, de-identification, and entry into standardised and secure databases. Study data was extensively cleaned during original data analysis. The Research Nurse for the current project, then checked and combined these data into a single database for secondary analysis.

2.5. Outcome definitions

In this secondary analysis, outcomes were pragmatically divided into vascular access-associated skin complications and individual abnormal skin signs or symptoms that were not otherwise diagnosed as a specific complication. Vascular access-associated skin complications were defined as the presence of bruising, infiltration (involving localised swelling), dermatitis (as evidenced by a raised red rash, with or without vesicles, which persisted for greater than 30 min (Broadhurst et al., 2017; McNichol et al., 2013)), mechanical injuries such as skin tears and blisters (McNichol et al., 2013; Thayer, 2012), and local infections (purulent discharge, or redness extending 1 cm beyond the site that prompted clinicians to order vascular access device removal, or commence antimicrobial therapy (Ullman et al., 2016b), surrounding the vascular access site. Vascular access-associated individual abnormal skin signs or symptoms included fluid leakage, erythema, pain, and itch from the vascular access site.

The individual types of vascular access-associated skin complications and symptoms were secondary outcomes of each included study. Study data were only included in the analyses if the definition of the complications and symptoms met the above-mentioned criteria.

2.6. Variables

Potential patient-related, catheter-related and healthcare-related risk factors were developed a priori, after a systematic review of the literature and consultation with interdisciplinary, international key opinion leaders, ensuring the variables were also consistently collected in the original trials. The characteristics included age, primary diagnosis, systemic skin integrity overall (good [healthy, well hydrated, elastic], fair [intact, mildly dehydrated, reduced elasticity], or poor [papery, dehydrated, small amount or no elasticity]), skin type (Fitzpatrick scale (Fitzpatrick, 1988)), underlying co-morbidities (e.g. renal impairment, diabetes, circulatory disorders), nutrition status (described by Body Mass Index [BMI]), dressing products, securement products, insertion site and dwell time. Data were not available on site decontamination procedures. The included variables were each collected using standardised definitions, as part of the original trials.

2.7. Data analysis

The 13 individual study databases were exported and combined into a single database for secondary analysis, with additional data cleaning undertaken. The demographic and clinical characteristics were descriptively reported, using categorical and continuous descriptors appropriate to their distribution. The primary outcomes were time-dependent (incidence rates, survival data/hazard rates reported with 95% confidence intervals); thus, Cox proportional hazards regression models were used for time-to-event analysis. Regression analyses were stratified by device class (peripheral or central); per-device analysis was performed as per-patient analysis is not appropriate if device-related covariates vary within patients. Univariate associations were undertaken, due to complexities with missing data in both outcomes and covariates making multivariate regressions unfeasible. The association between skin complication and dwell time were explored graphically through Kaplan Meier estimates. Missing data were not imputed. Statistical significance was declared at $p < 0.01$ to reduce the effect of multiple comparisons. The analysis was undertaken using Stata (version 15; StataCorp, College Station, TX).

3. Results

3.1. Participant, device and dressing characteristics

Table 1 describes the baseline characteristics of participants and devices included in the analyses. Participants' median age was 59 years (IQR 42, 71), with only a small representation (<2%) being less than 16 years of age. Comorbidities were common, (79% reporting one or more), and the majority of patients had pale white to white skin (75%). Data were collected on peripheral arterial (n = 341; 3%), peripheral venous (n = 9933; 91%) and central venous access (n = 585; 6%) devices. One quarter of devices (n = 2579; 25%) were associated with a complication prompting device removal, with a median dwell of 2.4 days for peripheral devices (IQR 1.5, 3.6) and 4.8 days for central devices (IQR 2.6, 10.1).

As displayed in Table 2, the majority of vascular access sites were dressed with either plain (n = 2699; 55%) or bordered (n = 1802; 37%) polyurethane dressings, with no additional security (n = 2488; 49%).

