Preventing medical device related pressure injuries: data extraction and appraisals

Search results for 2019 International Pressure Injury Guideline: Medical Device Related Pressure Injuries


 Identified in pressure injury searches
n=11,177

Excluded after screening title/abstract
- Duplicate citations
- Included in previous guideline
- Not related to pressure injuries
n=8,128

Identified citations
n=3,085

Excluded after review of full text
- Not related to pressure injuries
- Not related to the clinical questions
- Citation type/research design not meeting inclusion criteria
- Non-English citation with abstract indicating not unique research for translation
n=57

Identified in topic-specific key word searches for full text review and critical appraisal
n=106

Excluded based on key word searches
- Not related to the topic-specific questions
n=2,979

Identified as providing direct or indirect evidence related to topic and critically appraised
n=87

Additional citations
- Appraised for previous editions
n=11

Total references providing direct or indirect evidence related to topic
n=30

MDRPI keywords
Medical device, device*, mask, ventilation, oximeter, tube, catheter, tracheostomy, gastrostomy, brace, plaster, collar, equipment, airway

Additional citations
Identified by working group members
n=36

Identified in pressure injury searches
n=11,177

Excluded after screening title/abstract
- Duplicate citations
- Included in previous guideline
- Not related to pressure injuries
n=8,128

Identified citations
n=3,085

Excluded after review of full text
- Not related to pressure injuries
- Not related to the clinical questions
- Citation type/research design not meeting inclusion criteria
- Non-English citation with abstract indicating not unique research for translation
n=57

Identified as providing direct or indirect evidence related to topic and critically appraised
n=87

Additional citations
- Appraised for previous editions
n=11

Total references providing direct or indirect evidence related to topic
n=30


Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries

© NPUAP/EPUAP/PPPIA
Preventing medical device related pressure injuries: data extraction and appraisals

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resource and are not for reproduction.


<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical question 2 (local management strategies): Alternate oxygen therapy delivery options</td>
<td>Newnam et al., 2015</td>
<td>RCT investigating frequency and severity of nasal pressure injuries for different neonatal nasal continuous positive airway pressure (CPAP) systems in neonates of extremely low birthweight</td>
<td>Participants were recruited in a neonatal ICU in US (n=377 screened, n=138 met inclusion, 78 consented)</td>
<td>On extubation, randomized using block stratified according to birth weight (&lt;750g; 750 to 1000g; 1001 to 1250g; and 1251 to 1500g) to receive:</td>
<td>• Serial skin evaluation conducted during routine care with 8 hours of extubation and then every 8 to 12 hours using the validated Neonatal Skin Condition Scale that includes dryness, erythema, breakdown and excoriation each graded 1 to 3 giving total score 3 to 9 with higher score indicating worse skin condition</td>
<td>Skin breakdown • 24.2% of participants • Occurred at nasal septum (83.3%), nasal bridge (19.9%) and forehead (26.6%) • Factors associated with MDRPI: • Mean post menstrual age (p&lt;0.001) • Number of days on CPAP (p=0.006)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ref: Newnam et al., 2015

Level of evidence: 1

Quality: High
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Hampson et al., 2018 | Retrospective observational study exploring impact of alternate ET tube fasteners on incidence of oral pressure injuries | Retrospective record review for two periods of 2yrs 9mths (pre intervention and post intervention) in one hospital ICU in Australia (n=2008 admissions) | • First observation period the ET tube securement cloth tapes were used to secure ET tubes, with adjustment every 6 hours (n=1043 admissions)  
• Second observation AnchorFast™ (Hollister) and cloth tapes were used to secure ET tubes, with the device adjusted every 2 hours (cloth tape remaining at 6 hours) | • Pressure injury location and severity using NPUAP classification system was documented by a nurse | Conclusions: there was reduced nasal injuries by using rotation between nasal prongs and mask for babies with birth weights below 1,500g |  
Clinical question 2 (local management strategies): Alternative securing devices |
| Ambutas, Staffileno, & Fogg, 2014 | Quasi experiment comparing conventional | Retrospective record review in 3 long term care facilities in the US over 12 months (106,722 patient days) | • Participants had a 14 or 16 grade NG tube  
• Participants received either: | |  
Pressure injury rate  
There were significantly more pressure injuries in people who had the device securement versus the cloth securement (1.98/100 versus 4.03/100, incident rate ratio 2.03, 95% CI 1.17 to 3.51, p=0.02)  
Other outcomes  
• People with pressure injuries from the device were more likely to have a lip pressure injury (75%) and people with cloth securement were more likely to have a corner mouth injury (53.6%)  
• Greater compliance with protocols was observed in the second period (64.5% versus 9.1%, p=0.004)  
• No significant differences in time to pressure injury  
• Some pressure injuries were inside the mouth and would qualify as mucosal membrane injuries, these were still classified using the NPUAP system  
• Single center study  
• Findings may indicate increased surveillance for pressure injuries due to the study  
• Relied on medical records |  
Level of evidence: 2  
Quality: Low |
# Preventing medical device related pressure injuries: data extraction and appraisals

| Ref                  | Type of Study                          | Sample                                | Intervention(s)                                                                 | Outcome Measures & Length of Follow-up                  | Results                                                                                         | Limitations and comments                                                                 |
|----------------------|----------------------------------------|---------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Worsley, Prudden, Gover, & Bader, 2016 | Observational study investigating effect of varying NIV mask design and strap tension and the reaction at the skin interface | Healthy volunteers (n=13)             | Participants wore the following masks with Sebutape attached to the nose bridge and cheeks: | Interface pressure at nose bridge measured after 10 min application | Interface pressure | • For both masks, bridge of nose interface pressure was higher than cheek interface pressure (p<0.05)
• Strap tension was significantly associated with interface pressure for both masks (p<0.01) |
|                      |                                         | Participant characteristics:          | Philips Respironics Amara (mask 1) ResMed Mirage Quattro (mask 2) Straps tensioned to ensure central position of mask (T1) then incrementally increased tension by 5mm (T2) and then a further 5mm (T3) | Cytokine concentration before and after mask application | Cytokine analysis | There was increase in cytokine ratio with increase in strap tension, particularly IL-1α ratio |
|                      |                                         | • Mean age 25 years                   | Temperature and humidity                                                        | • Temperature and humidity                              | Temperature and humidity | * The result may be different if applying in hospitalized patients
* The data can be used as reference for clinicians for further study |

**Notes:**
- **Ref:** Reference
- **Type of Study:** Methodology of study
- **Sample:** Description of the sample used in the study
- **Intervention(s):** Description of the intervention(s) used in the study
- **Outcome Measures & Length of Follow-up:** Description of the outcome measures and length of follow-up used in the study
- **Results:** Summary of the results obtained in the study
- **Limitations and comments:** Summary of the limitations and comments related to the study

---

**Tape to a commercial device for securing nasogastric tube for reducing PUs**

**Inclusion criteria:** Intubated patients with facial burns
ET tube secured using non-twill and/or non-silicone pressure reducing strips methods

**Exclusion criteria:** Incomplete data regarding use of interventions

**Participant characteristics:**
- Mean age 59.9 years
- Primarily surgical participants

**Intervention(s):**
- Commercial nasogastric holder device (Dale Nasogastric Tube Holder®, n=115)
- Regular adhesive tape split with a cut down the tape and wrapping the two pieces around the NG tube, with additional tape securing across nose bridge (n=83)

**Outcome Measures & Length of Follow-up:**
- with regular adhesive tape (4% versus 23%, p<0.0001)

**Results:**
- There was no significant difference in adhesiveness of the two methods

**Author conclusions:**
Commercially design NG tube holders might lead to fewer PUs than regular adhesive tape.

**Limitations and comments:**
- Difference in PU rate
- Minimal information about participants including risk factors (e.g. fever, medical status, nutrition)
- No randomization or blinding
- Only one particular holder was used in one clinical setting

---

**Low**

---

**Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries © NPUAP/EPUAP/PPPIA Page 4**
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Otero et al., 2017   | RCT exploring efficacy of four different methods of preventing facial pressure injuries | Participants were recruited in a high dependency unit in Spain (n=220 screened, n=171 randomized, 152 analyzed) | • Participants were randomized to receive:  
  o Group1: regular facial mask (n=44 randomized, n=39 analyzed) | • Skin and dressing under mask assessed every 6 hours  
  • Assessment performed independently by two trained evaluators using GNEAUPP staging system | • Median relative humidity at skin-mask interface was 84% (significant compared to ambient temperature, p= not reported)  
  • No significant association between strap tension and either humidity or temperature  
  • Participants rated optimal tension as being more comfortable than either tightened tension (p<0.05 for both), with no difference between mask designs  
  • There was no significant difference in PU rate based on age, Norton score or number of hours with NIV  
  • 48.68% of participants developed a facial pressure  
  • No ITT analysis  
  • Approx 10% drop out that was not equivalent between groups – more drop outs | Author conclusion: Increases in strap tension that are small can lead to large difference in interface pressures and biomarker responses  
  | Clinical question 2 (local management strategies): Skin moisturizing          |                                                                        |                                                                 |                                                                                                           |                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                         |

Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries © NPUAP/EPUAP/PPPIA
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| **including prophylactic dressings and hyperoxygenated fatty acids (HOFA)** | • Acute respiratory failure requiring non-invasive ventilation (NIV)  
   • Aged > 18 years  
   • No facial deformity or tissue injury  
Exclusion criteria:  
• Facial lesions or deformities  
• Not consenting  
Participant characteristics:  
• Mean Norton score 10.69 (SD 2.85) indicating high risk patients  
• Average hours with NIV was 14.48, with HOFA having higher average duration than the other three groups  
• 20.5% taking vasopressors | **Group 2:** adhesive polyurethane thin prophylactic dressing (n=36 randomized, n=35 analysed)  
**Group 3:** 2-layered foam prophylactic dressing (n=46 randomized, n=39 analyzed)  
**Group 4:** HOFA applied over cheeks, nasal bridge and forehead (n=45 randomized, n=39 analyzed)  
• Dressings reapplied as required and if required according to hydration status the HOFA was reapplied | • Final assessment conducted 5-10 hours after ceasing NIV | injury, most frequently on the nasal bridge  
5.2% of participants developed > one facial pressure injury  
85% were category 1, 13.5% Category 2, 1.5% Category 3 | from dressing and HOFA groups  
• Reached the required recruitment for power calculation based on an approx. 15% decrease in PU  
• Minimal details re risk factors (e.g. vasopressors, concentrations of oxygen, nutritional profiles)  
• Non-blinded outcome measures |

