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Pressurised irrigation versus swabbing method in cleansing wounds healed by secondary intention: A randomised controlled trial with cost-effectiveness analysis

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A R T I C L E I N F O

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A B S T R A C T

Background: Wound cleansing should create an optimal healing environment by removing excess debris, exudates, foreign and necrotic material which are commonly present in the wounds that heal by secondary intention. At present, there is no research evidence for whether pressurised irrigation has better wound healing outcomes compared with conventional swabbing practice in cleansing wound.
Objectives: This study investigated the differences between pressurised irrigation and swabbing method in cleansing wounds that healed by secondary intention in relation to wound healing outcomes and cost-effectiveness.
Design: Multicentre, prospective, randomised controlled trial.
Setting: The study took place in four General Outpatient Clinics in Hong Kong.
Methods: Two hundred and fifty six patients with wounds healing by secondary intention were randomly assigned by having a staff independent of the study opening a serially numbered, opaque and sealed envelope to either pressurised irrigation ($n = 122$) or swabbing ($n = 134$). Staff undertaking study-related assessments was blinded to treatment assignment. Patients' wounds were followed up for 6 weeks or earlier if wounds had healed to determine wound healing, infection, symptoms, satisfaction, and cost effectiveness. The primary outcome was time-to-wound healing. Patients were analysed according to their treatment allocation. This trial is registered with ClinicalTrials.gov, number NCT01885273.
Results: Intention-to-treat analysis showed that pressurised irrigation group was associated with a shorter median time-to-wound healing than swabbing group [9.0 days (95% CI: 7.4–13.8) vs. 12.0 (95% CI: 10.2–13.8); $p = 0.007$]. Pressurised irrigation group has significantly more patients experiencing lower grade of pain during wound cleansing (93.4% vs. 84.2%; $p = 0.02$), and significantly higher median satisfaction with either comfort or cleansing method (MD 1 [95% CI: 5–6]; $p = 0.002$; MD 1 [95% CI: 5–6]; $p < 0.001$) than

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did swabbing group. Wound infection was reported in 4 (3.3%) patients in pressurised irrigation group and in 7 (5.2%) patients in swabbing group ($p = 0.44$). Cost-effectiveness analysis indicated that pressurised irrigation in comparison with swabbing saved per patient HK$ 110 (95% CI: −33 to 308) and was a cost-effective cleansing method at no extra direct medical cost with a probability of 90%.

Conclusions: This is the first randomised controlled trial to compare the pressurised irrigation and swabbing. Pressurised irrigation is more cost-effective than swabbing in shortening time that wound heals by secondary intention with better patient tolerance. Use of pressurised irrigation for wound cleansing is supported by this trial.

What is already known about the topic?

- Wound cleansing is an important part of assisting the wound to heal by secondary intention; by removing foreign debris and excess exudate, reducing bacterial bioburden and rehydrating the wound
- Swabbing is a dominant practice in wound cleansing despite the mention about its risk for tissue trauma thus compromising healing.
- Pressurised irrigation has been advocated as an acceptable practice to cleanse wounds, due to its merit in being able to cleanse without traumatising the wound bed.

What this paper adds

- Pressurised irrigation has better wound healing outcomes including shorter wound healing time, less pain during wound cleansing, and higher satisfaction with comfort and the cleansing method compared with swabbing practice to cleanse wound.
- Pressurised irrigation is a cost-effective alternative to swabbing for cleansing wounds that heal by secondary intention.
- This study is the first with randomised controlled trial design to compare the irrigation and swabbing, while accounted for cost analysis, which previous studies had not done.

1. Introduction

A wound heals by secondary intention if surgical closure is not indicated by reason of wound edges being unable to approximate due to tissue loss and wound being contaminated or infected, including acute traumatic wounds (Dire and Walsh, 1990), dehisced surgical wounds (Miller and Glover, 1999), chronic wounds (Falanga, 2000), leg ulcer (Waspe, 1996) and burn wound (McKirdy, 2001). By secondary healing, the wound is allowed to "granulate in", that is, the wound closes by contraction and filling with connective tissue, which may be a protracted process, more nursing time in managing the wound will be required. Wound cleansing is an important part of assisting this healing process; by removing foreign debris and excess exudate, reducing bacterial bioburden and rehydrating the wound (Atiyeh et al., 2009; Falanga, 2000).

The most appropriate technique of wound cleansing remains contentious over the years. The routines for cleansing wounds vary between countries, hospitals and departments, some literatures recommend not to use swabbing routinely due to the risk for tissue trauma thus compromising healing (Oliver, 1997), while others recommend swabbing with soaked non-woven gauze at appropriate pressure which can remove slough and loose necrotic tissue without damage (Towler, 2001; Young, 1995). In Hong Kong, the use of swabbing in cleansing wounds is a dominant practice in majority of healthcare setting despite the availability of literature and expert recommendation.

A number of narrative review articles have indicated various techniques for wound cleansing. However, irrigation of wounds is gaining widespread acceptance as clinicians recognise its benefits, namely preservation of newly granulating tissue, effective removal of bacteria and debris and patient comfort and convenience (Ennis et al., 2004; Oliver, 1997). The original Agency for Health Care Policy and Research (AHCPR) guidelines describe safe and effective irrigation pressures as being 4–15 psi, based on a series of different studies (Brown et al., 1978; Rodeheaver et al., 1975; Wheeler et al., 1976). Studies suggest that pressures of 8–12 psi are strong enough to overcome adhesive forces of bacteria (Chisholm et al., 1992; Longmire et al., 1987). Use of pressurised irrigation facilitates ease of irrigation, markedly decreases the time involved in this traditionally labour-intensive activity, and may decrease budgetary burden due to extra add needles or syringes for irrigation.

Since cleansing by irrigation being considered advantageous, there has been a lot of debate and research with regards to the most appropriate equipment and amount of pressure required to effectively cleanse a wound without causing trauma (Towler, 2001). No study that compared the technique of swabbing with either irrigation or pressurised irrigation was identified from the updated search.

A Cochrane Wound Group's review concluded that there were no randomised controlled trials identified that compared the common techniques of swabbing and scrubbing (Fernandez et al., 2006; Moore and Cowman, 2013). The conclusions in the Cochrane review were based on the Joanna Briggs Institute Best Practice report that the data were analysed using Cochrane Review manager, showing that there were only five trials comparing the effect of showering to non-showering patients in the post-operative period (Fernandez et al., 2006). The pooled results of four studies (Fraser et al., 1976; Goldberg et al., 1981; Riederer and Inderbitzi, 1997; Voorhees and Rosenthal, 1982) indicated that there was no statistical difference in the infection rate (OR = 0.80; 95% CI = 0.29–2.21) and the healing rate between the groups. However, two studies reported that patients who were in the showering group felt a sense of health and well-being derived from the hygiene and motivation of showering (Riederer and Inderbitzi, 1997; Voorhees and Rosenthal, 1982). A Cochrane review for wound cleansing of pressure ulcers identified only a small randomised controlled trial showing a statistically significant reduction in volume reduction in pressure ulcers cleansed with pulsatile lavage (MD −6.60, 95% CI: −11.23 to −1.97) compared with those cleansed using sham pulsatile lavage, and thus emphasised that well designed, robust studies are required (Moore and Cowman, 2013). By evaluating both healing outcomes and cost-effectiveness, a more complete overview of the wound cleansing by pressurised irrigation and swabbing can be obtained and used as guidelines. These guidelines can serve as a common repository of generally accepted practice.

