

Review Article on the Effects of Alpha Ointment (Fondermol)

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Abstract

Introduction : Alpha ointment (Fondermol) is an ounce of % 100herbal. The compounds of this drug are Lawson of Henna (active ingredient), bee wax (base drug), flavonoids, unsaturated yellow acids and curcumin (Turmeric effective ingredient). The aim of this study was to investigate the effects of alpha ointment .**Methods:** In this study, Google, ISI, Scopus, Medline, and Embase searches were extracted by entering the keywords of alpha ointment, fondendol, healing. The criteria for entering articles in the study included the insertion of search words in the title section or the articles' keywords. Articles with data. Incomplete articles and articles that were less relevant to the subject were excluded .**Results:** Alpha ointment with angiogenesis in the affected area and epithelization (density of the affected area) and increasing the tissue elasticity being restored and by reducing inflammation or swelling and preventing the spread of infection, restorative and analgesic and relieving effects Applies .**Conclusion:** Alpha ointment has an effect on the reduction of pain caused by ulcers or fuels and has a positive effect on the healing of wound healing caused by burn and does not affect the wound caused by episiotomy.

Keywords: Folderol, Alpha Ointment, Healing.

Introduction

Alpha (fundermol) ointment is 100% herbal, in which lawsone (2-hydroxy-4-naphthoquinone) is an active ingredient obtained from Lawsonia inermis plant (Khaksary and et al, 2008;Heidari and et al, 2013). The ingredients of this drug include lawsone (the effective ingredient) extracted from L. inermis, beeswax (base drug), flavonoids, unsaturated fatty acids, and curcumin (an effective ingredient in turmeric) (Kabirsalmany and et al, 2008; Tejada and et al, 2016). Alpha ointment stimulates angiogenesis in the damaged area, epithelialization (density of affected area), and increased elasticity of the regenerating tissue. It also exerts its own restorative effects by reduction of inflammation or swelling and prevention of infection spreading (Shariati and et al, 2000). According to the manufacturer, this ointment has analgesic and anti-inflammatory properties in addition to its therapeutic and antibacterial effects.

Beeswax contains various compounds (e.g. flavonoids) and is used as a base drug in alpha ointment. Flavonoids have a high chemical activity being naturally present in all photosynthetic cells. Their effects on animal systems include estrogenic and antibacterial, impacts on membrane permeability, reducing the formation of free radicals, anti-inflammatory effect resulting from inhibition of inflammatory mediators (e.g. prostaglandins), as well as palliative and local anesthetics properties comparable to those of cocaine (RASTGAR & Alaghebandan, 2002). Flavonoids are one of the most important antioxidants found abundantly in beeswax, and have tremendous impacts on the vitality of healthy cells and the suppression of cancer cells (Najafi and et al, 2012).

Beeswax contains a substance called propolis that has an effective anti-inflammatory property comparable to that of diclofenac (Kabirsalmany and et al, 2008). Propolis is an exudate collected by bees from buds or other parts of a plant. This substance is known to have biological, antibacterial, antifungal, and healing properties. Numerous studies have demonstrated the anti-fungal activity of propolis (Musavi and et al, 2011), which is also accounts for a disinfectant and an effective agent in preventing the incidence and prevalence of diseases in the hive (Musavi and et al, 2011).

Turmeric (curcumin) is an ingredient of alpha ointment. Turmeric is the common name for an Indian spice plant belonging to the Ginger family. In addition to such uses as a colorant and a food spice, turmeric has traditionally been used to treat various diseases, including inflammation of the joints, gastric ulcer, jaundice, wound healing, fever, trauma, and skin diseases. The medicinal properties and

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biological effects of turmeric are essentially related to curcumin, the main ingredient in its rhizome. Curcumin possesses antioxidant, antibacterial, antifungal, antiviral, anti-inflammatory, anti-growth, and pro-apoptotic properties, with a high therapeutic potential for a variety of cancers (Tejada and et al, 2016; Kamali and et al, 2012).

