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Evaluation of the effect of topical application of Chamomile
after surgical extraction of impacted lower third molars.

(A clinical study)

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Introduction:

Third molar surgery is one of the most commonly performed procedures in dentistry (Gümrükçü 2019). This procedure often necessitates incision, flap reflection, and bone removal that can cause trauma to the tissues, which results in triggering tissues' biological responses such as pain, edema, and trismus influence the patient's quality of life (Gümrükçü 2019). Therefore, it is important for the surgeon and patient to decrease the post-extraction complications and improve the control of pain, oedema and trismus on these patients in an attempt to improve their quality of life after surgical procedures (Glória, Douglas-de-Oliveira et al. 2020). Studies have verified the pre and postoperative effects of different drugs and /or clinical management to control these parameters (Glória, Douglas-de-Oliveira et al. 2020). Recently, some strategies have been developed for minimizing postoperative discomfort after third molar surgery, including the use of pharmacological therapy and alternative medicine , and complementary protocols have been suggested for the postsurgical therapy of third molar surgery (Glória, Douglas-de-Oliveira et al. 2020).

Alternative medicine (herbal medicines) has dramatically fewer side effects and is safer to use than conventional medications (Taheri, Azimi et al. 2011).

Several plants with antibacterial and healing applications are used in medicine such as Chamomile, which is one of the oldest, most broadly used and well recognized medicinal plants in the world. Medicinal plants can provide safe and effective treatments against many infections. Herbal medicines in wound management creating a suitable environment for natural healing process (Kazemian, Ghafourian et al. 2018)qew.

These results revealed the value of plant extracts to control antibiotic resistant bacteria in wound infections (Kazemian, Ghafourian et al. 2018).

Chamomile is known to have a variety of active flavonoids, the flowers of chamomile contain 1–2% volatile oils , which is rich in terpenoids, such as alpha bisabolol, azulene, matricine, chamazulene , apigenin, luteolin, and quercetin. These components provide its anti-inflammatory, antispasmodic, wound healing activities, smooth-muscle relaxing action, particularly in the gastrointestinal tract, anti-biofilm formation and antibacterial properties (Taheri, Azimi et al. 2011, Valenzuela, Pons-Fuster et al. 2016).

It also is used for gingivitis and periodontal disease as a mouth wash. Topical applications of chamomile have been shown to be moderately effective in the treatment of eczema. Topical use of chamomile ointment was also found to successfully treat mild stasis ulcers bed sores in elderly bedridden patient. In dentistry chamomile is used as mouthwash to prevent periodontal disease (Taheri, Azimi et al. 2011).

Side effects

Allergic reactions to chamomile have been reported, including bronchial constriction with systemic use and allergic skin reactions with topical use. People with allergies to plants of the Asteraceae family (ragweed, aster, and chrysanthemums), as well as mugwort pollen should avoid using chamomile. Chamomile is usually considered to be safe during pregnancy or breast-feeding. However, there is one case report in which a pregnant woman who took chamomile as an enema had an allergic reaction that led to the death of her newborn (Taheri, Azimi et al. 2011).

The aim of the present clinical study is to investigate the effects of topical application of chamomile gel on postoperative discomfort among patients who are undergoing mandibular third molar surgery.

Aim of the study:

Studying the effect of the topical application of chamomile gel on healing after impacted lower third molars surgical extraction, by studying:

- 1) Infection.
- 2) Swelling.
- 3) Pain.
- 4) Mouth-opening.
- 5) Soft tissue healing.

Methods and Materials:

Study design

Randomized triple-blind split-mouth placebo-controlled clinical trial.

Blinding:

Both chamomile gel and placebo gel were colored red and loaded in coded syringes ("A" and "B") in equal quantities (2ml), the researcher and the patients don't know which one is chamomile.

Randomization:

By coin flipping to determine the first side to do surgery (right or left), then to determine the gel sample to apply ("A" or "B").

Study Sample:

This study will include at least 20 patients undergoing bilateral impacted lower third molars surgery under local anesthesia. Sample size (n = 40)

We'll flip a coin to determine the first side to extract (right or left) and the gel sample to apply in the socket ("A" or "B"). The other sample will be applied in the other side after at least 21 days.

Place of study

Damascus University, Faculty of Dentistry
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Inclusion criteria

1. The patient's age (18-28) years.
2. Surgical extraction of symmetrically impacted lower third molars (class II-B of Pell-Gregory) is indicated.
3. Good general health and there are no uncontrolled systemic diseases.
4. The integrity of the periodontal tissues and the absence of periodontal diseases.
5. Good oral health.
6. There is no allergy or contraindication to the required postoperative prescription or to the applied medicinal substances.

Exclusion criteria

1. the period or pregnancy or lactation.
2. uncontrolled diabetes, uncontrolled hypertension, neoplasms, known neuropsychiatric illness, blood dyscrasia, coagulation disorders, or metabolic disorders.
3. Patients with pericoronitis, infection, pathological condition in the region of surgery.
- 4- allergy to chamomile or any plants of Asteraceae/compositae family.
- 5- The difference between the two operations was more than 10 minutes.

The surgical procedure

After determining which side (right or left) and which sample ("A" or "B") by coin flipping, local anesthesia with 2% lidocaine + 1:80,000 epinephrine solution, Triangle full thickness flap will be reflected and necessary bone removal will be performed by low-speed straight surgical headpiece under continuous irrigation of saline solution. After the impacted molar will be

removed and the socket will be rinsed with saline, the researcher will apply the elected gel in the extraction socket.

The extraction wound will be sutured with 3-0 silk.

After every surgery, patients will be received fixed postoperative instructions.

Post-surgical prescription

Paracetamol 500 mg: as necessary.

Antiseptic mouth wash

Clinical follow-up

Confirmed study participants were screened for assessment swelling measurements and mouth opening before surgery (T0). post-operative clinical assessments will be performed at third day (T1), 7th day(T2).

1- The swelling

Facial swelling will be evaluated by the method which measures 3 distances:

- from the tragus to oral commissure
- from the tragus to pogonion.
- from outer angle of eye to angle of mandible.

2- Mouth opening

Maximum mouth opening will be measured as the maximum distance between the maxillary and mandibular central incisors.

3- The pain

Postsurgical pain will be evaluated using visual analogue scale (VAS) of faces for 7 days after extraction.

4- Soft tissue healing

Soft tissue healing will be assessed at the seventh postoperative day through gingival healing index given by Landry et al.

Data Analysis

Data will be analyzed using SPSS version 2^o software

❖ The Kolmogorov-Smirnov test will be performed to study the normal distribution of the values of each of the measured parametric variables(radial bone density...). T-test will be used for correlated samples for comparison of time periods in each group

❖ If the distribution of the values is abnormal, then the Mann - Whitney U test will be used to compare the two groups, and the Wilcoxon test for the algebraic ranks will be used for the double comparison between the time periods in each group

❖ For the nominal variables (the degree of pain, ...), the Mann-Whitney U test will be used to compare the two groups, and the Wilcoxon test for algebraic signs will be used to compare the time periods in each group as well.

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