2. Methods

2.1. Study design and participants

This was a multicentre, randomised controlled trial that took place in four General Out-patient Clinics (GOPC) in Hong Kong. Participants were identified from the GOPC at their visit for dressing treatment. Eligible patients were those with wounds in any type to heal by secondary intention, speaking Chinese, with an abbreviated mental test score 7 or above indicating their normal cognitive ability; and being able to be accessible for wound cleansing and evaluation follow up. Exclusion criteria included unbroken skin; full-thickness skin loss and damage to muscle, bone or/and any supporting structures; wounds with a sinus; wounds to heal by primary intention including adhesive strips, sutures or super glue; wound that was prescribed to be cleansed by irrigation; and patients with a very poor life expectancy or with a clinical condition that severely interfere with wound healing such as malignancy, autoimmune disease. All patients provided written informed consent for trial participation.

2.2. Randomisation and masking

We enrolled patients and randomly allocated them to either pressurised irrigation or swabbing before wound cleansing. The group allocation of each participant was assigned by having a staff independent of the study opening a serially numbered, opaque and sealed envelope to ensure concealment. The envelopes containing the group identifier were prepared by a statistician blinded to the study using computer generated random codes prior to subject recruitment.

Patients and operators were aware of treatment allocation, the trial staff performing data collection and wound assessment was masked to treatment group.

2.3. Intervention

For patients allocated to the study group, wounds were cleansed with pressurised irrigation technique using a pressurised irrigation device (Fig. 1) which was modified by connecting an instrument DeVilbiss Syringe, to Gomco's® Vacuum/Pressure Pump Model 309, generating a steady irrigation stream at a consistent range of impact pressure from 4 to 13 psi. The Syringe is a small flexible tube with opening in forward end furnished with a bottle to hold liquid, which permits deep yet painless lavage.

Pressurised irrigation group received the 'standardised usual care' the same as those in the control group that had wounds cleansed with swabbing technique using forceps and cotton wool (in sterile dressing pack). The 'standardised usual care' included cleansing wound with normal saline solution at room temperature; used saline to be dated and used within 24 h after opening; selecting wound dressing according to the protocol of wound management in GOPC; all dressings being kept intact until next visit; and amount of saline used and frequency of dressing change depending on the amount of exudates.

The wound care practice in GOPCs was guided by the protocol consisting of three basic elements in wound management: cleansing techniques, cleansing solutions and dressings. Since the cleansing techniques were the key aspect this study was testing, only the standard care about cleansing solution and dressing used were addressed. Normal saline is isotonic that is the most commonly and safely used to cleanse wound. The principle of dressings selection is guided by moist wound theory in keeping wound moist and controlling exudate, as well as availability of the dressings that a variety types of dressing materials, e.g. alginates, hydrofiber, hydrocolloid, foam are usually available in the GOPCs.

All wounds were cleansed following the allocated method until the wounds were completely healed or for 6 weeks if the wounds had not yet healed.

2.4. Data collection

Data collection and wound assessment took place for all subjects at enrollment and upon healing of the wound or at the end of 6-week period if the wounds had not yet healed. Wounds that had not healed at the end of the 6-week period were reassessed and data relating to the wound characteristics were recorded. The operators who undertook dressing change were responsible for the ongoing assessment of the wound during cleansing and recording the information on the volume of solution and amount of cleansing materials used, frequency of dressing changes and the type of dressing applied at each visit.

Data for checking baseline differences and data related to wound healing problems were abstracted from the medical records. The collected data included age, sex, body weight & height, history of smoking, medical history, concomitant medication, current treatment and abbreviated mental test (AMT). Bates-Jensen Wound Assessment Tool (BWAT) (Bates-Jensen, 2000, 2001) comprising

