

A Randomised Controlled Trial Comparing the Use of Foam Polymer Nasal Tampons and BIPP in the Control of Acute Epistaxis in Primary Care

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Keywords:

Merocel, Epistaxis, Clinical trial,
BIPP, Therapy,

Abstract

Objective: To compare the effectiveness, usefulness and acceptability of foam polymer nasal tampons (Merocel[®] nasal tampons) to BIPP impregnated ribbon gauze in the management of acute epistaxis in ambulatory patients at primary care facilities.

Design: A randomised controlled trial.

Setting: Five private family practices, a community health centre and the general outpatient department of a referral hospital in the Cape Town Metropole.

Subjects: Ninety-nine cases, older than 14 years, presenting with acute epistaxis at these facilities.

Main outcome measures: Ease of introduction of nasal packing, comfort to patient, bleeding at 15 and 30 minutes, side effects and complications, bleeding after removal.

Results: The two methods were found to have similar effectiveness in stopping epistaxis at 30 minutes after insertion. Foam polymer nasal tampons were more painful and difficult to insert and caused more discomfort while in place. BIPP packs dislodged more easily. No serious side effects were found with either method.

Conclusions: The foam polymer nasal tampon is a safe, quick, relatively easy and reasonably effective method of controlling acute epistaxis in primary care patients. The cost of the foam polymer nasal tampon may limit its application in primary care practice.

SA Fam Pract 1999;21(1):14-19

Introduction

Acute epistaxis is a common emergency in primary care practice, the management of which is regarded as an essential skill for the general practitioner. The traditional methods of stopping severe nasal bleeds are digital pressure, cautery, and anterior and posterior packing.^{1,2,3} Anterior nasal packing requires some skill and is usually done with ribbon gauze coated with an antibiotic ointment.

Foam polymer nasal tampons (Merocel[®] Pope Posterior Nasal Packing[®]) is an easy-to-apply method of nasal tamponade, used both as a

post-operative nasal packing and also to control epistaxis. It has a low risk of serious side effects or discomfort to the patient.⁴⁻⁹ The tampon is made of a foam polymer of hydroxylated polyvinyl acetate that rapidly expands into a soft sponge when hydrated.⁶ Epistaxis is stopped by the direct pressure of the expanded sponge on the bleeder as well as by creating a surface for thrombus formation.

A previous trial compared the use of foam polymer nasal tampons and BIPP ribbon gauze packs in the control of acute epistaxis in a hospital setting. It

found no difference in the efficacy or patient tolerance of either treatment. The trial was a small, single centre, referral hospital study. Because patients were hospitalised after the procedure,⁹ the findings have limited generalisability to primary care settings.

The aim of the present study was therefore to evaluate the effectiveness, usefulness, acceptability and safety of the foam polymer nasal tampon in the management of acute epistaxis, when compared to BIPP ribbon gauze packing in primary care settings.

The study design was a randomised controlled trial, conducted in several primary care facilities in Cape Town. These settings included five private family practices, a public primary care facility (Bishop Lavis Community Health Centre) and the general outpatient department of a referral hospital (Polyclinic, Tygerberg Hospital). General practitioners were recruited at each facility, and were given a practical demonstration on both treatment methods and training on the application of the study protocol.

The study period was between February 1994 and August 1995. All consecutive patients that presented with epistaxis at these facilities were randomly allocated to either a study or a control group, if they met the inclusion criteria. Block randomisation was used to ensure an equal number of study and control subjects at each facility. The study group patients were managed with foam polymer nasal tampons while the control group patients received BIPP ribbon gauze packing. The doctor was unaware which treatment method was to be used for each patient until the pre-randomised numbered

envelope containing the nasal pack was opened.

Patients with epistaxis were included in the study only after they gave written informed consent. Patients were excluded if they were younger than 14 years of age or if both nostrils were bleeding at the time of the clinical examination. The study received ethical approval from the Research Committee of the University of Stellenbosch.

The affected nasal passage was cleaned by suction or by the patient gently blowing the nose. Two sprays of a Xylocaine® pumpspray (lignocaine 10 mg per measured dose) in the bleeding nostril provided local anaesthesia, allowing 5 minutes for effect. The foam polymer nasal tampon was cut to size if necessary, smeared with antibiotic Bactroban® ointment (mupirocin 2g per 100g) and lubricated with Regard® jelly (glycerine 6g per 100g). The tampon was inserted into the nasal passage parallel to the nasal floor and allowed to expand naturally. A 1 cm protruding tip was left to aid removal. The BIPP ribbon gauze was packed into the nasal cavity from bottom to top, using a standard forceps.

