A Prospective Randomized Controlled Trial Comparing Infection Rates of the Daily Dressing and Scheduled Dressing of Sutured Traumatic Wounds

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ABSTRACT

Objective: To evaluate outcome differences between DD and SD in 1) wound infection rates, 2) patients' satisfaction according to the wound care and cost of treatment.

Methods: A single-center, prospective randomized controlled trial of 350 traumatic-wound patients was conducted. Only adult traumatic wounds without a fracture, tendon injury and neurovascular injury were included. The patients were randomized into two groups: daily dressing (DD) and scheduled dressing (SD) groups. DD group patients received daily wound dressing changes, while those in SD group typically had dressing changed on days 3, 7 and one other scheduled day. Analyzed data included patients' demographics, clinical parameters, patient's satisfaction according to wound treatment and cost.

Results: Total wound infection rate was 1.2%. Although the incidence of wound infection in the SD group was lower than that of the DD group (0% vs 2.4%), statistically it was not significant (p=0.06). Patients' satisfaction level was also not significantly different between the two groups.

Conclusion: The study showed clinical non-inferiority of SD compared to DD while offering saving benefits both in time and cost. Therefore, SD can be substituted for DD for traumatic wound care after primary repair.

Keywords: Traumatic wound infection; scheduled dressing; daily dressing (Siriraj Med J 2018;70: 377-381)

INTRODUCTION

Traumatic wounds are defined as cuts, lacerations or puncture wounds that inflict damage to the skin and underlying tissues.[1] All traumatic wounds are considered to be contaminated upon presentation at an emergency department. They are generally sutured after wound irrigation and debridement. The risk of wound infection depends on the type and location of the wound, and the patient's clinical conditions.[2] Traditionally, a patient with sutured wound is required to come for wound dressing change every day until the stitches are removed. This daily dressing is commonly assumed to be better than the alternative non-daily dressing change because, firstly, the physicians or nurses can more regularly evaluate the wound for infection and, secondly, daily dressing change is believed to keep the wound cleaner. However, this wound care strategy not only leads to higher expenses, but also costs both patient's and medical personnel's time. Our study was designed to test the hypothesis that the scheduled non-daily dressing change is not inferior to daily dressing change scheme.

MATERIALS AND METHODS

We conducted a single-center, prospective, randomized controlled study between February 2009 and June 2016. All adult patients (≥20 years old) with traumatic wounds, defined by wound depth as encompassing the skin and subcutaneous layer, were included. Sites of the wound

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were face, head, neck, body and extremities. Excluded were patients who required surgery or admission, or those with bone fracture, tendon injury or neurovascular injury. Wound contamination was classified as 1) 'minor' if arrival time (T) to the hospital was less than 6 hours and happened in a clean environment or by a clean instrument, 2) 'moderate' – if T > 6 h, happened in a dirty environment or by a dirty instrument, or 3) 'heavy' – if T> 12 h and/or grossly contaminated and/or with foreign body present. Written informed consents were obtained from all participants.

A total of 350 patients were enrolled in the study. Block randomization, with randomly-selected block sizes of 2, 4 and 8, was generated by computer, and the patient assignments were delivered in sealed, opaque, sequentially-numbered envelopes. The patients were allocated equally (175 patients each) into 2: daily dressings (DD) and scheduled dressings (SD) groups. All wounds were routinely irrigated with normal saline solution, sutured under local anesthesia and sterilely dressed on the first day. In addition, all patients in both study groups were prescribed prophylactic oral antibiotics, usually cephalosporin. For cephalosporin-allergic patients, clindamycin was given instead.

Patients in DD group had their wound dressings changed every day by nurses while those in SD group only on the third and seventh days. However, if the stitches were to be removed before the seventh day, the third day dressing change would then be postponed to the day of suture removal. On the other hand, if the stitches were scheduled to be removed after the seventh day, then an additional dressing would be scheduled on that suture removal day (which could be either the tenth or the fourteenth day). This strategy reduced the outpatient visits for patients in the SD group to only 2, 3 or 4 times, depending on the site or condition of the wound, and the day of suture removal.

The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (Si 277/2009).

Objectives of the study

Primary endpoint – wound infection rate

Definition of infected wound

An "infected wound" was defined as a suture wound with inflammatory changes. These changes were further divided into major and minor categories. The major category consisted of 3 signs: fever (a temperature over 38 degrees Celsius), abscess, and lymphangitis, while the minor consisted of 5 signs: erythema, tenderness, swelling, purulent discharge, and leukocytosis. The diagnosis of infected wound was made when there were at least 1 out of 3 major signs or 4 out of 5 minor signs present.[3,4] A physician in the trauma outpatient unit assessed all wounds and made a determination. If an infected wound was detected, the stitches would be removed and a wet dressing applied daily until the infection cleared. Associated risk factors were recorded.