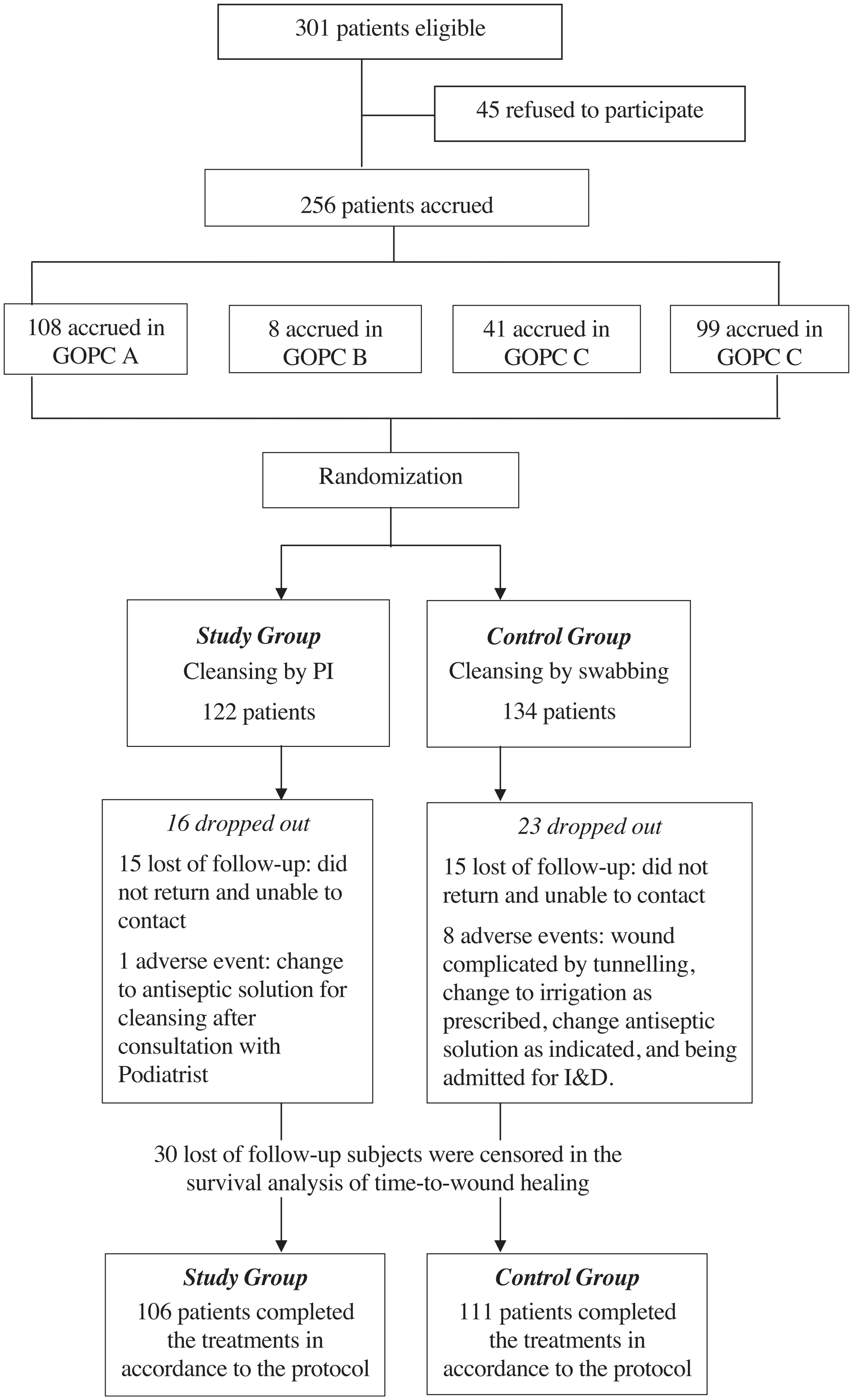

Fig. 1. Trial profile.

13 assessment scored items (size, depth, edges, undermining or pockets, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, surrounding skin colour, peripheral tissue oedema, peripheral tissue induration, granulation tissue, and epithelialisation) was adopted to capture the baseline wound features, and the lower scores indicates a healthier wound.

2.5. Clinical outcome measures

The primary outcome was time-to-wound healing defined as number of days from recruitment to complete healing which was indicated by complete coverage of the wound with epithelial tissue. Patient's wound that was observed to completely heal was verified by trial nurse who was masked to treatment allocation.

Secondary clinical outcomes included proportion of wounds completely healed and reduction of wound size during the 6 weeks of trial participation; presence of signs of wound infection and physician prescription of antibiotic for a wound infection at any time up to 6 weeks after randomisation. Visitrak digital planimetry system (Thawer et al., 2002) was used to measure and document the dimensions and attributes of wound, to ensure an objective, accurate and reproducible evaluation of wound size. Operator identification of signs of wound infection was verified by contacting a physician who was masked to treatment allocation to confirm prescription of an antibiotic for wound infection.

2.6. Other effectiveness outcome measures

Patient's symptoms and problems related to the wound were measured at enrolment and upon healing of wound or at the end of 6-week period if the wounds had not yet healed by using the self-rating scale of Wound Symptoms Self-Assessment Chart (WoSSAC) (Naylor, 2002). This WoSSAC divide wound symptoms into six aspects (pain from wound, pain related to dressing changes, fluid leakage from dressing, bleeding, smell, itching). Each of these aspects has two dimensions (severity and impact on patient's life) to be assessed.

Patient satisfaction related to wound cleansing and health-related quality of life were measured at the end of the patients' participation in the study. We used two self-rating questionnaires: a self-devised satisfaction survey which had 6-point scale with anchoring description at each of the points to measure patient's satisfaction with the cleanliness, comfort with wound cleansing, and overall satisfaction; and a generic health-related quality of life measure, SF12 (Lam, 2001; Lam et al., 2005).

A list of cost measurements for the wound cleansing was captured. The duration of the wound dressing performed in each visit, amount of follow-up and amount of dressings, solution and equipment used in cleansing were documented. Patient had a card on which the amount of solution and the amount of dressings required for cleansing were recorded when they attended the appointment for wound assessment in other hospitals.

2.7. Sample size

Previous studies have shown 40% (π_1) normal saline irrigation-cleansed wounds in community health centres healed completely within the 6-week period. In order to have 90% power, with a two-side 5% level test, to detect a 20% (δ) π_2 improvement in the healing of wound in the irrigation device arm as compared to the control practice arm (i.e., an increase to 60% (π_2) wounds healed within 6 week), we needed about 97 patients in each arm. The formula was as follow:

$$N = \frac{\{Z_{1-\alpha/2}\sqrt{2\bar{\pi}(1-\bar{\pi})} + Z_{1-\beta}\sqrt{\pi_1(1-\pi_1)+\pi_2(1-\pi_2)}\}^2}{\delta^2}$$

where$\bar{\pi} = (\pi_1 + \pi_2)/2$

Considering about 25% of patients loss to follow-up or withdrawn from this trial, the sample size was inflated to 122 patients in each arm.

2.8. Statistical analysis

All the main primary and secondary outcome measures, except patient satisfaction and health-related quality of life, were analysed on the basis of intention-to-treat (ITT) principle. In view of the gradually improving nature of these outcome measures, missing outcome data, except time-to-wound healing, were imputed using last observation carried forward approach, where more conservative efficacy results would generally be obtained. In the survival analysis of time-to-wound healing, the dropped-out cases owing to adverse events were considered as having unfavourable outcome (incomplete wound healing) throughout the study period (6 weeks) if they have not reached the endpoint before the occurrence of adverse events. All other dropped-out (lost to follow-up) patients were considered as censored cases in the survival analysis.

Time-to-wound healing was estimated by Kaplan–Meier method and compared between pressurised irrigation and swabbing using log rank test. Furthermore, Cox proportional hazards model was used to estimate the hazard ratios of the irrigation group versus swabbing group on time to wound healing with and without adjustment for covariates, including initial wound size, receiving antimicrobial treatment at the baseline and leg ulcer wound. These covariates are supposed to affect the progress of wound healing. Proportion of wounds completely healed and infection rate during follow-up as well as patient perceived wound symptoms at study completion were compared between the two arms using Pearson chi-square test or Fisher's exact test, as appropriate. Reduction of wound area and percentage of reduction were both assessed using Mann–Whitney test. Patient satisfaction and health-related quality of life scores were compared between the two arms in the per-protocol population using Mann–Whitney test and independent t-test respectively.

Since it is difficult to make justifiable imputations to the dropped-out cases, particularly, for cost data, cost-effectiveness analysis of wound healing with pressurised irrigation in comparison with swabbing was therefore performed in per-protocol population only. Total direct medical cost of wound dressing per patient was estimated for each treatment method by arithmetic mean (Thompson and Barber, 2000). Mean time-to-wound healing estimated by the approach of Efron (Efron, 1967) was adopted as the effectiveness measure. Biased-corrected and accelerated bootstrapping with 5000 replications (Efron, 1987) was used to estimate confidence intervals of mean difference in the medical cost and time-to-wound healing between the two arms. Mean cost difference between the two arms (pressurised irrigation – swabbing) and mean difference in time-to-wound healing between arms (swabbing – pressurised irrigation) were calculated to represent, respectively, the incremental cost and incremental effect of the pressurised irrigation over swabbing. The bootstrapped 5000 pairs of incremental cost and effect data were plotted on a cost-effectiveness plane to graphically illustrate their uncertainties. Cost-effectiveness acceptance curve (Fenwick et al., 2004) was generated to demonstrate the probability of cost-effectiveness of pressurised irrigation over swabbing at different thresholds for willingness-to-pay for saving one day to complete wound healing.

