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Advantages of Urgotul S.S.D over Silver Sulfadiazine Cream in the Outpatient Management of Partial Thickness Burns

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Abstract

Introduction: **Topical application of silver sulfadiazine has been used in the treatment of partial-thickness burns for many years. Pain during daily wound cleansing is the main problem. Urgotul SSD,™ a hydrocolloid dressing with silver sulfadiazine (SSD) has been reported to reduce infection and exhibit antimicrobial activity in burn wounds.**

Objectives: **The purpose of this study was to compare the efficacy of Urgotul SSD™ and 1% silver sulfadiazine for the treatment of partial thickness burn wounds.**

Materials and Methods: **We reviewed 70 patients who had partial thickness burn wound less than 15% total body surface area (TBSA%) and were treated at Siriraj out-patient burn clinic during July 2005-December 2006. All patients were divided into two groups: Urgotul SSD™ treated group (35 patients) and 1% silver sulfadiazine treated group (35 patients). Two patients were excluded; one was due to allergic reaction to silver sulfadiazine and another one in Urgotul SSD™ treated group was pregnant. The two groups were compared by the demographic data including age, gender, % total body surface area (TBSA) burn, % TBSA deep burn, as well as percent of wound infection, total cost of wound dressing, pain medication, level of pain and time of wound healing. There were no differences in demographic data of age, % TBSA burn, % wound infection and total treatment cost of burn wound care (US$ 52 ± 38 for Urgotul SSD™ versus US$ 45 ± 34 for silver sulfadiazine treated group).**

Results: **Time of wound closure was significantly shorter in Urgotul SSD™ treated group (10 ± 4 days in Urgotul SSD™ versus 12 ± 6 in 1% silver sulfadiazine treated group, $p < 0.05$). Average pain scores and pain medication in Urgotul™ treated group were significantly lower than in 1% silver sulfadiazine treated group (3 ± 1 versus 6 ± 2 respectively, $p < 0.05$). All of the patients who developed wound infection responded well to targeted topical and oral antibiotic treatment.**

Conclusions: **We conclude that Urgotul SSD™ has advantages of reducing pain symptom, pain medication requirement, increased patient convenience due to decreased time of follow-up at out-patient burn clinic, limiting the frequency of replacement of the dressing at comparable total cost and incidence of burn wound infection. This study confirms the efficacy of Urgotul SSD™ in the treatment of partial thickness burn wound at out-patient clinic.**

Key words: **Silver sulfadiazine, Urgotul SSD™, burn wound, wound infection**

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Introduction

Most burn injuries are minor and 80% to 90% of burn injuries can be treated on an out-patient basis.[1] It is traditional teaching and practice that silver sulfadiazine (SSD) is the agent of choice in the treatment of partial-thickness burn wounds at out-patient clinic.[2] Even though it is effective in the treatment of partial thickness burn wounds, one of its disadvantages is that the patient has to return for follow-up repeatedly for dressing change and silver sulfadiazine application. Anxiety and fear related to dressing change can have a dramatic effect on patients, with pain being the most dreaded aspect.[3] Also, more frequently, exposure of the second degree or partial thickness thermal burn to the environment during dressing changes predisposes patients to local infection that could cause the wound to be converted to third degree or full thickness.

Urgotul silver sulfadiazine (Urgotul SSD™) (Laboratoires Urgo S.A., Chenôve, France) is a non-adherent hydrocolloid dressing material impregnated with silver sulfadiazine, which has recently been introduced as an effective antimicrobial barrier dressing for partial thickness burn wounds.[4]

We hypothesized that temporary covering of the partial-thickness burn wound in a sterile surgical environment would maintain a clean wound environment and would facilitate reepithelialization, and that early application of temporary wound coverings would be superior to daily application of antimicrobial cream in terms of pain and wound healing. The purpose of this study was to compare the efficacy of Urgotul SSD™ and 1 % silver sulfadiazine in the treatment of partial-thickness burn wounds at out-patient burn clinic.

Materials and Methods

Patient population

This prospective randomized control trial study was conducted between July 2005 and December 2006. Seventy burn patients aged more than 17 years old who were treated at out-patient burn clinic with partial thickness burns of less than 15% total body surface area (TBSA) were eligible for enrollment. We compared the efficacy and outcome of conservative treatment with 1% silver sulfadiazine dressing versus the application of a hydrocolloid dressing Urgotul SSD.™ Sample size in this study was estimated at 70 patients (35 patients per group), taking a power of 0.80 and an alpha level of 0.05.

Our hypothesis was that coverage of second degree burns with this synthetic covering would decrease pain, labor cost, healing time. Inclusion criteria included the following: (1) age more than 17 years old, (2) second degree burn or partial-thickness burn, (3) total body surface area burn less than 15 percent, (4) treated at out-patient burn clinic within 24 hours after the injury, and (5) clean, non-infected wound as diagnosed by attending physicians.

