Determination of Efficacy of Adhesive Remover with Orange Oil Extract Solution

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Background: *Pain during dressing change period is one of the most concerned issues for patients. It can cause discomfort and also mental disability in long term. Adhesive bandages peeling off is one of the processes in dressing change that can create much pain. Alleviating pain from that process may improve patients' quality of life.*
Objective: *To evaluate the efficacy and side effects of orange extract solution in reducing the pain during bandage removal in dressing change procedure in surgical wound.*
Material and Method: *This study was a phase II clinical control trial research. The subjects were surgical patients who had a wound on his/her arm or hand. The study was conducted under approval of medical ethical review board of Bamrasnaradura Infectious Diseases Institute.*
Results: *Thirty patients were enrolled. There were 16 male and 14 female. Mean age was 50 years. Most of the patients (50%) had no underlying disease. This study found that the orange extract solution could help to reduce the pain during bandage removal from the wounds. The result was proved that it's safe without side effect.*
Conclusion: *Orange extract solution was effective in bandage removal without significant side effect.*

Keywords: *Bandage/adhesive remover, Orange oil extract solution, Dressing, Pain, Wound*

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Wound pain is one of the main concerns during the wound cleansing and dressing change period. Wound pain creates more stress not only for the patients, but also to the healthcare workers. Sometimes serious pain can result in bad experience that can convince patients to refuse a wound cleansing process which further delay the wound healing and increase the treatment costs[1,2]. In 2013, Upton D et al found that wound pain can induce stress which delays healing of the wound. Wound pain can increase the cost of care and worsen the quality of patients' life[3]. There are many ways to reduce the pain from adhesive wound bandage removal such as soaking the bandage with normal saline or other types of oil solution. Such methods were used; wound pain that was produced from the bandage removal still existed, especially in deep and large wound areas[4,5].

Orange oil extract solution is a solution extracted from orange's peels. The scientific name of orange is *Citrus Sinensis*. The orange oil extract solution has anti-carcinogenic and anti-inflammatory properties. For external use, the orange oil extract solution has an ability to dissolve glue and tar[5,6]. The orange oil extract solution was proved to be effective and safe for bandage removal in animals study in preclinical trial. There was only one commercially available product of orange oil extract solution (Oransol®, Bangkok Medisupply, Thailand) that was approved by Thai FDA for used as adhesive bandage removal. In first human phase, the orange oil extract solution was also safe and effective in healthy volunteers. This study was a phase II clinical trial study to test the efficacy and side effects of Oransol® on Fixomull® adhesive bandage removal from the wound.

Material and Method

Ethical consideration

All patients signed informed consents and

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the study protocol was approved by Bamrasnaradura Infectious Diseases Institute's review board. The study was conducted according to the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects.

Subjects enrollment process

A purposive sampling was done from the patients who visited the surgical out patients unit, Department of Surgery, Bamrasnaradura Infectious Diseases Institute, Thailand from 15 October 2014 to 15 January 2015.

Inclusion criteria

The patients age between 18 to 60 years.

Patients had the wound on their arm or forearm that needs to do wound cleaning once a day (only new cases).

All wounds dressed with adhesive bandage (Fixomull®) application.

All patients signed informed consents and willing to enroll in the study.

Exclusion criteria

The patients who had underlying skin diseases or other skin lesions on their forearm prior the enrollment.

Allergy history to orange or orange oil extract solution.

The patients could not sign informed consent.

Discontinuation criteria

Allergic lesion on tested site (healthy forearm) during the study period

Missed more than 2 times continuously of wound cleaning follow-up during wound care period.

Materials in this study

Orange oil extract solution (Oransol®, Bangkok Medisupply, Thailand).

Adhesive bandage (Fixomull® stretch, BSN medical, Germany).

Study method

Patients' wound was cleaned by using a standard wound care method. The opposite healthy forearm was also cleaned at the same time with sterile normal saline. 2 pieces of 7X7 cm^2 Fixomull® were used to apply as adhesive wound tape on both forearm or arm (both wounded and normal side of arm or forearm). On the next day (defined as day 1st), Orange oil extract solution (Oransol®) was applied on the wounded forearm Fixomull® and applied normal saline on Fixomull® on the other normal forearm for 1 minute. Then bandages on both sides were removed. All patients were assessed for pain level after adhesive bandages removal by using visual analog scale as numeric rating scale 11 (NRS-11) at day 1st to day 3rd. The patients were observed for any skin reaction to evaluate the side effects at 5, 15, and 30 minutes, respectively after bandages were removed. The experiments were repeated in the same process as mentioned above on the next day till last visit at day 10th (Fig. 1). All patients were appointed for the last visit at day 10th. On the last visit, treatment results and skin side effects were recorded.

Outcome measurement and data analysis

Assessment of efficacy

All patients were assessed for pain score after adhesive bandage removal by visual analog scale. Pain score of 0 was no pain and score of 10 was the most severe pain.

