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The effect of injection of 1:100 000 adrenaline solution in the pterygopalatine fossa on intra-operative bleeding during endoscopic sinonasal surgical procedures in chronic sinusitis: a blinded clinical trial

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Main Article

Maliheh Akbarpour takes responsibility for the integrity of the content of the paper

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Abstract

Objective. Rhinosinusitis is one of the most common reasons for a visit to otolaryngology clinics. Some patients are candidates for sinus surgery. Infiltration of 1:100 000 adrenaline in the pterygopalatine fossa was studied, with the aim of evaluating the effect on bleeding in the surgical field.

Methods. This double-blind clinical trial was conducted in 2021–2022 on 40 candidates for endoscopic sinus surgery. For each patient, one side of the pterygopalatine fossa was randomly selected to be infiltrated with a vasoconstrictor. Surgical field bleeding on each side was evaluated.

Results. Blood loss was 35.8 ± 20.9 ml in the study group and 38.4 ± 23.7 ml for the control group, with no statistically significant difference between groups ($p = 0.49$). In addition, there was no difference between the two groups in terms of the surgical field based on Boezaart scores.

Conclusion. Although there are some recommendations on the usage of vasoconstrictors via the pterygopalatine foramen, debate remains.

Introduction

Chronic rhinosinusitis is one of the most common reasons for a visit to the otolaryngology clinic. Patients who are unresponsive to maximal medical treatment, or those experiencing sinusitis of special causes such as fungal rhinosinusitis, are candidates for functional endoscopic sinus surgery (FESS). Despite technological advancements in endonasal equipment and the enhancement of surgical skills, possible complications are inevitable. Bleeding can alter the precise view of the surgical field, prolong operation time, and increase the risk of complications such as mucosal injuries and sequential synechia, cerebrospinal fluid leakage, and inadvertent trauma to adjacent structures.[1]

Various methods are effective in reducing surgical bleeding. Correction of coagulopathies, avoidance of predisposing medications in the pre-operative period, proper patient positioning, anaesthetic protocol, topical vasoconstriction, and some drugs like beta-blockers, tranexamic acid and desmopressin, are some of the preventive measures used to decrease blood in the surgical field.[2,3] There are limitations of beta-blocker usage in some patients (e.g. those with asthma); in addition, reports of blindness after the intranasal injection of vasoconstrictors, and limited accessibility of systemic and topical haemostatic agents, are encountered in some instances.

Although infiltration of the pterygopalatine fossa has been proposed by some senior rhinologists to be safe and effective regarding posterior bleeding during FESS,[4] there are some contrasting reports.[1] Furthermore, this technique has not gained popularity as a standard preparation method in sinus surgery. It seems that factors like the method and timing of injection, concentration of the solution, and duration of surgery may be effective.

The effectiveness of 1:80 000 adrenaline has been reported in a meta-analysis, and a significant effect of a 1:80 000 solution compared to a 1:100 000 solution was observed.[5] The current study aimed to assess the effect of 1:100 000 adrenaline injected in the pterygopalatine fossa half an hour before the operation on intra-operative bleeding during FESS.

Materials and methods

Patients

A double-blind clinical trial was conducted on 40 candidates for FESS in light of chronic rhinosinusitis of various causes, operated on in Amir al Momenin Hospital, Rasht, Iran,

during 2021–2022. The study was approved by the Ethical Committee of Guilan University of Medical Sciences (approval number: IR.GUMS.REC.1399.606) and complied with the rules delineated in the Helsinki Declaration. Also, the trial was registered in the Iranian Registry of Clinical Trials ('IRCT' trial number: 20210307050609N1). Informed consent was obtained from each subject before participation.

Patients were excluded if they had: asymmetric disease on both sides based on a computed tomography scan and a history of dysrhythmia or cardiovascular diseases (e.g. hypertension); a history of taking anticoagulants, vitamin E supplements, garlic, fish oil or ginseng; or had a hypersensitivity to lidocaine. In addition, candidates for endoscopic surgery on a single sinus on each side were not included.

All patients with nasal polyposis received low-dose systemic corticosteroids and oral antibiotics for 10 days before surgery. The same anaesthetic protocol was adopted for all patients.

Surgery

General anaesthesia was induced with propofol (2.5 mg/kg), fentanyl (2 µg/kg), lidocaine (20–40 mg) and cisatracurium (0.1–0.2 mg/kg). Anaesthesia was maintained with remifentanil (0.1 µg/kg/min) and propofol (50–150 µg/kg/min), until systolic blood pressure reached 80–100 mmHg; the remifentanil infusion rate was then adapted to maintain hypotension at this level. All patients were placed in a 20-degree reverse Trendelenburg position, to improve venous drainage. Infiltration of the pterygopalatine fossa via the greater palatine foramen was performed by either saline or lidocaine and adrenaline solution (1:100 000), on each side of the patient.