Alpha ointment is a cheap and domestic medicinal product. The compounds of this drug have been proven in various literature to be effective on wound and pain healing. Therefore, considering that no review study exists on alpha ointment according to the author(s)' search in the literature, this study was conducted to evaluate the effects of alpha (fundermol) ointment.

Methods

In the current review, aiming at investigating the effects of alpha (fundermol) ointment, the databases of Embase, Medline, Scopus, ISI, Pubmed and Google's search engine were thoroughly reviewed for published articles using the keywords of alpha ointment and fundermol. The inclusion criteria were insertion of the search words in the titles and keywords of articles. Articles with incomplete data and those less relevant to our topic were excluded from the study. The keywords were searched in the titles and/or keywords of articles, and finally 12 articles were reviewed regarding the alpha ointment. Because alpha ointment is an Iranian drug, all of the articles found had been conducted in Iran, as follows.

- Impact of alpha ointment on episiotomy wound healing in primiparous women,
- Effect of alpha ointment on episiotomy pain in primiparous women,
- Effectiveness and safety of alpha topical ointment (containing natural *L. inermis*) in comparison with 1% hydrocortisone ointment in the healing of radiotherapy-induced dermatitis in patients with advanced breast cancer,
- Comparing the effect of 1% silver sulfadiazine ointment and fundermol herbal ointment on pain relief in patients with second-degree burns,
- Comparison of restoration time of second-degree burns with fundermol (alpha) and 1% silver sulfadiazine ointment,
- Impact of alpha ointment on second-degree burns in rats
- Comparing the effect of alpha ointment on pseudomonas infection in rats with third-degree burns,
- Effect of denervation on the response of burn wounds to herbal fundermol ointment in rats,
- Effect of alpha ointment on epithelialization of third-degree bedsore in rats,
- And comparing the effect of alpha ointment and Abukhalsa plant on wound healing.

Findings

The results of this review were arranged in four sections: (Khaksary and et al, 2008) Articles on wound healing in rats; (Heidari and et al, 2013) Articles dealing with wound healing in humans; 3) Articles addressing pain; and 4) Articles referring to other effects of alpha ointment.

Articles on burn wound healing in rats

Most of such studies have investigated the effect of alpha ointment on the process of in vitro burn wound healing on rats. Bagheri Yazdi et al. (2001), for instance, investigated the effect of alpha ointment on healing of second-degree infectious burns in rats and found that fundermol ointment was effective in tensile strength of the regenerating tissue and also in the angiogenesis at the burn wound site by accelerating wound healing process. They concluded that the speed and quality of wound healing in fundermol group was greater and better than the control (Bagheri Yazdi and et al, 2001). Khaksari et al. also confirmed the effectiveness of alpha ointment on burn wound healing in rats showing complete recovery with alpha ointment treatment after 48 days while it lasted 68 days in the control group, which was statistically significant ($p < 0.01$). They further observed lower prevalence of hypertrophic scars in healed burn wounds in the group treated with alpha ointment compared to other groups. The faster wound healing in this group was attributed to the antimicrobial and restorative effects of lawsone (Khaksary and et al, 2008). Kabir Soleimani et al. studied the effect of alpha herbal ointment on epithelialization of third-degree bedsore burn wounds in rats. Their results showed that the recovery time in the two groups of alpha ointment and 1% omeprazole sulfadiazine was shorter than the control group with a statistically significant difference (Kabirsalmany and et al, 2008). The authors concluded that alpha ointment increases regional circulation, thereby, it stimulates angiogenesis in the damaged area, which induces epithelialization and elasticity of regenerating tissues promoting wound closure (Kabirsalmany and et al, 2008). Yar Mohammadi et al. examined alpha ointment and 1% silver sulfadiazine ointment in terms of their effects on the healing of third-degree wounds infected with *Pseudomonas* in laboratory animals. They reported that alpha ointment was more effective in treating burn wounds than 1% silver sulfadiazine balm. Alpha ointment could better control the infection, reduced likely scar at the site of burn wound, and was cost-effective as well (Hosseini and et al, 2007).

