Postoperative Ecchymosis and Edema following Subperiosteal Tunnels in Rhinoplasty: A Blinded Randomized Clinical Trial

Trial Protocol

Background

Osteotomies of the nasal bones are frequently performed during rhinoplasty for a variety of purposes, including narrowing the bony pyramid of the nose or closing an open-roof after removing a dorsal hump. Periorbital edema and ecchymosis is a minor but common sequela of osteotomies (1). It is theorized that edema and ecchymosis are attributed to the disruption of the vascularity contained within the periosteum or venules and capillaries in the more superficial layers. Various interventions have been utilized to minimize this morbidity including intra-operative hypotension, corticosteroid administration as well as the creation of a subperiosteal tunnel (SPT). Subperiosteal tunnels (SPT) consist of elevating the periosteum off the bony cortex in order to reduce bleeding and subsequent bruising. Despite the long-accepted principle that periosteal preservation prior to osteotomy reduces postoperative ecchymosis, its efficacy is not objectively established and recent literature even suggests the opposite (2, 3). The conflicting data is worth examining as this short-term outcome can have a significant impact on the length of patients' recovery and time off work needed.

Aim

The goal of this current study is to prospectively evaluate the efficacy of transnasal SPT prior to lateral osteotomy in reducing postoperative ecchymosis by performing a matched-pairs prospective analysis.

Methods

Study Design: A blinded randomized matched-paired analysis where each patient will undergo rhinoplasty with bilateral osteotomies. One side of the nose will be randomly selected for the creation of a subperiosteal tunnel.

Study Population:

Inclusion criteria: Patients aged ≥17 years old undergoing aesthetic rhinoplasty requiring bilateral osteotomies

Exclusion criteria: Patients undergoing rhinoplasty without osteotomies, with unilateral or intermediate osteotomy, patients declining to participate or failing to provide consent, and patients in whom follow-up after exactly 7 days was not possible due to scheduling conflicts.

Outcomes Evaluations

Baseline demographic data will be collected including age, sex, nasal anatomical characteristics and presenting complaints.

Patient will be seen in follow up on post operative day 2 and 7 and photographs will be taken. Grading of both post-operative ecchymosis and edema, will be performed on each of these days using a 0 to 10 visual analogue scale by three non-expert evaluators who will be blinded to the side with SPT.

Data Analysis

Each evaluator will rate ecchymosis and edema separately, for each side of the nose, on a visual analog scale of 0 to 10. Each side of the nose will receive an average score based on all three evaluators for both ecchymosis and edema. The difference in the average score between sides will be used to quantify the effect that periosteal tunneling has on ecchymosis or edema. Once the difference average score is obtained for each individual subject, a within subject paired t-test will be computed using 95% confidence intervals.

Sample Size

Using a 95% confidence interval to estimate between group differences, a sample size of 14 per group (28 subjects in total) will be sufficient to estimate the between group difference to an accuracy of +/-0.75 (total CI width 1.5). This is well within the clinically important difference of 3, and so is a conservative sample size estimate. 34 patients will be enrolled to account for a drop out rate of 10%.

Funding

No funding received

Start date

April 2015

Expected end date

August 2015

References

1. Kara CO, Kara IG, Yaylali V. Subconjunctival ecchymosis due to rhinoplasty. Rhinology. 2001;39(3):166-8.

2. Kara CO, Kara IG, Topuz B. Does creating a subperiosteal tunnel influence the periorbital edema and ecchymosis in rhinoplasty? Journal of oral and maxillofacial surgery: Official Journal of the American Association of Oral and Maxillofacial Surgeons. 2005;63(8):1088-90.

3. Al-Arfaj A, Al-Qattan M, Al-Harethy S, Al-Zahrani K. Effect of periosteum elevation on periorbital ecchymosis in rhinoplasty. Journal of plastic, reconstructive & aesthetic surgery: JPRAS. 2009;62(11):e538-9.