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The effect of zinc sulfate on prevention, incidence, and severity of mucositis in leukemia patients undergoing chemotherapy

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ABSTRACT

Purpose: This study aimed to evaluate the effect of zinc sulfate on the incidence and severity of mucositis in leukemia patients undergoing chemotherapy.

Methods: This was a randomized clinical trial and placebo-controlled, triple blinded study. This study was conducted on leukemia patients undergoing chemotherapy. The subjects were randomly allocated into an experimental (received 50 mg zinc sulfate capsules) and a control group (received placebo capsules). Zinc and placebo capsules were administered three times daily for 14 days from the first day of chemotherapy. Mucositis was measured by the oral mucositis index and World Health Organization mucositis scale on the 4th, 7th, and 14th days after chemotherapy. The data were analyzed using independent *t*-test, chi-square test, and Repeated Measures Analysis of Variance (RM-ANOVA).

Results: The results showed a significant difference between the two groups in terms of the incidence of mucositis, which was 2.1 times higher in the control group in comparison to the zinc sulfate group. The results of RM-ANOVA also indicated a significant difference between the two groups regarding the mean score of objective and subjective evaluation of mucositis during the three study periods ($F = 7.83$, $p = .007$ and $F = 5.79$, $p = .01$, respectively).

Conclusion: The results of this study indicated that zinc sulfate reduced the incidence and severity of mucositis in leukemia patients undergoing chemotherapy. As zinc sulfate prevented and relieved mucositis in leukemia patients under chemotherapy, using zinc sulfate is recommended in clinical setting. Yet, further studies are suggested to confirm these findings.

1. Introduction

Leukemia is a cancer of blood and blood cells involving an unregulated proliferation of leukocytes in the bone marrow (Hinkle and Cheever, 2014). The incidence of leukemia was reported to be 3.7 per 100 000 person-years in a city in Iran and 11.25 per 100 000 person-years in other countries, such as UK (Bhayat et al., 2009; Dastgiri et al., 2011). Overall, 8% of total cancer patients suffer from leukemia (Koohi et al., 2015).

To date, major advancements have occurred in management of cancer patients (Rastogi et al., 2011). Evidence has also shown that more aggressive regimens, such as chemotherapy, have improved locoregional tumor control and survival of cancer patients (Rastogi et al., 2011). However, these treatments lead to some problems, such as mucositis. Chemotherapy-induced mucositis, as an acute condition, usually occurs one week after chemotherapy (Sonis, 2009). Additionally, the highest frequency of mucositis has been reported on the 10th day after chemotherapy (Martinez et al., 2014). However, it resolves during three weeks (Sonis, 2009). A previous study revealed that 81.3% and 90% of patients with cancer (Al Ibraheemi and Shamoun, 2016) and acute leukemia (Martinez et al., 2014) under chemotherapy suffered from mucositis. It should be noted that use of concomitant chemotherapy and/or targeted agents increased the risk for mucositis (Villa and Sonis, 2015).

Mucositis consists of four phases, including "initial inflammatory/vascular, epithelial breakdown, ulcerative/bacteriological and healing phases" (Sonis, 1998). In ulcerative phase of mucositis, some complications, such as pain (Sonis et al., 2004), dysphagia (Mercadante et al., 2015), and difficulties in eating, swallowing, and talking might occur (Scully et al., 2006). Therefore, patients have to receive painkillers and nutritional support (Jensen and Peterson, 2014). Other complications of mucositis are treatment discontinuation (Campos et al., 2014) and

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weight loss (Elting et al., 2007). In addition, oral hygiene care, medical and healthcare appointments, and hospitalization might increase as a result of mucositis (Jensen and Peterson, 2014). In a study on malignant hematologic patients (acute leukemia and non-Hodgkin lymphoma), 21.9% of hospitalization episodes were related to mucositis (Martinez et al., 2014). Moreover, quality of life of cancer patients was significantly affected by mucositis. Cancer patients with mucositis experienced pain, physical limitations, and psychological discomfort (Martinez et al., 2014). Furthermore, inability to eat and drink and mouth pain limited the quality of life of leukemia patients with mucositis (Martinez et al., 2014).

Despite the high incidence and serious and debilitating complications of mucositis, no preventive and treatable interventions are currently available. Although some Complementary and Alternative Medicines (CAM), such as Chinese herbal medicine, have been used to prevent and treat mucositis, their therapeutic outcomes are not approved (Meyer-Hamme et al., 2013). Moreover, it was shown in a systematic review that chlorhexidine was not effective in preventing the incidence of mucositis and decreasing its severity (Cardona et al., 2017). Some mucositis management strategies and other therapeutic modalities, including drugs such as amifostine, palifermin, benzydamine HCl, and pentoxifylline, low-level laser therapy, gene transfer interventions, and several organic products, have been also used in this regard (Villa and Sonis, 2015). However, the effects of these interventions have not been completely confirmed. In order to gain better treatment outcomes, some researchers preferred to use zinc sulfate.