Rastegar Lari et al. also performed a comparative study on alpha ointment and 1% silver sulfadiazine balm in rats. The results showed that fundermol ointment was not more effective in burn wound healing with relative thickness than 1% silver sulfadiazine ointment and that bacterial mortality and activity as well as wound healing were not statistically different between the two groups (RASTGAR & Alaghebandan, 2002).

Articles dealing with wound healing in human

Heidari (2010) in a study at Boroujen University compared the duration of second-degree 2 burn treatment with fundermol (alpha) and 1% silver sulfadiazine ointments on 50 patients with Grad 2 burns ranging 1-10%, who referred to the Imam Musa Kazem (as) Clinic of Burn Injuries. The researchers examined average burn wound healing time in the group treated with fundermol (4.4 days) and the one (5.9 days) received 1% silver sulfadiazine ointment. They accounted that fundermol ointment more effective in second-degree burn wound mending than 1% silver sulfadiazine balm (Heidari and et al, 2013).

Navinejad et al. conducted a study on the effect of alpha ointment in healing of episiotomy ulcers in 70 women who referred to Umm al-Banin Hospital. They detected that although average scores of episiotomy wound healing were acceptable both in the medication and the placebo groups according to the numbers accepted in the REEDA Table, there was no positive effect on accelerated wound healing by alpha ointment during the study days. No infections and drug allergies were observed among the subjects. There were no significant differences between two groups in terms of the gap between two edges of the wound every three days, and alpha ointment did not affect the closure of the wound edges.

Articles dealing with pain

Heidari (2013) compared 1% silver sulfadiazine and alpha ointments on pain relief in patients with second-degree burns and concluded that alpha balm was more effective in pain relief than 1% silver sulfadiazine ointment, hence, it could be a suitable alternative for pain relief in burn patients ($p < 0.001$) (Wilasrusmee and et al, 2008; Heidari and et al, 2013). Heidari attributed the analgesic effects of fundermole (alpha ointment) to beeswax as an ingredient of this drug.

Abedian et al. (2018) aimed at investigating the effect of alpha ointment on episiotomy pain in 70 primiparous women in Umm Al-Benin Hospital. Despite the presence of beeswax, curcumin and *L. inermis* (all of which alleviate pain and inflammation) in alpha ointment, and also in spite of a lower mean pain score in alpha ointment treatment than the placebo group, alpha ointment was not effective in episiotomy pain relief since the two groups were not statistically different in pain scores after episiotomy (Abedian and et al, 2018).

Ansari (2013) compared the effects of alpha and 1% hydrocortisone ointments on the healing of post-radiotherapy dermatitis after breast cancer in 60 subjects. The author found alpha ointment to be more operative in healing radiation-induced dermatitis than 1% hydrocortisone ointment, and that alpha ointment reduced itching, discharge, and pain (Ansari and et al, 2013).

Articles denoting other effects of alpha ointment

Shariati et al. (2000) investigated the effect of denervation on the response of burn wounds to fundermol plant ointment in 120 rats. They used alpha and 1% silver sulfadiazine ointments on the wound 24 h after second-degree burn. The wound surface, wound percentage, hair follicle growth, and blood vessel growth were measured for 30 days. The results showed that the two groups receiving the ointments were not significantly different in the percentage of wound healing, with similar values in both nerved and the denerved groups (Shariati and et al, 2000).

In their research, Hosseini et al. (2007) comparatively investigated alpha and 1% silver sulfadiazine ointments for the treatment of second-degree burns with *Pseudomonas* infections in 60 rats, and observed the highest use of alpha ointment in various problems of skin, pimples, burns and feet burns. They also reported that alpha ointment inhibited bacterial growth and that wound infections were lower in the alpha ointment group, hence, it was a good alternative to burn medication because of an affordable price (Hosseini and et al, 2007).