#### Clinical question 2 (local management strategies): Padding of casts

| Murgai, Compton, Patel, Ryan, & Kay, 2018 | **Retrospective review of patients undergoing lower extremity (LE) casting after elective surgery to determine if Participants were recruited at a children’s hospital in US (n=920 patients, n=2481 casts; n=612 casts had foam padding under cast)  
Inclusion Criteria:  
All patients who underwent LE casting after elective surgery | Casts were analyzed as:  
• having padding (n=612, 24.7%) when foam was applied, it was applied to the heel, patella and padding the top of the cast  
• Or not having padding (n=1869, 75.3%) | **Types of skin complications and anatomical locations** were analyzed for casting with and without foam  
Skin complications included pressure injury, blister and unspecified skin breakdown  
Unspecified skin breakdown: | **Incidence of skin complication**  
• Overall incidence 3.3%  
• Incidence with A frame case: 8.2%  
• Incidence with hip spica 4.3%  
• Incidence with long cast 3.1%  
• Incidence short leg casts 2.5%  
• 59.8% of skin complications were described as pressure | Relied on records  
No staging of pressure injuries and method of assessment was unclear  
Unclear classifications of skin complications | Level of evidence: 4  
Quality: Moderate |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
|     |               | foam padding reduced incidence of skin complication in children |                    |                                        | injuries, 31.7% were blisters and 8.5% unspecified | Incidence of skin complications: padding vs no padding  
- A frame cast skin complications incidence was significantly reduced with padding vs no padding (4.5% vs 13.4%, p=0.03)  
- Long leg cast skin complications incidence was significantly reduced with padding vs no padding (0.9% vs 4.3%, p=0.02)  
- Static encephalopathy cast skin complications incidence was significantly reduced with padding vs no padding (0.7% vs 3.6%, p=0.01)  
- Other types of cast showed no significant difference for skin complication in padded vs no padding | Concurrent management was not reported (particularly positioning of the casted leg and what support surface was used) |
|     |               | Exclusion criteria: If the patient did not have a minimum of 2 months of follow-up or if their case was split at the time of surgery |                    |                                        |         |                          |
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Balch Samora, Samora, Dolan, & Klingele, 2018 | Quality improvement project derived from the Plan-Do-Study-Act (PDSA) cycles, to decrease the cast complication rate | Participant recruitment methods were unclear (3,559 patients pre-intervention and 13,635 post-intervention) | QI project involving several interventions  
- Resident casting: education program with a competency “checklist” to ensure that casts are applied, bivalved, and removed in a safe, standardized manner to prevent harm.  
- Cast safety strips (AquaCast Saw Stop Protective Strips, Newark, DE) were required for every cast  
- Residents were required to demonstrate competency with 3 cast applications and 3 removals before they were permitted to apply or remove casts independently. | Review of electronic health records  
The main complications included cast-saw burns and stage 1 and stage 2 pressure ulcers, as defined by the National Pressure Ulcer Advisory Panel. Cast complication rate was measured over a two year period Jan 2015 to Jan 2017  
identified patients that had received upper and/or lower extremity casts and had subsequent complication encounters. | Cast complications  
Rate of complications reduced from 5.65/1000 to 0.16 per 1000 after 18 months of the program  
This represented a 97.33% improvement (p<0.001)  
Pressure injuries were reduced by from 22/3559 (0.61%) to 11/13635 (0.08%) |  
- Similar resources may be unavailable at other institutions.  
- Multimodal QI project, unclear what specific intervention might have accounted for improvement.  
- No assessment of severity of fracture, concurrent management or other confounding factors  
- Method of assessment and categorization of pressure injuries is not reported |
| Difazio, Harris, Feldman, & Mahan, 2017 | Quasi-experiment (prospective interrupted time-series design), quality improvement project to | Project was conducted in a pediatric institution in the USA over 2 years (Pre-intervention 5514 casts applied; post-intervention 11,210 casts applied) |  
- Pre-intervention: usual care with cotton lined cast (n=5514 casts applied)  
- Post-intervention: modifying the lower extremity casting technique to include  
  - The data collection tool contains 6 domains:  
    - demographic characteristics, clinical characteristics  
    - cast characteristics  
    - casting characteristics  
    - skin complications |  
- Reliance on staff reporting for skin complaints  
- Variation in classification of skin injury between observers |

© NPUAP/EPUAP/PPPIA
## Preventing medical device related pressure injuries: data extraction and appraisals

### Clinical question 2 (local management strategies): Support surface use in neonates

**Ref:** Levy, Kopplin, & Gefen, 2016

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
|     | Laboratory study to discover mechanical load on supine lying newborn’s head in different conditions | Used 4 finite element computational models to simulate a newborn’s head developed by the authors bioengineering laboratory in Israel | Pressure stresses were measured in the following situations:  
- Weight bearing in supine position  
- Lying on flat foam mattress  
- Medical device (Electode) beneath the head and mattress  
- Medical device (wire) beneath the head and mattress | Pressure stress on tissues on the newborn head model were evaluated in the biomechanical laboratory | • More pressure stress on tissue from the wire medical device was beneath the newborn model head  
• Increased stress values were found when donut-shaped headrest was used beneath the head model. | • Computational models use animal tissue not human skin  
• The authors comment that this manuscript is only the 2nd paper on biomechanics of medical device related (MDR) pressure injury in pediatric patients |

**Author conclusions:** Medical devices beneath a newborn’s head may increase risk for a MDRPI

**Indirect evidence (computational modeling)**

### Clinical question 2 (local management strategies): Adapting the medical device

**Ref:** Limpahayo m, Skaggs, McComb, Krieger, & Tolo, 2009

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
|     | Retrospective case series reporting on complications associated with Halo use in children and strategies to address MDRPI | Participants were those treated in a children’s hospital in USA from 1996 to 2005. (n=97 eligible, n=68 with complete medical records included)  
Inclusion:  
• Treatment with halo | Halo used for immobilization (n=37), halo traction (n=12) or halo traction followed by halo vest (n=19). Mean duration of treatment was 12 weeks when used for immobilization and 3 | Development of pressure ulcers as a complication. Frequency of assessment, assessment methods or staging are not reported. | • Incidence of pressure injuries was 7.3% (severity not reported)  
• In no cases did development of a pressure injury require cessation of halo use or surgical intervention.  
• The authors suggest that “cutting off the offending | • Retrospective review  
• Small sample size  
• 30% eligible records were not reviewed due to being incomplete, which leads to an unreliable |

**Level of evidence: 4  
Quality: Low**
**Preventing medical device related pressure injuries: data extraction and appraisals**

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whitley, Nygaard, &amp; Endorf, 2017</td>
<td>Cohort study exploring reduction in MDRPU using silicone pressure reducing strips underneath straps securing endotracheal (ET) tubes</td>
<td>Participants were recruited in a burns center in US (n=115)</td>
<td>Phase one (4 years and 10 months): Twill tie to secure the ET tube by securing to tube and wrapping around head (n=77)</td>
<td>Skin inspection performed by nursing and respiratory specialists</td>
<td>MDRPU rate: Phase 1 (pre-intervention): 25 MDRPU in 16 patients (20.7%), 21% had ≥1 MDRPU. Phase 1 (post-intervention): 2 MDRPU in 2 patients (5.2%), 5% had ≥1 MDRPU. There was a significant reduction in MDRPIs related to using silicon pressure reducing strips (p=0.032).</td>
<td>Retrospective comparison – other factors may have been related to change in MDRPU rate. Minimal information on assessment methods.</td>
</tr>
</tbody>
</table>

**Clinical questions 3 and 4 (prophylactic dressings): Use of prophylactic dressings to prevent MDRPI**

- Incomplete medical record
- Mean age was 10 years (range 1 to 20 years)
- 54% sample male

weeks when used for traction.

- Portion of the halo vest may reduce discomfort. (expert opinion)
- The authors recommend routine skin checks by parents at home and during clinic visits, but do not detail frequency or assessment strategies. (expert opinion)
- Study conclusions: The report highlights the potential complications associated with medical device use in children and ways to adapt a device

- Insufficient detail of pressure injury preventative strategies used, duration of treatments, participant characteristics, severity and duration of pressure injury or management of pressure injury while halo in use were provided in this study.
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Singh, Sood, Kerai, & Puri, 2017 | Case series reporting efficacy of a polyvinyl alcohol foam dressing to prevent nasal PU in individuals with nasotracheal tube | Participants were recruited in an Indian hospital over 9 months (n=33) | • Incomplete data regarding use of interventions  
Participant characteristics:  
• Age range 0 to 92 years  
• Postintervention group (Phase 2) had a larger mean burn area size and higher mortality  
• Length of stay mean pre vs post was 33 days vs 27, p=0.372  
• Mean ventilator days pre vs post 14 days vs 14 days, p=0.997  
• Percent facial burns pre vs post was 4% vs 4%, p=0.235 | | |
| O'Toole et al., 2017 | Pretest/posttest study investigating | Participants were recruited prospectively in a tertiary care center in the US (n=155) and | • Most patent (or right side) nostril selected  
• After general anesthetic, nasal intubation with flexometallic ETT (size 7.5 for males and 6.5 for females)  
• Foam dressing (8cm) trimmed to shape of nasal cavity and lubricated with ointment  
• Foam dressings then used for packing nasal alae forming a cushion around the tube  
• PU classified using EPUAP/NPUAP classification system  
• Assessment immediately post-operative and at 24 hours | | |

### Results
- Author conclusions: silicon pressure reducing strips in conjunction with twill tape is a safe way to secure an ET tube with lower risk of Pus than when using twill alone.

