Rhinology, 44, 58-61, 2006

Evaluation of calcium alginate nasal packing (Algostéril®) versus polyvinyl acetal (Merocel®) for nasal packing after inferior turbinate resection*

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SUMMARY

Nasal packing is commonly used to control postoperative bleeding in patients undergoing endonasal surgical procedures. Bleeding and pain on packing removal are frequently reported. The principal objective of this study was to investigate the efficacy and safety of Algosteril® to control post-operative nasal bleeding. The secondary objective was to assess nasal bleeding and pain on packing removal, and to evaluate the endoscopic appearance of nasal mucosa 9 days after the procedure.

This open, multicenter, randomized, controlled study was conducted on 50 patients undergoing partial bilateral inferior turbinectomy, packed with Algosteril® on one side versus Polyvinyl acetal tampon (Merocel®) on the other side following a left/right randomization.

Both nasal packs effectively prevented post-operative bleeding. However, bleeding on packing removal was statistically less frequent and less severe with Algosteril® than with Polyvinyl acetal ($p = 0.016$). In addition, pain was statistically lower with Algosteril® than with Polyvinyl acetal ($p = 0.0001$). A trend to a better healing of the wound on day 9 was observed with Algosteril®, leading us to further investigations.

Algosteril® nasal packing is as effective as Polyvinyl acetal in preventing postoperative bleeding following partial inferior turbinate resection. Its removal, however, is less traumatic for the nasal mucosa and less painful for the patient, therefore improving patient's comfort.

Key words: Algosteril®, nasal packing, nasal bleeding.

INTRODUCTION

Nasal packing is commonly used to control postoperative bleeding in patients undergoing endonasal surgical procedures. Besides rare serious complications such as severe nasal mucosal damage, allergic reactions or toxic shock syndrome, packing is often associated with patient discomfort and bleeding at the time of packing removal [1].

Several types of nasal packs are used post-operatively in nasal and sinus surgery. These include Polyvinyl acetal nasal tampon (Merocel®) and Algosteril® nasal packing (calcium alginate).

Polyvinyl acetal is a packing foam acting by direct wound compression after expansion of its initial volume due to fluid and blood uptake *in situ* [1]. Although effective for controlling postoperative bleeding, Polyvinyl acetal packs have been shown to be associated with more bleeding and pain on removal when compared to others [1-3].

Algosteril® nasal packing has both haemostatic and wound healing properties. It produces contact hemostasis through local activation of platelet aggregation and acceleration of the coagulation process. Gelification of the fibers constituting Algosteril® seems to provide easier and non-traumatic removal. When compared to paraffin gauze and glove finger nasal packing after inferior turbinectomy, calcium alginate nasal packing was associated with less bleeding on removal [4,5].

The aim of this study was to compare the efficacy and safety of Algosteril® nasal packing versus Polyvinyl acetal tampon after partial bilateral inferior turbinate resection. The second objective of the study was to evaluate bleeding and pain level on packing removal and to assess the endoscopic appearance of nasal mucosa nine days after the procedure.

*Received for publication: September 16, 2004; accepted: June 24, 2005

MATERIALS AND METHODS

This open, multicenter, randomized, controlled study was conducted in five hospital otorhinolaryngology departments in France. The study protocol was approved by the ethics committee of Versailles. All patients were required to sign a written informed agreement before participating in the study. We decided to choose partial inferior turbinectomy as a model in our study because of its well known high post-operative haemorrhagic risk due to the rich vascular supply of the inferior nasal turbinate [6]. Surgical resection was always limited to the lower third of the inferior turbinate and performed under endoscopic control as described in previous papers [7,8].

Patients

Patients included in this study had to be at least 18 years old and had to require partial bilateral inferior turbinectomy for chronic nasal obstruction. Exclusion criteria were known sensitivity to Algosteril® and/or Polyvinyl acetal or major anatomical abnormalities with nasal cavity asymmetry. Patients with haemostatic disorders, chronically treated with medications interfering with hemostasis (acetyl-salicylic acid, NSAID or anticoagulant) during the 2 weeks preceding surgery or patients with severe concomitant diseases were also excluded from the study.

Study design

During a pre-operative visit, patients had a physical examination and a nasal endoscopy. Their medical history was recorded and ordinary pre-operative blood tests were performed. Those who met all eligibility criteria were included in the study which lasted 9 days for each patient. A left/right randomization allocated one of the two tested nasal packing products to either left or right nasal cavity.

On day zero, surgery was performed and the packs were inserted. Polyvinyl acetal tampon was inserted in the nasal cavity and then hydrated with normal saline solution (0.9%). According to manufacturer's recommendations, Algosteril® nasal packing was hydrated with normal saline solution (0.9%) and then gently squeezed before insertion in the nasal cavity. The packs were then to stay *in situ* for 48 hours.

No vasoconstrictor medications were used. Patient's blood pressure was recorded. Steroids and systemic antibiotics were administered according to investigators' usual prescribing habits. Per and post-operative bleeding were assessed.