3.2. Frequency of vascular access-associated skin complications, and signs and symptoms

Overall, 12.3% of peripheral devices (n = 482; IR 46.2 per 1000 catheter days [95% CI 42.1–50.7]) and 11.7% of central devices (n = 40; IR 22.5 per 1000 catheter days [16.5–30.6]) were associated with a skin complication after insertion (see Table 3). The most common vascular access-associated skin complications were bruising in peripheral (both venous and arterial) and central devices (3.7%, 6.8% respectively), infiltration in peripheral devices (n = 296; 2.9%) and dermatitis in central devices (n = 13; 2.2%). There were infrequent reports of mechanical injuries or infections, however both were more common in central devices than in peripheral devices. Signs and symptoms of skin complications were more evident, with peripheral device leakage (n = 2069; 25%), peripheral and central device erythema (5.3%, 3.2% respectively)

Table 1
Participant and device characteristics: (7669 participants and 10,859 devices).

Variable		Frequency (%)
By participant		
Age (years)[a] (n = 7662)		59 (42–71)
	Infant (<12 months)	12 (0)
	Paediatric (1–15 years)	126 (2)
	Adult (16–69 years)	5386 (70)
	Elderly (70 years or older)	2138 (28)
Diagnosis at insertion (n = 7662)	Surgical	5003 (65)
	Medical	1963 (26)
	Oncology/haematology	225 (3)
	Other	471 (6)
Skin integrity overall (n = 6864)	Good	3980 (58)
	Fair	2206 (32)
	Poor	678 (10)
Skin type (Fitzpatrick scale) (n = 4014)	Pale white	347 (9)
	White	2676 (67)
	Light brown	582 (14)
	Moderate brown	358 (9)
	Dark brown/black	51 (1)
Wound at baseline (n = 7192)		1528 (21)
BMI category (n = 3396)	Normal/underweight	1545 (45)
	Overweight/obese	1851 (55)
Comorbidities (n = 7293)	None	1556 (21)
	One	1685 (23)
	Two or more	4052 (56)
By device		
Catheter type (n = 10,859)	Peripheral venous	9933 (91)
	Peripheral arterial	341 (3)
	Peripherally inserted central catheter	317 (3)
	Non-tunnelled CVAD	220 (2)
	Tunnelled CVAD	48 (0)
Insertion site (n = 10,847)	Forearm	4881 (45)
	Hand	1514 (14)
	Antecubital	1032 (10)
	Cephalic	808 (8)
	Foot	628 (6)
	Wrist	430 (4)
	Basilic	337 (3)
	Radial	332 (3)
	Internal jugular	249 (2)
	Brachial	32 (0)
	Subclavian	18 (0)
	Other	586 (5)
Dwell time (days)[a] (n = 10,488)	Total	2.5 (1.5–3.8)
	Peripheral[b]	2.4 (1.5–3.6)
	Central[c]	4.8 (2.6–10.1)
Any complication prompting device removal (n = 10,487)		2579 (25)

Frequencies and column percentages shown unless otherwise noted; [a] median and inter-quartile range; [b]peripheral venous and arterial catheters; [c]peripherally inserted central catheter, non-tunnelled and tunnelled CVAD; n = number of non-missing values; BMI = body mass index; CVAD = central venous access device.

Table 2
Dressing and securement characteristics (n = 4965).

		Frequency (%)
Sutured (n = 4965)		146 (3)
Dressing type (n = 4931)	Plain polyurethane	2699 (55)
	Bordered polyurethane	1802 (37)
	Integrated securement dressing	236 (5)
	Fabric	134 (3)
	Honeycomb	60 (1)
Securement device type (n = 4965)	Sutureless securement device	1365 (27)
	Tissue adhesive	852 (17)
	Elasticised bandage	166 (3)
	Additional plain polyurethane	109 (2)
	Bandage	25 (1)
	Non sterile tape	8 (0)
	Additional bordered polyurethane	2 (0)
	None	2438 (49)
Dressing changes (n = 2895)	Zero	2396 (83)
	One	304 (10)
	Two	99 (3)
	Three	47 (2)
	Four or more	49 (2)

and peripheral device pain (n = 626; 6.3%) at the vascular access site common.

The Kaplan-Meier estimates of skin complications over dwell time are presented in Fig. 1. For the bruising and infiltration associated with peripheral vascular access devices the rate of failures was approximately constant in the first 8 days of dwell time. For central devices, the rate of bruising was approximately constant in the first 10 days of dwell time, while most other abnormalities appeared only well into the dwell time: dermatitis after 6 days, blister after 7 days, and tearing after 4 days (all approximate).