The attending doctor graded the

patient's co-operation, pain caused by insertion and the ease of application according to a 5 point scale with a neutral mid-point. Any bleeding 15 and 30 minutes after insertion was noted. If the bleeding did not stop after 30 minutes, the patient was referred to an ENT specialist for further treatment. If the bleeding was stopped by the nasal pack, the patient was sent home and asked to come back between 24 and 48 hours later for removal of the pack.

On return, the patient was questioned about side effects or problems encountered with the pack in-situ. The nasal pack was removed by gentle traction and any bleeding was noted.

The data was captured and analysed using Epi Info (Version 6) software.¹⁰ Categorical data (in 2x2 tables) were analysed by means of odds ratios to contrast the relative frequencies associated with the two treatments under comparison. Confidence intervals (95% CI's) were constructed for the odds ratios. Two-tailed Student's t-tests were used for comparison of means of continuous variables between the treatment groups. A 5% level of significance was adopted as criterion for test-statistics.

Results

One hundred and one (101) patients with acute epistaxis entered the trial. Two cases were excluded because they were younger than 14 years of age (1 foam polymer nasal tampon, 1 BIPP).

The majority of cases (78%) were seen at the general outpatient department of the referral hospital (Table I). There was no significant difference between the foam polymer nasal tampons and the BIPP groups with regard to the cause of epistaxis, disease profile, allergies, smoking or current use of medication. Six cases treated with foam

polymer nasal tampons started with bleeding in both nostrils, compared to one BIPP case ($P < 0.05$). (See table I overleaf)

The outcomes during and after the insertion of the nasal packs are tabulated in Table II. Foam polymer nasal tampons were more frequently rated difficult to insert than BIPP ($p < 0.05$). Foam polymer nasal tampon insertions were also considered to be more frequently painful to the patient than BIPP. (Odds Ratio=24.8: 95% CI 7.23-

112.01). In spite of this, only 4 patients were regarded as uncooperative during insertion of the packs, two in each group.

BIPP packs were more effective than foam polymer nasal tampons in stopping bleeding at 15 minutes after insertion (Odds Ratio=3.4: 95% CI 1.01-13.3). At 30 minutes after insertion, there was no longer a statistically significant difference between the effectiveness of the two methods.

Table I: Comparison of subjects in study and control groups

	Merocel® (N = 48)	BIPP (N = 51)	P value
Male/ Female	25/23	30/21	NS
Mean age (yr.)	40	44	NS
Present at hospital	38	39	NS
Anterior bleeding	34	37	NS
Started in both nostrils	6	1	< 0.05

NS: P value > 0.05

Table II: Results: Comparison of outcomes at insertion

	Merocel® (N = 48)	BIPP (N = 51)	P value
Difficult insertion	11	2	< 0.05
Pain with insertion	33	4	< 0.05
Patient uncooperative	2	2	NS
Bleeding: 15 min.	13	5	< 0.05
Bleeding: 30 min.	10	4	NS

NS: P value > 0.05

Eight (6 Merocel®, 2 BIPP) of the 14 patients whose bleeding had not stopped 30 minutes after insertion of the pack were referred to an ENT specialist and so lost to follow up. The remaining 6 patients' bleeding stopped within an hour of treatment.

Of the remaining 91 patients (42 Merocel®, 49 BIPP), only 12 patients (13%) (4 Merocel®, 8 BIPP) never returned for removal of their packs. Two of these patients were subsequently seen with other complaints. One reported that her BIPP pack had partly fallen down her pharynx and was removed by a private practitioner. The other patient removed the BIPP gauze himself after a day and had no subsequent epistaxis.

Table III: Results: Comparison of side effects

	Merocel® (38/48)	BIPP (41/51)	P value
None	20	23	NS
Pain	4	1	NS
Discomfort	12	4	< 0.05
Re-bleeding	7	10	NS
Dislodgement	1	11	< 0.05

NS: P value > 0.05

The side-effects caused by the remaining 79 packs are tabulated in Table III. Side-effects or problems such as pain or re-bleeding reported by patients while the

nasal pack was in situ were similar for foam polymer nasal tampons and BIPP. No exanthema, pyrexia, diarrhoea or iodine allergic reactions were reported. Discomfort was more frequently reported while foam polymer nasal tampons were in place (25%) than for BIPP gauze packings (8%) (Odds Ratio=4.2; 95% CI 1.11 to 19.86). Only one foam polymer nasal tampon pack became dislodged while 11 BIPP packs (22%) dislodged before removal (Odds Ratio = 0.1; 95% CI 0.00 to 0.57).

One patient developed left-sided facial oedema and headache after a foam polymer nasal tampon had been in place for 16 hours. The condition cleared after removal of the pack.