On day 2, both packs were removed without any analgesics or tranquilizers pre-treatment. Bleeding and pain level on removal were assessed. On day 9, nasal endoscopy was performed to evaluate the appearance of the nasal mucosa.

Assessment criteria

The main efficacy criteria was the amount of bleeding on nasal packing removal on day 2. It was quantified according to the following scale:

0: no bleeding or minimal bleeding
1: anterior and/or posterior bleeding lasting less than 3 minutes, not requiring a vasoconstrictor
2: anterior and/or posterior bleeding lasting less than 3 minutes, requiring a vasoconstrictor
3: anterior and/or posterior bleeding lasting 3 minutes or more, requiring a local procedure
4: severe bleeding requiring repacking for more than 24 hours and/or surgery.

The other efficacy criteria were the control of post-operative bleeding, pain level on packing removal and the appearance of nasal mucosa.

Post-operative bleeding was assessed by the presence or absence of bleeding through the nasal packing. Pain on packing removal was evaluated with Visual Analogue Scales. Two vertical parallel visual analogue scales measuring 10 cm, corresponding to the right and left nasal cavities, were presented to patients immediately after removal of the nasal packs. Patients were asked to draw a horizontal line between 0 cm (no pain) and 10 cm (severe pain) on the right and left scales. Scores were measured in centimeters. Packing removal always started with the right nasal cavity.

Endoscopic appearance of nasal mucosa on day 9 (±1) was scored as follows: 1 = bare bone; 2 = crusted lesions; 3 = granulation tissue; 4 = healing.

Safety was assessed based on the number and type of adverse events reported during the study.

Statistical analysis

Treatments were allocated according to the randomization sequence. Efficacy analysis included all randomized patients. For quantitative parameters, the tested null hypothesis was equality of the mean values in the two treatment groups. They were compared using a Student's t- test or a Kruskal-Wallis test. For qualitative parameters, patient data in the two treatment groups were compared using a Chi^2 test or a Fisher exact test, with the null hypothesis being independence between the parameter treatment group and the studied parameter.

RESULTS

Patients

Overall, 50 patients were enrolled and 100 nasal cavities were randomized. All patients were included in the statistical efficacy analysis. One patient was lost to follow-up after day 2, therefore, 49 patients were evaluated on day 9. The mean patient age was 40 and the M/F gender ratio was 1.77 (32/18). Forty-six patients underwent a primary partial inferior turbinectomy and 4 patients had already undergone turbinate reduction procedures before. Turbinectomy was performed under general anesthesia after topical vasoconstrictor administration in all patients. The mean blood pressure recorded was 128/78 mmHg. Six patients developed intra-operative bleeding.

Efficacy

Both packs controlled the immediate post-operative bleeding.

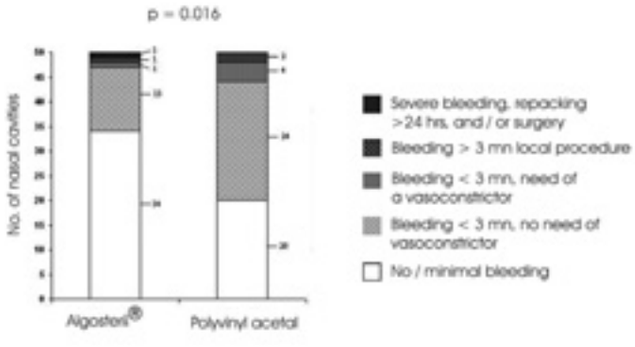

Figure 1. Amount of bleeding following packing removal on day 2.

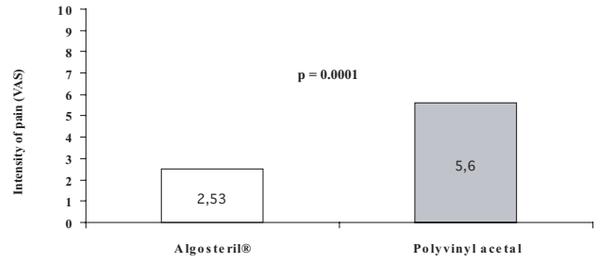

Figure 2. Pain level on packing removal on day 2 (VAS).

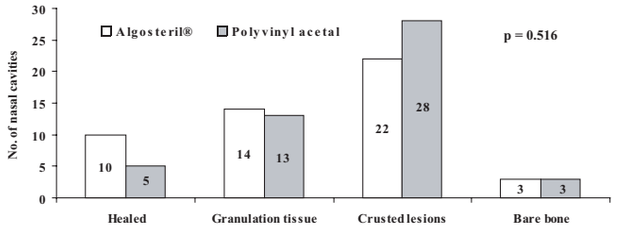

Figure 3. Endoscopic appearance of nasal mucosa on day 9.

There was no significant difference between the two groups in term of incidence of bleeding with the nasal packing in place. Bleeding through Algosteril® packing was observed in 12 nasal cavities versus 13 with Polyvinyl acetal ($p = 0.817$). No patient bled sufficiently to require repacking of the nose.