The bootstrapping was performed using Matlab 7.0 (The Mathworks, Inc). All other statistical analyses were done using SPSS 20.0 (SPSS Inc., Chicago, IL). All statistical tests were two-sided and a p value <0.05 was considered statistically significant.

3. Results

Between April 2008 and August 2010, we screened 502 patients and randomly assigned 256 patients to have wound cleansed by the pressurised irrigation (122 patients) or the swabbing (134 patients). 45 eligible patients were not enrolled due to twice suspension of study, caused by emergence of the human swine influenza case in HK between May 2009 and July 2009; and implementation of vaccine programme in GOPCs between October 2009 and February 2010. 39 (15.2%) of 256 patients included in the analysis could not complete this trial, because 30 patients (15 patients in pressurised irrigation and 15 patients in swabbing) were lost to follow-up mainly owing to majority being male who defaulted visit and rushed to back to work before wounds healed; and adverse events occurred in 9 patients (Fig. 1).

The wounds that have been recruited were all by secondary healing, including trauma wound, i.e. laceration/abrasion, burns/scalds, dehisced surgical wound, leg ulcer, dog bite, etc. Trauma wound accounted for nearly one third (30.1%) of the wounds, followed by burns/scalds (17.6%) and dehisced surgical wounds (17.2%). The most common anatomical regions of wound were lower extremity, followed by upper extremity, trunk and head or neck.

Baseline demographic and clinical characteristics in the two study groups were well balanced except for a slightly more female in the pressurised irrigation group (Table 1). A higher proportion of patients in swabbing group (5.9% vs. 0.8% in pressurised irrigation group) developed adverse events thus requiring change of wound treatment that all of them were not deemed directly related to the used cleansing technique (Table 2).

Table 1
Baseline characteristics of the study subjects by randomisation group.

	Cleansing by swabbing group ($n = 134$)	Cleansing by irrigation group ($n = 122$)
Age (years)†	47.1 ± 17.1	47.9 ± 18.2
Gender		
Male	99 (73.9%)	76 (62.3%)
Female	35 (26.1%)	46 (37.7%)
Education level		
Primary or below	50 (37.3%)	48 (39.3%)
Secondary	70 (52.2%)	64 (52.5%)
Tertiary or above	14 (10.5%)	10 (8.2%)
Employment		
Employed full-time	58 (43.3%)	58 (47.5%)
Retired	36 (26.9%)	26 (21.3%)
Other	40 (29.8%)	38 (31.2%)
Body mass index (kg/m^2)†	23.8 ± 4.2	23.7 ± 3.7
Know chronic diseases		
No	91 (67.9%)	89 (73.6%)
Yes	43 (32.1%)	32 (26.4%)
Smoking status		
Non-smoker	80 (65.0%)	69 (61.6%)
Ex-smoker	22 (17.9%)	19 (17.0%)
Current smoker	21 (17.1%)	24 (21.4%)
Initial wound size (cm^2)ψ	2.0 (0.8–9.5)	1.7 (0.6–6.6)
Wound duration from onset to study inclusion (days)ψ	6 (3–14)	5 (3–9)
Overall wound status score†	28.1 ± 3.8	27.4 ± 3.6
Wound types		
Trauma wound	36 (26.9%)	41 (33.6%)
Burns/scalds	25 (18.7%)	20 (16.4%)
Dehisced surgical wound	21 (15.7%)	23 (18.9%)
Leg ulcer	10 (7.5%)	2 (1.6%)
Dog bite	6 (4.5%)	4 (3.3%)
Other	36 (26.9%)	32 (26.2%)
Wound anatomical region		
Upper extremity	52 (38.8%)	54 (44.3%)
Lower extremity	61 (45.5%)	57 (46.7%)
Trunk	16 (11.9%)	8 (6.6%)
Head/neck	5 (3.7%)	3 (2.5%)
Delayed healing due to bacteria		
No	133 (99.3%)	122 (100.0)%
Yes	1 (0.7%)	0
Wound with risk of infection		
No	132 (98.5%)	120 (98.4%)
Yes	2 (1.5%)	2 (1.6%)
Discolouration of granulation tissue		
No	133 (99.3%)	122 (100.0%)
Yes	1 (0.7%)	0
Foul odour		
No	134 (100.0%)	122 (100.0%)
Yes	0	0
Infection in wound receiving antimicrobial treatment		
No	97 (72.4%)	98 (80.3%)
Yes	37 (27.6%)	24 (19.7%)

Data marked with '†' are presented as mean ± standard deviation and with 'ψ' as median (inter-quartile range), all others are presented as frequencies (%).

3.1. Primary outcomes

Kaplan–Meier estimates of median time-to-wound healing was 9.0 days (95% CI: 7.4–10.6 days) in the pressurised irrigation group and 12.0 days (95% CI: 10.2–13.8 days) in the swabbing group ($p = 0.007$, log rank test) (Fig. 2 and Table 3a). Based on Cox proportional hazards

Table 2
Adverse events during the study period.

	Cleansing by swabbing group (n = 134)	Cleansing by irrigation group (n = 122)
Changed to antiseptic solution for cleansing after consultation with podiatrist or wound specialist nurse	2 (1.5%)	1 (0.8%)
Wound complicated by tunnelling requiring admission and expert consultation	2 (1.5%)	0
Wound changed to cleansing by irrigation after other clinicians' review	2 (1.5%)	0
Changed to surgical intervention and incision and drainage of wound after consulting General Practitioner or physician	2 (1.5%)	0
Total	8 (6.0%)	1 (0.8%)

Data are presented as frequencies (%).
No patient had more than one adverse event.

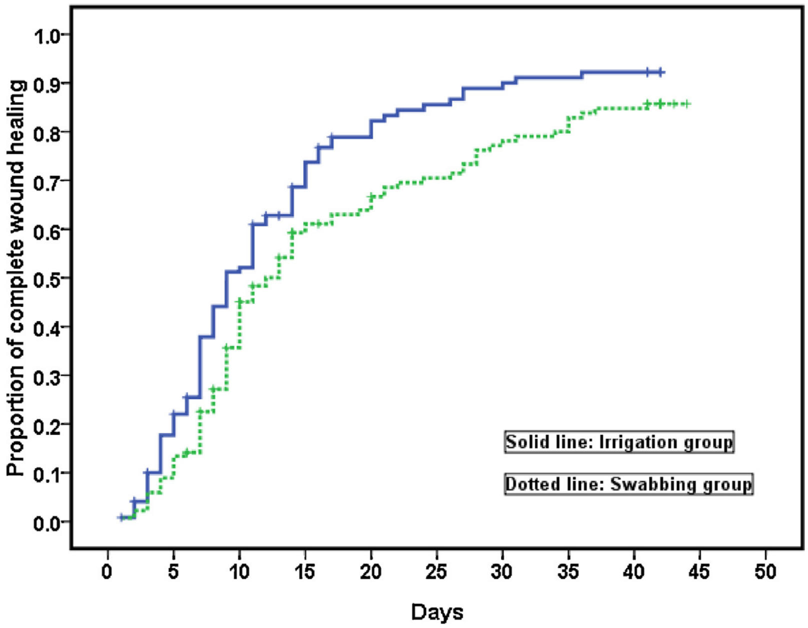

Fig. 2. Proportion of patients with their wound healed across time in ITT population.

