

Appendix

Summary of studies included in the literature

Article Title Author(s)	Product / Technique used in the management of ulcers	Summary of evidence
<p>Water for wound cleansing</p> <p>Fernandez <i>et al.</i>⁸</p>	<p>Revision of eleven works of literature on the effectiveness of the following detergents in cleansing ulcers:</p> <ul style="list-style-type: none"> i) tap water and non-cleansing; ii) tap water with the physiological solution; iii) tap water with cooled boiled tap water; iv) tap water with any other solution. 	<p>10 out of 11 studies included in this review were carried out in emergency departments and one in a community environment.</p> <p>3 RCTs compared the use of tap water and non-cleansing in patients with surgical wounds⁹⁻¹¹ showing no differences in terms of infection rate and wound healing (RR 1.06.95% CI 0.07-16.50).</p> <p>The comparison between tap water and the physiological solution has been reported in 6 studies.¹²⁻¹⁷</p> <p>No difference in the infection rate of the lesions was reported for acute, chronic, and even lesions in pediatric subjects, except for a study in which an increase in infections was reported in subjects cleansed with saline, which could be attributed to the temperature difference of the irrigant used.</p> <p>Only in one study¹³ was the wound healing rate reported without any significant difference between saline and tap water (RR0.57 95% CI 0.30-1.07).</p> <p>Museru <i>et al.</i>¹⁸ compared boiled chilled water with isotonic saline solution reporting an infection rate of 29% in patients in whom wounds had been cleaned with cooled boiled water and 35% in patients in whom the lesions were cleaned with isotonic saline solution (RR 0.83.95% CI 0.37 -1.87).</p> <p>No study compares tap water with boiled tap water.</p> <p>The comparison between the preparation of procaine (Hcl 2% and spirit) and tap water used in the cleaning of wounds in the post-surgical period did not reveal statistically significant differences both in the healing process and in the management of pain.</p> <p>Only one study¹² reported a lower rate of infection in wounds cleansed with tap water than the saline solution, but in this study the cleaning solutions were administered at different temperatures.</p> <p>In 3 studies the details of the randomization method of the participants is not present^{11,15,18} and 6 contain selection bias.^{9-12,16,19}</p>
<p>Wound cleansing for pressure ulcers</p> <p>Moore <i>et al.</i>²⁰</p>	<p>Assess how cleansing can affect the healing rate of pressure ulcers, considering both the choice of solution and the cleansing technique used. All Randomized Controlled Trials (RCTs) that compare different wound cleansing solutions and techniques have been included, reporting an objective measure of pressure ulcer healing. The studies involve people of all ages with pressure ulcers regardless of context. In this review, cleansing has been described as the use of a detergent on pressure ulcers to</p>	<p>The first RCT¹³ examined the cleansing of pressure ulcers in patients in nursing homes, comparing the use of the physiological solution with tap water. Both solutions used for cleansing were delivered at room temperature through a syringe and the 20-gauge cannula. The results obtained from this double-blind study show that there are no significant differences in the healing process for both groups (RR3.00, 95% CI 0.21 - 41.89). Bellingeri <i>et al.</i>²¹ compared the use of the</p>