Any skin side effect was observed at 5, 15, and 30 minutes after the bandage removal. The photographic records were used for recording any skin adverse effects.

Patient' satisfaction was assessed by visual analog scale; 0 to 3 was interpreted as unsatisfied, 4 to 7 were neutral, and 8 to 10 were defined as satisfied.

Statistics for data analysis

Patients' baseline characteristics, side effects and patients' satisfaction were described by descriptive statistics such as number and percentage. Pair Student's t-test was used to compare the efficacy and

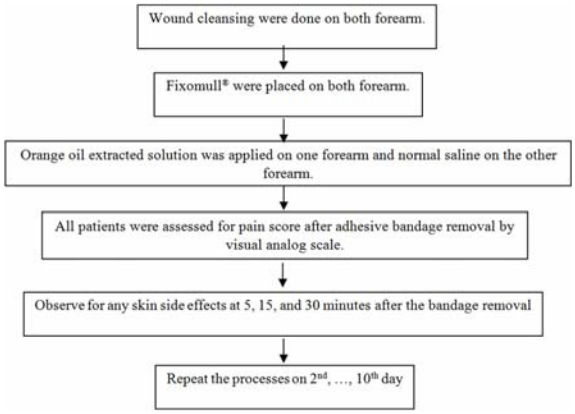

Fig. 1 Flow chart of the study.

pain score after adhesive bandage removal between the two groups; orange oil extract solution as experimental group and normal saline as control group. The statistical significant (*p*-value) was set as equal to or less than 0.05.

Results

A total of 30 patients were enrolled in the study. There were 16 male and 14 female. The average age was 50.43±20.14 years. Fifteen patients (50%) had no underlying diseases. There were 8 diabetic patients, 7 hypertensive patients, 1 gouty patient, and 1 deep vein thrombosis patient (Table 1). All patients had no history of drug allergy.

All surgical patients'wound were improved and healed by the end of schedule of treatment. Patients' pain score were assessed by visual analog scale (NRS-11) (0 = no pain, 10 = severe pain). Orange oil extract solution group had significant lesser pain during adhesive dressing removal than control group ($p<0.01$). There were no side effects from orange oil extract solution usage seen from 1st day (first day of solution application) to 10th day (the last day of visit for each patient) (Table 2 and Fig. 2).

Table 1. Patients' underlying diseases

Underlying diseases	Sex		Total
	Male	Female	
No	10	5	15
Diabetes mellitus	1	5	6
Hypertension	1	4	5
Gout	1	0	1
Deep vein thrombosis	1	0	1
Diabetes mellitus and hypertension	2	0	2
Total	**16**	**14**	**30**

Discussion

Wound dressing change was proved to be one of the most painful steps in wound treatment process. Pain from dressing change make patient's quality of life worse and sometimes the repeated trauma that happens in chronic case can lead to psychiatric problem[8,9]. Wounds heal completely using numerous pathways. Some of them are still unknown. Close the wound with wound dressing is one of the main principles of wound treatment. It was believed to shield the wounds from minor trauma, microorganism and also create proper environment to heal faster than the open technique. Many previous studies tried to invent new dressing material to solve pain while dressing change with enhancing healing[10]. Plaster or adhesive pad to fix the wound dressing on the wound by using acrylic component as a glue to make the pad stick with the skin. That means the peeling process of plaster or

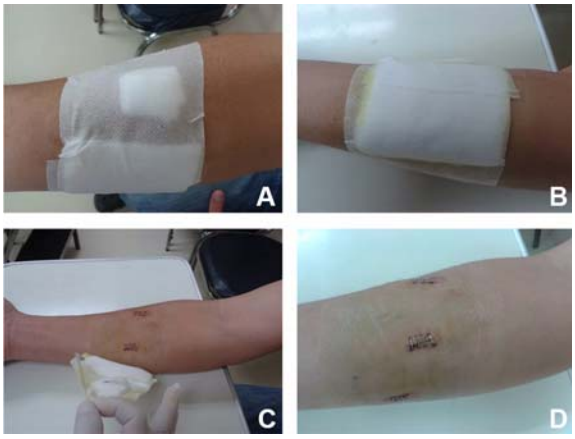

Fig. 2 Process of adhesive bandage (Fixomull®) removal by orange oil extract solution (Oransol®). A) Wound dressed with adhesive bandage, B) Soaked the bandage with orange oil extract solution, C) Removal of adhesive bandage, D) After removal of the adhesive bandage.

