Recommendation 5.0 Evidence Profile

Recommendation question 5: Should the use of health technologies be recommended or not for the treatment of pressure injuries?

Recommendation 5.0: The expert panel suggests that nurses and health providers, in collaboration with the person and their essential caregivers, consider using negative pressure wound therapy for treatment of pressure injuries if the person meets indications and there are no contraindications.

Population: Persons with pressure injuries (PI)
Intervention: Use of negative pressure wound therapy (NPWT)
Comparison: No technology or standard care
Outcomes: Healing of existing pressure injury [critical], Pain [critical], Worsening pressure injury [critical] (not measured), Health provider compliance with use of health technology [critical] (not measured), Person/caregiver satisfaction [critical] (not measured)

Setting: All health-care settings, including but not limited to: community care, outpatient care, and acute care.

Bibliography: 78, 1077

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Healing of existing pressure injury (follow-up 9 weeks to 10 months, or wound closure)											
9[a]	RCTs (as reported in 2 SRs)	Serious[b]	Not serious	Not serious	Serious[c]	Detected[d]	Healed PIs/ participants: n=101/164 Additional RCT Healed PIs/total PIs: 1/6	Healed PIs/ participants: n=56/153 Additional RCT Healed PIs/total PIs: 0/6	RR 1.32 (1.03-1.70) For every 100 people who receive NPWT, 12 more people will have complete wound healing (ranges from 1 more to 26 more). An additional pilot RCT reported that the proportion of PI completely healed did not differ between intervention and control groups.	⊕⊕◯◯ Low	78: Song et al., 2020 1077: Shi et al, 2023
Pain[e] (follow-up to cure [scale not reported])											
3[f]	RCTs	Serious[g]	Serious[h]	Not serious	Serious[i]	Detected[j]	N=88	N=88	Three studies in the review demonstrated a large effect in favour of negative pressure wound therapy over standard care in relieving pain in the hospital. WMD = −2.39, 95% CI [−3.47,−1.30][k]	⊕◯◯◯ Very low	78: Song et al., 2020

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Worsening pressure injury (not measured)											
N/A											
Health provider compliance with technology (not measured)											
N/A											
Person/caregiver satisfaction (not measured)											
N/A											

Additional table- Individual study details:

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: healing rate of existing pressure injury						
Ali et al., 2015 Ford et al, 2002 Guo et al., 2013 Li et al, 2009 Liu and Ge, 2012 Shen et al, 2015 Su and Tang, 2012 Wang and Wu, 2012 (Taken from review Song et al., 2020)	8 RCTs	China (6 studies), India, USA	Patients meet the stage III or IV PIs diagnostic criteria according to National Pressure Ulcer Advisory Panel (NPUAP); I (intervention): NPWT devices used for PIs compared with SWC N=164	Any type of SWC such as moist gauze and various wound dressings. N=153	The number of PIs healed in the NPWT group was 61.54% and in the standard treatment group was 36.90%. The use of NPWT increased healing of PIs in patients compared with SWC (RR = 1.32; 95% CI 1.32-1.70). Number of PIs healed (%) treatment/control Ford et al, 2002: 10/13.3 Ali, 2015: 83.3/66.7 Li et al, 2009: 68.2/10 Shen et al, 2015: 59.5/35.1 Su and Tang, 2012: 64/24 Wang and Wu, 2012: 94.4/91.7 Guo et al, 2013: 50/20 Liu et al, 2012: 66.7/40	Systematic review: LOW Individual studies: SERIOUS

Ashby, 2012 (Taken from Shi et al., 2023)	1 RCT	UK	N= 6 participants Group A: the wound was closed using a Wound Care Kit that includes foam dressing (V.A.C. Granu Foam Silver), film drape, TRAC pad with tubing and a drainage canister. Steril foam material was placed inside the wound and was attached to the canister through tubing. The canister was attached to the Vacuum-Assisted Closure device (V.A.C.® Therapy System Patient Support – KCI), which is a portable device that applies intermittent or continuous negative pressure. The device was operated at 125 mmHg pressure for 5 min with and 2 min without active vacuum. Wound dressings were changed every 48 h. The wound area was measured after all three rounds of treatment. Offloading of the sore was performed by position change, airflow mattress usage and it was taken into consideration not to raise the head of the bed, more than 30◦	N= 6 participants Group B: The wound was initially evaluated for any necrotic findings and debrided if needed, and then washed with an antiseptic solution. A culture specimen was obtained from the wound. 3DWM was used to measure the pressure sores by taking pictures. The length and width of wounds were measured with disposable paper rulers. Wound depth was determined in centimetres with a sterile cotton-tip applicator by measuring against a ruler. Wounds were finally covered with gauze dressing soaked with saline. Wounds were treated three times a day, and measurements were repeated every 48 h.	There was no evidence of a difference in the number of wounds healed in the NPWT group (1/6) and the dressing group (0/6) (RR 3.00, 95% CI 0.15 to 61.74).	Systematic review: LOW Individual studies: NOT SERIOUS
Outcome: Pain [scale not reported]						
Shen et al, 2015 Su and Tang, 2012 Zhou, 2014 (Taken from review Song et al., 2020).	3 RCTs	China	Patients meet the stage III or IV PIs diagnostic criteria according to National Pressure Ulcer Advisory Panel (NPUAP); I (intervention): NPWT devices used for PIs compared with SWC	Any type of SWC such as moist gauze and various wound dressings.	All three analyses showed that the use of NPWT showed to be an advantage that relieved the pain in the hospital (WMD = −2.39, 95% CI [−3.47, −1.30],).	Systematic review: LOW Individual studies: SERIOUS

Acronyms
CI: Confidence interval
NPWT: negative pressure wound therapy
PI: Pressure Injuries
RCT: randomized control trial
RR: risk ratio
ROB: risk of bias
SWC: standard wound care
vs: versus
WMD: weighted mean difference

Reference

Shi J, Gao Y, Tian J, Li J, Xu J, Mei F, et al. Negative pressure wound therapy for treating pressure ulcers. Cochrane Database Syst Rev. 2023 May 26;5(5):CD011334.

Song Y, Wang L, Yuan B, Shen H, Du L, Cai J, et al. Negative-pressure wound therapy for III / IV pressure injuries: A meta-analysis. Wound Repair Regeneration. 2021 Jan;29(1):20–33.

Explanations

[a] Eight RCTs were included from a systematic review (Song et al., 2020).
[b] Both SRs was assessed as low risk of bias following the ROBIS tool. Review authors rated studies using ROB 2.0 tool. Most studies had very serious risk of bias due to inadequate randomization, allocation concealment and lack of blinding as well as other bias We downgraded by 1.
[c] The number of events was below the optimal size of 300 (n=158). We downgraded by 1.
[d] The funnel plot showed evidence of publication bias based on the 10 RCTs. However, the sensitivity analysis showed the result is robust.
[e] Pain scores in the individual studies were not reported.
[f] Three RCTs were included from a systematic review (Song et al., 2020).
[g] The SR was assessed as low risk of bias following the ROBIS tool. Review authors rated studies using ROB 2.0 tool. Most studies had very serious risk of bias due to inadequate randomization, allocation concealment and lack of blinding as well as other bias. We downgraded by 1.
[h] Strong evidence of heterogeneity (I^2 93.5%). We downgraded by 1.
[i] The sample size was less than the optimal size of 800 (n=176). We downgraded by 1.
[j] The funnel plot showed evidence of publication bias based on the 10 RCTs. However, the sensitivity analysis showed the result is robust.
[k] Note: pain scale not reported in the systematic review (e.g. 1-10 or 1-100).