Active re-bleeding after removal of the pack occurred in 12 foam polymer nasal tampon and 7 BIPP cases, which was not statistically significant. Thirteen of these 19 patients (8 foam polymer nasal tampons, 5 BIPP) had to be referred for further specialist management.

Discussion

The effectiveness, feasibility and safety of foam polymer nasal tampons in the management of acute epistaxis, was studied in various primary care settings. Patients were not hospitalised after treatment, the general practitioners had no specialised skills and used only basic surgical equipment. The sample size was fairly large (99 cases).

Foam polymer nasal tampons and BIPP nasal packing demonstrated similar effectiveness in stopping epistaxis 30 minutes after insertion, and immediately after removal of the nasal packs. The time taken by the foam polymer nasal tampons to expand in the nostril may account for the greater effectiveness of BIPP at 15 minutes after insertion, as well as the tendency for greater effectiveness (although not statistically significant) at 30 minutes. It may be recommendable to drip sterile water on the foam polymer nasal tampon in order to hasten expansion. The tampons were inserted completely dry in this study.

The assessment of the practical usefulness of Merocel® nasal tampons in the management of acute epistaxis by the general practitioner was an important part of this trial. BIPP packs were rated easier and less painful to insert than Merocel®. Although not measured in this study, the practitioners generally reported that Merocel® insertion takes less time than BIPP, so that the duration of discomfort is shorter with Merocel®.

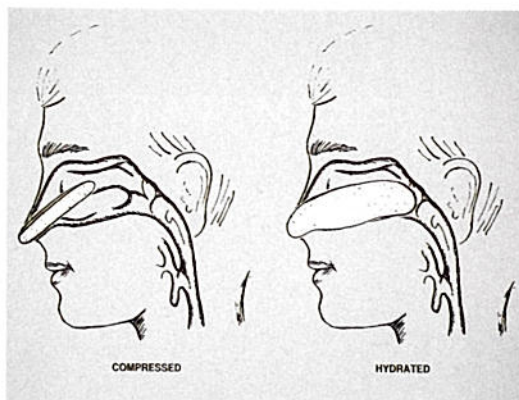
A possible reason for the painful insertion of the foam polymer nasal tampons may be that 56% of the tampons were found to be too wide or too long for particular patients. Their application may also be made less painful by soft-ening the edges of the tampon with water, as suggested by Corbridge et al⁹. Both foam poly-mer nasal tampons and BIPP were, however, found to be generally acceptable to patients, as is demonstrated by the excellent patient co-operation (96% foam polymer nasal tampons, 96% BIPP) in the study (Table II).

The 20 patients (20%) lost to follow up influences the validity of the reported complications. Patients who returned complained more frequently about the discomfort caused by foam polymer nasal tampons in situ, perhaps because the tampon dried out. BIPP packing became dislodged more frequently than the nasal tampons, probably due to the loose nature of ribbon gauze. Premature dislodging is a disadvantage for ambulatory patients managed in primary care settings.

A limitation of this study is the possibility of observer bias, since the attending general practitioner carried out the procedure as well as the observation and questioning the patient. Using an

independent observer to interview the patient after the insertion and removal of the nasal pack⁹ could perhaps have reduced it. Blinding to the type of treatment would however have been impossible to obtain.

This study was designed to provide information useful to primary care. Although most cases in the study were treated at the general outpatient department of the referral hospital (78%), at the time of the study it was mainly being used as the primary care facility for the suburbs surrounding the hospital. Some selection bias, favouring more serious bleeds, may have occurred because a number of the study subjects had been referred by family practitioners to the hospital.



The overall results indicate that foam polymer nasal tampons can be used effectively by general practitioners in the management of acute epistaxis. It is reasonably effective when

compared to BIPP, quick and easy to use, safe, and acceptable to most patients. It is, however more painful to the patient during insertion and causes more discomfort, when compared to BIPP. Cutting the tampon to size and wetting the edges of the tampon can reduce the discomfort. No instruments are needed to insert the nasal tampon. It also does not dislodge as easily as BIPP, which is an advantage in the ambulatory care setting

The foam polymer nasal tampons nasal packs are however far more expensive than BIPP nasal packs, which may curtail its widespread use in family practice. The tampons have a much longer shelf-life than BIPP due to its sterile packing, making it ideal for private practices with a relatively low caseload of epistaxis.

Acknowledgements

The authors wish to acknowledge the advice of Prof. J. Reynecke (Department of Ear Nose and Throat Surgery, University of Stellenbosch) and Mrs. J. Barnes (University of Stellenbosch) in the design of this study. This research was made possible by a grant from Merocel® Corporation, Mystic, Connecticut, U.S.A. SmithKline Beecham supplied the Bactroban® ointment.

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