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EFFECT OF SESAME OIL DROP AND MUPIROCIN ON BURN WOUNDS – A RANDOMIZED CLINICAL TRIAL

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ABSTRAC

Introduction:
Sesame oil is also one among the agents that are currently used to treat burns; it has shown different effects on wound healing. A similar study conducted by Kiran et al. reported a shorter length of epithelialization and wound closure in mouse treated with sesame seeds and oil compared to the control group.

Method: The sample included 50 available patients in Nekuee hospital (in Qom) who were divided into two groups. The first group consisted of 25 patients who were treated using Sesame Drop. After washing the wound with normal saline solution, 3-5 Drops of Sesame oil was applied over the wound.

Results: gain in days of in-hospital stay, days needed for 50% wound healing Significant differences were observed between sesame oil and the standard therapy with mupirocin ointment ($p = 0.03$) in effectiveness in total groups.

Conclusion: Results suggest that Sesame Oil Drop may be considered for further investigation as a potential first line treatment modality for facial burns.

Introduction:

The main goals of managing burns are to accelerate tissue repair and to prevent infection. [1] Infection is the most serious and fatal side effect of acute burns, which is produced by various microorganisms; however, correct and on-time treatment is effective in curing the patient. [2] Topical antibiotic creams such as mupirucin and silver sulfadiazine are among the most common medicines used for the treatment of burns. However, these drugs may also have cytotoxic properties; [8] therefore, finding drugs with fewer side effects can be very helpful in treating this kind of patients. Sesame oil is also one among the agents that are currently used to treat burns; it has shown different effects on wound healing. [16] Sesame oil was reported to be effective in reduction of cholesterol and blood glucose [17] and it has antioxidant effect. [18] Unfortunately, very few studies have been done on sesame oil in healing wounds, while some studies have shown its beneficial effects. [12,16,20-22]

Topical sesame oil application can be effective in tissue regeneration (21). A similar study conducted by Kiran et al. reported a shorter length of epithelialization and wound closure in mouse treated with sesame seeds and oil compared to the control group. Ebrahimi Fakhar et al. reported that application of sesame oil in burn wound is competitive with conventional topical chemical that they help debridement of necrotic tissues (22).

The present study intends to investigate the therapeutic effect of sesame oil on facial burn injury and to compare it with Mupirocin ointment.

Using Fisher exact test, the collected data were analyzed with SPSS 21 software to compare the qualitative variables between the two groups. The Kaplan –Meier survival curve was also used to compare granulation tissue formation time. The average time of granulation tissue formation was compared between the two groups using log-rank test.

Method and material:

This is a randomized controlled trial. This study was approved by the ethical committee of Qom University of Medical Sciences (Project No.: 34/12078/پ) and was registered in Iran Registry of Clinical Trial (RCT registration code: IRCT201201188769N1). The inclusion criteria for patients enrolled in the study were: Having facial burns; aged between 15 and 55 years; gave consent to participate in the study; referred during the first 24 h of injury; and had negative ulcer culture on admission. Patients with underlying conditions such as diabetes, chronic renal or hepatic diseases, and those with simultaneous burns, trauma, and skin lacerations were excluded.

The sample included 50 available patients in Nekuee hospital (in Qom) who were divided into two groups using simple randomized method and table of random numbers; the chance of entering the control group was twice as that of the case group. The first group consisted of 25 patients who were treated using Sesame Drop. After washing the wound with normal saline solution, 3-5 Drops of Sesame oil was applied over the wound and closed dressing was performed every day until the patients were discharged, by one of the researchers. The second group consisted of 25 patients; they were treated using mupirocin ointment every 12 h, which is a broad-spectrum bacteriostatic ointment against gram-negative bacteria and is easily accessible. Patients and researchers were aware about the treatment groups.

Using Fisher exact test, the collected data were analyzed with SPSS 21 software to compare the qualitative variables between the two groups. The Kaplan –Meier survival curve was also used to compare granulation tissue formation time. The average time of granulation tissue formation was compared between the two groups using log-rank test.

Results:

Patient's characteristics Table 1 presents demographic and medical characteristics of the sample. Statistical tests of homogeneity for the different patient characteristics (e.g. gender, age, type of burns, percentage of facial burn, cause of burn), as well as for intermediate outcomes were used (c2 test, t-test and Mann Whitney test for non-normal data). Patients of all groups had similar characteristics concerning the most important parameters such as burn size ($p > 0.5$ in all cases) and age ($p > 0.5$ in all cases).

Table 1 Patient's characteristics and homogeneity tests

	Sesame Group	Mupirocin Group
Age(mean)	30.76	30.92
Gender	Male:16 Women:9	Male:15 Women:10
Percentage of facial burn	1.62	1.56
Cause of burn	Boiling water:7 Oil:5 Fire flame:12 Chemical:1	Boiling water:7 Oil:4 Fire flame:13 Chemical:1

Final outcomes: gain in days of in-hospital stay, days needed for 50% wound healing Significant differences were observed between sesame oil and the standard therapy with mupirocin ointment ($p = 0.03$) in effectiveness in total groups. Sesame oil Drop further reduced by nearly 1 day (sd: 4.5) in average the in-hospital stay in relation to the mupirocin therapy. This means it reduced the hospitalization time by nearly 20.6% (mean gain in days: 3.63, sd: 2.19 versus mean: 3.01, sd: 2.02) [27]. Also, Sesame oil Drop was more effective than the mupirocin therapy in the case of superficial burn wounds since: 1. It nearly reduced by 1 day (sd: 5.05) in average the in- hospital stay, that is it significantly reduced ($p = 0.02$) the hospitalization time by 29.63% in relation to the standard therapy (mean gain in days: 4.20, sd:2.1 versus mean:3.24, sd: 2.1). 2. It significantly reduced ($p = 0.00$) the time of 50% wound healing by 2 days in average in relation to the mupirocin therapy group. That is, the time of 50% wound healing was shorter by 19.07% in relation to the mupirocin therapy group (8.7 days, sd: 3.0 versus 10.75, sd: 3.8).

Discussion:

That is, this randomized trial supported the hypothesis that Sesame Oil Drop reduces the time of hospitalization of facial burning. The effectiveness results were consistent with the results of previous studies [10-16]. Also, the data suggest that Sesame Oil Drop was the dominant therapy for facial burns with significantly lower costs and significantly superior effectiveness due to a lesser time of recovery. In this case the results support the corresponding hypotheses.

The major limitation of this study is that it was single centered. The follow-up of this study was rather short (21 days). Second, although the design of this study was pragmatically oriented, protocol induced costs and outcomes were observed. These protocol induced costs and outcomes were easily detected and were omitted. Nevertheless, as protocol induced costs and outcomes have appeared it may be difficult or impossible to exclude the full impact of these services of the analysis and this could bias the final differences [36]. Also, the research was not blinded. An unblinding trial could be highly susceptible to classification bias [26,35]. Nevertheless, the persons evaluating treatment outcomes were blinded to treatment group assignment in order to eliminate classification bias [37].

Finally, the sensitivity analysis compared the actual situation with some hypothetical scenarios that were somewhat arbitrary, and the trade-offs between costs and effects may have been different from what was presented.

Conclusions:

Results suggest that Sesame Oil Drop may be considered for further investigation as a potential firstline treatment modality for facial burns. Nevertheless, in light of the above mentioned limitations our findings should be interpreted with some caution and must be verified in a larger multi-center trial. It is our recommendation that such a trial should be conducted in the near future.

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