### Limitations and comments
- Recruitment strategy is not clear  
- Participant details are minimal

### Level of evidence: 4  
**Quality: Low**

---

**Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries**

© NPUAP/EPUAP/PPPIA
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Clay, Cruz, Ayotte, Jones, & | effectiveness of a care bundle that included prophylactic dressings to reduce tracheostomy-related pressure injuries | compared with a retrospective review of cases over 12 month period (pre-intervention) (n=183) | protocol was used (n=183)  
- In intervention phase the following interventions were introduced (n=155):  
  - Hydrocolloid dressing (DuoDERM Signal) placed under tracheostomy flare in immediate postoperative period  
  - At 7 days, suture removal and placement of polyurethane PolyMem foam dressing (Ferris Mfg Corp) with head/neck in neutral position | NPUAP classification used for staging on a monthly basis by WOCN | Incidence of pressure injuries reduced after introduction of intervention from 10.93% (20/183) to 1.29% (2/155) (p=0.0003)  
- Pre-intervention pressure injuries included Stage II (n=5), Stage III (n=9) and unstageable (n=6). In post-intervention phase, unstageable (n=2)  
- Pressure injuries occurring in the intervention phase were determined to be due to non-implementation of the intervention | staging validation may influence the documented incidence rate  
- No blinding or randomization  
- Reliance on medical records for comparison group incidence |
| The purpose of this quality improvement | Participants were children requiring non-invasive ventilation or prone surgery (n=not reported) | In collaboration with the respiratory therapists, an adhesive foam dressing |  
- Number of device related pressure injuries | After intervention zero pressure injuries occurred when the adhesive foam |  
Author conclusions: The care bundle protocol was related to reduction in tracheostomy-related pressure injuries | Single site  
No statistical data presented | Level of evidence: 3 |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality</th>
</tr>
</thead>
</table>
| Fowler, 2018            | (QI) project was to explore incidence of MDRPIs in children, develop and implement a plan to reduce MDRPIs and compare the incidence of MDRPIs pre and post implementation | Inclusion/exclusion criteria not reported                              | was selected to pad and protect the face under all positive airway pressure masks                                                                   | between Jan 2014-Dec 2016.             | dressings were applied to the potential pressure injury areas.  
• One intraoperative pressure injury occurred since implementation of the initiative | No clear indication of sample (size or demographic)  
No indication of confounding factors  
Very little information regarding how the outcomes were measured/collated.                                                  | low       |
| Boesch et al., 2012     | Qualitative Plan Do Study Act (PDSA) investigating a multi-faceted intervention in reducing tracheostomy-related pressure injuries (TRPI) in children | Conducted in an academic children’s hospital in the US (490 beds)  
Results included 834 tracheostomy patients and 10,132 tracheostomy patient days.  
Patient characteristics:  
• Mean age 2yr 8 mo  
• 87% ventilator dependent | Professional intervention  
PDSA cycle to implement a bundle that included:  
• Risk (Braden scale) and skin assessment  
• Moisture and pressure free device interface  
• Hydrophilic polyurethane foam dressing (Mepilex Lite®) used under tracheostomy tube to wick moisture away from the stoma and skin surface  
• Extended tracheostomy tube design  
• Online nursing education on risk and skin assessment  
Organizational intervention | TPRI rate | Mean TRPU rate  
• Pre-intervention ranged from approx. 3.8% to 16% over 6 months (mean rate 8.1%)  
• During bundle development and implementation ranged from 0% to 12% over 12 months (mean rate 2.6%)  
• Post-intervention ranged from 0% to 3% over 10 months (mean 0.3%)  
• Statistical analysis on effect of extended tracheostomy tube design found a significant reduction in number of TRPIs (p=0.007) and number of days with TPRU (p<0.0001) |  
• The study is limited to a single hospital unit design and was not a randomized controlled trial  
• Measurement periods were different for pre-during and post-intervention which influences mean rates | 2  
Quality: moderate
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forni et al, 2011</td>
<td>Historical controlled clinical trial investigating effectiveness of polyurethane foam applied inside a foot plaster cast for reducing MDRPI</td>
<td>Participants recruited from an orthopaedic ward in Italy (n=156, 156 completed study). Study used an historical control group. <strong>Inclusion:</strong> • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel • “Sore skin” (stage I pressure injury) on presentation OR undergoing chemotherapy <strong>Exclusion:</strong> • Cast not including foot • Pressure injury &gt; stage I • Not having a risk factor of sore skin or chemotherapy <strong>Characteristics:</strong> • No significant difference in demographics at baseline • Mean age 28 to 30 years • Primarily quick setting plaster cast including spica casts, above</td>
<td>Study group: received sterile polyurethane foam pad measuring 10 x 10 cm in contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. <strong>Control group:</strong> retrospective participants with the same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.</td>
<td>Presence/absence of PU in the treated limb using NPUAP staging</td>
<td><strong>Participants with stage I pressure injury (sore skin) as a risk</strong> (n=56 in study group, n=49 in control group) • Significantly less in experimental dressing group who presented with stage I pressure injury experienced heel pressure injury on cast removal (3.6% versus 42.9%, p &lt; 0.0005) • Relative risk of heel pressure injury on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4). <strong>Participants with chemotherapy as a risk factor</strong> (n=24 in study group, 54 in control group)</td>
<td>• Historical control • Length of plaster cast in situ is not reported and may be significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups</td>
</tr>
</tbody>
</table>
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Weng, 2008 | Quasi-experiment investigating effect of Tegaderm and Tegasorb in preventing MDRPI of the nasal bridge from oxygen masks | Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90)  
Inclusion:  
- Diagnosed with respiratory failure  
- Using and tolerating with non-invasive face mask  
- No facial skin breakdown  
Exclusion:  
- Not reported  
Characteristics:  
- No significant differences between groups at commencement for any demographics including BP and bloods  
- Primarily classified as having adequate nutrition and no sensory impairment  
- Majority had no sweating observed | Participants were assigned to one of three groups:  
- Control group with no dressing (n=30)  
- Tegasorb™ (hydrocolloid dressing) group (n=30)  
- Tegaderm™ (transparent film dressing) group (n=30)  
The materials were used to cover the nasal bridge and patients were observed for pressure injury formation | Formation of pressure injuries assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after change of position).  
- Time until pressure injury formed in minutes | Incidence of grade I pressure injury lower in transparent film dressing compared with control group (53.3% versus 96.7%, p<0.01)  
Incidence of grade I pressure injury lower in hydrocolloid dressing group compared with control group (40% versus 96.7%, p<0.01)  
PUs formed significantly faster in control group (1111±2169 mins) versus the transparent film dressing (2628±1655mins) or hydrocolloid dressing groups (3272±2566 mins, p=0.0)  
No significant difference in occurrence duration and time between the hydrocolloid dressing and transparent film dressing group  
- Small number of subjects  
- No blinding, no power calculations  
- Several factors may influence the findings (e.g. skin colour precluding accurate assessment of pressure injury formation)  
- Facial formation may influence pressure injury formation  
- No reporting of skin breaks/damage associated with dressing removal | Level of evidence: 2  
Quality: moderate |
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang, Tseng, Lee, Yeh, &amp; Lai, 2009</td>
<td>Quasi experiment investigating effectiveness of a prophylactic dressing in preventing nasal pressure injuries in nasal intubation</td>
<td>A sample of participants was recruited in China (n=18) Inclusion: • Nasal intubation • head/neck surgery for squamous cell carcinoma Characteristics: • No significant difference between groups for age, length surgery, diameter of endotracheal tube length of tube inserting or operative time • Mean age 60 to 62 years • Mean surgery length 9.8 to 10.4 hours</td>
<td>• Participants were managed with either: • Duoderm® (hydrocolloid dressing) and Soft Liner used for a custom-made cushioning • Pressure injury area (strategy for measuring area was not reported)</td>
<td>• Transparent film dressing adhered less effectively than hydrocolloid dressing Study conclusions: A protective dressing was associated with decreased incidence of stage I pressure injury in older adults wearing non-invasive face masks</td>
<td>• Recruitment of participants not reported • No statistical analysis • Small sample size • Unclear how outcomes were measured Study conclusion: Protective dressing was associated with lower incidence of nasal pressure injuries</td>
<td></td>
<td>2</td>
<td>Low</td>
</tr>
<tr>
<td>Kuo et al., 2013</td>
<td>Retrospective cohort study record investigating effectiveness of a preventative dressing under tracheostomy ties</td>
<td>Participants were children with tracheostomies receiving care in a 6 year period in a US hospital (n = 134) Inclusion: • had a tracheostomy within the retrospective review period Characteristics: • Age range 2 weeks to 16 years</td>
<td>Mepilex® Ag (antibacterial foam dressing) was applied underneath tracheostomy ties for the last 15 months of the retrospective review period. (n=41) Prior to that, no dressing was applied under tracheostomy ties (n=93) No-stated</td>
<td>• Mean pressure injury surface area was less in participants who had protection with hydrocolloid dressing (8.0±9.0 mm² versus 35.2±27.5mm², p=not reported) • Few participants who had protection with hydrocolloid dressing experienced nasal pressure injuries (60% versus 100%, p= not reported)</td>
<td>• Other care interventions/changes in ward routine over the 6 year period may have influenced findings • Skin assessment method not reported • Relied on documentation for</td>
<td></td>
<td>3</td>
<td>Low</td>
</tr>
</tbody>
</table>
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Günlemez, Isken, Gükalp, Türker, &amp; Arisoy, 2010</td>
<td>RCT investigating effectiveness of silicone gel in preventing nasal pressure injuries in neonates</td>
<td>Participants were recruited in a NICU in India over a 2 year period (n = 179)</td>
<td>All participants had the same tracheostomy tube</td>
<td>Nasal injuries including: bleeding, crusting, excoration, columella necrosis assessed daily by the same plastics surgeon 1 month follow up</td>
<td>Nasal injury incidence was significantly greater in the group that did not have prophylactic gel sheeting (4.3% versus 14.9%, OR 3.43, 95% CI 1.1 to 10.1, p&lt;0.05)</td>
<td>Determination of an event</td>
</tr>
<tr>
<td></td>
<td>Inclusion:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• premature infant</td>
<td></td>
<td>Participants were randomized to receive:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• nasal CPAP</td>
<td></td>
<td>• 1.8mm thick silicone gel sheeting applied to nares surface during ventilation (n=92)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion:</td>
<td></td>
<td>• No sheeting (n=87)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• term gestation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• nasal deformity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• shock</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• coagulant defect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Characteristics:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• no significant difference at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• mean birth weight approx. 1760 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean age 32 gestational weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean ventilation duration 5-6 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visscher et al., 2015</td>
<td>Prospective cohort study exploring different consideration for selecting facial mask associated pressure injury in children</td>
<td>Participants were recruited over a 3 year period (n=50)</td>
<td>Masks individually selected for each participant based on ventilation requirements</td>
<td>Skin compromise was evaluated (none, erythema, stages I to IV pressure injury, unstageable pressure injury, DTI)</td>
<td>PU rate</td>
<td>Minimal reporting of randomization, allocation concealment and blinding</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
<td></td>
<td>Mask positioning was assessed 4 hourly</td>
<td></td>
<td></td>
<td>Duration of therapy confounded results</td>
</tr>
<tr>
<td></td>
<td>• Children and adult in-patients using facial mask for non-invasive ventilation</td>
<td></td>
<td>Participants with skin erythema or a pressure</td>
<td></td>
<td></td>
<td>Included no PU in the outcome measure</td>
</tr>
<tr>
<td></td>
<td>Characteristics:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unclear how assessment was performed</td>
</tr>
<tr>
<td></td>
<td>• Age 10.4±9.1 years (range 0.1 to 32.5 years)</td>
<td></td>
<td>Skin compromise was evaluated (none, erythema, stages I to IV pressure injury, unstageable pressure injury, DTI)</td>
<td></td>
<td></td>
<td>No a priori power calculation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level of evidence: 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Quality: moderate</td>
</tr>
</tbody>
</table>

