Comparing the Effects of Tea Tree Oil (Melaleuca alternifolia) and Conventional Topical Dressing on Healing of Second-Degree Burn Wounds"

Heba Elsayed[1†] (PhD), Hoda Fathy[2†](PhD), Mohamed Ahmed Seweed[3](PhD), Thoraya Mohamed Abdelaziz[1](PhD)

Study protocol

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Introduction

Burn is one of the most devastating injuries that have a catastrophic effect on people in terms of human life, suffering, disability, and financial loss. Burns are the third leading cause of accidental death in the United States; approximately5000 people die each year from burns. Each year an estimated 2 million Americans experience burns severe enough to seek medical care [1,2].

In Egypt, minimal studies discussed epidemiological records of burn, however it has been reported that burn cases were around 100.000 in 2018. Statistical records of the Burn Unit at the Main University Hospital; Alexandria, revealed that; 314 burn cases were admitted to unit in 2020 [3,4].

Burns are caused by transfer of energy from a heat source to the body; which may be transferred through conduction or electromagnetic radiation. The depth of the injury depends on the temperature of the burning agent and the duration of contact with that agent. Burns are categorized as thermal (which include electrical burns), radiation, or chemical, in which tissue destruction results from coagulation, protein denaturation, or ionization of cellular contents.[5, 6]

Wound healing is a complex process, involves optimizing patient local and systemic conditions in conjunction with an ideal wound healing environment. Many different products have been developed to influence this wound environment to provide a pathogen-free, protected, and moist area for healing to occur. Newer products are currently being used to replace or augment various substrates in the wound healing cascade; such as Silver, Negative Pressure Wound Devices, Skin Substitutes, Growth Factors and Biologic Wound Products, Hyperbaric Oxygen, and herbal therapy [6, 7].

Burn hospital wound's protocols vary, but the most common wound cleaning involves saline and povidone-iodine (Betadine). Wound is cleansed at each dressing change and is observed for signs of infection and rate of healing. This may be done in the hydrotherapy tub, shower, or at bedside [8, 9].

Recent studies showed that alternative therapies are used as first aid treatment for burns as Aloe Vera, saliva and a tea tree oil impregnated dressing applied as first aid to a porcine deep dermal contact burn, results of it showed significantly decrease sub dermal temperature within the skin during the treatment period [10-12].

Tea tree oil [TTO] (Melaleuca alternifolia) is a clear, colorless to pale yellow liquid, and is insoluble in water. It is lipophilic and works through penetrating the skin and mucous membranes. The active ingredients responsible for killing bacteria and fungi in TTO include terpinene-4-ol, alpha-terpineol and alphapinene, which inhibit cell respiration and disruption of cell membrane permeability with the resultant leakage of potassium [13, 14].

Inherent in the previous statements, is the belief that there is a need to investigate whether TTO would be more cost effective, enhance rapid healing than the conventional topical agent.

Aim of the study

Compare the effect of two topical dressing techniques on the healing of second degree burn wounds; melaleuca alternifolia (tea tree oil) and conventional dressings.

Operational definition

Conventional dressing:

Sterile topical gauze dressing are impregnated with or laid over a topical antibiotic, silver sulphadiazine with adhesive tape to secure dressing.

Materials and method

Materials

Design: An experimental design will be utilized.
Setting: The present study will be conducted at the burn unit, Alexandria Main University Hospital, Alexandria, Egypt.
Subject: A convenient sample of 50 patients admitted to burn unit suffering from second-degree burns will be included in the present study.

The fifty patients will be sequentially enrolled into two equal groups:-

- The first group (25 patients) will be managed conventional dressings (control group).

- The second group (25 patients) will be managed by local application tea tree oil (study group).

Patient's inclusion criteria will include:

- Adults of both genders (18-60 years), able and willing to cooperate and communicate.
- Newly admitted to the study setting with recent 2nd degree burns whether superficial or deep ≤10%TSBA.
- Free of associated illness that affect wound healing as DM, immune disorder, or associated injuries.
- Free from pre-existing skin conditions such as eczema

Tools: Two tools will used on this study:

Tool I: (Burn patient's assessment sheet)

This tool will mainly aim to assess burn parameters (as extent, depth, and cause of burn), criteria of wound healing (as wound color, appearance of burn wound, signs of infection and presence of exudates). It will be comprised of three parts.

Part I: Patient Sociodemographic data: including:

- Personal characteristics: as Patients' age, gender, level of education, occupation, date of burn, date of admission, date of discharge and habits.
- Patient history including past and present history.

Part II: Laboratory studies:

- Complete blood count.
- Serum proteins.
- Electrolytes.

Part III: Burn parameters: This part will include data regarding**:** Site of burn, extent, cause, and depth.

Part IV: Type of wound dressing: Whether TTO or Conventional dressing.

Tool II: (Burn wound follow up sheet)

This tool will comprise two parts:

-Morphological changes of the wound:

This part will be used to assess burn wound healing, and determine signs of infection including signs of inflammation as wound color, presence of exudates (amount, color, and type), size, depth, edema, as well as frequency of dressing change.

- **Photographic pictures:**

Colored digital photographs will be taken three times to assess wound healing process (day of burn, each other day till healing and after one month)

Method

1. Written approval will be obtained from the hospital administrator and head of Burn Department, after explanation of the study aim.
2. The study tools will be developed by the researcher after review of relevant literature.
3. The developed tools will be submitted to 5 experts in the fields of plastic surgery &burn and Medical Surgical Nursing to test its content validity and necessary modification will be done accordingly.
4. Reliability of the tool will be tested.
5. Ethical considerations:

   a. Patient's written informed consent will be obtained after explanation of the study aim.

   b. Confidentiality, privacy and right of withdrawal will be assured.

   c. Ethical committee approval will be obtained.
6. Pilot study will be conducted on 5 patients for testing, clarity, feasibility and applicability of the developed tools and modification will be done.
7. The study subjects meeting inclusion criteria and will be sequentially divided into two groups, the first group will receive conventional dressing (control group), and this dressing will be changed routinely once every other day. For the second group the wound will be dressed by TTO, which will be changed every other day till healing occurs. This frequency is advocated, since more frequent dressing change will interfere with granulation tissue formation.
8. All burn wound will be washed gently with Saline, and all open blister and loose non-viable tissue will be removed from the burn, intact blisters will be

left, and then the topical agents will be applied directly on wound. Burns involving body joints will be kept in functional position.

9. Initial assessment of all patients will be done using tool I. Subsequent assessment will be done on 4^{th}, 14^{th},21^{th} of topical dressing agents use until the wound healing from both groups using tool II.
10. Colored digital photographs will be taken-if possible- to assess wound healing process at the (day of burn, each other day till healing, after one month)
11. Initial and ongoing assessment results for the conventional dressing, compared to TTO dressings, will be carried out using appropriate statistical methods.

Statistical Analysis Plan (SAP):

Data will be analyzed using IBM SPSS software package version 23.0. The Shapiro-Wilk will be used to verify the normality of distribution of variables; Comparisons between groups for categorical variables will be assessed using Chi-square test (Monte Carlo or Fisher Exact). Student t-test will be used to compare two groups for normally distributed quantitative variables, Mann Whitney test will be used to compare two groups for not normally distributed quantitative variables, Friedman Test for multiple comparisons between the different periods in each group. Significance of the obtained results will be judged at the 0.5% level.

Results

The collected data will be analyzed, categorized and tabulated, the appropriate correlation and significant test will be done.

Discussion

Discussion of the obtained findings will be done based on the current related literature.

Conclusions and Recommendations

Conclusion and recommendation will be developed from the discussion.

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