The pterygopalatine fossa was approached through the greater palatine foramen. That is found half-way between the midline and alveolar ridge in the posterior hard palate.[6–8] We identified the greater palatine foramen using the technique described by Mercuri.[9] It is located by placing a finger in the mouth and palpating the junction of the hard and soft palate. The finger is drawn anterior to the hard palate's posterior rim for 3–5 mm, until the foramen is felt.

We inserted a 26-gauge needle into the greater palatine canal, bent at 20–25 mm from the tip. After aspiration to exclude intravascular penetration, 2 ml of saline or lidocaine and adrenaline solution (1:100 000) was slowly injected on each side of the patient.

The surgeon injected a small quantity of lidocaine and adrenaline solution or saline on the right pterygopalatine fossa, and lidocaine and adrenaline solution or saline (whichever had not been used on the right side) on the left side of each patient. Each participant was considered as their own control. Patients and surgeons were blinded as to which compound (lidocaine and adrenaline solution or saline) was used on either pterygopalatine fossa. The block randomisation method was used for allocating the side of the nasal cavity to either the experimental group (lidocaine and adrenaline solution) or the control group (saline). Block randomisation was used to reduce bias and achieve balance in the allocation of the side of participants' nasal cavities to treatment arms.

All surgical procedures were performed by one surgeon. At 30-minute intervals, mean arterial blood pressure and pulse rate were recorded. The quality of the surgical field was graded using the Boezaart scale[10] every 15 minutes. This is a measure of the visibility of the surgical field associated with intra-operative blood loss, calculated using a five-point scale (ranging from 1 = 'no bleeding' to 5 = 'severe bleeding with constant suctioning required'). Blood volume was assessed every 15 minutes for each side separately. Blood loss was measured by subtracting the amount of saline solution used to irrigate the surgical field from the amount of blood and fluids aspirated from the surgical field. All nasal sponges for each side were weighed at the end of the surgery, and each 1 g increase in pack weight was taken as 1 ml of blood loss. After surgery, patients were asked about and checked for possible complications.

Statistical analysis

The data were analysed with SPSS® statistical software version 26, using paired *t*-tests and repeated measured analysis of variance (ANOVA) for the quantitative data.

Results

After evaluating 47 patients (94 sides), and after considering the exclusion criteria, 40 patients were included (Figure 1).

Of the 40 patients (80 sides) who participated in the study, 26 (65 per cent) were men. The mean age of the participants was 42.4 ± 12.4 years (range, 18–67 years) (Table 1).

The mean duration of surgery was 81.4 ± 24.2 minutes. The mean Lund–Mackay score, reflecting disease severity, was 18.4 ± 4.9. In 7 patients (17.5 per cent), Samter's triad was reported. Two patients (5 per cent) experienced unilateral facial pain after surgery. The most common type of chronic rhinosinusitis was chronic rhinosinusitis with nasal polyposis ($n = 19$; 47.5 per cent). Five patients (12.5 per cent) reported associated diseases other than asthma.

The evaluation of mean arterial blood pressure at different time-points during surgery, according to a repeated measure ANOVA test, revealed a significant difference ($p = 0.038$) (Figure 2). However, the difference in pulse rate was not statistically significant ($p = 0.20$) (Figure 3).

Blood volume was measured by summating the volume of blood in different bottles and nasal packs used for haemostasis

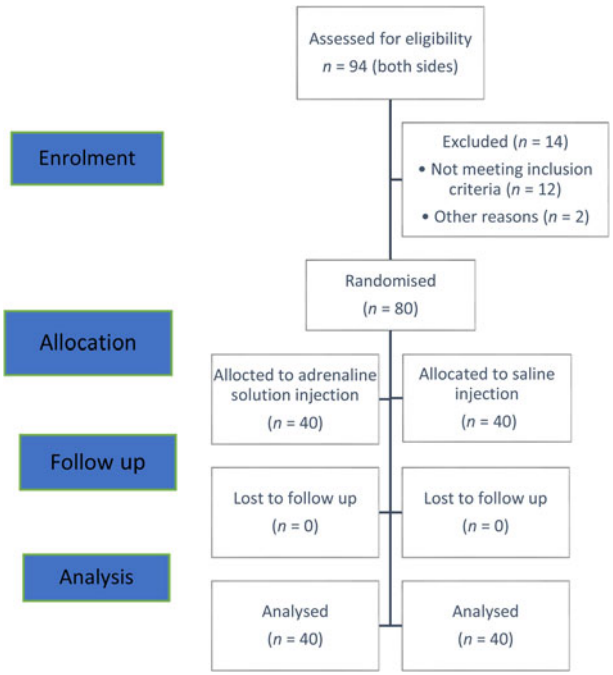

Figure 1. Patient flow diagram according to the Consolidated Standards of Reporting Trials ('CONSORT') guidelines.