	<p>remove exudate, debris and contaminants excluding mechanical debridement.</p>	<p>physiological solution with the physiological spray solution containing aloe vera and silver chloride for the cleansing of pressure ulcers above the first stage in a hospital setting. Only those who completed the study were included in the final analysis. Wounds cleansed with aloe vera solution showed a significant improvement in the Pressure Sore Status Tool (PSSIT) scale compared to those cleansed with saline (P=0.025).</p> <p>The third study²² examined cleansing with pulsatile low-pressure saline and non-cleansing of pelvic level third and fourth stage pressure ulcers (coccygeal, ischial and trochanteric) in patients with spinal cord injury within a context hospital. At the end of the cleansing the participants received standard care. The study was blinded for the participants, but the nurse was aware of the patient's group.</p> <p>Hartman <i>et al.</i>²³ found a statistically significant reduction in ulcer volume: wounds cleaned with pulsatile washing showed an average reduction in ulcer volume (-4.9 cm³) compared to wounds in the sham group (3-3.7cm³) (MD - 6.60, 95% IC-11.23 to-1.97).</p> <p>According to Moore <i>et al.</i>²⁰ the results obtained from the studies included in the systematic review should be interpreted with caution since the samples analyzed are small and undersized. The authors conclude that there is no evidence to support the use of a particular wound cleaning solution or pressure ulcer cleansing technique.</p>
<p>Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide for wound irrigation</p> <p>Romanelli <i>et al.</i>²⁴</p>	<p>The purpose of this RCT was to evaluate the effects of using the solution containing betaine and polyhexanide (prontosan) in the cleansing of chronic venous ulcers for the control of the bacterial load, through a clinical and instrumental evaluation.</p> <p>This randomized, single-blind randomized study includes forty participants (22 females and 18 males) followed in the dermatology department, aged 55 to 73 years, who have had a chronic painful leg injury for more than eight weeks, with clinical signs and instrumental venous insufficiency, wound size greater than 100 cm² and who have received compression therapy for at least two weeks. Patients were randomized to two groups of 20 patients with an electronic system and each group was assigned a treatment regimen for four weeks. The interventions for the 20 patients assigned to group A were daily cleansing with a detergent solution containing polyhexanide and betaine associated with a standard dressing or with polyurethane foam and elastic compression. While the 20 patients assigned to group B were treated every day with physiological solution followed by standard dressing.</p>	<p>The use of prontosan as a wound cleanser has shown good efficacy and tolerability in controlling the bacterial load of chronic venous ulcers with different levels of microbial involvement, showing that lowering the pH of the lesion to a more acidic environment causes an increase in the rate of healing. The pH measurement was considered sufficient to demonstrate an improvement in the wounds treated with prontosan.</p> <p>In this study, the sample size is very small, in fact in the future other studies are needed to confirm the correlation of the use of prontosan for the eradication of the biofilm. Therefore, further research is needed to determine a correlation between the reduction of the wound pH and the objective increase in the healing rate. It is also important that additional parameters are used to detect the reduction of the infection rate and that the cleaning technique used is defined in detail.</p>
<p>Pressurized irrigation versus swabbing method in cleansing wounds</p>	<p>The multicenter randomized controlled trial was conducted in four Hong Kong General Out-Patient Clinics (GOPC). Eligible patients were those with wounds of any</p>	<p>The healing time of the wounds cleaned with pressurized irrigation was 9 days (95% CI 7.4-10.6 days) while in the swabbing group it was 12 days (95% CI: 10.2-13.8 days). The</p>