3.3. Risk factors for vascular access-associated skin complications and symptoms in peripheral devices

The patient-, device- and healthcare-related risk factors associated with the development of skin complications and symptoms in peripheral devices are displayed in Table 4. Bruising was significantly associated with multiple patient and device characteristics, including increasing age (HR 1.01), medical diagnosis (HR 2.97), poor skin integrity (HR 4.12), wounds at baseline (HR 3.71), peripheral device insertion in the cephalic (HR 4.11) and foot (HR 3.15) veins (in comparison to forearm). Mechanical skin tears were significantly associated with poor skin integrity (HR 48.4), two or more comorbidities (HR > 100), arterial devices (in comparison to venous; HR 16.0), and radial (HR 18.0) and basilic (HR 26.0) vessels (in comparison to forearm).

The only vascular access-associated skin complication or symptom associated with a dressing and securement product, was a significant increase in itch for tissue adhesive as a securement product (HR 6.92), in comparison to none.

3.4. Risk factors for vascular access-associated skin complications and symptoms in central devices

The patient-, device- and healthcare-related risk factors associated with the development of skin complications in central vascular access devices are displayed in Table 5. Increasing age (HR 1.02) and wounds at baseline (HR 3.67) were associated with an increased risk of bruising. Co-morbidities were associated with a HR of >100, in development of dermatitis, while a medical diagnosis (in comparison to surgical diagnosis) was associated with a HR of >100, in development of a MARSI blister. The use of tissue adhesive was associated with a HR of >100, in the development of a MARSI skin tear. There were no significant risk factors identified with the development of skin signs and symptoms in central vascular access devices.

4. Discussion

Using a large, high quality dataset, this secondary analysis has demonstrated that patients reliant upon vascular access for treatment, develop skin complications and, signs and symptoms surrounding their vascular access site during their placement. This

Table 3
Vascular access associated skin complications, and signs and symptoms by device.

Variable	Peripheral		Central		Total
	freq. (%)	IR (95% CI)	freq. (%)	IR (95% CI)	freq. (%)
Skin complications					
Any complication (n = 3928)	**442 (12.3)**	**46.2 (42.1–50.7)**	**40 (11.7)**	**22.5 (16.5–30.6)**	**482 (12.3)**
Bruise (n = 4072)	134 (3.7)	14.0 (11.8–16.6)	33 (6.8)	10.2 (7.27–14.4)	167 (4.1)
Infiltration (n = 9820)	296 (2.9)	11.0 (9.79–12.3)	1 (0.3)	0.56 (0.08–3.99)	297 (3.0)
Dermatitis (n = 4653)	19 (0.5)	1.85 (1.18–2.91)	13 (2.2)	3.03 (1.76–5.21)	32 (0.7)
Mechanical injury (tear) (n = 4598)	12 (0.3)	1.17 (0.66–2.06)	10 (1.7)	2.33 (1.25–4.33)	22 (0.5)
Mechanical injury (blister) (n = 4598)	6 (0.2)	0.59 (0.26–1.30)	8 (1.4)	1.86 (0.93–3.72)	14 (0.3)
Local infection (n = 4974)	9 (0.2)	0.88 (0.46–1.68)	2 (0.3)	0.47 (0.12–1.86)	11 (0.2)
Skin complication signs and symptoms					
Any sign or symptom (n = 2554)	**356 (15.2)**	**57.0 (51.4–63.3)**	**11 (5.0)**	**17.0 (9.40–30.6)**	**367 (14.4)**
Leakage (n = 8723)	2069 (24.8)	86.6 (83.0–90.4)	6 (1.5)	2.59 (1.16–5.76)	2075 (23.8)
Erythema (n = 8446)	438 (5.3)	18.5 (16.9–20.3)	7 (3.2)	10.8 (5.15–22.7)	445 (5.3)
Pain (n = 10,246)	626 (6.3)	22.6 (20.9–24.5)	0 (0.0)	–	626 (6.1)
Itchiness (n = 3020)	15 (0.6)	2.23 (1.40–3.85)	21 (3.6)	4.89 (3.19–7.50)	36 (1.2)
Overall (n = 2128)	**494 (25.9)**	**88.8 (81.3–97.0)**	**20 (9.1)**	**30.9 (19.9–47.8)**	**514 (24.2)**

Column percentages calculated using the number of non-missing observations in the denominator; n = number of non-missing observations; IR = incidence rate per 1000 device-days; CI = confidence interval; combined values shown as "Any" are not necessarily equal with the sum of frequencies of the components due to missing data; freq. = frequency.

represents the first systematic description of a significant healthcare-related injury, which is causing preventable harm to patient's worldwide. Overall, skin complications developed in 12.3% of peripheral devices and 11.7% of central devices, with further signs and symptoms of skin complications also occurring. Skin complications surrounding the vascular access site included bruising, infiltration, dermatitis and mechanical injuries, which were not evident prior to the device insertion. While individual skin complications may, at first, appear low, with over two billion vascular access devices inserted annually (Rickard and Ray-Barruel, 2017), their occurrence is a significant burden on health systems. These are under appreciated healthcare-associated complications, resulting in patient discomfort that may be preventable in many situations.