model, the unadjusted hazard ratio (HR) of irrigation group versus swabbing group on time-to-wound healing was 1.44 [95% confidence interval (CI): 1.09–1.89; p = 0.010]. Using hierarchical Cox regression modelling, the adjusted HRs (95% CIs) of irrigation group versus swabbing group on time-to-wound healing were, respectively, 1.43 (1.09–1.89), p = 0.011; 1.35 (1.02–1.79), p = 0.034; 1.29 (0.97–1.70), p = 0.077, with adjustment for successively adding covariates (1) initial wound size, (2) receiving antimicrobial treatment (yes/no) and (3) leg ulcer wound (yes/no) into the model (Table 3b). Regarding the other primary outcome, there was no significant difference found in proportion of wounds completely healed after 6 weeks between the two groups (Table 3a).

Table 3a
Wound healing outcomes in ITT population.

	Cleansing by swabbing group (n = 134)	Cleansing by irrigation group (n = 122)	p value
Proportion of wound completely healed	78.4%	82.0%	0.470[a]
Time to complete wound healing (days)[d,ψ]	12.0 (10.2–13.8)	9.0 (7.4–10.6)	0.007[b]
Reduction of wound area (cm^2)[ψ]	1.4 (0.3–6.9)	1.3 (0.3–6.3)	0.701[c]
Percentage of wound area reduction (%)[ψ]	100.0 (100.0–100.0)	100.0 (100.0–100.0)	0.225[c]
Infection rate during follow-up	5.2%	3.3%	0.443[a]

Variables marked with 'ψ' are presented as median (inter-quartile range), all others unless specified are presented as percentage.
[a] Pearson chi-square test.
[b] Log rank test.
[c] Mann–Whitney test.
[d] Estimated median time for completely wound healing and its 95% confidence interval by Kaplan–Meier method.

Table 3b
Hazard ratios of the irrigation group versus swabbing group on time-to-wound healing.

	Time-to-wound healing	
	Hazard ratio (95% CI)	*p*
Unadjusted model[a]		
Group		
Swabbing (ref)	1	
Irrigation	1.44 (1.09–1.89)	0.010
Adjusted model 1		
Group		
Swabbing (ref)	1	
Irrigation	1.43 (1.09–1.89)	0.011
Initial wound size (log-transformed)	0.95 (0.87–1.03)	0.188
Adjusted model 2		
Group		
Swabbing (ref)	1	
Irrigation	1.35 (1.02–1.79)	0.034
Initial wound size (log-transformed)	0.95 (0.87–1.03)	0.183
Receiving antimicrobial treatment		
No (ref)	1	
Yes	0.61 (0.44–0.86)	0.005
Adjusted model 3		
Group		
Swabbing (ref)	1	
Irrigation	1.29 (0.97–1.70)	0.077
Initial wound size (log-transformed)	0.95 (0.87–1.03)	0.199
Receiving receiving antimicrobial treatment		
No (ref)	1	
Yes	0.72 (0.51–1.02)	0.065
Leg ulcer wound		
No (ref)	1	
Yes	0.38 (0.16–0.89)	0.027

ref: reference group.
[a] Unadjusted Cox regression model.
Adjusted model 1: Cox regression model with adjustment for initial wound size (log-transformed to correct its skewness).
Adjusted model 2: Cox regression model with adjustment for the covariate in adjusted model 1 + receiving antimicrobial treatment (yes/no).
Adjusted model 3: Cox regression model with adjustment for the covariates in adjusted model 2 + leg ulcer wound (yes/no).

3.2. Secondary outcomes

The proportion of wounds to heal completely before the end of the 6-week study period was 82% in the pressurised irrigation group and 78.4% in the swabbing group, however difference was not statistically significant. Majority of wounds decreased in size over the study period. The reduction in wound size did not differ significantly between groups (Table 3a). An increase in the size of a wound that dermatitis happened on the skin around the wound was noted in the control group, which was then improved after steroidal treatment started. The overall wound infection rate during follow up was 3.7%. Incidence of wound infection up to 6 weeks after randomisation did not differ significantly between groups (Table 3a).

Lower grade of pain experienced during wound cleansing was more frequent in the pressurised irrigation group than in the swabbing group (93.4% vs. 84.2%; $p = 0.02$), but the level it interfere less with patients' life was similar (95.1% vs. 91.0%; $p = 0.201$). Other adverse symptoms (pain on wound; fluid leaking from wound cleansing; wound bleeding; wound smell; itchiness on wound or surrounding skin) at any grade and the level they interfere with patients' life correspondingly were not different between groups (Table 4).

Patients allocated to pressurised irrigation had significantly higher satisfaction with comfort after wound cleansing and wound cleansing method than did patients allocated to swabbing, but the satisfaction with cleanliness after wound cleansing did not differ between groups (Table 5). Patient generic health-related quality of life did not differ between groups during follow-up (Table 5).

3.3. Cost analysis

In the 6-week follow-up period, mean total direct medical cost per patient in swabbing and pressurised irrigation groups were respectively HK$ 354 (SD 882) and HK$ 244 (SD 283) in per-protocol population (Table 6). The total direct medical cost did not differ between groups based on the bootstrapped 95% confidence interval. The cost of cleansing wound with pressurised irrigation saved per patient was HK$ 110 (95% confidence interval: HK$ −33 to 308) compared to the swabbing. The mean time-to-wound healing in the swabbing and pressurised irrigation groups were respectively 14.5 and 11.4 days. On average, cleansing wound with pressurised irrigation could save 3.1 days (95% confidence interval: 0.3–5.9 days) to complete wound healing when compared to swabbing. The cost-effectiveness plane (Fig. 3) displays the distributions of the incremental cost and effect data of the bootstrapped results with 5000 replications. The majority (90%) of the bootstrapped cost-effectiveness pairs were located in the south-east quadrant, indicating that the pressurised irrigation was dominantly more effective and less expensive than the swabbing method. The cost-effectiveness acceptability curve (Fig. 4) shows the probability of cost-effectiveness of the pressurised irrigation in comparison with swabbing versus the ceiling amount of willingness-to-pay for saving one day to complete wound healing. The probabilities of cost-effectiveness of the pressurised irrigation in comparison with swabbing were 90%, 95% and 98% at willingness-to-pay an extra of HK$ 0, 8 and 28 respectively per patient per one day saved to complete wound healing.

4. Discussion

4.1. Uniqueness of the study

This paper is the first reported randomised controlled trial comparing swabbing and pressurised irrigation as techniques for cleansing wound, which has shown pressurised irrigation applied to wounds healed by secondary intention, is safe, and more cost-effective in shortening the healing time of wound. However, it is worth noting that the hazard ratio of pressurised irrigation group against swabbing group on wound healing became only borderline significant [HR = 1.29 (95% CI: 0.94–1.70), $p = 0.077$] after adjusting for initial wound size, receiving

Table 4
Patient perceived wound symptoms at study completion in ITT population.