The comparison including all levels on the bleeding scale showed that bleeding was less severe in the Algosteril® group comparing to Polyvinyl acetal ($p=0.016$) (Figure 1). Furthermore, no or minimal bleeding (rated 0) was recorded in 34 (68%) of the nasal cavities packed with Algosteril® versus 20 (40%) in the Polyvinyl acetal group ($p=0,005$). An episode of bleeding lasting 3 minutes or longer and requiring a local procedure (rated 3) occurred 2 times with Polyvinyl acetal and 1 time with Algosteril®. A severe bleeding episode requiring repacking (rated 4) occurred in one nasal cavity packed with Algosteril® after premature removal 24 hours post-operatively (instead of 48 hours according to the protocol), the other nasal cavity being rated 0. After repacking with the same pack, no further complications occurred.

Late episodes of bleeding were observed in two patients; the first occurred with Polyvinyl acetal the day following packing removal and was treated by suctioning. The second one was bilateral and occurred 4 days after packing removal. This patient had bilateral repacking using the same packing as planed by the initial randomization; both packs were removed 72 hours later without any complications.

Pain level on packing removals at day 2 on Visual Analogic Scale from 0 to 10 was rated 2.53 in the Algosteril® group and 5.60 in the Polyvinyl acetal group ($p = 0.0001$) (Figure 2).

Endoscopy of the nasal mucosa performed on 49 patients on day 9 showed that 10 healed nasal cavities in the Algosteril® group versus 5 in the Polyvinyl acetal group (Figure 3). Nevertheless, the comparison between the two groups, taking into account all four steps of the scale Algosteril® versus Polyvinyl acetal (bare bone, crusted lesions, granulation tissue, healing) showed no statistical difference ($p = 0.516$).

Safety

Both treatments were well tolerated. Neither local infection, sensitivity nor other adverse events related to the products were observed.

DISCUSSION

Primary objective of a post-operative nasal packing is to control bleeding. In this study, both tested nasal packing devices achieved this aim despite their different way of action. Nevertheless, important differences were found at the moment of packing removal in terms of bleeding and pain level.

Incidence of bleeding on packing removal 48 hours after surgery was significantly different depending on the pack used. Thus, 68% of nasal cavities packed with Algosteril® were free of bleeding versus only 40% of those packed with Polyvinyl acetal and this was highly statistically significant. The fact that the only patient who exhibited severe bleeding had nasal packing removal 24 hours postoperatively instead of 48 hours as stated in the protocol, confirms previous results: in a comparison between 3 types of packing (alginate, paraffin gauze, glove fingers), the authors found that, irrespective of the material used, leaving the packing in situ for 48 hours produced less bleeding than when it was removed after 24 hours [5].

Patient comfort is an important aspect to be considered. Indeed, many patients treated with nasal packs after surgery consider packing removal as the most unpleasant part of the procedure [1]. In the present study, the level of pain assessed by visual analogue scales was dramatically lower with Algosteril® than with Polyvinyl acetal.

The increased rate of additional bleeding and discomfort during and after removal of Polyvinyl acetal has already been reported

Figure 4. Gelified Algosteril® packing removal on day 2.

in other studies and may be related to mucosal adherence of the pack [2,3]. In post-operative wound healing, the regenerating tissue grows and may penetrate the packing material. Thus, nasal mucosa trauma may occur as epithelium and granulation tissue are torn away when the packing is removed [1].

The improved results of Algosteril® at the time of packing removal are related to the transformation of Algosteril® fibers in contact with blood and exudates into a hydrophilic gel (picture 1). Thereby, Algosteril® does not stick to the nasal mucosa and can be easily removed from the nasal cavity. Packing removal is painless and does not disturb the healing process.

As for the nasal mucosa appearance, examination 9 days after partial inferior turbinectomy usually shows the presence of crusted lesions. This was confirmed by the study, with greater tendency to crusts after Polyvinyl acetal tampon than after Algosteril®. Statistical analysis was performed globally on all the parameters (bare bone, crusted lesions, granulation tissue, healing) and no significant difference was found. Nevertheless, the rate of healed cavities was particularly higher with Algosteril® (10 vs 5).

Benefits in control of secondary post-operative bleeding and in patient's comfort associated with a tendency to an improved healing of the nasal mucosa, are strong arguments making us prefer Algosteril® for nasal packing after inferior turbinate surgery.

In conclusion, Algosteril® nasal packing is equally effective as a Polyvinyl acetal nasal tampon in preventing post-operative bleeding after inferior turbinate surgery. Algosteril® provides a significantly lower pain level and bleeding at the moment of the removal, therefore improving the patient's comfort. Confirmation of the tendency that we observed for a better mucosa wound healing with Algosteril® requires further investigation.

ACKNOWLEDGEMENT

This study was funded by Laboratoires Brothier.

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ERRATUM

Supplement 19, page page 6 right colum, line 25 contains an error.
The sentence: "the combination amoxicillin-clavulanic acid in 2 or 3 doses of **19** each for 7 to 10 days" should read:
"the combination amoxicillin-clavulanic acid in 2 or 3 doses of **1 g** each for 7 to 10 days"