<p>healed by secondary intention: a randomized controlled trial with cost</p> <p>Mak <i>et al.</i>²⁵</p>	<p>etiology that heal by secondary intention, who speak Chinese and with normal cognitive ability. Patients were randomly assigned to the pressure cleansing or tamponade method. 256 patients with wounds healing by secondary intention were included, including lacerations, abrasions, burns, burns, surgical wound dehiscences, dog bite in any anatomical region. Patients were randomly assigned, opening an opaque and sealed numbered envelope, forming a group of 122 patients assigned to pressure irrigation and a group of 134 patients to swabbing. Of the 256 patients, 30 did not participate because they were lost during follow-up (respectively 15 patients in the pressure group and 15 patients in the tamponade group). 45 were eligible but not enrolled due to swine flu.</p> <p>The primary outcome measured was the wound healing time, indicated as complete coverage of the wound with epithelial tissue.</p> <p>Secondary outcomes include portion of the wound healed, reduction of the size of the wound during the six weeks of participation in the trial, presence of signs of infection, symptoms and problems related to the wound such as pain even during the dressing change and finally satisfaction and comfort of the patient.</p> <p>For the patients assigned to the first group the wounds were cleaned with a pressure irrigation device with a shock pressure between 4-13 psi, while for those of the second group the cleansing was done with forceps and gauze through the tamponade method.</p> <p>The physiological solution used as a detergent had to be consumed within 24 hours of opening and kept at room temperature for both groups. Cleansing was subsequently followed by dressing according to the wound management protocol; the latter had to be maintained until the next check; the quantity of solution used and the frequency for changing the dressing were dependent on the exudate. The wounds were cleaned with the method that had been assigned to him until complete recovery or for a maximum duration of six weeks.</p>	<p>pressurized irrigation group showed a significant number of patients who reported reduction of pain during wound cleansing (93.4% <i>vs</i> 84.2%; P=0.02) and greater comfort and satisfaction compared to the swabbing group (MD1 [95% CI: 5-6]; P=0.002; MD1 [95% CI 5-6]; P<0.001).</p> <p>Wound infection was reported in 3.3% of patients in the pressure irrigation group and 5.2% in the swabbing group (P=0.44).</p> <p>The cost-benefit analysis indicated that the pressure irrigation method is more convenient than that for tamponade.</p> <p>This is the first RCT that has shown that pressure irrigation is safer, more convenient and reduces the healing time of wounds that heal by secondary intention.</p> <p>The study is well structured and accurately reports every part of it, specifying in detail the method of recruiting the participants, the interventions carried out and the measured outcomes, making the study reproducible in another reality.</p> <p>The risk of bias in the evaluation of the results was reduced to a minimum, since the staff who carried out the evaluation of the lesion was not aware of the cleaning method used.</p> <p>However, the samples obtained are not homogeneous and not very balanced due to the different etiologies, in fact the study sample mainly included patients with acute wounds, but in the swabbing group a high percentage of participants with chronic leg ulcer was detected compared to the group of cleansing for pressurized irrigation (7.5 <i>vs</i> 1.6).</p> <p>The number of participants recruited in the 4 GOPCs was similar in each center, however according to the authors the sample should have a greater number in order to generalize the data to another population.</p>
<p>A multicenter comparison of tap water versus sterile saline for wound irrigation</p> <p>Moscato <i>et al.</i>¹⁷</p>	<p>This multicenter prospective randomized study conducted in two hospitals; it has as its population people over the age of seventeen who present themselves in the emergency department with simple acute wounds that need to be sutured or with metal clips or with sutures. The subjects were randomized to the use of the physiological solution or to the use of tap water by opening a numbered envelope. The envelopes were pre-randomized from a PC based on a random number generator.</p> <p>Participants were asked to return to the emergency room for the removal of the stitches and those who did not return were contacted by phone.</p> <p>The objective of this study is to compare the</p>	<p>A total of 715 subjects were enrolled in the study. Follow-up data were obtained on 634 of the subjects enrolled (88%), 4% of the subjects treated with tap water found a wound infection compared to 3.3% of the subjects treated with physiological solution (RR 1.21; 95% CI = 0.5-2.7).</p> <p>During irrigation, the staff was aware of the irrigation method, but when patients returned to the Emergency Department for the removal of the points, the staff was unaware of the irrigation method used.</p> <p>Patients who did not return to the Emergency Department were contacted by phone and the presence or absence of infection was assessed by processing the data collected with the</p>