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Table 1. Participants' demographic features

Parameter	Value
Number of patients	40
Sinusitis type (*n* (%))	
– Fungal	3 (7.5)
– Chronic rhinosinusitis with nasal polyps	19 (47.5)
– Chronic rhinosinusitis without polyps	18 (45)
Lund–Mackay score (mean ± SD)	18.4 ± 4.9
Samter's triad (*n* (%))	7 (17.5)
Sex (*n* (%))	
– Male	26 (65)
– Female	14 (35)
Age (mean ± SD; years)	42.4 ± 12.4

SD = standard deviation

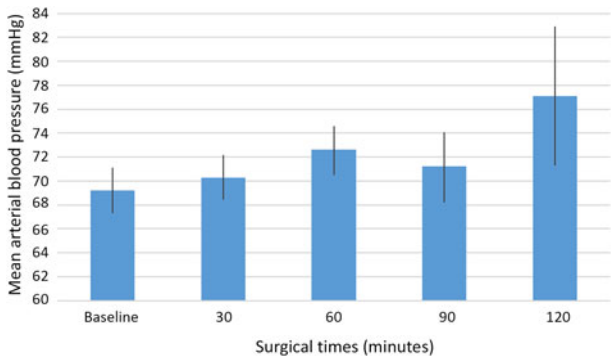

Figure 2. Mean arterial blood pressure at different surgical times.

during the operation, for each side. The mean blood volume in the study group was 35.8 ± 20.9 ml (range, 8–92.6 ml), versus 38.4 ± 23.7 ml (range, 9–104 ml) in the control group (p = 0.49) (paired t-test = 0.70).

In a comparison of bleeding based on the Boezaart score, the surgical field was classified as clean (Boezaart score of 0, 1 or 2) or bloody (score of 3, 4 or 5). The odds ratio of the Boezaart score for pterygopalatine infiltration was 1.18 (95 per cent confidence interval (CI) = 0.59–2.37) (p = 0.64) at 30 minutes, 0.66 (95 per cent CI = 0.4.0–1.01) (p = 0.10) at 60 minutes, and 0.66 (95 per cent CI = 0.3–1.48) (p = 0.3) at 90 minutes. Notably, at 1 hour from the initiation of surgery, the difference in blood in the surgical field based on Boezaart scores was marginally significant, with a cleaner surgical field in the study group at this time-point.

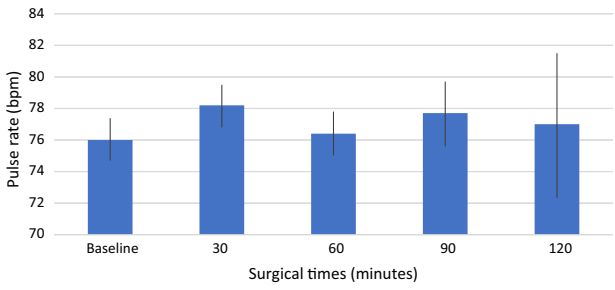

Figure 3. Changes in pulse rate at different surgical times. bpm = beats per minute

Discussion

Various methods and precautions to manage surgical field bleeding have been documented. Infiltration of the pterygopalatine fossa has been proposed by some authors. All of these studies agree that this method is safe, and none have reported any serious complications. In this study, as in previous reports, we did not observe any complications of transoral injection in the pterygopalatine fossa.

- Rhinosinusitis is one of the most common reasons for a visit to the ENT clinic
- Infiltration of the pterygopalatine fossa has been found to be safe and effective in terms of bleeding during endoscopic sinus surgery
- Achieving a clean surgical field was marginally significantly greater in the 1:100 000 adrenaline solution group compared to the control (saline) group

Although some have recommended this technique as an effective way of reducing blood loss during surgery,[2–4,11–13] we could not find any significant difference in bleeding between the study and control sides (p = 0.49), similar to the results of Kumar *et al.*[14] and Valdes *et al.*[1] In a review paper by Shamil *et al.*, in 2017, of seven articles, only two demonstrated a decrease in blood volume in the surgical field in the study group.[15] In contrast, Hwang and colleagues reviewed five articles, which were in favour of this method; additionally, the authors declared that the concentration of 1:80 000 adrenaline solution had a better result in comparison to 1:100 000.[5]

The study was designed to be double-blind. The technique is similar among the studies, and the injection volume is within a similar range. Thus, the difference in data may be attributable to the diversity of anaesthetic protocols in different centres and the degree of vasoconstriction applied intranasally. These differences may point to the importance of these factors in achieving a clean surgical field.

Conclusion

The results of the current study did not show any significant difference in intra-operative bleeding during sinus surgery after the injection of 1:100 000 adrenaline solution in the pterygopalatine fossa. Surprisingly, at 1 hour of surgery, the probability of achieving a clean surgical field was marginally significantly greater in the study group. This shows the importance of designing a study with a larger study group to reach more precise results.

Fortunately, patients were hemodynamically stable throughout the operation and complications were not reported. Hence, this method can be proposed as an adjunctive method of controlling bleeding, although the effects are still a matter of debate.

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Competing interests. None declared

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