Bruising was the most common skin complication surrounding vascular access device sites, evident in 3.7% of peripheral devices (n = 134), and 6.8% of central devices (n = 33), and occurred at a mostly constant rate throughout dwell time. While many of the risk factors associated with the development of bruising were not modifiable (e.g., increasing age, medical diagnosis, poor skin integrity), insertion and management strategies are available to minimise the development of bruising. Our data demonstrates that peripheral device insertion in the cephalic (HR 4.11) and foot (HR 3.15) veins were associated with significant increased risk of bruising. While these veins are often reserved as a 'last resort', after insertion failure in other places, clinicians should take into consideration the risk of bruising surrounding these vessels, and minimise their use, wherever possible. Ultrasound guidance has been demonstrated to improve insertion success in both peripheral (Doniger et al., 2009; Egan et al., 2013) and central vascular access devices (Froehlich et al., 2009; Lau and Chamberlain, 2016). Haemostatic agents at the vascular access insertion site may also be useful to reduce post-insertion bruising (Kleidon et al., 2017), especially for patients with treatment-induced coagulopathies. Post-insertion bruising may also be a result of poor vascular access device security, resulting in localised movement (Ullman et al., 2015a). As part of contemporary, evidence-based practice clinicians should work to apply strategies to promote post-insertion haemostasis, and device security in high risk patient groups, to prevent bruising development.

There is growing evidence on the effectiveness of tissue adhesive, or medical-grade superglue, to secure, prevent infection, and promote function of vascular access devices (Bugden et al., 2016; Chan et al., 2017; Edwards et al., 2014; Kleidon et al., 2017; Marsh et al., 2015a; Reynolds et al., 2015; Rickard et al., 2016; Ullman et al., 2017a). Our data demonstrates that tissue adhesive is

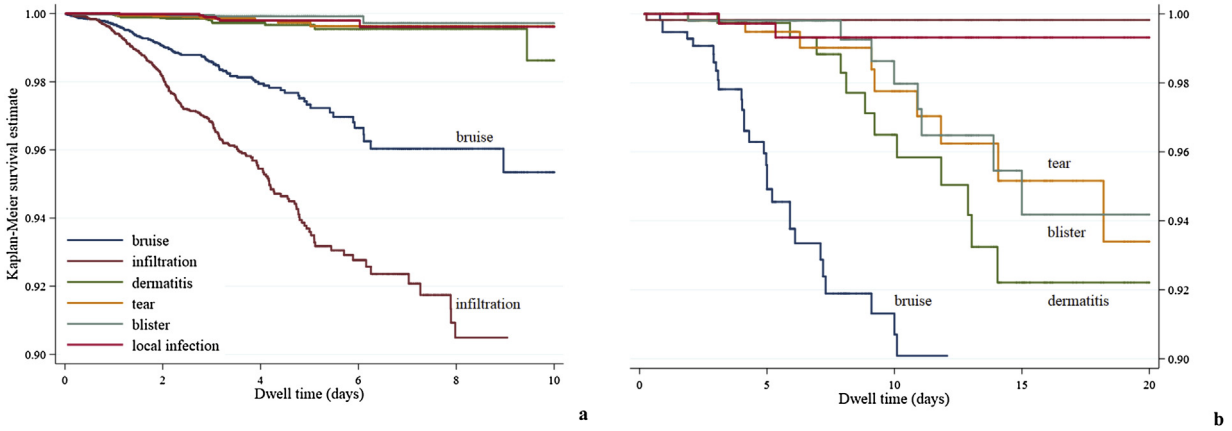

Fig. 1. Kaplan Meier estimates of skin complications development over dwell time: [a]Peripheral (venous and arterial) [b]Central.