Secondary endpoints – patient's satisfaction level with the treatment cost and outcomes

After completion of the treatment, all patients were given a rating scale questionnaire, which comprised four questions: Was the cost of traveling appropriate? Was the charge for the wound dressing reasonable? Were you satisfied with the results of the wound dressing? and what was your impression of the overall treatment? Patients answered by marking one of the following simple responses: very satisfied, satisfied, not satisfied.

Sample size calculation and statistical analysis

Given that the purpose of the study was an equivalence trial, we performed a sample size calculation for non-inferiority. Based on an estimated incidence of wound infections of 7%, an equivalence limit of 5%, an alpha of 0.05 and 85% power, the sample size was determined to be 175 per group.

Descriptive statistics for the baseline demographic and clinical variables were reported. Data were analyzed according to the intention-to-treat principle. Differences in the infection rates and satisfaction levels were analyzed using a Chi-square test. All statistical analyses were performed using SPSS Statistics for Windows, version 18.0 (SPSS Inc., Chicago, Ill., USA).

RESULTS

Eighteen patients out of 350 were lost to follow-up, leaving 332 for analysis (Fig 1).

Patients' demographics and other clinical parameters are as shown in Table 1. Their ages ranged from 20 to 84 (Mean 39 years). The average wound size was 2.5 cm (2.53 ± 1.76). Distribution of wounds by body site between DD and SD group was similar (p=0.455), with face and upper extremities being the two most common sites. All patients were prescribed prophylactic antibiotics and had wound sutured under local anesthesia. The median arrival time to the hospital from injury was 30 minutes. The majority (>90%) of wounds in both groups were classified as "moderately" contaminated wounds.

There were 4 infected wounds in this study and all were (Table 2) female and 3 of those sustained injury

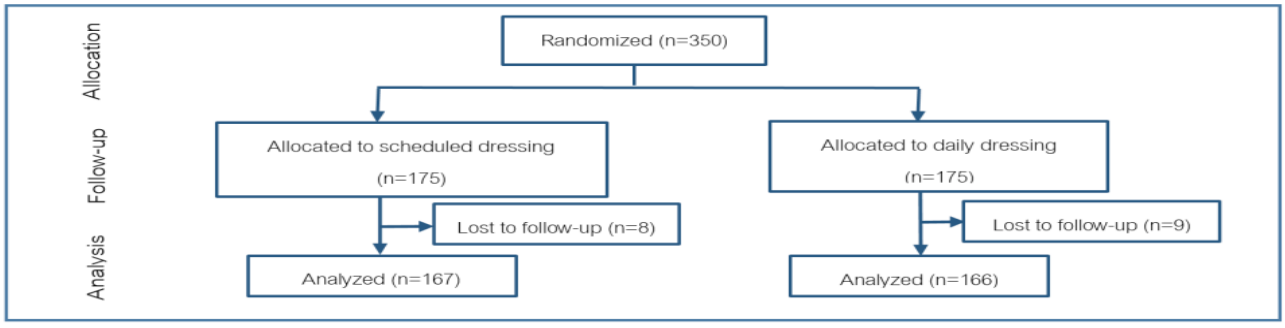

Fig 1. The flowchart showing the process of randomization.

TABLE 1. Patients' demographics and clinical parameters.

	Daily dressing (n=166)	Scheduled dressing (n=167)
Age (mean±SD)	38.26 ± 13.1	39.01 ± 16.3
Sex (male, %)	55.6%	50.9%
Antibiotics	100%	100%
Diabetes mellitus (%)	3.2%	3.4%
Mechanism of injury		
Penetrating wound	41.5%	34.1%
Crushed/blunt	58.5%	65.9%
Site of wound (n, %)		
Head	30 (18.1%)	36 (21.6%)
Face	57 (34.3%)	68 (40.7%)
Chest/abdomen	1 (0.6%)	0
Upper extremities	39 (23.5%)	36 (21.6%)
Lower extremities	39 (13.5%)	27 (16.2%)
Size of wound (cm, mean, SD)	2.78 ± 2.04	2.29 ± 1.39
Wound contamination		
Minor		
Moderate	1%	0%
Heavy	94.7%	95.5%
Debridement (n)	4.3%	4.5%
Local anesthesia	2	1
	100%	100%

to the foot. Two patients had a large-sized wound. All 4 infections occurred on or after post-repair day 2, with the latest one found on post-repair day 10.

Regarding risk factors, only wound size and location in the lower extremities were found to be significant factors associated with wound infection (Table 3).