### Clinical question 1 (selecting medical devices): Factors influencing use of oxygen therapy delivery devices

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visscher et al., 2015</td>
<td>Prospective cohort study exploring different consideration for selecting facial mask associated pressure injury in children</td>
<td>Participants were recruited over a 3 year period (n=50)</td>
<td>Masks individually selected for each participant based on ventilation requirements</td>
<td>Skin compromise was evaluated (none, erythema, stages I to IV pressure injury, unstageable pressure injury, DTI)</td>
<td>PU rate</td>
<td>Selection of participants unclear</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
<td></td>
<td>Mask positioning was assessed 4 hourly</td>
<td></td>
<td></td>
<td>Assignment of participants to interventions unclear</td>
</tr>
<tr>
<td></td>
<td>• Children and adult in-patients using facial mask for non-invasive ventilation</td>
<td></td>
<td>Participants with skin erythema or a pressure</td>
<td></td>
<td></td>
<td>Patients receiving interventions had displayed erythema</td>
</tr>
<tr>
<td></td>
<td>Characteristics:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level of evidence: 3</td>
</tr>
<tr>
<td></td>
<td>• Age 10.4±9.1 years (range 0.1 to 32.5 years)</td>
<td></td>
<td>Skin compromise was evaluated (none, erythema, stages I to IV pressure injury, unstageable pressure injury, DTI)</td>
<td></td>
<td></td>
<td>Quality: Low</td>
</tr>
</tbody>
</table>

Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries © NPUAP/EPUAP/PPPIA
# Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Lemyze et al., 2013 | Prospective observational study exploring outcomes for individuals | Participants were recruited in a ICU in US (n=74) | • 69% had a diagnosis associated with craniofacial abnormality (e.g. spinal muscular atrophy)  
• 9% had abnormal facial dimensions | • Skin hydration measured as capacitive reactance units at mask contact points (nose bridge, upper/lower/ left/right cheeks and chin), except when open wound present  
• Interventions were removed 4 hourly for skin hydration measurement | • When participants were changed from face mask to total face mask it was most likely to occur early in treatment (in total 36/74) | but controls had no erythema |

## Ref

- **Lemyze et al., 2013**

**Prospective observational study exploring outcomes for individuals**

Participants were recruited in a ICU in US (n=74)

Inclusion criteria:
- Acute respiratory failure

All general management was similar for all participants

**Outcome Measures & Length of Follow-up**

- Skin hydration measured as capacitive reactance units at mask contact points (nose bridge, upper/lower/ left/right cheeks and chin), except when open wound present
- Interventions were removed 4 hourly for skin hydration measurement

**Results**

- Right cheek (18%), forehead (10%) and chin (3%)

**Facial shape**

People with facial abnormalities had higher rate of pressure injury

| Study conclusion: The cloth mask led to reduced hydration, and there was no erythema or tissue damage. Skin microclimate studies showed that increased humidity, increased skin temperature, and reduced permeability of materials in contact with skin increased is associated with increased risk of superficial pressure injuries. |

| Level of evidence: 4 |
---|---|---|---|
| Quality: Moderate |

### Limitations and comments

- Minimal details about risk factors
- Cohorts were not equivalent regarding time spent with mask

---

**© NPUAP/EPUAP/PPPIA**

**Page 18**
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chidini, Calderini, &amp; Pelosi, 2010</td>
<td>Quasi experiment comparing a CPAP delivery devices (face mask versus helmet) and reporting on complications including pressure injuries</td>
<td>Participants were recruited from a PICU in Italy and experimental participants were matched to controls for age, organ failure, PaCO₂ and PaO₂:F10₂ (n=40)</td>
<td>Participants had CPAP delivered via either: - facial mask chosen to provide optimal fit to the contour of the child’s face, with nasal masks used as facial masks in the smallest children. Colloid dressing was applied to facial pressure points to reduce risk of pressure injury. (n=20) - helmet: an infant helmet made of</td>
<td>Primary outcome was improvement in gas exchange - Secondary outcome included pressure injuries assessed on a four point scale of severity</td>
<td>- There was significantly more stage 1 pressure injuries associated with the facial mask compared with the helmet (75% versus 0%, p=0.002) - Participants with facial mask CPAP delivery had significantly less hours wearing the delivery device compared with the helmet group (6.4±1.8 versus 10.8±2.0 hours, p=0.001) - CPAP delivered via both the helmet and the mask led to significant improvements in gas exchange, with no</td>
<td>• Small sample size - Of 97 potential participants, only 20 met the selection criteria to use the helmet - Non-blinded, non-randomised study</td>
</tr>
</tbody>
</table>
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>transparent latex-free polyvinyl chloride secured to a soft collar that adheres to the child’s neck (n=20)</td>
<td>difference between the groups.</td>
<td>Other adverse events (CPAP associated outcomes and eye irritation, gastric distension) were equivalent between the groups</td>
<td>Intolerance of the device leading to sedation was higher in the facial mask group (70% versus 5%, p=0.001)</td>
</tr>
</tbody>
</table>

**Clinical question 2 (local management strategies: Device design and tension)**

**Worsley, Stanger, Horrell, & Bader, 2018**

- **Randomized cross-over trial** to fit 15 healthy volunteers with **two difference cervical collars (StifNeck versus Aspen)** to measure interface pressures and inflammatory biomarkers at the skin

  **Participants** were healthy volunteers (n=15)
  - Participant characteristics:
    - aged 18-65, mean age 24 years
    - 9 males and 6 females
  - Participants were fit with either StifNeck or Aspen collar at three randomly applied tensions (low, optimal, high)
  - Collars were applied for 15 minutes.
  - A 10-minute refractory period was imposed between each application to enable adequate soft tissue recovery.
  - Sebutape was applied to the chin for the duration to enable biomarker analysis
  - Interface temperature and humidity measurements were recorded
  - Researchers regularly checked for skin blanching in accordance with NPUAP/EPUAP guidelines.

  **Interface pressure**
  - Significant increase in interface pressures with greater collar tension – low, optimal, high (p<0.01, for both collar designs), with the highest pressures measured at the occiput which were higher in each tension in the StifNeck collar.
  - Asymmetries noted on the left and right mandible for optimal and high tensions for both collars.
  - No significant association between interface pressures

  **Indirect evidence (healthy volunteers)**

  **Healthy volunteers in lab conditions**
  - Results of skin assessment using the NPUAP/EPUAP guidelines not reported

Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries © NPUAP/EPUAP/PPPIA
## Ref

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Hanou & Karadag, 2016 | Cross-sectional prevalence survey exploring risk of MDRPI in ICUs | ICUs in Turkey selected due to their high PU point prevalence rate (>15%) in the year prior to the study (n=5) | • Participants were recruited within 24 hours of ICU admission  
  • Skin observation was conducted at 48-hour intervals including a head-toe inspection that included removal of medical devices to check underlying tissues  
  • NOTE: for MDRPI, only re-checked under the  
  • Braden Scale  
  • NPUAP/EPUAP Classification System  
  • Patient Characteristics Form (demographics)  
  • Assessments were made by researcher and wound/stoma nurse | HAPU prevalence  
  • 15.4% developed at least one a non-MDRPI  
  • 40% developed at least one MDRPU  
  • 9% had a non-MDRPI on admission and 8% had a MDRPU on admission  
  • Devices related to MDRPI  
  • 45% related to endotracheal tubes, 40.4% continuous positive airway pressure  
  • The study required 150 participants to achieve statistically significant results  
  • Likely underestimation of MDRPU prevalence in this population as only followed sites with a device attached within first 24 hours | and BMI or neck circumference (p>0.05)  
  **Temperature and humidity**  
  There were no significant differences for either temperature or relative humidity values (p>0.05) between collars  
  Outcome 3  
  There were statistically significant differences in the cervical ROM for both flexion and total rotation between all three tensions (p<0.001), with the StifNeck demonstrating slightly more restriction (non-significant)  
  **Authors comments:** Increased strap tension and collar height generated higher interface pressures at all contact sites, with the occiput recording the greatest values  
  **Background:** Risk factors for MDRPI  
  Inclusion criteria: Admitted to a participating ICU (anesthesia reanimation, neurosurgery, cardiovascular  
  • Participants were recruited within 24 hours of ICU admission  
  • Skin observation was conducted at 48-hour intervals including a head-toe inspection that included removal of medical devices to check underlying tissues  
  • NOTE: for MDRPI, only re-checked under the  
  • Braden Scale  
  • NPUAP/EPUAP Classification System  
  • Patient Characteristics Form (demographics)  
  • Assessments were made by researcher and wound/stoma nurse |
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coyer, Stotts, &amp; Blackman, 2014</td>
<td>Prospective cross sectional study exploring</td>
<td>Participants were recruited in two ICUs in Australia and the USA over surgery, general surgery and intern medicine)</td>
<td>device if the device was present on the first inspection (i.e. devices attached after 24 hours were not checked underneath)</td>
<td>(CPAP) masks, 8% arterial oxygen saturation (SpO₂) probe, 6.6% nasal cannulas.</td>
<td>• Possible non-generalizable results as sites selected due to previously high HAPU rates</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Stages of MDRPI</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 42.6% Stage 2, 37.9% Stage 1, 17.5% unstageable and 1.9% deep tissue injury</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Locations</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>44% lips, 15.6% nose, 7.5% fingers, 6.1% ears and 17.6% other locations including buccal mucosa, genitalia and tongue.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Risk factors for MDRPI</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Having a non-MDRPI (OR 6.6, 95% CI 1.21 to 15.12, p&lt;0.05)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Receiving enteral feeding (OR 2.12, 95% CI 0.79 to 3.13, p=0.045)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• High Braden risk score (OR 1.81, 95% CI 1.03 to 3.21, p&lt;0.05)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Type of ICU also significantly related to having a MDRPI</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• No significant increased risk associated with older age, mechanical ventilation, steroids, anticoagulants, sedatives, low albumin or low hemoglobin.</td>
<td></td>
</tr>
</tbody>
</table>