Zinc is needed for multiple cellular activities, and the immune system is particularly dependent on adequate availability of this crucial trace element (Chandra and McBean, 1994). Moreover, zinc performs as an organelle stabilizer and a stabilizer of the structure of DNA, RNA, and ribosome. It is also a significant cofactor for DNA synthesis, an important factor for wound healing, and a necessary trace component for improving the immune system (Ertekin et al., 2004). However, how zinc affects mucositis is not completely clear (Kwon, 2016).

Researchers have reported that zinc increased the gastrointestinal epithelial barrier function and consequently decreased cell death and detachment (Skrovanek et al., 2014). Zinc increased the overall survival of patients with advanced nasopharyngeal cancer (Lin et al., 2009). Surprisingly, some researchers believed that zinc sulfate might decline the intensity of mucositis in cancer patients under chemotherapy (Arbabi-kalati et al., 2012). In a study on pediatric cancer patients, Cheng et al. (2001) indicated that severity of chemotherapy-induced oral mucositis and the related pain was significantly reduced in zinc sulfate group (Cheng et al., 2001). Moreover, taste of the patients who had received zinc sulfate was recovered more quickly one month after radiotherapy (Ripamonti et al., 1998). On the other hand, some studies have reported that zinc sulfate was not effective in severity and incidence of mucositis. Mansouri et al. indicated that zinc sulfate could not prevent or decrease the severity and duration of mucositis in patients undergoing hematopoietic stem-cell transplantation (Mansouri et al., 2012). Additionally, Sangthawan et al. demonstrated no significant differences between zinc and control groups concerning the incidence of grade 2 oral mucositis and pharyngitis at every week during radiation and within the first month after completion of radiation (Sangthawan et al., 2013). However, the question remains whether zinc sulfate is effective in preventing mucositis in leukemia patients. Previous studies on mucositis have shown somehow contradictory results regarding the effect of zinc sulfate (Arbabi-kalati et al., 2012; Cheng et al., 2001; Ertekin et al., 2004; Mansouri et al., 2012; Mosalaei et al., 2010). Indeed, review of the literature revealed that a few studies have been performed on the effect of zinc sulfate on prevention of chemotherapy-induced mucositis (Arbabi-kalati et al., 2012; Mansouri et al., 2012; Mehdipour et al., 2011). Moreover, a limited number of studies have been focused on leukemia patients. It should be noted that mucositis has many complications that decrease leukemia patients' quality of life (Martinez et al., 2014). On the other hand, zinc sulfate improved cancer patients' survival and treatment rates (Lin et al., 2009). Considering the limited number of studies on leukemia patients' mucositis and the valuable effect of zinc sulfate, this study aims to evaluate the effect of zinc sulfate on prevention, incidence, and severity of mucositis in leukemia patients under chemotherapy.

2. Methods

2.1. Hypothesis

In this study, the three following hypotheses were examined:

1) Zinc sulfate would prevent mucositis in leukemia patients under chemotherapy.
2) Mucositis in leukemia patients under chemotherapy would happen later in the zinc sulfate group in comparison to the control group.
3) Severity of mucositis in leukemia patients under chemotherapy would be milder in the experimental group in comparison to the control group on 4th, 7th, and 14th days of the study.

2.2. Design

In this randomized clinical trial and placebo-controlled study, leukemia patients under chemotherapy were randomly assigned to receive either zinc sulfate or placebo. Therefore, it was a parallel study.

2.3. Allocation

In this study, allocation concealment was used to prevent selection bias. To achieve this goal, the patients and individuals who enrolled them into the study were unaware of group allocations. The allocation concealment mechanism was performed in three steps; i.e., capsules form and appearance, randomization, and outcome measurements, by three individuals with no clinical involvement in the trail as follows:

First, zinc sulfate or placebo capsules were prepared in similar color, shape, and weight by a pharmacologist who was a faculty member of Shiraz University of Medical Sciences (SUMS). He allocated zinc sulfate or placebo capsules to A or B codes randomly. Then, he prepacked 42 capsules in similar bottles for each patient. He was the only person who knew the groups until the analysis was finished. Second, in order to achieve allocation concealment, a researcher's assistant who was blind to the study groups performed the randomization. Third, the study outcomes were evaluated by a nurse who was blind to the study groups.

2.4. Randomization

Leukemia patients under chemotherapy were assigned to an experimental and a control group by block randomization with block sizes of two. In so doing, an online statistical randomization program was used to generate the randomization sequence. The randomization was performed by a researcher's assistant who was not involved in the trail and was blind to the study groups. In this step, based on the allocation sequence, bottles A or B were sequentially numbered in opaque sealed envelopes. They were kept in a place with appropriate humidity and temperature. To enter the study, the researcher's assistant gave the next numbered envelope to the patient.

2.5. Blinding

In this triple blind study, the researchers and participants were blind to zinc sulfate and placebo capsules. To achieve this aim, zinc sulfate and placebo capsules were completely similar in color, shape, and weight. The researcher's assistant who collected the data and the statistician who analyzed the data were also blind to the study groups.

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