Ansari et al. (2013) examined the efficacy and safety of topical alpha ointment (containing natural *L. inermis*) in comparison with 1% hydrocortisone ointment for the treatment of radiotherapy-induced dermatitis in patients with advanced breast cancer at Namazi Hospital, Shiraz. They showed the use of alpha ointment to be more effective than 1% hydrocortisone ointment used twice a day for three weeks. They observed no systemic, localized or exacerbated dermatitis reactions in none of the subjects (Ansari and et al, 2013).

Discussion

This is a review study on the various effects of alpha ointment in humans and animals. The most usage of alpha ointment found in the literature was on burn wound healing for betterment of wound and relief of pain.

Alpha ointment ingredients include lawsone (an active ingredient) from *L. inermis*, beeswax (base drug), flavonoids, unsaturated fatty acids, and curcumin (an effective ingredient in turmeric) (Kabirsalmany and et al, 2008). Alpha ointment improved angiogenesis in the damaged area, stimulation of epithelialization (density of the affected area), and elasticity of the regenerating tissue. It also exerted its own restorative effects by reducing inflammation or swelling and preventing the spread of infection (Shariati and et al, 20005). According to the manufacturer, alpha ointment has analgesic and palliative properties in addition to therapeutic and antibacterial effects. In the cellular inflammation phase, white blood cells engulf bacteria and cellular debris, macrophages (larger phagocytic cells) interfere with ulcer debridement and contribute to the cessation of microbes through production of oxygen radicals and nitric oxide, and the infection increases inflammation and necrosis leading to delayed wound healing. The use of microbe-free methods reduces intrusion of pathogenic microorganisms to the site, and cleansing the affected area and washing the hands before wound contact help wound healing (Aradmehr and et al, 2015; Taylor & Laylsyn, 2010). In order to expedite wound healing process, it is recommended to use disinfectants because disinfectant compounds help increase the migration of epithelial cells and accelerate wound healing by cleansing discharge and extra wound layers (Mitani and et al, 2016).

Khaksari et al. reported a lower incidence of hypertrophic scar in an improved burn wound in subjects treated with alpha ointment compared to other groups, and also accounted that faster wound healing in this group was due to antimicrobial and restorative effects of lawsone. The lower infection and inflammation exist in the wound site, the faster the wound healing would be (Khaksary and et al, 2008). Kabir Soleimani et al. described that alpha ointment increased regional circulation, thereby, it stimulated angiogenesis and epithelialization in the affected area, increased restoring tissue elasticity, and promoted the wound toward closure (41). Yar Mohammadi et al. presented evidence that alpha ointment was more effective in infection control, reduced likely scar traces at the burn wound site, and was also cost-effective (Hosseini and et al, 2007).

Nayak et al. (2007) observed an improvement of wound healing with alcoholic extract of *L. inermis* in mice, which led to increased wound contraction, decreased epithelialization period, enhanced skin firmness against cracking, significant rise in granulated tissue weight, and elevated hydroxyproline (a substance affecting wound healing) (Nayak and et al, 2007).

Hosseini et al. (2007) argued that alpha ointment stopped bacterial growth and that wound infections were lower in alpha ointment group. They recommended the ointment to be a proper alternative in burn medications because of an affordable cost (Hosseini and et al, 2007).

Mohammad (2005) showed that *L. inermis* could influence microorganisms (e.g. *Staphylococcus aureus*, *Streptococcus sp.*, *Candidia albicans*, *Aeruginosa*) affecting burn wound infections, and inhibited the growth of these microorganisms, hence, it was introduced as an effective agent in infectious ulcers (Muhammad & Muhammad, 2005). Ansari (2013) discussed that alpha ointment could more effectively heal radiation-induced dermatitis than 1% hydrocortisone ointment, and that the ointment reduced itching, discharge, and pain. The fatty acid present in alpha ointment is anti-inflammatory (Ansari and et al, 2013).

