Official Title: Effect of Preoperative Dexpanthenol Moisturizer on the Prevention of Angular Cheilitis After Pediatric Adenotonsillectomy: A Randomized Controlled Trial

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MATERIALS AND METHODS

This prospective, randomized, controlled study was designed and conducted in strict adherence to the ethical principles of the Declaration of Helsinki. The study protocol was approved by the institutional ethics committee (approval date: 07.07.2021; number: 309) and written informed consent was obtained from patients' parents. This study was designed and reported in compliance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines for randomized controlled trials. A CONSORT flow diagram illustrating the progress of participants through the trial phases is included **(Figure 1)**. Given the limited prior literature, confined to a single pilot study by England et al. [4], a precise power analysis was not feasible. Initially, the target sample size was set at 60 patients over a 3-year period. To enhance statistical power, enrollment continued throughout the planned period, ultimately yielding a sample of 106 participants.

A total of 106 children aged 3-15 years scheduled for adenotonsillectomy between July 2021 and July 2024 at a tertiary referral ENT facility were enrolled in the study. Patients were randomized into study and control groups using computer-generated random numbers. In the study group, a water-in-oil emulsion formula containing 5% dexpanthenol (Bepanthol® Derma moisturizing cream, Bayer Türk Kimya San. Ltd. Şti. İstanbul, Türkiye) was administered to both oral commissures as a moisturizer immediately before mouth gag insertion while the control group received no cream. The Brodsky Grading Scale was used to assess pre-operative tonsillar hypertrophy. Pre-operative Mallampati scores of patients were also recorded. The conventional cold steel tonsillectomy technique was preferred in all patients to ensure consistency. Under the supervision of the same senior surgeon, all surgeries were performed by the same resident. Under general anesthesia, the Boyle Davis mouth gag was inserted. The size of the tongue depressor of the Boyle Davis mouth gag was recorded. Prior to incision, the distance between the upper and lower central incisors was measured using a ruler.

Adenoidectomy was performed first using a standard curette technique under direct visualization with a mirror. Following excision of adenoid tissue, gauze packs were placed in the nasopharynx to achieve hemostasis and bipolar cautery was applied when necessary. Subsequently, tonsillectomy was performed using the cold steel dissection technique. Once the pericapsular plane was identified, the tonsils were dissected bluntly and excised. Bipolar electrocoagulation and nonabsorbable 2.0 silk ties were utilized simultaneously to manage hemorrhage in all surgeries. The inferior tonsil poles were consistently ligated with 2.0 silk ties. The surgical time was recorded. A single dose of prophylactic cefazolin sodium (25 mg/kg) was administered parenterally to all patients preoperatively, and in the postoperative period, all patients received oral paracetamol suspension (20 mg/kg) three times daily for pain control.

Postoperative evaluations were conducted by a senior surgeon who was unaware of the patients' group assignments. On the first postoperative day, patients were assessed for the presence of AC and the severity of pain. The presence of AC was assessed and recorded as either present or absent. Pain intensity was evaluated by the patients' parents by utilizing the Wong-Baker Faces Pain Rating Scale, which ranges from 0 to 10 points. All patients underwent reevaluation for the same measures on the seventh day postoperatively.

Statistical Analysis

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA; RRID:SCR_002865). Categorical variables were presented as frequencies and percentages (%). Numerical variables were expressed as mean and standard deviation (SD). The comparison of categorical variables was performed using the Pearson Chi-Square test. The normality of numerical variables was assessed using the Kolmogorov-Smirnov test, and variables following a normal distribution

were compared using the Independent Samples T-Test. Binary logistic regression analysis was used to evaluate the independent effect of topical dexpanthenol use on the occurrence of AC on postoperative first day and first week. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. The model's explanatory power was assessed using Nagelkerke R^2. A p-value less than 0.05 was considered statistically significant.