Exclusion criteria included (1) patients less than 17 years of age (2) pregnancy (3) full-thickness or third degree burns, (4) burns that need hospital admission (5) initial visit beyond 24 hours after the injury and (6) wounds noted to be contaminated or infected.

Patients included in this study were randomized into two groups. They were informed of the study and their written consent was obtained. After superficial debridement of blisters and debris, patients were randomized to receive treatment with hydrocolloid dressing Urgotul SSD™ (35 patients) or 1% silver sulfadiazine dressing (35 patients). Patients in the Urgotul SSD™ treated group received an appointment for dressing change every two days, and everyday in the 1% silver sulfadiazine treated group. Both groups were comparable with regard to patient demographics including age, gender, cause of burn, total body surface area (TBSA) burn % and deep burn (% deep partial or full thickness).

Patients were also reviewed for the documentation of efficacy of treatment including, time of wound closure, total treatment cost of burn wound dressing (total number of gauze dressings, bandages, pieces of Urgotul SSD™ or 1% silver sulfadiazine cream in grams and labor costs), follow-up times, pain scores and pain medications (number of doses of acetaminophen ± ibuprofen per day).

Wound dressing protocol

In Urgotul SSD™ treated group, the treatment consisted of the application of an Urgotul SSD™ then a dry secondary dressing. The Urgotul SSD™ dressings were changed every two days until completion of wound closure. Treatments in the another group consisted of the removal and application of 1% silver sulfadiazine (AgSD) and dry gauze dressings daily until completion of wound closure. Wounds were

observed by attending surgeons at each out-patient visit. Day at completion of wound closure was considered when all areas of initial injury were found closed. Wound infection was evaluated by two experienced burn physicians. Criteria for the diagnosis of wound infection included the presence of cellulitis, erythema, induration or purulent discharge. All infected wounds were swabbed and the specimen sent for culture.

Pain assessment and pain medication

Pain medication regimen included acetaminophen 15 mg/kg/dose every six hours with or without ibuprofen (10 mg/kg/dose) every eight hours, orally administered. Average pain scores before dressing change in both groups were compared. Pain score was assessed and reported by patients at the time of follow-up to determine if there was a difference between the two methods, using the visual analog pain scale 1-10; 0 being no pain, 5 moderate pain and 10 severe pain (Figure 1). Pain assessment was not obscured due to the nature of the study.

Statistical analysis

Demographic predictors including age, TBSA burn (%), % deep burn, healing time (days), pain scores, labor cost of wound dressing, follow-up times, pain medications between both groups were analyzed by two-tailed unpaired student t-test. We compared potential differences of percentage of wound infection between both groups using Fisher's two-tailed unpaired exact test. P value of less than 0.05 was considered to indicate statistical significance. Statistical analyses were performed with the use of Stata, v 6.0 software (Stata Corp, College Station, TX 1999).

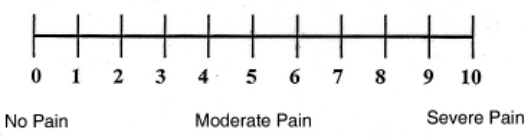

Figure 1 The visual analog pain scale 1-10; 0 being no pain, 5 moderate pain and 10 severe pain

RESULTS

Thirty-four patients were enrolled in each group (20 males and 14 females with 29 scald and 5 flame in the Urgotul SSD™ treated group; 19 males and 15 females with 31 scald and 3 flame in the 1% silver sulfadiazine treated group).

Two patients were excluded; one pregnant woman in Urgotul SSD™ treated group and one patient with allergic reaction to 1% silver sulfadiazine. Patients in both groups were comparable in demographic data including age, % TBSA burn and % TBSA deep burn ($p > 0.05$ evaluated by paired Student's t -test) (Table 1).

Pain scores, labor cost of wound dressing, follow-up times and time from burn injury to complete wound healing are summarized in Table 2. Patients treated with Urgotul SSD™ had significant lower pain score ($p = 0.02$), follow-up times ($p = 0.03$) and time of burn wound closure ($p = 0.04$) compared to silver sulfadiazine treated group. Patients treated with Urgotul SSD™ had significant decreased requirements of pain medications including acetaminophen ($p = 0.02$) and ibuprofen ($p = 0.01$) compared to patients in silver sulfadiazine group. Patients in the Urgotul SSD™ treated group demonstrated higher, but not statistically significant, labor cost of wound dressing ($p > 0.05$). Two patients (6%) developed wound infection; 1/34 (3%) in Urgotul SSD™ treated group and 1/34 (3%) in 1% silver sulfadiazine-treated group. In both cases, no growth of organisms was found. All of the patients who developed wound infection responded well to targeted topical and oral antibiotic treatments and, finally, all wounds healed without the requirement of skin grafting.