	<p>infection rate of acute lacerations irrigated with tap water and those irrigated with sterile physiological solution before suturing with wire or with metal clips inside an emergency department.</p> <p>The primary outcome assessed was the infection rate in both cleansing methods. In the study, the lesion in which the stitches had to be removed early, in which there was loss of exudate or if in need of antibiotic therapy was considered infected. The secondary outcomes observed were patient satisfaction and cost analysis.</p> <p>In the group that uses tap water, upper limb wounds were cleaned under the tap for at least 2 minutes. For wounds in other positions of the body, a transparent plastic tube was used to facilitate irrigation; the tube was not sterile but disposable. The wounds treated with saline were irrigated with a minimum quantity of 200 mL with a sterile 35 mL syringe with splash guard. There were no maximum times or maximum volumes for both groups. All the wounds included were sutured in a standard manner at the discretion of the clinician without the use of any antibiotic prophylaxis or use of antiseptic preparations. All participants had to return to the emergency department after 5-14 days to remove the stitches; on this occasion, the presence of infection could be observed. Those who did not return for the removal of the points were contacted by phone.</p>	<p>administration of a questionnaire that was the same for all participants.</p> <p>The authors conclude that compared to the physiological solution, tap water is more convenient and seems to be equally safe and effective, since the same infection rate has been found with the use of both detergents. For this reason, tap water should be considered, in the context of emergency departments, as a reasonable alternative to the physiological solution.</p>
<p>Solution, technique and pressure in wound cleansing</p> <p>Joanna Briggs Institute ²⁶</p>	<p>The New South Wales Center for Evidence Based Nursing & Midwifery in collaboration with the Joanna Briggs Institute conducted a systematic review reporting the effectiveness of solutions, technique and pressure in wound cleansing.</p> <p>Randomized controlled trials, comparative studies, cohort and case control studies that assessed the effectiveness of various solutions, techniques and pressures for wound washing were taken into consideration. Studies on adults or children and those describing objective or subjective measures of infection and wound healing were also included.</p> <p>Ten RCTs, two cohort studies and a comparative study assessed the effectiveness of tap water, physiological solution, povidone iodine, procaine, distilled water, isotonic saline for wound cleansing.</p>	<p>Comparison between tap water and non-cleansing</p> <p>Data collected (483 patients) compared patients with surgical wounds with primary intention healing who were allowed to bath or shower, compared to those who were not allowed to shower. No significant difference was found on the wound infection rate (OR = 0.80; 95% CI = 0.29, 2.21) or healing (OR = 1.24; 95% CI = 0.27, 5.68) between the groups. Similar results were found in 2 non-randomized controlled studies (300 patients) that showed either a lower percentage or an absence of infection in patients in whom the wounds were washed, compared to those who were not allowed to clean them. (OR = 1.24; 95% CI = 0.27, 5.68).</p> <p>Comparison between tap water and the physiological solution</p> <p>It was compared the rate of infections in wounds cleansed with tap water compared to those cleansed with saline. A study of 705 patients with acute wounds reported a higher infection rate in wounds that were cleaned with normal saline (P<0.05), while the Griffiths study that had 49 chronic wounds as a sample showed no difference both in the rate of infection and healing of clean wounds and with normal (non-sterile) saline solution or tap water.</p> <p>This supports the use of drinking water as a safe and effective solution for cleansing both</p>

acute and chronic wounds.

Comparison between physiological solution and non-cleansing

It was assessed the rate of infections in wounds cleaned with saline (n=7) and in those that were not cleansed (n=8). The results showed that wounds cleaned with saline showed an increase in bacterial count after treatment (P=0.0001). This result can be linked to the technique used for cleaning rather than to the solution itself. This study has a small sample and the percentage of pre-treatment infection of all wounds in the study group is not reported, therefore the results lack power and validity to suggest a clinical decision-making.

Comparison between 1% povidone iodine solution and sterile physiological solution

It was compared the rate of infections between wounds cleansed with 1% povidone iodine and wounds cleansed with sterile saline. The RCT undertaken on 531 simple soft tissue lacerations did not show any significant difference in the number of infected wounds between the 2 groups, while the studies undertaken on contaminated wounds reported a lower infection rate in wounds cleaned with povidone iodine 1%. Wound healing is an outcome reported only in an RCT undertaken on contaminated wounds. The results showed that primary wound healing had increased in wounds cleaned with povidone iodine. However, no statistically significant difference was reported in the number of wounds that healed in less than 3 months, or between 3-6 months between the 2 groups.

Comparison between 1% povidone iodine solution and no treatment

It was compared the cleansing of heavily contaminated traumatic wounds cleaned with 1% povidone iodine (n=8) and those that did not receive treatment. The results did not demonstrate a statistically significant difference in bacterial count and in the number of infections in both groups.

Comparison of povidone-iodine and a solution containing surfactant

It was evaluated the efficacy of povidone iodine (184 subjects) compared to a surfactant solution (158 subjects) to reduce the rate of infection in case of uncomplicated soft tissue lacerations. The results revealed a difference in the infection rate between the 2 groups (4.3% with povidone iodine and 5.7 with surfactant) but this difference was not statistically significant.

Comparison of surfactant solution with respect to physiological solution

It was compared the effectiveness of a

surfactant solution (58 subjects) compared to the sterile physiological solution to cleanse traumatic lacerations. There were no differences in the infection and cure rates between the 2 groups. The surfactant solution also seems safe for lacerations in the periorbital area.

Comparison between water (distilled water and/or cooled boiled water) and physiological solution

It was compared the rate of infection and healing in the cleansing of exposed fractures using distilled water, cooled boiled water or physiological solution. The results of the distilled water, the cooled boiled water were unified and compared with the physiological solution, without finding some statistically significant differences in the number of infections (OR = 0.55; 95% CI 0.18, 1.62).