Table 2. Comparision of patients' pain score between routinely removal of adhesive bandage method to orange oil extract solution during wound cleansing

Pain score 0 = no pain 10 = severe pain	Orange oil extract solution group	Control group	*p*-value (paired t-test)
Day 1	0.0±0.0	2.13±0.78	<0.01*
Day 2	0.0±0.0	2.10±0.71	<0.01*
Day 3	0.0±0.0	2.07±0.69	<0.01*

* Statistic significant due to *p*-value <0.05

adhesive pad cannot be avoid when the dressing was changed. More sticky ability of plaster tape provide more durable attached the dressing with the wound, but it also creates other problems such as pain when it was peeled off. Orange oil extract solution was one of the solution that can effectively dissolve glue and acrylic compounds in coating material of the plaster that act like glue for the plaster to attach with the wound dressing. When sticky components of the plaster were dissolved by orange oli extract solution, it made it easier to remove without difficulty and pain. That can explain the significant difference of pain scores in experimental group when compared with the control group. From our study, we found it had no side effect on periwound skin.

Conclusion

Orange oil extract solution is the oily solution extracted from orange's peels (*Citrus Sinensis*). The solution has the chemical property which can dissolve adhesive glue and tar[5,6]. The solution is commercially available in the name of Oransol® supplied by Bangkok Medisupply, Thailand. In pre-clinical phase, orange oil extract solution was safe and had good efficacy for adhesive dressing removal in animal studies. The orange oil extract solution was approved to use in human by Thai FDA. This study was confirmed the efficacy of the orange oil extract solution. The study showed that the orange oil extract solution could reduce pain from adhesive dressing removal without side effect on the patients' skin. Orange oil extract solution (Oransol®) is a new alternative method to reduce the pain from adhesive dressing in surgical patients.

What is already known on this topic?

Wound pain is one of the most concerned topics of both patient and medical personels while dressing change.

What this study adds?

Orange oil extract solution is a new effective choice for decreasing pain during adhesive bandage removal while dressing change.

Potential conflicts of interest

None.

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การทดสอบประสิทธิภาพของการลอกผ้าปิดแผลด้วยสารละลายน้ำมันส้ม

สุทัศน์ โชตนะพันธ์, ตันภัย จิระมานะพันธ์, กุสุมา ชินอรุณชัย, จตุพร ศิริกุล, สมพล ฤกษ์สมถวิล, พรพรหม เมืองแมน

ภูมิหลัง: อาการปวดที่เกิดขึ้นระหว่างการเปลี่ยนผ้าปิดแผลในการรักษาแผลในแต่ละครั้งของการทำแผลเป็น หนึ่งในปัจจัยที่ทำให้ผู้ป่วยกังวลเนื่องจากอาการปวดนอกจากจะเป็นต้นเหตุของความไม่สะดวกสบายแล้วยังอาจนำไปสู่สภาวะทุพพลภาพทางจิตใจได้ในระยะยาว การลอกพลาสเตอร์ปิดแผลซึ่งเป็นหนึ่งในขั้นตอนของการเปลี่ยนแผลอาจเป็นหนึ่งในสาเหตุที่ก่อให้เกิดความเจ็บปวดมาก ถ้าสามารถลดความเจ็บปวดจากขั้นตอนนี้ได้อาจทำให้คุณภาพชีวิตของผู้ป่วยดีขึ้น

วัตถุประสงค์: มุ่งหวังเพื่อทดสอบถึงประสิทธิภาพและผลข้างเคียงของผลิตภัณฑ์น้ำยาทำความสะอาดผิวที่มีสารสกัดจากน้ำมันส้ม ในการช่วยลอกพลาสเตอร์ปิดแผลชนิดเทปเหนียว

วัสดุและวิธีการ: การศึกษานี้เป็นการศึกษาทางคลินิกระยะที่ 2 โดยทำการศึกษาในกลุ่มผู้ป่วยศัลยกรรมที่มีบาดแผลที่มือหรือแขนภายใต้การควบคุมของคณะกรรมการจริยธรรมในการวิจัยของสถาบันบำราศนราดูร

ผลการศึกษา: ผู้ป่วยทั้งหมดจำนวน 30 รายในการศึกษานี้เป็นผู้ป่วยชายจำนวน 16 รายและผู้ป่วยหญิงจำนวน 14 ราย มีอายุเฉลี่ยประมาณ 50 ปี โดยผู้ป่วยส่วนใหญ่ซึ่งคิดเป็นจำนวน 50 เปอร์เซนต์ของผู้ป่วยที่ทำการศึกษาทั้งหมดเป็นผู้ป่วยที่ไม่มีโรคประจำตัว ซึ่งผลการศึกษาพบว่าผลิตภัณฑ์น้ำยาทำความสะอาดผิวที่มีสารสกัดจากน้ำมันส้มช่วยลดอาการปวดในขั้นตอนการลอกพลาสเตอร์ปิดแผล ระหว่างขั้นตอนของการเปลี่ยนทำแผลได้อย่างมีประสิทธิภาพ ปลอดภัย และปราศจากผลข้างเคียง

สรุป: ผลิตภัณฑ์น้ำยาทำความสะอาดผิวที่มีสารสกัดจากน้ำมันส้มสามารถลอกพลาสเตอร์เทปเหนียวที่ใช้ปิดแผลได้อย่างมีประสิทธิภาพโดยปราศจากผลข้างเคียง