**Exclusion criteria:**
None stated

**Participant characteristics:**
- Mean age 62.5±16.6 yrs (range 20 to 97)
- 42.8% female
- 36% had hypertension, 27% diabetes, 25% respiratory diagnoses, 24% cardiac diagnoses, 10% chronic renal failure, 3% obesity
- 17.1% vasopressors, 78% taking antibiotics, 56% steroids

**Devices used in ICU**
- Respiratory, vascular lines, gastrointestinal or urinary,

**Level of evidence:** 4
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality:</th>
</tr>
</thead>
</table>
| PU prevalence and progression | 1 day per month for 6 months (n=483) | Inclusion criteria:  
- Admitted to ICU  
- > 16 years in AU and greater than 18 in USA  
- Consent opted in in USA and opted out in AU | PU prevalence and progression | MM (mucous membranes) pressure injuries  
- Collected information on device, pressure injury stage and type, associated pain and infection, blood clot (for MDRP-MM)  
- Staging with NPUAP/EPUAP classification system  
- Braden scale for pressure injury risk  
- Pain rated on 11 point VAS  
- PU healing measured using size x length, tissue type, exudate over time  
- Followed for 7 days after pressure injury development | Monitoring devices and preventive devices  
- Mean device per patient was 7.6 (SD 1.9) |  
- Minimal information about intervention or length of time using devices  
- Minimal information about participant-level risk factors | Moderate |
| Yamaguti et al., 2014 | Prevalence study reporting facial pressure injuries associated oxygen delivery systems | Retrospective record review in an ICUs and a semi-ICU in a hospital in Brazil over 12 months (n=414) | Rate of pressure injuries | 13.1% developed Stage 1 pressure injury  
1.3% developed stage 2 pressure injury | Factors related to pressure injury  
- In univariate analysis, no significant difference |  
- Selected individuals at risk of pathologic tissue changes associated with pressure injuries (>2 hours of acute respiratory failure)  
- Relied on medical records  
- Single site study | Prognostic: High |
# Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amirah, Rasheed, PJ, Nu‘man, &amp; Muteb, 2017</td>
<td>Cross-sectional study reporting prevalence of MDRPI in an intensive care unit (ICU)</td>
<td>The study was conducted in an ICU in a tertiary hospital in Saudi Arabia over 6 months (n=431)</td>
<td>No intervention</td>
<td>Demographic characteristics collected by the investigator from patient’s medical records</td>
<td>between those with or without a pressure injury based on age, BMI, gender, type of respiratory therapy or primary medical diagnosis</td>
<td>Minimal data on participant risk factors (e.g. nutritional status, hydration, medication not reported)</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: admitted to one of 4 ICU wards during the study period</td>
<td></td>
<td></td>
<td></td>
<td>Multivariate analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: Aged ≤16 years</td>
<td></td>
<td></td>
<td></td>
<td>• Using an oronasal mask was significantly associated with pressure injury (p&lt;0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Acute moderate-to-severe dyspnea</td>
<td></td>
<td></td>
<td></td>
<td>• Length of respiratory therapy longer than 24 hours significantly associated with pressure injury (p=0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: • Glasgow scale &lt; 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Death during hospitalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pre-existing skin breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Sleep apnea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participant characteristics: • Mean age 75 to 78 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 42.5% male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prevalence data**
- 26.7% admissions developed at least one MDRPI
- 32.4% of pressure injuries caused by a medical device
- 37% of MDRPIs were secondary to endotracheal tube, 37% to Foley catheter, 12.5% to neck collar, 9.4% to nasogastric tube and 4.6% to other devices
- Medical devices caused injury to lips, penis, nose, occipital area, nick, ankle, clavicle and fingers
- Medical devices caused injury to lips, penis, nose, occipital area, nick, ankle, clavicle and fingers

**Factors associated with MDRPI**
- Statistically significant association between gender and developing MDRPI (males had 2.8 times the risk of MDRPI compared to females)
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Moura et al., 2017 | Cohort study reporting PUs associated with continuous EEG electrode related pressure injury | Participants were recruited over 22 months in an academic hospital in US (n=1519) | Participants were undergoing cEEG for a range of different clinical purposes including investigation of epilepsy, pre-surgical analysis | Development of any EERPU, which was reported as a skin lesion appearing at or near the cEEG site | • 7.8% developed a pressure injury  
• Mean duration of continuous EEG was 1.8±.7 days  
• 92.4% of pressure injuries occurred in adults, 46.6% in females  
• 92.3% Stage/Category 1, 6.7% Stage/Category 2, 0.8% Stage/Category 3 | • No details on diagnoses that may be related to risk factors  
• Interventions were not reported or considered (some patients had the electrodes moved during treatment to prevent pressure injuries)  
• Assessment methods not reported  
• Presence of pressure injury before intervention not reported  
• Excluded approx. 25% of EEG participants due to methods of treatment (see exclusion criteria) |

- Inclusion criteria:  
  - Undergoing continuous EEG in routine management
- Exclusion criteria:  
  - Repeated cEEG sessions with same patient within 24 hours of previous session  
  - Temporary of emergency set up of cEEG equipment

- Participant characteristics:  
  - 84.3% were aged >18 years with a mean age of 59 years  
  - 15% aged <18 years with a mean age of 5.5 years  
  - 55% male  
  - 19.4% taking vasoconstrictors  
  - 88.5% had a feeding tube  
  - 36.6% had skin allergies  
  - 22.6% had a fever  
  - 99% had a head wrap

- Electrodes were standard international 10-20 electrode placement using either plastic or metal (gold, silver or silver chloride) disk electrodes  
- Skin was cleaned with abrasive gel before application  
- Electrodes fixed with Micropore tape  
- Application of equipment by technicians with > 2 years’ experience  
- Daily skin care protocol while

- Development of any EERPU, which was reported as a skin lesion appearing at or near the cEEG site  
- Time to EEG appearance  
- Documentation of potential risk factors included fever, vasoconstrictive medication, nutrition interventions

- Multivariate analysis  
  - Aged older (71 to 80 years) was associated with increased risk (hazard ratio HR 6.84, 95% CI 1.95 to 24, p<0.01)  
  - No other variable was a significant prognostic factor

- Author conclusions: cEEG related pressure injury is not common and if it occurs, more likely to be of mild severity.
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Turjanica et al., 2011 | Descriptive correlational design reporting characteristics associated with development of ear pressure injury | Convenience sample recruited from a medical-surgical unit in the US (n=100) | • A graduate student and the patient’s staff nurse jointly assessed the skin condition around the patient’s ears  
• If skin breakdown was present the nurses appropriately staged and documented the lesions on the Turjanica Pressure Ulcer of the Ear Data Collection Tool | • Skin assessment aided by the Turjanica PU of the Ear Data Collection Tool used to assess skin, patient discomforts at the ears, length of time using oxygen, eyeglasses, skin diagnoses that may influence skin condition | Prevalence/incidence  
• The incidence of skin breakdown was 37% (range 28 to 47%)  
• Only one patient exhibited ear pressure injury on admission  
• Predominately Stage I pressure injury, no stage III or IV pressure injury  
Factors associated with ear pressure injury  
• No statistically significant associations existed between skin integrity and patient demographics (use of glasses, fever, other skin conditions, Braden scale)  
• Lack of oxygen use at home predicted the presence of ear pressure injuries ($\chi^2 = 6.113, p = 0.013$) | • Used a non-validated data collection tool  
• No multivariate analysis  
• Unclear how pressure injury was assessed and staged  
Level of evidence: 4  
Quality: Low |
| Fujii, Sugama, Okuwa, Sanada, & Mizokami, 2010 | Prospective cohort study | Survey of seven NICUs in Japan in 2006 (n=81) | • Skin was assessed daily by nurses and researchers  
• Skin texture was assessed using Dubowitz neonatal maturity assessment scale | • 86% of pressure injuries were associated with CPAP or DPAP  
Risk factors associated with pressure injuries ($p<0.05$):  
• endotracheal intubation  
Multivariate analysis risk factors for pressure injury  
• endotracheal intubation OR 4.0 (95% CI 1.04 to 15.42, p=0.047) | High level of non-consent (61.8%) led to high exclusion  
• Most neonates were not extremely underweight (<500g)  
• Potential Hawthorne effect as researcher visited hospitals to | Level of evidence: 1 (prognostic)  
Quality: Moderate |
### Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Multivariate analysis risk factors for pressure injuries:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• bilevel or CPAP OR 2.004 (95% CI 1.509 to 2.661, p&lt;0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• mechanical ventilation OR 1.334 (95% CI 1.031 to 1.726, p=0.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• high frequency oscillatory ventilation OR 2.057 (95% CI 1.208 to 5.134, p=0.01)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• extracorporeal membrane oxygenation OR 2.490 (95% CI 1.208 to 5.134, p=0.01)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Schindler et al., 2011 | Retrospective database study | Survey of nine PICUs in trauma centers in USA | Clinical audit of pressure injuries | Did not reach sample size based on power calculation (15 sites) | Site may have influenced risk factor analysis as there was differing use of support surfaces between facilities | Inter-rater reliability not established | Does not report pressure injury classification scale used |

