

Supplementary Online Content

Yu W, Jin Y, Yang J, et al. Occurrence of bruise, hematoma, and pain in upper blepharoplasty using blunt-needle vs sharp-needle anesthetic injection in upper blepharoplasty: a randomized clinical trial. *JAMA Facial Plastic Surgery*. Published online November 23, 2016. doi:10.1001/jamafacial.2016.1376

Trial Protocol.

This supplementary material has been provided by the authors to give readers additional information about their work.

Protocol

Background

Blepharoplasty, one of the most common surgeries performed by plastic surgeons, is a procedure which can improve dermatochalasis, a common condition of excess skin hanging over the upper eyelids or even beyond the eyelashes, mostly caused by aging.¹ Moreover, in Asia patients, in particular, double eyelidplasty, also known as “Asian blepharoplasty” or “double eyelid” surgery, is frequently performed together with epicanthoplasty to create a superior eyelid with a crease and remove the epicanthal fold in Asian upper eyelid. The surgical procedure creates an illusion of larger and relaxed eyes and has become one of the most common cosmetic surgeries in Asia.²⁻⁴

Conventional sharp needles have been widely used to administer local anesthesia injections in upper blepharoplasty. However, blunt needles have been considered as less prone than sharp ones to produce bleeding due to the unintended entry into blood vessels⁵. Akins et al⁵ demonstrated that 18g blunt needles may be less likely than sharp ones to unintentionally enter blood vessels and produce bleeding. Hence, Surgeons use blunt tipped devices to avoid inadvertent penetration of arteries or adjacent vital structures⁶. In previous studies, Complications resulting from interventional pain procedures have raised the issue of the safety of blunt vs. sharp needles for doing these procedures.⁷

To our knowledge, this is the first prospective, side by side, comparison study evaluating these supposed advantages of blunt needle on complications in patients undergoing upper blepharoplasty, by investigating such complications as incidence of hematoma and interventional pain procedures.

Specifically, by using both, blunt and sharp needles to inject local anesthesia in each patient undergoing

upper blepharoplasty, to evaluate whether the blunt needles reduce complication of upper blepharoplasty compared with the sharp ones.

Aim

This prospective study aimed to investigate whether any benefit exist in using blunt needle for local anesthesia injections to reduce hematoma and pain in the eye after upper blepharoplasty.

Methods

Study design

A prospective, side by side, comparison study.

The study will enroll healthy patients who will schedul for bilateral upper blepharoplasty agreed to participate in the study and provided written informed consent.

In the upper blepharoplasty surgery, patients are administered local anesthesia (2% lidocaine) will injected into both eyelids of each patient using a blunt needle(27Gx2", 50 mm) for one upper eye lid, and a sharp needle (27Gx1.4", 35 mm) for the other eyelid. The selection of each upper eyelid to be injected with either needle type will determined by a randomization procedure.

This study was conducted at the plastic reconstruction surgery and approved by the ethics committee of Shanghai 9th hospital affiliated to Shanghai Jiaotong University School of Medicine, Shanghai, China.

Study population

Inclusion criteria:

- 1) Aged 18-65.
- 2) healthy patient.
- 3) Having not accepted any upper blepharoplasty surgery before.
- 4) Having not accepted any oral drugs which will affect blood clotting.
- 5) Ability and willingness to sign an inform consent form after fully understanding the therapeutic and follow-up strategies.

Exclusion criteria

- 1) Insufficient pulmonary functions and hepatorenal functions.
- 2) Patients with fever or WBC less than 2500 / cubic millimeter.
- 3) The combined use of other drugs which will affect blood clotting.
- 4) Serious underlying systemic disease requiring treatment until illness either completes therapy or achieves clinical stability on therapy for at least 6 months before enrolled the study. The systemic diseases include insufficient pulmonary functions(COPD, pneumonia, pulmonary fibrosis and asthma), insufficient cardiac and hepatorenal functions, infection , hemorrhagic tendency, immunologic disease(SLE, urticaria, HIV).
- 5)Patient who had upper blepharoplasty surgery before.

The termination criteria to a subject

- 1) upper blepharoplasty surgery is finished.
- 2) The subject requests to terminate treatments.
- 3) A good effect over expectation prior to sixth treatment evaluated by authors including dramatic degeneration of the volume, absolute disappearance of malformed pulse and decreased skin temperature.
- 4) Serious major complications classified by the SIR occurs.
- 5) The subject becomes pregnant.

Intervention

Immediately prior to the operation, local anesthesia (2% lidocaine) was injected are administered by a plastic surgeon through a percutaneous approach into both eyelids of each patient using a blunt needle(27Gx2", 50 mm) for one upper eye lid, and a sharp needle (27Gx1.4", 35 mm) for the other eyelid. The selection of each upper eyelid to be injected with either needle type was determined by a randomization procedure. Observation of complications is conducted after each injection.

Outcomes Evaluation

Visual analogue scale (VAS, 0 to 10) was used to blindly measure and score pain in patients receiving local anesthesia injections with both sharp and blunt needles, which will to evaluate the difference of interventional pain procedures between the use of blunt and sharp needles for local anesthesia injections.

The incidence of hematoma at the sharp and blunt needle sites of local anesthesia injections given

to each patient for both upper eyelids was assessed by photographic evaluation. Photographs were taken After injection of both eyelids each patient and then two plastic surgeons (who were blinded and did not know which needle type was used at the site of local anesthesia injections) were identify the hematomas in sharp and blunt needle sites.

The side effect follow-up includes clinical symptoms evaluated by doctors and the pain receiving local anesthesia injections with both sharp and blunt needles, self-evaluation of patients through doctors visiting. All study-related data was synthesized for subsequent analysis by the SPSS 19.0 (IBM Corporation, Armonk, NY, USA) and GraphPad Prism 5 (GraphPad Software, Inc., Carlsbad, CA, USA) software packages. A p-value of ≤ 0.05 indicated that the difference between the two outcomes was statistically significance in all comparisons.

Sample size

About 50 patients would be enrolled this study.

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Eighteen 10, 2014

Expected end date

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