Evaluation of the Effect of Black Tea Extract on the Primary Bleeding Cessation after Molar Extraction: A Randomized Controlled Trial

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1. Study Objectives

1.1 General Objectives:

To evaluate the effect of black tea extract on bleeding cessation after molar extraction

1.2 Specific Objectives:

a) To determine the bleeding cessation time with used of normal sterile gauze with 0.5% povidone iodine (PVI)after molar extraction.
b) To determine the bleeding cessation time with used of black tea extract-impregnated (BTEI) sterile gauze after molar extraction.
c) To identify adverse effect of BTEI sterile gauze and PVI sterile gauze on post-extraction sites.
d) To compare the bleeding cessation with used of the BTEI sterile gauze and PVI sterile gauze on post-extraction area.

2. Research Hypotheses

There is no difference of bleeding cessation time between BTEI gauze and 0.5% PVI sterile gauze.

3. Methodology

3.1 Preparation of Black Tea-Extract Impregnated Sterile Gauze

For the preparation of black tea-extract impregnated (BTEI) gauze, 5 gauzes were prepared for each time. High-performance liquid chromatography (HPLC) was used to determine the tannin concentration in the black tea extract, which was 4.67 % w/w. 10 grams of black tea-extract powder was mixed with 24ml of saline using magnetic stirrer with 200 rpm for 10 minutes to achieve 18.67 mg/mL of tannin concentration in the solution. 5ml of solution was measured and inserted into sterilized ice cube tray. Sterile gauzes were soaked into each cube. It was covered with sterile lid and stored in 4 °C refrigerator for 24 hours for uniform absorption for each gauze. Then, the gauzes were sent for ultraviolet germicidal irradiation. 10 minutes for 1 side and flipped the gauzes for another 10 minutes. After that, the gauzes were folded and packed into sterile sealed plastic bag until usage.

3.2 Preparation of 0.5% Povidone Iodine Impregnated Sterile Gauze

5 gauzed were prepared at the same time together with BTEI gauzes. 5ml of 0.5% povidone iodine solution was inserted into each cube followed by soaking a gauze into each cube. The gauzes were stored in refrigerator and sent for ultraviolet germicidal irradiation together with BTEI gauzes.

3.3 Study Design and Intervention

This is a randomized controlled trial performed in Manipal University College Malaysia's (MUCM) Oral and Maxillofacial department (OMFS), from April to December 2024. The study protocol was approved Research Ethics Committee of MUCM (MUCM/ Research Ethics Committee- 042/2023). The trial is registered with National Clinical Trial Network with registration number NCT06687824. Informed consent from all participants was collected prior commencement of study. After selection of patient according to inclusion criteria and exclusion criteria, the demographic details (age, gender) of participants were recorded. Participants that are sensitive to black tea, use of complementary medical methods within the past month, having history of exposure of surgery site to radiation and use of antibiotic, corticosteroid, anticoagulant and contraceptive drug over the past month were excluded from the study. After exclusion of participants, we included participants that were age $\geqslant$18 years old and included in American Society of Anaesthesiologist (ASA) I and II. Those who met the inclusion and exclusion criteria were randomly selected and allocated into Group A and Group B using block randomization with block size 4.

After patient selection and allocation, the extraction site was anaesthetized with mepivacaine hydrochloride 2%/ adrenaline 1:100,000 and molar was extracted with simple

extraction without odontotomy, flap incision, flap elevation and bone removal. Time of extraction was within 20 minutes. After irrigating the socket with 0.5% povidone iodine solution, BTEI gauze was applied for intervention group and PVI gauze for control group. The primary bleeding cessation state was evaluated at 2, 5 and 7 minutes. The result was investigated and recorded as <2, 2-5, 6-7 and > 7 minutes. When the bleeding stopped, the participant was discharged and a new gauze was given and participant was instructed to bite the gauze for 1 hour. 3 days later, all participants were contacted for follow-up assessment via phone to evaluate the presence of adverse effect in all participants.

4. Statistical Analysis Plan (SAP)

4.1 Primary and Secondary Outcomes

4.1.1 Primary outcomes

To evaluate the effect of BTEI gauze primary bleeding cessation after molar extraction.

4.1.2 Secondary Outcomes

To identify the adverse effect of using BTEI gauze and PVI gauze

4.2 Analysis Population

After randomization, there was no dropouts, Intent-to-Treat (ITT) and Per Protocol (PP) population were identical which was 44 participants, 22 participants for each group.

4.3 Statistical Methods

The demographic details of the participants were analysed using IBM SPSS Statistics version 26. The primary bleeding cessation time at post-extraction site after using BTEI gauze and PVI gauze was assessed at 2,5 and 7minutes post-extraction and recorded using categorical method. The proportion of participants in each group achieving haemostasis at each time point will be compared using Chi-square test. A two-tailed p-value of less than 0.05 will be considered statistically significant. The assumption for the Chi-square test will be assessed prior to analysis.