A PROSPECTIVE RANDOMISED CONTROLLED TRIAL COMPARING MEROCEL AND RAPID RHINO NASAL TAMpons IN THE TREATMENT OF EPISTAXIS”

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Abstract

A prospective study was performed to compare the efficacy and patient tolerance of Merocel® and Rapid Rhino® nasal tampons in the treatment of epistaxis. A total of forty-two patients were studied. There was no significant difference between the two types of pack in efficacy or patient discomfort with pack in-situ. Rapid Rhino® produced significantly lower scores for subjective patient discomfort during insertion and removal of pack.

Keywords: epistaxis, Merocel, Rapid Rhino, nasal tampon,
**Introduction**

Epistaxis is the most common otorhinolaryngological emergency with a reported incidence of 30 per 100000 [1]. It is estimated that approximately 10% of the population suffer a significant epistaxis in their lifetime [2]. Petrusen and Rudin showed that 66% of men had experienced an epistaxis by the age of 60 years [3]. Although epistaxis may settle spontaneously or cease following simple measures such as pressure or intranasal cautery [4], patients may, however require nasal packing in order to curtail the haemorrhage.

Nasal tampons, as a form of anterior nasal pack, in the treatment of acute epistaxis have been in regular use in E.N.T. departments for a number of years. These packs have provided an easy, convenient and rapid form of packing with no detriment to efficacy when compared to the more traditional forms of anterior nasal packing [5,6]. In recent years, the choice of tampon material has increased greatly, though the type of pack preferred by an individual surgeon is often determined by learnt practice or habit.

Two of the newest nasal tampons in common use are Merocel® and Rapid Rhino®. Merocel® (Medtronic Xomed, Florida, USA) is a compressed, dehydrated sponge composed of hydroxylated polyvinyl acetate (figure 1). The pack requires rehydration with normal saline in order to achieve optimal size within the nasal cavity. Its claims include the ability to act by tamponade as well as acting as a surface for platelet aggregation actively encouraging haemostasis. Rapid Rhino® (Applied Therapeutics, UK)
is a single cuffed PVC nasal catheter covered in a layer of reinforced weft knitted hydrofibre (figure 2). The cuffed catheter design allows inflation of the pack to the individual required volume. The hydrofibre fabric forms a gel in contact with water. This gel acts to facilitate coagulation, controlling minor bleeding and provides a moist, well-lubricated surface, which aims to facilitate ease of placement and removal and reduce associated pain.

These two nasal tampons individually have produced encouraging results but until now have never been directly compared in the treatment of epistaxis. The aims of this study were: 1. To compare the effectiveness of Merocel® and Rapid Rhino® nasal packs at controlling haemorrhage and 2. To compare the subjective level of discomfort associated with each pack, in patients presenting with epistaxis where nasal packing was required.
**Materials and methods**

All adult patients (≥ 16 years old) with epistaxis presenting to the Otolaryngology department at Addenbrooke’s Hospital, Cambridge, over a two year period were studied. Criteria for entering patients into the trial included epistaxis unresponsive to first aid measures or unsuitable for cauterization. Patients taking anticoagulants or non-steroidal drugs were included in the study. Those patients who already had any form of nasal pack inserted elsewhere prior to their attendance in the Otolaryngology department at Addenbrooke’s hospital, were excluded from the study.

Patients were allocated randomly to one of two treatment groups via sealed envelopes selected by a third party. Group 1 received a Merocel® 8cm anterior nasal pack in the ipsilateral nasal cavity, and Group 2 received a Rapid Rhino® 7.5cm pack in the ipsilateral nasal cavity. Packs were inserted according to the manufacturers’ instructions by the on-call E.N.T. Senior House Officer after first spraying the nose with two metered doses of Xylocaine 5% (lignocaine), (equivalent to 20mg). Merocel® packs were lubricated with Naseptin cream prior to insertion and were expanded using 10 millilitres of normal saline. Rapid Rhino® packs were moistened with sterile water for 30 seconds prior to insertion. After insertion, the packs were inflated via the cuffed catheter to the relevant individual volume. The packs were left in situ for 24-48 hours before removal unless bleeding was not adequately controlled when an alternative form of treatment was initiated.

The following aspects for each nasal pack were assessed:
A. Objective assessment by staff for control of bleeding

B. Subjective assessment by the patient for:
   a. Discomfort during pack insertion
   b. Discomfort with the pack in situ
   c. Discomfort during pack removal

Patients’ subjective impression of discomfort was based on an eleven point pain scale (range 0 to 10, 0 being no pain whatsoever and 10 indicating the most severe pain imaginable). All patients were asked to record the discomfort they encountered during pack insertion or removal within 5 minutes of the procedure. Statistical analysis performed using non-parametric Mann-Whitney test for comparing the level of discomfort associated with each pack and chi-squared test for comparing their effectiveness at controlling haemorrhage.
Results

Forty-two patients meeting the inclusion / exclusion criteria were entered into the trial. These comprised 23 (55%) male and 19 (45%) female patients with an age range of 18-91 years (mean age 73.9 years). The relevant associated aetiological factors to each patient are shown in table 1.