Results of endpoints analysis are summarized in Table 4. There were 4 infected wounds out of 333 (1.2%). All 4 were found in wounds size larger than 2 cm in the lower extremities of patients in the DD group. In terms of the patients' perceptions, the majority of patients were "satisfied" to "very satisfied" both in the costs and the outcomes of the treatment. There was no significant difference between the groups.

TABLE 2. Characteristic of the patients who had wound infection.

Patient	Age (years)	Sex	Wound size (cm)	Wound site	Occupation	Underlying disease	Mechanism of injury	Day of infection
1	49	Female	15	Leg	Laborer	Obesity	Toilet seat injury	10
2	78	Female	12	Foot	Laborer	Allergic rhinitis	Fall	7
3	55	Female	3	Foot	Housewife	Bipolar disease	Fall	5
4	29	Female	3	Foot	Laborer	Thalassemia	Motorcycle accident	2

TABLE 3. Risk factors of wound infection.

	Non infection group	Infection group	P-value
Arrival time to hospital (min)	30	30	0.76
Wound size (cm)	2	7.5	0.012
Diabetes mellitus (%)	3.6%	0%	1.00
Heavy wound contamination	4.7%	0%	1.00
Crush/blunt injury (%)	61.5%	66.7%	1.00
Wound location: lower extremities (%)	19%	100%	0.015

TABLE 4. Summary of primary and secondary endpoints analysis.

	Daily dressing (n=166)	Scheduled dressing (n=167)	P-value
Wound infection (n, %)	4 (2.4%)	0	0.06
Wound infection in lower extremities wound (n, %)	4 (10.5%)	0	0.13
Wound infection in wound size > 2 cm (n, %)	4 (5.4%)	0	0.13
Wound infection in wound size > 2 cm and in lower extremities (n, %)	4 (23.5%)	0	0.13
Patient's perception (%)			
Traveling cost			
Very satisfied	73.4%	73.3%	0.31
Satisfied	24.7%	26.1%	
Not satisfied	1.9%	0.6%	
Dressing cost			
Very satisfied	9.4%	13.1%	0.24
Satisfied	89.3%	86.9%	
Not satisfied	1.3%	0%	
Wound care			
Very satisfied	91.2%	94.4%	0.29
Satisfied	8.8%	5.6%	
Not satisfied	0%	0%	
Overall Impression			
Very satisfied	92.5%	93.8%	0.66
Satisfied	7.5%	6.2%	
Not satisfied	0%	0%	

DISCUSSION

Traumatic wounds are classified as contaminated wounds that are associated with high risk of wound infection. Although the risk can be reduced by adequate wound cleansing and debridement, it is still significant in some groups of patients with certain risk factors. Quinn et al., reported a high 2.6% infection rate in their series of patients with traumatic lacerations. They identified diabetes, wound contamination, wound length greater than 5 cm and a location on the lower extremities as high risk factors.[2,5] For patients with such risk factors, prophylactic antibiotics are often recommended, especially for those with dirty wounds or wounds with signs of infection.[6,7] Taylor et al., routinely administered prophylactic antibiotics for patients with traumatic wounds undergoing suture repair and found it to be cost effective.[8]

Conventionally, patients are advised to keep their wound clean and dry by using a protective dressing for at least 24 hours after repair.[9] However, there has not been to date any evidence-based data to suggest the optimal frequency of the wound dressing change after suturing. Based on the incubation period, wound infection would generally be detected on day 3 post-repair.[10] Therefore, some physicians would schedule wound-dressing change on the third day and subsequent 2 to 3 days interval thereafter until stitches are eventually removed. However, most physicians in Thailand would still err on the cautious side and perform a wound-dressing change daily. To date, the frequency of wound dressing change remains a contentious and unsettled issue.

We conducted our study in an attempt to provide evidence, if there is any, of the difference in the infection rate between the two approaches to wound-dressing changes: DD vs SD. Although all 4-infection cases were found in the DD group and none form the SD group, there was no significant clinical-superiority of the SD statistically in lowering the infection rate. Regarding the patients' satisfaction with the wound treatment and the associated costs, there were no differences between the two study groups: patients in each group were satisfied with the wound dressing quality, and each perceived the costs as reasonable.

As for risk factors, we found wound size (>2 cm) and location of wounds (lower extremities) to be the only significant factors associated with wound infection. The lower-than-expected infection rates could be attributed to small-average wound size and the higher proportion of wounds on the face and upper extremities, which carry a lower risk of infection.

Although our study did not show significant superiority of SD compared to DD in lower wound infection rate, SD offers obvious economic advantages both in reducing treatment costs and time.

CONCLUSION

Our study demonstrated a lower incidence of wound infections among SD patients compared to those in DD group. Although it was not statistically significant, given that SD showed clinical non-inferiority to DD in preventing wound infection while being more cost-effective and time-efficient, it could be considered as a standard treatment for traumatic wounds.

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