Navi Nezhad et al. (2017) reported that variables related to skin reaction or skin allergy (itching, redness, burning and skin blemishes) were not observed in none of the subjects. Although average scores of episiotomy wound healing were acceptable both in medication and placebo groups according to the numbers accepted in the REEDA Table, there was no positive effect on accelerated wound healing by alpha ointment during the study days. Possible causes of this observation was attributed to the differences in episiotomy wounds with the studied wounds, the use of chromic catgut sutures for wound healing, and a possible effect of alpha ointment on the absorption of sutures, deepness of episiotomy wounds compared to other wounds, and location of episiotomy wound. No cases of infection and drug allergy were observed among the subjects (Navi Nezhad and et al, 2017).

A comparison was made by Mohseni Kia et al. (2015) between alpha ointment and *Halothamnuson* (*Abukhalsa*) plant on healing of wounds caused by heat or trauma, in which the plant and ointment yielded similar results in wound healing (Mohsenikia and et al, 2015).

Rastegar Lari et al. comparatively studied alpha and silver sulfadiazine 1% ointments in rats. They realized that fundermol was not more effective than 1% silver sulfadiazine ointment in healing burn wounds with relative thickness. In addition, mortality rate, bacterial activity, and wound healing were not statistically significant between the two groups. They further recognized that wound epithelialization process by 1% silver sulfadiazine ointment was more effective than fundermol, which reduced wound infection (85% vs. 58%).

Alpha ointment may produce analgesic effects through several mechanisms described below. Flavonoids present in the bee wax contained in alpha ointment have estrogenic, palliative, and local anesthetic effects with good anti-inflammatory impacts owing to inhibition of inflammatory mediators (e.g. prostaglandins). Moreover, the propolis content of beeswax has effective anti-inflammatory and palliative effects (Heidari and et al, 2013), which was also found to be comparable to that of diclofenac (Kabirsalmany and et al, 2008).

In a study by Heidari (2013) on the comparison of 1% silver sulfadiazine and alpha ointments on pain relief in patients with second-degree burns, it was concluded that alpha ointment was more effective in pain relief than 1% silver sulfadiazine ointment, which could be used as a suitable alternative for pain relief in burn patients ($p < 0.001$) (2 and 13). Heidari attributed the analgesic effects of fundermol (alpha ointment) to the bee wax (an ingredient of this drug).

Beeswax is used as the drug base in alpha ointment containing various compounds including flavonoids, which is naturally present in all photosynthetic cells and has a high chemical activity. In animal systems, it has been shown to possess estrogenic and antibacterial effects, impact on membrane permeability, and reduction of free radical formation, anti-inflammatory effect and consequently inhibition of inflammatory mediators (e.g. prostaglandins), palliative influences, and local anesthetics comparable to those of cocaine (RASTGAR & Alaghebandan, 2002).

Roughni et al. (2012) studied the analgesic effect of curcumin, an effective ingredient in turmeric, in diabetic rats and evaluated the role of lipid peroxidation. They concluded that administration of curcumin reduced pain intensity in two acute and chronic phases of formalin test in diabetic rats and that it increased the threshold of thermal pain (Roghani, 2011). Chepodiora et al. also presented evidence of curcumin's painkiller effects (Cheppudiran and et al, 2013), which was found to be effective in pain relief along with other ingredients of alpha ointment. Nesa et al. (2014) confirmed the analgesic and anti-inflammatory effects of *L. inermis* in their study (Nesa and et al, 2014).

Conclusion

A number of human and animal studies have used alpha ointment, most of which reported healing of burn wounds and effective pain relief. Adverse effects of infection and allergy were not observed in none of the studies. Given the proven effects of alpha ointment ingredients in pain relief and wound healing, further studies are recommended on human specimens and various types of ulcers.

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