Table 4
Unadjusted Hazard Ratios: Peripheral venous and arterial catheters.

	Skin complications				Signs and symptoms			
	Bruising	Infiltration	Dermatitis	Mechanical (tear)	Leakage	Erythema	Pain	Itch
Age (years)	1.01 (1.00,1.02)				0.99 (0.99,1.00)	0.99 (0.99,1.00)	0.99 (0.98,0.99)	
Diagnosis (ref. surgical)								
Medical	2.97 (2.09,4.22)	1.95 (1.53,2.48)	4.22 (1.70,10.5)		0.69 (0.62,0.77)		1.33 (1.12,1.59)	7.70 (2.42-24.6)
Not medical/oncology/ surgical	12.4 (5.90,26.0)	6.13 (3.23,11.6)						
Skin integrity (ref. good)								
Fair		1.61 (1.26,2.06)			0.76 (0.69,0.84)		0.75 (0.63,0.90)	
Poor	4.12 (2.66,6.39)	1.98 (1.39,2.84)		48.4 (5.94,>100)	0.69 (0.58,0.82)		0.58 (0.41,0.82)	
Wound at baseline	3.71 (2.63,5.22)	5.62 (4.47,7.06)	3.58 (1.44,8.91)		0.17 (0.13,0.21)		1.53 (1.27,1.84)	
Comorbidities (ref. none)								
One	3.40 (1.62,7.14)							
Two or more	3.74 (1.89,7.41)			>100 (>100, >100)				
Arterial catheter (ref. venous)				16.0 (3.30,77.4)	0.13 (0.04,0.40)			
Insertion site (ref. forearm)								
Hand		0.41 (0.22,0.77)			1.78 (1.60,1.97)			
Antecubital					1.57 (1.37,1.79)			
Cephalic	4.11 (2.58,6.54)	4.38 (3.23,5.95)			0.11 (0.07,0.18)	0.38 (0.22,0.65)		4.50 (1.47,13.8)
Foot	3.15 (1.73,5.72)	5.31 (3.80,7.41)			0.04 (0.02,0.11)	0.09 (0.02,0.37)	1.91 (1.42,2.57)	
Wrist					0.65 (0.51,0.84)			
Radial				18.0 (3.27,98.6)	0.13 (0.04,0.40)			
Basilic		4.15 (1.93,8.91)	12.4 (2.74,55.9)	26.0 (5.04,>100)	0.11 (0.03,0.43)			
Other	6.17 (3.87,9.83)	3.32 (2.25,4.90)			0.27 (0.19,0.39)	0.17 (0.06,0.46)	1.80 (1.34,2.43)	
Securement (ref. none)								
Tissue adhesive								6.92 (2.08,23.0)

Unadjusted (univariable, or crude) statistically significant ($p < 0.01$) Hazard Ratios (and 95% confidence intervals) shown; blank = non-significant at $p \geq 0.01$; complications and abnormalities with no statistically significant associations are not shown.

associated with increased risk of itch (peripheral devices; HR 6.92) and mechanical skin tears (central devices; HR > 100). Clinicians should take these risks into consideration when applying this new technology within complex health situations involving patients with pre-existing skin impairments, or those who are at increased risk of developing it due to clinical- and device-related characteristics (e.g., comorbidities).

While dermatitis and mechanical skin injuries were less common, their development was significantly associated with several clinical risk factors, including comorbidities, medical diagnosis and wounds at baseline, and appeared to develop later in the central device dwell time. Over recent years, these conditions have been the focus of several clinical practice guidelines and algorithms (Broadhurst et al., 2017; LeBlanc and

Table 5
Unadjusted Hazard Ratios: Central venous access devices.

	Bruising	Dermatitis	Mechanical (tear)	Mechanical (blister)
Age (years)	1.02 (1.01, 1.04)			
Diagnosis (ref. surgical)				
Medical				>100 (>100, >100)
Wound at baseline	3.67 (1.77, 7.63)			
Comorbidities (ref. none)				
One		>100 (>100, >100)		
Two or more		$		
Securement (ref. none)				
Sutureless securement device	0.28 (0.11, 0.68)			
Tissue adhesive			>100 (>100, >100)	

Unadjusted (univariable, or crude) statistically significant ($p < 0.01$) Hazard Ratios (and 95% confidence intervals) shown; blank = non-significant at $p \geq 0.01$; CVAD = Central venous access device; complications and abnormalities with no statistically significant associations are not shown; $ = cannot be calculated.