	Cleansing by swabbing group ($n = 134$)	Cleansing by irrigation group ($n = 122$)	p value
Wound symptom			
Pain over wound			
No/mild	80.6%	81.1%	0.911[a]
Moderate/severe/very severe	19.4%	18.9%	
Pain during wound cleansing			
No/mild	84.2%	93.4%	0.020[a]
Moderate/severe/very severe	15.8%	6.6%	
Fluid leaking from wound cleansing			
No/mild	85.1%	86.1%	0.822[a]
Moderate/severe/very severe	14.9%	13.9%	
Wound bleeding			
No/mild	96.3%	97.5%	0.725[b]
Moderate/severe/very severe	3.7%	2.5%	
Wound smell			
No/mild	99.3%	99.2%	0.999[b]
Moderate/severe/very severe	0.7%	0.8%	
Itchiness over wound or surrounding skin			
No/mild	79.9%	73.8%	0.249[a]
Moderate/severe/very severe	20.1%	26.2%	
Life interfered by wound symptom			
Pain over wound			
Not at all/a little bit	82.8%	78.7%	0.400[a]
Somewhat/quite a lot/very much	17.2%	21.3%	
Pain during wound cleansing			
Not at all/a little bit	91.0%	95.1%	0.201[a]
Somewhat/quite a lot/very much	9.0%	4.9%	
Fluid leaking from wound cleansing			
Not at all/a little bit	95.5%	95.1%	0.868[a]
Somewhat/quite a lot/very much	4.5%	4.9%	
Wound bleeding			
Not at all/a little bit	98.5%	97.5%	0.671[b]
Somewhat/quite a lot/very much	1.5%	2.5%	
Wound smell			
Not at all/a little bit	100.0%	99.2%	0.477[b]
Somewhat/quite a lot/very much	0.0%	0.8%	
Itchiness over wound or surrounding skin			
Not at all/a little bit	93.3%	91.8%	0.652[a]
Somewhat/quite a lot/very much	6.7%	8.2%	

Variables are presented as percentage.
[a] Pearson chi-square test.
[b] Fisher's exact test.

Table 5
Patient satisfaction and health-related quality of life scores (SF-12) at study completion in per-protocol population.

	Cleansing by swabbing group ($n = 111$)	Cleansing by irrigation group ($n = 106$)	p value[a]
Patient satisfaction			
Overall patient satisfaction with wound cleansing method	5 (5–6)	6 (5–6)	0.161[a]
Patient satisfaction with comfort after wound cleansing	5 (5–6)	6 (5–6)	0.002[a]
Overall patient satisfaction with wound cleansing method	5 (5–5)	6 (5–6)	<0.001[a]
SF-12 subscale scores			
Physical functioning	67.3 ± 25.2	65.1 ± 28.6	0.539[b]
Role physical	22.1 ± 40.8	23.6 ± 42.1	0.788[b]
Bodily pain	57.2 ± 30.4	59.2 ± 28.3	0.619[b]
General health	50.0 ± 28.0	47.8 ± 26.9	0.553[b]
Vitality	70.3 ± 28.0	69.4 ± 28.6	0.828[b]
Social functioning	74.5 ± 34.0	71.9 ± 36.3	0.584[b]
Role emotional	64.9 ± 40.8	62.7 ± 42.6	0.707[b]
Mental health	72.8 ± 25.1	71.9 ± 23.7	0.785[b]

All the patient satisfaction items were rated by 6-point Likert scale (from 1 = very dissatisfactory to 6 = very satisfactory) and presented as median (interquartile range).
The SF-12 subscale scores are presented as mean ± standard deviation.
[a] Mann–Whitney test.
[b] Independent samples t-test.

Table 6
Cost-effectiveness of time to complete wound healing with pressurised irrigation method compared with swabbing method per-protocol population.

	Cleansing by swabbing group ($n=111$)	Cleansing by irrigation group ($n=106$)	Mean difference (95% CI)
Cost for sterile dressing set (with forceps) HK$ [1]	27.2 ± 28.9	21.8 ± 24.7	
Cost for sterile gauze HK$ [2]	0.30 ± 1.17	0.53 ± 0.94	
Cost for sterile cotton wool ball HK$ [3]	0.22 ± 1.00	0.00 ± 0.04	
Cost for normal saline HK$ [4]	0.99 ± 1.16	1.10 ± 1.09	
Basic cost for wound cleansing materials HK$ [1 + 2 + 3 + 4]	28.7 ± 30.6	23.4 ± 25.6	
Cost for dressing fixation materials HK$ [5]	126.2 ± 716.8	37.4 ± 150.8	
Cost for supplementary dressing materials HK$ [6]	153.0 ± 764.7	53.5 ± 158.1	
Nursing time spent in dressing (minutes)	59.4 ± 73.7	57.5 ± 60.1	
Cost for nurse labour HK$ [7][a]	172.1 ± 213.7	166.7 ± 174.4	
Total cost: materials + labour HK$ [1 + 2 + 3 + 4 + 5 + 6 + 7]	353.8 ± 882.0	243.7 ± 283.2	110.1 (−32.8 to 308.3)[b]
Mean time to complete wound healing (days)[c]	14.5 (1.1)	11.4 (1.0)	3.1 (0.3–5.9)[b]

Data are presented as mean ± standard deviation or mean (standard error).
[a] Nursing time spent in dressing × HK$2.9 (HK$2.9 = nurse cost in 1 min for an average salary of HK$30,604 with reference to HGPS Point 15–25—HK$23,460 to HK$37,748 per month).
[b] The 95% confidence intervals were estimated using bootstrap method.
[c] Mean (standard error) time to complete wound healing was estimated by the approach of Efron (1967).

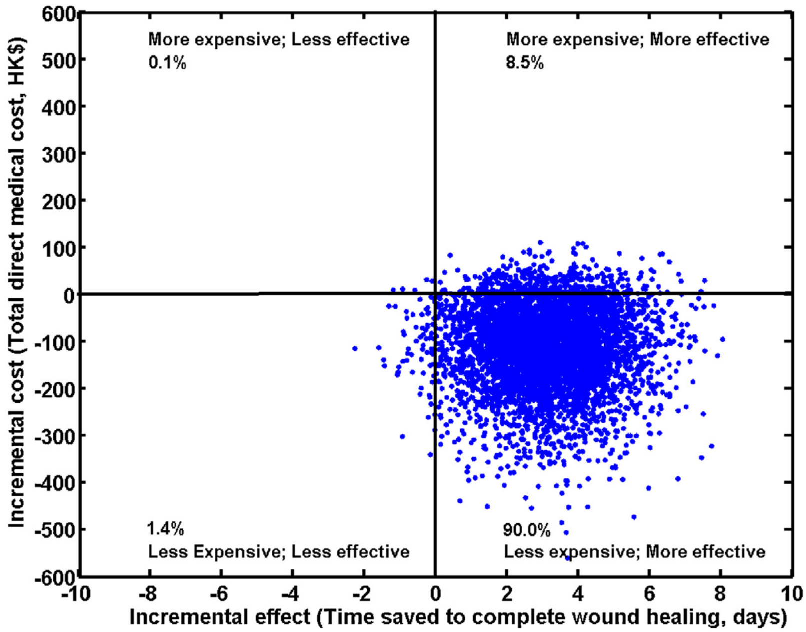

Fig. 3. Cost-effectiveness plane of time to complete wound healing with pressurised irrigation method compared with swabbing method in per-protocol population.