Control of bleeding

Merocel® was successful at controlling epistaxis in 17(81%) of the 21 patients initially treated with this pack. In four patients the pack failed to control bleeding so an alternative form of management was initiated: three patients required insertion of B.I.P.P. (bismuth iodoform paraffin paste) soaked ribbon gauze packing and Foley’s catheter and 1 patient went to theatre for examination under anaesthesia and sphenopalatine artery ligation.

The results were similar using Rapid Rhino® nasal packs. Sixteen patients (76%) were treated effectively and bleeding was controlled. Four patients needed B.I.P.P. pack and Foley’s catheter as a post-nasal pack, and in 1 patient, where bleeding was uncontrolled with any form of packing, a sphenopalatine artery ligation was required to achieve haemostasis.

Statistical analysis of the results obtained shows there to be no significant difference in the effectiveness of either treatment in controlling epistaxis ($p= 0.917$). Results are summarised in table 2.
Subjective assessment of pain

Pain on insertion

The mean visual analogue score value in patients with a Merocel® pack was 6.47 ranging from 3 to 9 (figure 3). In contrast, the mean value in patients with a Rapid Rhino® pack was 3.85 (range: 1-7). This represents a highly significant difference in the patients’ discomfort during insertion of the packs (p<0.001).

Pain while pack in situ

While the packs were in situ, there was no statistically significant difference in the discomfort caused by the packs (p=0.979). The mean pain scores while the packs were in position were 2.28 (range: 0-4) for Merocel® and 2.33 (range: 0-5) for Rapid Rhino® (figure 4).

Pain on pack removal

There was a significant difference between pain scores on pack removal with Merocel being significantly more painful (p<0.001). The mean pain scores on pack removal were 5.04 for Merocel® (range: 2-8) and 2.47 (range: 0-5) for Rapid Rhino® (figure 5).

The results of all aspects of patients’ assessment of pain are summarised in Table 3. No patients in either group required repacking of the nose and there were no complications associated with using either pack.
Discussion

An ideal nasal pack should provide an effective control of epistaxis, be easy to insert and remove, comfortable when in place with minimum risk of aspiration, and promote a minimal amount of tissue sensitivity or infection [7]. Both Merocel® and Rapid Rhino® packs appear to conform to these criteria.

There is always a potential risk of aspiration of any nasal pack [8]. Because of the size of Merocel® the chance of aspiration or swallowing is very small, however, as a safeguard it is recommended that the drawstring is secured to the cheek. Hashmi et al reported a case of a Rapid Rhino® pack being swallowed during the treatment of a patient with epistaxis [9]. The pack caused bowel obstruction and perforation. This is a report of an isolated incident with a new medical device and it is not clear whether this mishap was due to the balloon design or to erroneous placement. However since this report a simple design modification in the Rapid Rhino® packs has incorporated a safety cuff to prevent the pack from migrating posteriorly. It is also advisable that the free end of the catheter is taped to the cheek as per the Merocel® packs drawstrings. There where no complications in this study with either pack.

In this study, bleeding was successfully controlled in over 80% of patients treated with Merocel®. This rate is less than those reported in studies by Pringle et al. and Corbridge et al. who reported success rates of 91.5% and 92.6% respectively in patients with epistaxis treated with Merocel® pack [5,6]. Our study numbers are relatively small, but are comparable to other comparative studies of nasal packing materials [6,10,11].
The success rate of Rapid Rhino® in this study was 76%. No previous studies have been performed in order to estimate the efficacy of Rapid Rhino packs in patients with epistaxis.

A significant difference in patient discomfort on insertion of the packs was found between Merocel® and Rapid Rhino® (mean 6.47 vs. 3.85, p=<0.001). Similar findings were obtained by Arya et al when comparing Merocel® and Rapid Rhino® in patients following nasal surgery [12]. Rapid Rhino® is smaller, softer and more flexible when compared to Merocel®. These factors may partially explain the reduced discomfort during insertion associated with Rapid Rhino®, although the most likely explanation for this is the self-lubricating gel exterior that this form of pack possesses.

Whilst in-situ, both packs were well tolerated and patients had minimal discomfort with no significance difference in patient’s mean score between the two packs. Similar results were obtained by previous authors [5,7,12,13].