Baranoski, 2011; McNichol et al., 2013). Preventative strategies include the application of skin barrier films, adhesive removal agents, silicone and other high-technology dressings, and high quality dressing change procedure practices. The application of dressings onto skin still wet from decontaminants, is considered to be a major, preventable cause of dermatitis (Thayer, 2012). A recent clinical trial in intensive care settings demonstrated increased risk of skin reactions with the use of chlorhexidine in alcohol (3%), in comparison to povidone iodine in alcohol (1%) (Mimoz et al., 2015), but also demonstrated the superiority of chlorhexidine in alcohol to prevent catheter-related infections (HR 0.15; 95% CI 0.05–0.41; $p < 0.001$). Further evidence is urgently needed to inform practice in this area, as many dermatitis and mechanical skin injury prevention and treatment recommendations are based upon low quality evidence, with contradicting indications between infection prevention and skin health promotion (Broadhurst et al., 2017; LeBlanc and Baranoski, 2011; McNichol et al., 2013).

The identification of these sometimes complex skin conditions is difficult. Researchers and clinicians advocate for systematic skin assessments as part of routine clinical practice (Broadhurst et al., 2017; Thayer, 2012). However, differentiating between skin complications is challenging for clinicians with limited wounds expertise (e.g., irritant contact dermatitis versus allergic contact dermatitis). Many patients are quickly labelled as 'allergic' to adhesives and dressings, who may have instead had a local trauma or irritant dermatitis (Broadhurst et al., 2017). This mislabelling leads to significant difficulty with future dressing choices. As demonstrated within these data, as the populations requiring vascular access devices continue to become more complex and elderly, these clinical conditions are likely to become more prevalent. Comprehensive resources are essential to guide clinicians to identify and treat skin complications, around these common vascular access devices.

While based upon a large, prospectively collected dataset, this study has several limitations. The individual studies involved were not focussed on skin complications, and some data were not collected throughout all trials, therefore there is missing data in multiple variables and outcomes. Due to these missing data, a multivariate analysis could not be completed, so the confounding or interaction between co-variables could not be assessed, and some of the reported significant risk factors may not be accurate. However all missing data have been reported throughout, and the significance reduced to <0.01, to reduce the effect of multiple comparisons. The data are up to 10 years old and based out of Australian hospitals only, so it may not be reflective of current contemporary practice outside of Australia. Finally, the research nurses involved in each study were trained regarding skin assessments, however were not wound experts. Nevertheless this study provides a systematic description of a previously under-reported phenomenon, and is useful to inform future research and practice innovation.

5. Conclusion

The insertion of a vascular access device creates a wound that persists for as long as the device is in situ. This study demonstrates that skin complications and symptoms can develop during the life of peripheral and central vascular access devices, and that these complications are associated with several modifiable and non-modifiable risk factors. Many of these uncomfortable and disfiguring complications may be preventable, with the implementation of high quality patient care. It is now necessary to develop, identify and systematically evaluate products, technologies and care practices to prevent and treat skin complications associated with vascular access devices.

Conflicts of interest

Griffith University has received investigator-initiated grants and unrestricted donations from vascular access product manufacturers (i.e. 3 M, Adhezion, Angiodynamics, Becton Dickinson, BBraun, Centurion Medical Products), to support research led by AJU, unrelated to the current project.

GM, KO, CM, SB and MS have no conflicts of interests to declare.

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Contributors' statement

Amanda J Ullman: Dr Ullman conceptualized and designed the study, drafted the initial manuscript, and approved the final manuscript as submitted.

Gabor Mihala: Mr Mihala assisted with the conception and design of the study, led the acquisition and analysis of data, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Nicole Marsh, Christine Woods and Claire Rickard: Ms Marsh, Ms Woods and Dr Rickard assisted with the conception and design of the study, interpretation of the data, reviewed and revised the manuscript for important intellectual content, and approved the final manuscript as submitted.

Kate O'Leary: Ms O'Leary assisted with the acquisition of data, drafting the initial manuscript, critically reviewed the manuscript and approved the final manuscript as submitted.

Simon Bugden and Mark Scott: Drs Bugden and Scott were clinical leads for the IVL-GONE study, contributed to the acquisition of data, reviewed and revised the manuscript, and approved the final manuscript as submitted.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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