antimicrobial treatment or not and leg ulcer wound or not. In fact, the study sample consisted predominantly of acute wounds and a relatively higher proportion of participants in swabbing group with chronic leg ulcer than in the irrigation group (7.5% vs. 1.6%) might explain the lost in significance in the adjusted analysis. Future research and trials are recommended to replicate the study particularly in chronic wound populations. Nevertheless, patient presented less pain during wound cleansing over the course of treatment; and reported higher satisfaction with comfort after wound cleansing and with cleansing method. There was no clinically important difference in the variation of wound infection rates between two groups.

The results agree with narrative review about benefits of irrigation namely promoting wound healing and patient comfort (Oliver, 1997); and shortcoming of swabbing that extra pressure applied on to the wound has repeatedly been shown to have deleterious effects on tissue and thus the healing of wounds (Miller and Glover, 1999; Oliver, 1997). This result echoes with that of the Ho's trial (Ho et al., 2012), which demonstrated a statistically significant reduction in volume of pressure ulcer cleansed with

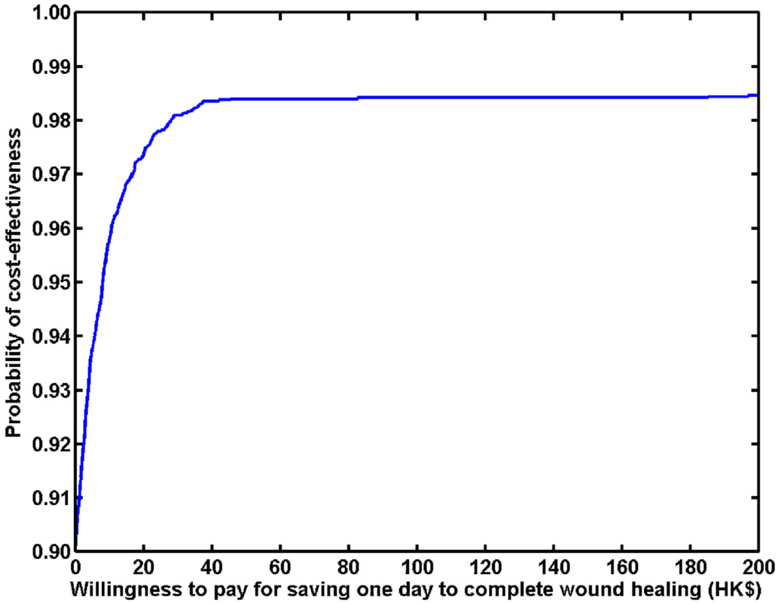

Fig. 4. Cost-effectiveness acceptability curve for comparison between pressurised irrigation method and swabbing method in per-protocol population.

pulsatile lavage at 11 psi of pressure compared with those cleansed using sham pulsatile lavage. However, Ho's trial was a small study and these between group differences did need to be confirmed in a larger study.

Presence of pathogens in a wound microbiological culture is not, in itself, indicative of clinical infection (Cutting and Harding, 1994), which would not enhance methodology or inform the results. We therefore used a primary patient-assessed wound infection signs and symptoms backed by physician action of antibiotic prescription. This analysis was designed to reflect usual clinical care and experience, with less bias to capture relevant events. 23.8% of patients were assessed to have wound infection requiring antibiotics treatment at entry of study, suggesting a higher initial infection rates in our sample due to all recruited wounds healing by secondary intention that a large number of pathogenic flora usually colonise there (Miller, 1996). Majority of the wounds had infection resolved then and overall wound infection rate fell to 3.7% during follow up. Griffiths et al. (2001) reported higher wound infection rates of 6.1% in patients followed up in community health centres; however, it compared the effects of irrigation by tap water and normal saline, and the sample size was small. Moscati et al. (2007) reported similar wound infection rates of 3.65% in patients with acute lacerations treated in emergency departments; however, it compared tap water versus sterile saline for wound irrigation.

The pressure used for irrigation has repeatedly been shown to be an important variable in the infection rates of wounds. The pressurised irrigation device (Fig. 5) modified from the already long available but decreasingly used equipment in Hospital Authority hospitals, was able to generate steady irrigation stream at pressure from 4 to 15 psi which was purposively to be tested in this study. The glass bottle and stainless steel nozzle were reusable between patients, and they were cleansed and autoclaved after use every 24 h. Although samples of saline from the reusable glass bottle and stainless steel nozzle were not subjected to laboratory analysis to determine if there was contamination, our results did not demonstrate significantly increased infection rates in cleansing wound using the self-modified irrigation device for irrigation.

Most notably, nine adverse events were reported, eight from the swabbing arm. Three of them developed wound complication such as tunnelling and abscess requiring further surgical intervention. Two patients were prescribed to change to irrigation method during hospitalisation and doctor consultation and three were prescribed with betadine solution for wound cleansing. Need for change of treatment did imply the wounds were difficult to heal. It is possible that some wound infection may have occurred in the group. Removal of them from the analysis might contribute to underestimate the infection rate in swabbing group.

4.2. Strengths and limitations

Our trial is the first with randomised controlled trial design to compare the pressurised irrigation and swabbing. It was designed to minimise confounding factors that could influence outcomes and test the wounds to be healed by secondary intention despite acute or chronic. Our results from a larger sample size and multi-centre comparison of wound cleansing technique should be more generalisable. Although recruited numbers of participants varied in the four GOPCs due to the environmental factors when the trial conducted, the proportion of recruited patients between groups was similar in each centre. The bias in outcome assessment has been minimised by having assessor who was different from the operator undertaking dressing change in this study, and instructing the trial staff