Arya et al performed a double blind randomised controlled trial comparing Merocel® with Rapid Rhino nasal packs after routine nasal surgery, and concluded that Rapid Rhino® is associated with significantly less pain on removal than standard Merocel® packs [12]. Similarly, our results concur with these findings, and show that Rapid Rhino® is more acceptable to patients as it causes significantly less discomfort than Merocel® packs on removal. Although Merocel® packs could be removed easily in some patients, most of them found its removal very uncomfortable. As a result of its internal catheter
design, Rapid Rhino® is deflated prior to removal, decreasing its size, and resulting in less pressure applied to and less potential for trauma to, the nasal mucosa. Again, the external gel coating of Rapid Rhino® remains in-situ for the duration of the packing and reduces friction allowing the pack to be removed with minimal force.

Patient with epistaxis most frequently present to A&E departments or general practice and are initially managed by doctors other than ENT surgeons. Lately, with the introduction of the “cross covering system”, patients are frequently managed by generic doctors who provide cover between different specialities in out of hours. Further, with the centralisation of ENT services many A&E departments do not have ENT surgeons on site and patients are transferred to another hospital for treatment of severe epistaxis. It is preferable that bleeding should be controlled prior to transfer with nasal packing if necessary either in the A&E department or in the community. Therefore, the ideal nasal pack should be easily taught, rely on minimal ENT experience, and be simple to insert and remove. Merocel® and Rapid Rhino® nasal packs meet all of these criteria and either could be used safely by doctors other than ENT surgeons.

Although both varieties of pack provide adequate control of haemostasis, are relatively easy to use and associated with minimal complications, there is a significant difference between these packs in patients’ comfort on insertion and removal. These findings may influence the choice of nasal tampon used in the treatment of epistaxis in the future.
Conclusion

There was no statistically significant difference in efficacy between Rapid Rhino® and Merocel® packs. Both nasal packs, where shown to be safe, with no complications reported. Rapid rhino® packs, however, resulted in significantly reduced patient discomfort on insertion and removal when compared to Merocel® packs.
References


Legends

Figure 1
Merocel® pack 8cm with drawstring.

Figure 2
Rapid Rhino pack 7.5cm with Pilot Cuff™

Figure 3
Visual Analogue score of pain assessment during insertion of packs, where 0=no pain and 10= most severe pain imaginable.

Figure 4
Visual Analogue score of pain assessment while packs in place, where 0=no pain and 10= most severe pain imaginable.

Figure 5
Visual Analogue score of pain assessment on removal of packs, where 0=no pain and 10= most severe pain imaginable.

Table 1
Associated aetiological factors in epistaxis.

Table 2
Control of bleeding.
Table 3

Summary of subjective pain results.
## Table 1: Associated aetiological factors in epistaxis

<table>
<thead>
<tr>
<th>Associated Factor</th>
<th>No of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idiopathic</td>
<td>17 (40%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>13 (31%)</td>
</tr>
<tr>
<td>Anticoagulants (Warfarin)</td>
<td>7 (17%)</td>
</tr>
<tr>
<td>Trauma</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Bleeding disorders</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>

## Table 2: Control of bleeding.

<table>
<thead>
<tr>
<th>Control of bleeding</th>
<th>Merocel®</th>
<th>Rapid Rhino®</th>
<th>Significant Difference (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled with primary pack</td>
<td>17</td>
<td>16</td>
<td>p= 0.917</td>
</tr>
<tr>
<td>Required repacking with BIPP +/- catheter</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Uncontrolled with any pack and proceed to surgery</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
</tbody>
</table>

## Table 3: Summary of subjective pain results.

<table>
<thead>
<tr>
<th>Score</th>
<th>Merocel®</th>
<th>Rapid Rhino®</th>
<th>Significant difference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insertion score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>3-9</td>
<td>1-7</td>
<td>p= &lt;0.001 Significant</td>
</tr>
<tr>
<td>Mean</td>
<td>6.47</td>
<td>3.85</td>
<td></td>
</tr>
<tr>
<td><strong>Packs in place score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0-4</td>
<td>0-5</td>
<td>p= 0.979 Not significant</td>
</tr>
<tr>
<td>Mean</td>
<td>2.28</td>
<td>2.33</td>
<td></td>
</tr>
<tr>
<td><strong>Removal score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>2-8</td>
<td>0-5</td>
<td>p=&lt;0.001 Significant</td>
</tr>
<tr>
<td>Mean</td>
<td>5.04</td>
<td>2.47</td>
<td></td>
</tr>
</tbody>
</table>
Figure 3: Visual Analogue score of pain assessment during insertion of packs, where 0=no pain and 10= most severe pain imaginable.

Figure 4: Visual Analogue score of pain assessment while packs in place, where 0=no pain and 10= most severe pain imaginable.

Figure 5: Visual Analogue score of pain assessment on removal of packs, where 0=no pain and 10= most severe pain imaginable.