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>NPUAP staging system</td>
<td>Relied on records</td>
</tr>
</tbody>
</table>

| Kayser, VanGilder, Ayello, & Lachenbruch, 2018 | Cross sectional prevalence study evaluating MDRPI in US and Canadian facilities | Record review in 115 facilities (mixed clinical types) | N/A | • Records reviewed by WOC Nurses • WOC nurses verified MDRPU before entering in | Characteristics of MDRPI • Across three centers, 142 MDRPUs over 12 months | Each facility had a different monitoring system | Level of evidence: 4 | Quality: |

| Arnold-Long, Ayer, & Borchert, 2017 | Cross sectional prevalence study evaluating | Retrospective record review in 3 long term care facilities in the US over 12 months (106,722 patient days) | N/A | • Records reviewed by WOC Nurses • WOC nurses verified MDRPU before entering in | Characteristics of MDRPI • Across three centers, 142 MDRPUs over 12 months | Each facility had a different monitoring system | Level of evidence: 4 | Quality: |

### Background: Prevalence of MDRPI

- Kayser, VanGilder, Ayello, & Lachenbruch, 2018
  - Cross sectional prevalence study evaluating MDRPI in US and Canadian facilities
  - Record review in 115 facilities (mixed clinical types)

- Arnold-Long, Ayer, & Borchert, 2017
  - Cross sectional prevalence study evaluating
  - Retrospective record review in 3 long term care facilities in the US over 12 months (106,722 patient days)
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDRPI in aged care settings</td>
<td>Inclusion criteria: Not reported</td>
<td>Exclusion criteria: None stated</td>
<td>to data base but it is unclear how this occurred given retrospective collection of data</td>
<td>• Per cent of PUs that were related to medical devices ranged from 35% to 50% across the three facilities</td>
<td>• MDRPU were most often Stage 2 (51% of MDRPUs) followed by Stage 1 (18%) and SDTI (18%)</td>
<td>• Most common site was ear (71%), flank (14%) and ankle (14)</td>
<td>• Splints and brace was most common cause (20%) followed by oxygen tubing (15%) and catheter tubing (15%)</td>
<td>Low</td>
</tr>
<tr>
<td>Asti et al., 2017</td>
<td>Retrospective prevalence study exploring MDRPIs from nasogastric (NG) tubes in individuals having surgery</td>
<td>Inclusion criteria: • Individuals have abdominal or thoracic surgical procedures • General anesthetic</td>
<td>• N/A</td>
<td>• Unknown</td>
<td>MDRPI rate</td>
<td>• 4.8% of individuals with NG tube developed a nasal pressure injury</td>
<td>• Length of operative time was significantly and positively related to prevalence of PUs: surgery &lt; 2 hours, prevalence 2.3% (95% CI 1.6 to 3.4); surgery &gt; 4 hours, prevalence 12.6% (95% CI 9.2 to 17.1)</td>
<td>• Age, gender, type of NG tube size, ASA score, duration of NG tube and hospital length of stay were not significantly associated with risk of PU in univariate analysis</td>
</tr>
<tr>
<td>Hobson et al., 2017</td>
<td>Prevalence study exploring MDRPIs from</td>
<td>Inclusion criteria: Emergency surgery • No NG tube placed</td>
<td>• Weekly rounds conducted by WOC nurse and nursing</td>
<td>MDRPI rate</td>
<td>• 7.2% of individuals developed PIs</td>
<td>• Single hospital, but results in three units were similar</td>
<td>Level of evidence: 4</td>
<td>Quality: Moderate</td>
</tr>
</tbody>
</table>
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonell-Pons, García-Molina, Balaguер-López, Montal, &amp; Rodríguez, 2014</td>
<td>Retrospective prevalence study exploring facial pressure injuries in neonates in ICU</td>
<td>Participants were recruited in a neonate ICUs in Spain for unknown period of time (n=41 or 47??)</td>
<td>NA</td>
<td>Neonatal Skin Risk Assessment Scale (NSRAS)</td>
<td>31.7% experienced at least one pressure injury</td>
<td>Small sample size in a single unit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unknown the scale used for PU severity or how assessments were made</td>
<td>Incidence density was 2.2 pressure injuries per 100 neonate days</td>
<td>No information about management strategies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MDRPI rate</td>
<td>22.7% experienced a pressure injury related to masks delivering non-invasive ventilation</td>
<td>Level of evidence: 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Quality: Low</td>
<td></td>
</tr>
</tbody>
</table>
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
</table>
| Bakhshi, Kushar, Banskota, Nelson, & Dormans, 2015 | Retrospective observational study investigating complications associated with the pinless halo in children | Retrospective record review identified all patients in one US institution treated with pinless halo over a period of 9 years (n = 61) | Pinless halo device (ring connects to a molded vest or body cast and immobilizes the cervical spine) | Complications including pressure ulcers (method of assessment and Category/Stage not reported) | • Complication rate 13/61 (21%) of patients.  
  • 2 patients experienced a pressure injury as a ‘major complication’ (anatomical location scalp and chest)  
  • 1/61 experienced occipital redness as a ‘minor complication’ | • Relied on record review  
  • Cofounding factors not considered  
  • Method of diagnosis and assessment of pressure injury not reported  
  • No Category/Stage reporting | Level of evidence: 4  
  Quality: Moderate |
| Su & Nan, 2014 | Case series of babies wearing brace fixation following surgery for clubfoot deformity in children | Participants were consecutive admissions in one department over a 4 year period in China (n=32 with 56 deformities) | • Brace worn after surgery, then when in maintenance phase brace worn at night for 3-4 years  
  • No information about the brace, padding (if any) or skin care | Initial skin check every 2 to 3 hours  
  • Prakt’s scoring to assess foot deformity  
  • Followup ranged from 12 to 48 months (mean 29 month) | MDRPI rate  
  Two participants (6.25%) had PU | • Insufficient information about the intervention  
  • Unknown how long therapy was for, how brace was fitted or how skin was cared for  
  • Unclear if brace applied by parents | Level of evidence: 4  
  Quality: Low |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Schallom, Prentice, Sona, Arroyo, & Mazuski, 2018 | Observational study exploring use of oximetry in critically ill people | Participants were critical ill adults (n=43) | • Study explores accuracy of oximetry devices  
• Used forehead sensor, (n=26), nasal sensor (n=31) and digital sensor (n=31) | • Daily assessment  
• NPUAP categorization  
• All PIs confirmed by a second nurse | Pressure injuries  
Forehead sensor was associated with significantly more pressure injuries (13/26) compared to nasal sensor (3/31) (p=0.006)  
Mean time of device use  
Forehead sensors used for a mean 37.4 hours versus nasal sensor mean 66.2 hours | Primarily focuses on efficacy of the sensors  
No confounding factors reported |
| Wilbrand et al., 2012 | Retrospective observational study reporting rates of adverse events including pressure injury associated with helmet therapy | Participant group for record review, location and selection of records was not reported (n = 410 children)  
Exclusion:  
• records without adequate follow up  
Characteristics:  
Children categorized as ploiocephaly (n=230), brachycephaly (n = 32) or both (n148) | • All records were analyzed for adverse effects | • Complications:  
• Pressure sores  
• Local ethanol erythema  
• Skin infection  
• Bacterial abscess  
• Helmet fitting issues  
• Failure to achieve therapeutic success  
• Did not state how often or by whom the participants were inspected | • Complications were seen 22.4% of the cohort.  
• Pressure injuries were found in 43 cases (10.5%)  
• Local ethanol related erythema found in 26 cases (6.3%)  
• Deficient fitting of the helmet was noted in 24 cases (5.9%)  
• Pressure injuries primarily seen in initial phase of therapy  
• In the discussion the researchers provided expert opinion that firm manual | Primarily focuses on efficacy of the sensors  
No confounding factors reported |

Exclusion criteria:  
• PU on the heel was not categorized as compression-stocking related

Participant characteristics:  
• 24 participants had bilateral deformity  
• Primarily males  
• Mean age 38 days (range 0 days to 5 months)
# Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black et al., 2010</td>
<td>Secondary analysis of incidence and prevalence study data</td>
<td>Prevalence rates measured in a subset of participants at one US hospital (n=2079)</td>
<td>• No intervention, prevalence survey</td>
<td>Hospital acquired pressure injury (HAPI) determined by identifying if a pressure injury was documented on admission report &lt;br/&gt;Wound nurse confirmed pressure injury</td>
<td>The overall rate of HAPI was 5.3%&lt;br/&gt;Medical device related HAPI 1.3%&lt;br/&gt;Proportion of HAPI that were related to medical devices was 34.5%</td>
<td>• Unclear how cases were selected</td>
<td>4</td>
<td>Low</td>
</tr>
<tr>
<td>Jaryszak, Shah, Amling, &amp; Peña, 2011</td>
<td>Retrospective case series reporting on wound complications associated with</td>
<td>Participants were those identified from the Children’s National Medical Center database in the USA as being coded for tracheostomy over a 15-month period (2008 to 2009) (n=665).</td>
<td>Clinical audit of pressure injuries in tracheostomy patients  &lt;br/&gt;Number of participants developing wound complications as assessed using the NPUAP PU staging system &lt;br/&gt;Type of tracheostomy tube</td>
<td>29.2% participants developed a post-operative wound complication &lt;br/&gt;No significant difference in age between those with and without wound complications</td>
<td>• Risk with a medical device &lt;br/&gt;• Patients with a medical device were significantly more likely to develop a pressure injury (p = 0.008). &lt;br/&gt;• Patients with a medical device were 2.4 times more likely to develop a pressure injury of any kind (95% CI 1.2 to 4.8, p = 0.10) &lt;br/&gt;Types of medical device HAPI &lt;br/&gt;• Stage I – 35% of HAPI &lt;br/&gt;• Stage III – 3% of HAPI &lt;br/&gt;• Unstageable – 24% of HAPI &lt;br/&gt;• 43% of HAPI were on head (primarily ears)</td>
<td>• Specific medical devices were not recorded &lt;br/&gt;• Procedures for performing survey were not reported</td>
<td>4</td>
<td>Low</td>
</tr>
</tbody>
</table>
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schluer, Halfens, &amp; Schols, 2012</td>
<td>Cross-sectional clinical</td>
<td>Participants recruited in 14 paediatric hospitals including paediatric intensive care units (PICU), neonatal intensive care</td>
<td>Clinical audit of pressure injuries</td>
<td>Classification using EPUAP staging</td>
<td>• Overall pressure injury prevalence 35%</td>
<td>Category 1 pressure injuries may be over- or underdiagnosed in this study</td>
</tr>
</tbody>
</table>

Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy

(1) tracheostomy in children

Inclusion:
- Coded for tracheostomy
- Electronic medical record in audit period

Characteristics:
- Mean age at time of tracheostomy was 45±8.7 months
- Most common indication was pulmonary disease (36.9%)

Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy

(mean age 39.3 versus 47.4 months, p=0.068)

• Higher wound complication rate in participants aged < 1 year compared with those > 1 year (39% versus 17%, p=0.04)

• Use of extended mechanical ventilation (p=0.58), weight (p=0.55), positive preoperative wound culture (p=0.06), positive postoperative wound culture (p=0.28) and maturation of stoma at time of surgery (p=0.14) were not associated with wound complications.

• Type of tracheostomy tube was associated with wound complications (p=0.02) with a Bivona® Flex-Tend™ predicting wound complications (likelihood ration 4.9, p=0.03) compared with a Standard Bivona® or a Shiley™.

• Wound complications were not associated with increased hospital length of stay or readmission.

Conclusions: Highlights potential of wound complications associated with medical device use in children.

preventative strategies used, duration of treatments, participant characteristics, severity and duration of pressure injury or management of pressure injury were provided in this study.

• As a result of wound complication rates, facility instituted a specialty trained tracheostomy nurse, use of barrier protection between tube flange and skin and aggressive wound care to prevent progression, but evaluation of these interventions is not reported.
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barakat-Johnson, Barnett, Wand, &amp; White, 2017</td>
<td>A qualitative study exploring MDRPI in a large Australian tertiary hospital</td>
<td>Participants were recruited in a large urban tertiary Australian hospital (n=50 patients for a head-to-toe assessment; n=22 nurses were interviews)</td>
<td>A prospective clinical review and once-only head-to-toe assessment of consenting patients with a reported MDRPI</td>
<td>- Based on a once-only assessment of consenting patients</td>
<td>The prevalence of PUs for patients with an external device (tubes, IVs, continuous positive airways pressure, splints, and other installations) was 40%</td>
<td>unclear, although the interrater reliability suggest the scores are reliable.</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

### Background: Knowledge of nurses regarding MDRPI

Barakat-Johnson, Barnett, Wand, & White, 2017

Participants were recruited in a large urban tertiary Australian hospital (n=50 patients for a head-to-toe assessment; n=22 nurses were interviews).

Inclusion criteria for patient participants:
- Had a MDRPI

Inclusion criteria for nurse participants:
- Not stated, although assumed to be caring with a patient with a MDRPI

Only patient characteristics reported.

Nurses noted importance of various interventions, but also noted that this did not always happen. Practices reported included:
- Checking under devices
- Correct sizing of devices
- Moving/rotating devices

Nurses referred to new interventions being used including:
- Silicone gel pads under devices
- Educating nurses
- Finding new ways to secure devices

Author conclusions: Findings add to the literature and confirm previous studies that suggest that medical device related pressure

- Omission of indwelling urinary catheters and their securements as a medical devices
- Focus in critical care setting where patients receive one-on-one care, rather the general medical-surgical patient, is a limitation
- Potential bias related to nurse self-selection without a process of informed consent.
- No information about nurse participants

Indirect evidence: qualitative study

Quality: Low
# Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Zaratkiewicz et al., 2010 | Quality improvement report/retrospective review of electronic records to describe change in oral pressure injury rates associated with practice changes | Participants were those who had been critical care patients at a level I trauma center in the US | • Pre-intervention: March–July 2007 n=1571  
• Post-Intervention Aug – Dec 2007 n=1522  
• Follow up post Intervention Jan – Dec 2009 n=3010 | In July 2007 the unit was using two ET tubes, Hollister™ ETAD and B&B Medical Universal Bite Block™  
In December 2007 months the ETAD was discontinued and a new device the Hollister™ Anchor Fast was introduced | Pressure ulcers rates associated with ET tubes  
Analysis of the number of PUs on the lips, mouth, gums, and tongue of orally intubated patients pre-intervention (phase 1) group compared to post-intervention (phases 2 and 3) groups  
No staging was conducted in line with the NPUAP policy for mucosal PU | Pre-intervention (March – July 2007)  
• Total n=1517 (ventilator days: 7175)  
Oral/lip PUs: 19  
Post intervention (Aug – Dec 2007)  
• Total n=1522 (ventilator days: 7592)  
Oral/lip PUs: 2  
Follow up Jan – Dec 2009  
• Total n=3010 (ventilator days: 14328)  
Oral/lip PUs: 2 |

### Mucosal membrane pressure injuries

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Jatana et al., 2010  | Cross-sectional study investigating effect of nasal | Participants were a consecutive sample enrolled in NICU over a one year period (n=100, n=200 nasal cavities) | • External nasal examinations and anterior nasal endoscopy (0°)  
• Incidence and characteristics of internal and external nasal findings categorized as ulceration,  
• Nasal complications were seen in 12 of the 91 patients (13.2%) | |  |  |

---

**Data Tables:** 2019 Guideline Update: Preventing medical device related pressure injuries

© NPUAP/EPUAP/PPPIA
Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality</th>
</tr>
</thead>
</table>
|    | continuous positive airway pressure (CPAP) and cannula use in neonates | Inclusion:  
• younger than 12 months in age  
• at least 7 days of CPAP or cannula use  
Excluded:  
• Pyriform aperture stenosis  
• choanal atresia  
• cleft lip/palate  
• previous nasotracheal intubation or nasal surgery  
Characteristics:  
• Nasal CPAP use (n=182 nasal cavities),  
• Nasal cannula (n=18 nasal cavities) | telescope) and digital photographic documentation | granulation or vestibular stenosis  
• Vestibular stenosis graded as mild, moderate or severe | • Nasal complications from CPAP were associated with lower Apgar scores at one minute (p=0.02) and 5 minutes (p=0.06) and no association with gestational age, birth weight, CPAP setting or CPAP duration  
Internal examination  
• Ulceration in 3.3% of nasal cavities  
• Granulation in 1.6% cavities  
• Vestibular stenosis in 2.2% nasal cavities  
• All abnormalities located wt the top of the CPAP nasal prong and occurring as early as 8 days after administration of CPAP  
External examination  
5.5% of participants who used CPAP had columnar necrosis occurring 5 to 25 days after exposure | at time endoscopy performed | Moderate |
Preventing medical device related pressure injuries: data extraction and appraisals

**Table 1: Level of Evidence for Intervention Studies**

<table>
<thead>
<tr>
<th>Level</th>
<th>Experimental Designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Randomized trial</td>
</tr>
<tr>
<td>Level 2</td>
<td>Quasi-experimental design</td>
</tr>
<tr>
<td></td>
<td>• Prospectively controlled study design</td>
</tr>
<tr>
<td></td>
<td>• Pre-test post-test or historic/retrospective control group study</td>
</tr>
<tr>
<td>Level 3</td>
<td>Observational-analytical designs</td>
</tr>
<tr>
<td></td>
<td>• Cohort study with or without control group</td>
</tr>
<tr>
<td></td>
<td>• Case-controlled study</td>
</tr>
<tr>
<td>Level 4</td>
<td>Observational-descriptive studies (no control)</td>
</tr>
<tr>
<td></td>
<td>• Observational study with no control group</td>
</tr>
<tr>
<td></td>
<td>• Cross-sectional study</td>
</tr>
<tr>
<td></td>
<td>• Case series (n=10+)</td>
</tr>
<tr>
<td>Level 5</td>
<td>Indirect evidence: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models</td>
</tr>
</tbody>
</table>

**Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>Non-consecutive studies or studies without consistently applied reference standards.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies or poor or non-independent reference standard.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.</td>
</tr>
</tbody>
</table>

**Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>A prospective cohort study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.</td>
</tr>
</tbody>
</table>

**APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS)**

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria
Preventing medical device related pressure injuries: data extraction and appraisals

### CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representative sample</th>
<th>States number invited participants</th>
<th>Clear outcome measures</th>
<th>Valid reliable outcome measurement</th>
<th>Comparable results for multiple sites</th>
<th>Confounders identified and accounted for</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>2273</td>
<td>Bakhshi et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>NA</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>4</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>10762</td>
<td>Hanonu &amp; Karadag, 2016</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>3</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>16832</td>
<td>Amirah et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>NA</td>
<td>N</td>
<td>Y</td>
<td>4</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>6674</td>
<td>Coyer et al., 2014</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>1848</td>
<td>Lemyze et al., 2013</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>7419</td>
<td>Bonell-Pons et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>NA</td>
<td>N</td>
<td>N</td>
<td>4</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>14405</td>
<td>Arnold-Long et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>4</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>14232</td>
<td>Asti et al., 2017</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>13959</td>
<td>Hobson et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>17252</td>
<td>Murgai et al., 2018</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>NA</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>17558</td>
<td>Balch Samora et al., 2018</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>NA</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>4</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>17568</td>
<td>Schallem et al., 2018</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>17153</td>
<td>Kayser et al., 2018</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>High</td>
<td></td>
</tr>
</tbody>
</table>
Preventing medical device related pressure injuries: data extraction and appraisals