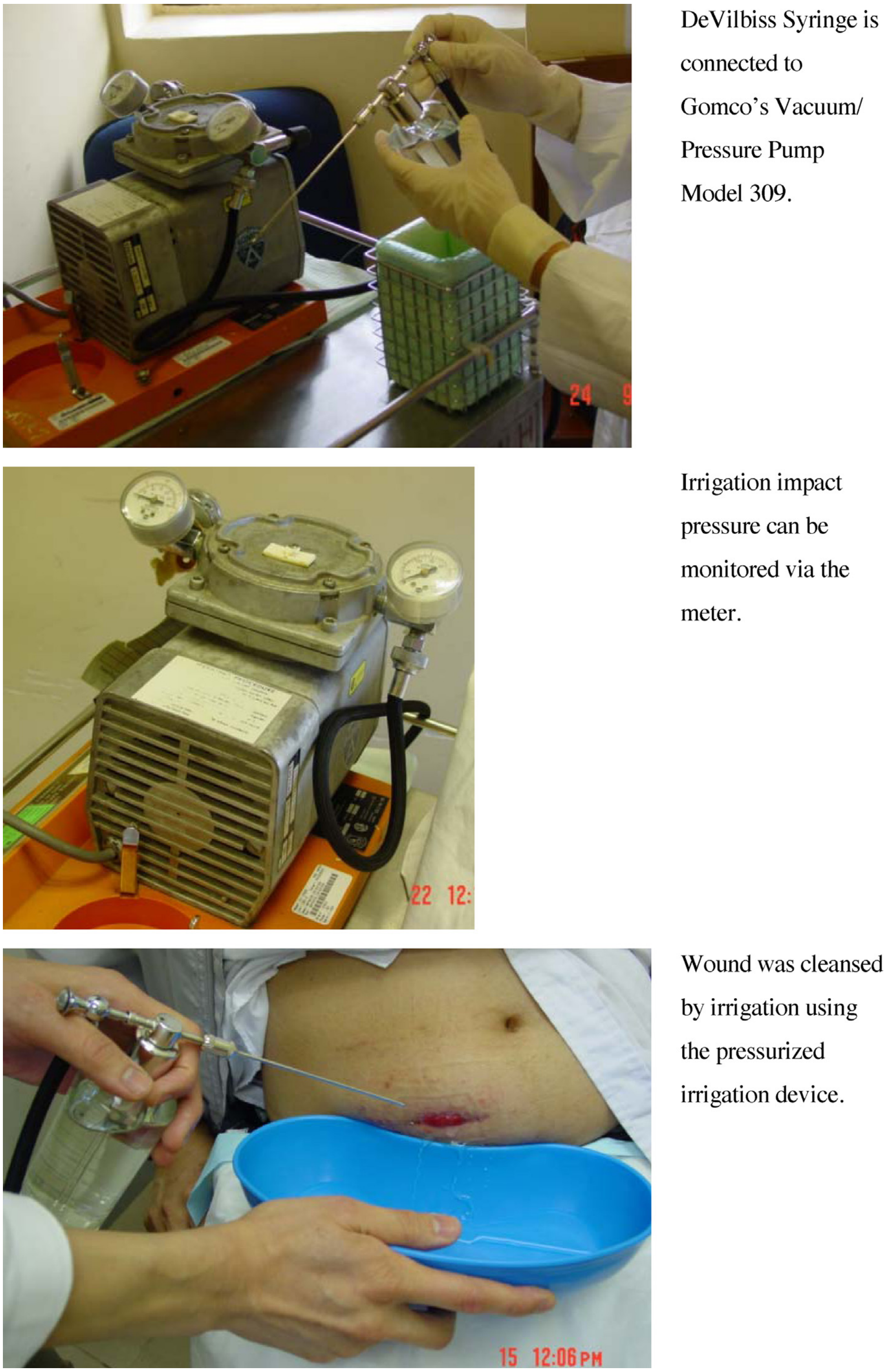

Fig. 5. Self-modified pressurised irrigation device.

who performed assessment not to ask about the method of cleansing during patient follow-up visit. The pragmatic design of our trial, sufficiently powered sample size, and use of primary outcomes combining perspectives from patients and cost expense on the wound cleansing technique, provide clear evidence for the cost-effectiveness of pressurised irrigation in shortening the healing time of wound that heals by secondary intention and superior patient tolerance compared with swabbing.

The trial has some limitations: moderate compliance in returning back for assessment (24 (80%) of 30 patients lost to follow-up were male in working age); no masking of patients; imperfect masking of the assessors (because of some patients talking their allocated treatment to assessors, which could bias detection of our primary outcome); no masking of operators (which might bias their use of background treatment); unpredictable trial suspension in a short notice affecting recruitment in a few of GOPCs; and our data contain a lower proportion of chronic type of wounds. Although the trial protocol did not intentionally select for certain wound types, recruitment of a higher proportion of acute wound (trauma wound, burns/scalds and dehisced surgical wound) was probably attributable to region demographic characteristics that there was large population performing labour work and thus more vulnerable to injury such as cuts or scald. This might bias the estimate of the effect of pressurised irrigation. Other potential limitation included imbalance in the background use of wound dressing materials but we deem this is unlikely to have introduced bias or altered the external validity of the results.

4.3. Implications and explanations of findings

We noted the basic cost of wound cleansing materials per patient was less for wounds allocated to pressurised irrigation than wounds allocated swabbing. While the average dressing materials (dressing fixation materials, supplementary dressing materials) and labour cost per patient were also lower for pressurised irrigation. All of these contribute to a lower total direct medical cost in the pressurised irrigation group. It was however a great variance in the total direct cost for swabbing was reported. This may be attributable to variations in costs especially for supplementary dressing materials among the sub-populations with different wound types. Costs are considerably higher for chronic wounds than acute wounds, which may therefore create great variability of central tendency in the costing analysis. This indicated we would need more subjects with wounds taking longer to heal, i.e. chronic wound for sufficient power to detect difference in outcomes between groups. Considering the widespread use of swabbing for wound cleansing in the community, more large high quality randomised controlled trials of the wound cleansing techniques are warranted.

Pressurised irrigation may also have advantage of potential cost saving at indirect cost over conventional swabbing technique, although the effect is difficult to analyse fully. The dressing packs used extensively in swabbing, however, generates unnecessary waste from the disposal of unused items—swab, gauze and wrappings; and items that have reusable alternatives—forceps or tray. Landfill space is so scarce in HK where the three existing landfills are full in the mid to late 2010s (GovHK, 2013). As a result, landfill disposal fees are increasing per year. These financial and environmental liabilities of waste disposal make reducing the quantity of non-hazardous waste imperative. The self-modified pressurised irrigation device tested in this trial will represent a prototype model to demonstrate how effective wound irrigation can be performed without using sterile dressing pack. The hospital pays $4.5 for each dressing pack. Specific substitutions in the dressing packs may yield a net cost savings which is albeit seemingly low. The difference is huge when applied to over 1 million wounds treated in all cross-cluster GOPCs each year as well as counting expensive fee of landfill, furthermore adding to the additional total direct medical cost in wound dressing change (HK$ 110 more in the swabbing group). There is a need to further analyse the indirect cost between the cleansing methods.

5. Conclusions

This study suggests that wound cleansed by pressurised irrigation method is more cost-effective in shortening the healing time of wound that heals by secondary intention; moreover, pressurised irrigation is highly well tolerated by patient presenting less pain during wound cleansing, and higher satisfaction with comfort and the cleansing method. Importantly, pressurised irrigation is not associated with an excess of major adverse events and wound infection, reassuring about its safety in the community population with a variety types of wounds.

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Conflict of interest: The authors declare that there is no conflict of interest.

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