Table 1 Demographics of patients in both groups

	1% Silver sulfadiazine treated group (N = 34)	Urgotul SSD™ treated group (N = 34)	P value
Age (years)	38 ± 4	32 ± 13	0.2
TBSA Burn (%)	8 ± 4	9 ± 5	0.7
Deep partial thickness burn (%)	3 ± 2	4 ± 4	0.9

Table 2 Comparison of results in both groups

	1% Silver sulfadiazine treated group (N = 34)	Urgotul SSD™ treated group (N = 34)	P Value
Pain scores (scale 1- 10)	6 ± 2	3 ± 1	0.02
Labor cost (US$)	45 ± 34	52 ± 38	0.6
Out-Patient visits (times)	10 ± 5	5 ± 2	0.03
Time of burn wound closure (days)	12 ± 6	10 ± 4	0.04
Number of doses of acetaminophen/person/day	2.3 ± 1.4	0.4 ± 0.5	0.02
Number of doses of ibuprofen/ person/day	3 ± 1	1.7 ± 1.2	0.01

Discussion

Eighty percent to 90% of burn injuries are minor which can be treated on an out-patient basis.[1] Second degree or partial-thickness burns have been treated for many years by daily, painful washing and cleansing of the burn wound, followed by topical application of silver sulfadiazine cream.[5-7] Pain is the main problem with this type of treatment.[8,9] The frequent dressing changes cause a higher rate of epithelium breakdown which may impair wound healing.[10] Temporary covering of the partial-thickness burn wound in a sterile surgical environment with less frequent dressing changes would facilitate re-epithelialization and that early application of temporary wound covering would be superior to daily application of antimicrobial creams in terms of pain and wound healing.[3]

The purpose of this prospective randomized study was to evaluate the use of Urgotul SSD™ wound dressing (Laboratoires Urgo S.A., Chenôve, France) and 1% silver sulfadiazine (Silvadene, Marion) cream in the out-patient management of partial-thickness burns. The application of Urgotul SSD™ proved to be superior to topical treatment with 1% silver sulfadiazine in that it significantly decreased pain, follow-up times, number of doses of acetaminophen and ibuprofen/person/day. Urgotul SSD™ is a non-occlusive antibacterial lipido-colloid interface containing a mixture of CMC-Na dispersed in a lipophilic network of petroleum jelly, combined with silver sulfadiazine (SSD).[5] It is intended for topical treatment of second degree burn at risk of secondary infection.[6-8,11]

This non-occlusive dressing has good, low-adherent properties, which means that the dressings can be changed less frequently, depending on how the treated wound develops.[7,12,13] It also contains an antibacterial agent with active prophylaxis against a broad spectrum of bacteria.[4] Previous studies have demonstrated the efficacy of URGO products in the management of the healing process, including using Urgotul® as an alternative to conventional non-adherent dressings.[7] Bernard et al. reported that this type of dressing promoted wound healing process by stimulation of proliferation of human dermal fibroblasts.[10] Partial-thickness burns might cause high level of pain which normally decreases as the wound heals.[9] Anxiety which is oftenly exacerbated by dressing changes is another feature of these injuries.[9] The results of the present study suggest that the overall magnitude of pain scores, follow-up times and the amount of oral analgesic medication requirement in wounds treated with Urgotul SSD™ were significantly lower than in the wounds treated with silver sulfadiazine. This might be due to the reduction in the number of dressing changes following the application of Urgotul SSD™ as well as the non-adherent property of Urgotul SSD™ to the wound bed, which leads to increased patient comfort and pain relief during dressing replacement. This can also be deduced from decline in the use of oral analgesic medication.

In our study, no differences were observed in the rates of wound infection and time of burn wound closure between both groups. Rate of wound infection in each group was low (3%) and all were local wound infections and easily controlled. This suggested that Urgotul SSD™ has also been shown effective in preventing burn wound infection with comparable results to the traditional wound treatment with silver sulfadiazine. The time of burn wound closure in the Urgotul SSD™-treated group was significantly lower than those in the silver sulfadiazine-treated groups. This might be due to the daily dressing changes in the

silver sulfadiazine group which caused wounds to be exposed to mechanical and chemical manipulation.[3] In addition, a more frequent burn wound dressing changes in the silver sulfadiazine group may cause a higher rate of breakdown of epithelialization on the wound surface. This might disturb the time of wound healing.[10,14-16] These circumstances have a significant impact on wound healing. In our protocol, Urgotul SSD™ already has low-adherent property and it was left intact on the wound with dressing changes less often, ie. every other day. So the wound underneath could heal undisturbed. Reduction in the number of dressing changes following the application of Urgotul SSD™ leads to decrease in appointment time, wound cleansing solutions, number of gauzes, bandages and labor cost.

Conclusion

The application of Urgotul SSD™ to partial-thickness burns has many advantages over topical treatment with 1% silver sulfadiazine, including the significant decrease in the level of pain, follow-up times, time of wound closure with a comparable rate of wound infection and cost of treatment. Urgotul SSD™ may be used as an effective burn wound dressing in the treatment of partial thickness burn at out-patient burn clinic.

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