### RCTs

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Assignment randomised</th>
<th>Adequate concealment method</th>
<th>Subjects and investigators blinded</th>
<th>Groups comparable at commencement</th>
<th>Only difference in treatment</th>
<th>Valid, reliable outcome measure</th>
<th>% drop out in study arms reported and acceptable</th>
<th>Intention to treat analysis</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
<th>Other relevant topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>6437</td>
<td>Newnam et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>U</td>
<td>1</td>
<td>High</td>
<td>pediatrics</td>
<td></td>
</tr>
<tr>
<td>14020</td>
<td>Otero et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>NA</td>
<td>Y</td>
<td>U</td>
<td>Low</td>
<td>prophylactic</td>
<td></td>
</tr>
</tbody>
</table>

### Case Series

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Focussed question</th>
<th>Participant characteristics reported</th>
<th>Inclusion criteria defined</th>
<th>Consecutive recruitment</th>
<th>Participants entered at same disease stage</th>
<th>Intervention clearly reported</th>
<th>Outcomes relevant and measured</th>
<th>Valid, reliable outcome measurement</th>
<th>Per cent drop out reported and acceptable</th>
<th>Estimates of random variability</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singh et al., 2017</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>NA</td>
<td>U</td>
<td>Y</td>
<td>4</td>
<td>Low</td>
</tr>
<tr>
<td>Su &amp; Nan, 2014</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>NA</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>Low</td>
</tr>
</tbody>
</table>

### Qualitative Studies

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Focussed question</th>
<th>Participant characteristics reported</th>
<th>Inclusion criteria defined</th>
<th>Consecutive recruitment</th>
<th>Participants entered at same disease stage</th>
<th>Intervention clearly reported</th>
<th>Outcome measurement</th>
<th>Valid, reliable outcome measurement</th>
<th>Per cent drop out reported and acceptable</th>
<th>Estimates of random variability</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Preventing medical device related pressure injuries: data extraction and appraisals

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Appropriate qualitative methodology</th>
<th>Recruitment method</th>
<th>Appropriate to research</th>
<th>Appropriate sample</th>
<th>Methods for data collection</th>
<th>Researcher, role in data collection</th>
<th>Ethics</th>
<th>Sufficiently rigorous data analysis</th>
<th>Clear statement of findings</th>
<th>Research contributes to the existing knowledge</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>14697</td>
<td>Barakat-Johnson et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Indirect</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

### QUASI EXPERIMENTAL STUDIES

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Focussed question</th>
<th>Subjects and investigators blinded</th>
<th>Groups comparable at commencement</th>
<th>Only difference between groups was treatment</th>
<th>Valid, reliable outcome measurement</th>
<th>Per cent drop out in study arms is reported and acceptable</th>
<th>Intention to treat analysis</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambutas et al., 2014</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>N</td>
<td>2</td>
<td>low</td>
</tr>
<tr>
<td>Difazio et al., 2017</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>2</td>
<td>low</td>
</tr>
<tr>
<td>O'Toole et al., 2017</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>NA</td>
<td>U</td>
<td>U</td>
<td>2</td>
<td>high</td>
</tr>
<tr>
<td>Hampson et al., 2018</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>2</td>
<td>low</td>
</tr>
</tbody>
</table>

### PROGNOSTIC STUDIES

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Appropriate qualitative methodology</th>
<th>Recruitment method</th>
<th>Appropriate to research</th>
<th>Appropriate sample</th>
<th>Methods for data collection</th>
<th>Researcher, role in data collection</th>
<th>Ethics</th>
<th>Sufficiently rigorous data analysis</th>
<th>Clear statement of findings</th>
<th>Research contributes to the existing knowledge</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>3015</td>
<td>Ambutas et al., 2014</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>Y</td>
<td>U</td>
<td>U</td>
<td>N</td>
<td>2</td>
<td>low</td>
<td></td>
</tr>
<tr>
<td>16132</td>
<td>Difazio et al., 2017</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>2</td>
<td>low</td>
<td></td>
</tr>
<tr>
<td>15823</td>
<td>O'Toole et al., 2017</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>U</td>
<td>2</td>
<td>high</td>
<td></td>
</tr>
<tr>
<td>17778</td>
<td>Hampson et al., 2018</td>
<td>Y</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>U</td>
<td>N</td>
<td>2</td>
<td>low</td>
<td></td>
</tr>
</tbody>
</table>
### Preventing medical device related pressure injuries: data extraction and appraisals

#### Table 1: Data Tables: 2019 Guideline Update: Preventing medical device related pressure injuries

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Baseline sample adequately described</th>
<th>Study attrition (&lt;20% lost to follow-up)</th>
<th>Clear definition of risk factors</th>
<th>Range of potential risk factors used (i.e., confounders identified)</th>
<th>RF measure/method valid and reliable</th>
<th>Method/setting of measurement same for all</th>
<th>Adequate % sample with complete data</th>
<th>Appropriate imputation method</th>
<th>Potential confounders accounted for in analysis</th>
<th>Adequate sample size (rule of thumb &gt;10 events per risk factor)</th>
<th>No selective reporting</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamaguti et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>Y</td>
<td>3</td>
</tr>
<tr>
<td>Moura et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
</tr>
<tr>
<td>Visscher et al., 2015</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>NA</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>3</td>
</tr>
<tr>
<td>Whitley et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>NA</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>3</td>
</tr>
<tr>
<td>Clay et al., 2018</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>3</td>
</tr>
</tbody>
</table>

#### Level of evidence

- **High (prognostic)**

#### Quality

- **High**
- **Moderate**
- **Low**

### COHORT STUDIES

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Focused question</th>
<th>Comparable source populations</th>
<th>States number invited</th>
<th>Likelihood of outcome at enrolment considered</th>
<th>Per cent dropout in study arms is reported</th>
<th>Comparison by drop outs and participants</th>
<th>Clear outcome measures</th>
<th>Assessment blinded, or discuss potential bias</th>
<th>Valid, reliable assessment with supporting reference evidence</th>
<th>More than one measure of exposure</th>
<th>Confounders identified and accounted for</th>
<th>Provides confidence intervals</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moura et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>1</td>
<td>Moderate</td>
</tr>
<tr>
<td>Visscher et al., 2015</td>
<td>U</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>3</td>
<td>Low</td>
</tr>
<tr>
<td>Whitley et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>NA</td>
<td>NA</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>3</td>
<td>Low</td>
</tr>
<tr>
<td>Clay et al., 2018</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>3</td>
<td>Low</td>
</tr>
</tbody>
</table>
SYSTEMATIC REVIEWS FOR DISCUSSION

RATING CRITERIA:
1 Partial yes: states review question, search strategy, in/exclusion criteria and risk of bias were a-priori; full yes: meta-analysis/synthesis plan, investigation of heterogeneity and justification for protocol deviation
2 Partial yes: At least 2 databases, provides keywords and search, justifies publication restrictions; full yes: searched reference lists of included studies, searched trial registries, consulted experts in field, searched grey literature, search within 24 months of review completion
3 At least two reviewers independently agreed on selection of studies to include or reviewers achieved 80% agreement on a sample of studies
4 Either two reviewers did data extraction and had >80% agreement, or two reviewers reached consensus on data to extract
5 Partial yes: list of all relevant studies that were read and excluded; full yes: every study that was excluded is independently justified
6 Partial yes: described populations, interventions, comparators, outcomes and research design; full yes: detailed descriptions of same plus study setting and timeframe for follow-up
7 FOR RCTS Partial yes: appraised risk of bias from unconcealed allocation and lack of blinding; full yes: appraised risk of bias on true randomisation, selection of reported result from multiple measurements/analyses
FOR non randomised studies: Partial yes: appraised confounding and selection bias; full yes: appraised methods to ascertain exposures and outcomes, selection of reported result from multiple measurements/analyses
8 Must include reporting of the source of funding of individual studies, or reports that the reviewers considered this even if individual funding sources aren't listed in review

Endnote ID | Author/year | PICO research question and inclusion criteria | Explicit states a priori protocol | Rationale for selection of study designs | Comprehensive search | Duplicate study selection | Duplicate data extraction | Excluded studies listed | Adequate description of included studies | Risk of bias assessed | Source of funding reported | Appropriate meta-analysis including weighting and adjustment for heterogeneity | Meta-analysis considers risk of bias of studies | Discussion consider risk of bias of studies | Assessment of publication bias if quantitative analysis is done | Potential conflicts of interest of authors reported and managed | Review Quality |
1489 | Newnam et al., 2013 | N | N | Y | NA | N | N | N | N | N | N | exclude |
17421 | Alqahatani & Alahmari, 2018 | N | N | N | N | N | N | N | N | N | N | exclude |
## QUALITY IMPROVEMENT STUDIES - reporting

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Title/abstract is accurate with information to guide searching</th>
<th>Introduction summarizes problem, significance, known information, rationale for study</th>
<th>Specific project aims</th>
<th>Methods outlines context</th>
<th>Methods includes detailed description of intervention and how it was implemented</th>
<th>Reports how methods were assessed and how sustainability was measured over time</th>
<th>Results reports observed associations, unintended consequences and missing data</th>
<th>Ethical issues addressed</th>
<th>Impact of intervention discussed</th>
<th>Results compared to other studies</th>
<th>Cost effectiveness reported</th>
<th>Reports limitations</th>
<th>Funding sources reported</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difazio et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>2</td>
<td>Quasi-experiment, low quality</td>
<td></td>
</tr>
</tbody>
</table>
Preventing medical device related pressure injuries: data extraction and appraisals

Full reference list of citations in tables:


Preventing medical device related pressure injuries: data extraction and appraisals


Visscher, M. O., White, C. C., Jones, J. M., Cahill, T., Jones, D. C., & Pan, B. S. (2015). Face masks for noninvasive ventilation: Fit, excess skin hydration, and pressure ulcers. *Respir Care, 60*(11), 1536-1547