Comparison between distilled water and cooled boiled water

17% of patients or six of 35 patients in the distilled water group compared to 29% or 9 of 31 patients in the chilled boiled water group developed a wound infection. This difference was not statistically significant (OR = 1.98; 95% Ci 0.61, 6.39).

Comparison between distilled water and physiological solution

In the group treated with saline, 35% of patients or 7 of the 20 subjects had wound infections compared to 17% of the distilled water group (OR = 0.38; 95% CI 0.11, 1.37). These were not significant results

Comparison between chilled boiled water and saline

In this comparison, 29% of patients, or 9 out of 31 subjects whose wounds were cleaned with boiled cold water, developed an infection compared to 35% of those cleaned with saline (OR = 0.76; 95% CI 0.23, 2.53). These were not significant results.

The use of povidone iodine for the cleansing of traumatic wounds²⁷

Wound cleansing is a key component in wound management. This consists in the application of a fluid to remove exudate, slough and contaminants. Any traumatic injury should be considered contaminated; however the cleansing of these lesions has shown to reduce the infection rate. The literature describes that in addition to the disparity between the different cleaning techniques, there is also a disparity on the type of detergent to be used. Different solutions ranging from tap water to physiological solution have been used for wound cleansing and all have shown to have both advantages and disadvantages. Cleansing,

however, appears to be a ritual rather than evidence-based practice.

The use of antiseptics, especially povidone iodine, in the management of acute wounds has remained a substance that inhibits the growth and development of microorganisms that cause wound sepsis.

The pressure for cleansing the wound

Three RCTs investigated liquid pressure in wound cleansing.²⁸⁻³⁰ One study compared irrigation with a syringe and needle and the other with a bulb syringe.²⁸

The second compared 2 new devices equipped with a valve or cap that could be connected to a 1,000mL bottle.³¹ The third study compared irrigation using a pressurized container compared to irrigation with a 30 mL syringe and a 20 G. needle.²⁹

Comparison of liquid pressures

Comparison of liquid pressure equal to 13 psi obtained with a 12-cc syringe and 22 G needle and a pressure equal to 0.05 psi obtained with a bulb syringe.

In recent traumatic wounds (n=335) irrigated with a pressure of 13 psi, a statistically significant reduction in inflammation (P=0.034) and infection (P=0.017) was observed compared to those cleaned using a pressure of 0.05 psi.²⁸ The criteria for stable infection or inflammation were not established and the volumes of water and the method of application were different in the two groups, the results should be considered in light of these factors.

Comparison between the use of a pressurized container with 8 psi and the 30-mL syringe with a 20 G needle with 8 psi.

A pressure of 8 psi is extremely effective in washing wounds. The study compared irrigation times and infection rate in 535 wounds. Although the difference in the complication rate observed in the 2 groups was not statistically significant (P=0.05), the time used to irrigate the wounds was significantly less (P<0.0001).²⁹ Comparison between a pressurized container with a pressure equal to 8 psi and a bulb syringe with a pressure equal to 0.005psi.³¹

Techniques used for cleansing

A comparison study between irrigation with syringe and needle from 18-20 G and cleansing with gauze only did not find significant differences in the infection rate (P=0.28).³²

However, the wounds subjected to suture removal irrigation were aesthetically better. Four studies^{9-11,33} compared the effects of showering in the post-operative period compared to non-washing. The results showed no significant difference in the infection or cure rate between the 2 groups (OR 0.80, 95% CI

		<p>0.29–2.23). However, studies reported that the subjects of the shower group had a feeling of well-being that resulted from hygiene and the desire to wash. A single study³⁴ that evaluated the effects of whirlpool bath therapy on pain relief and wound healing after abdominal surgery indicated that 31 subjects treated with whirlpool therapy and with analgesic therapy in the first 72 hours after surgery they had reduced pain and improved inflammation compared with 32 untreated subjects. Whirlpool therapy followed by vigorous rinsing compared to whirlpool therapy alone showed a significant reduction in bacterial counts in venous stasis ulcers.</p> <p>Research in this area is limited and the results are based on a single study and the samples are limited in size.</p>
--	--	---