

A randomised controlled trial comparing Rapid Rhino Mannheim and Netcell series 5000 packs following routine nasal surgery*

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SUMMARY

Objective: To determine whether there is a difference in discomfort between Netcell Series 5000 and Rapid Rhino Mannheim 8.0 cm (Cat. No. 800) packs used after routine nasal surgery, whilst in situ and during removal. This was tested in a single blind, randomised controlled trial at the ENT Department, Royal Devon & Exeter Hospital.

Participants: Adults aged 16-65 undergoing nasal septal surgery and trimming of inferior turbinates. Patients were excluded if they were undergoing revision surgery, taking anticoagulants, or had a history of sino-nasal disease or trauma. Thirty nine entered and 32 completed the study. The intervention was a different nasal pack in each side of the nose, removed the morning after surgery.

Main outcomes measures: Pain experienced by patients while packs are in situ and on removal as recorded on a standard unmarked 100mm visual analogue scale.

Results: There was no difference in the pain scores whilst in situ. Rapid Rhino Mannheim was more painful on removal (difference = 10.6 mm, $p < 0.001$, Wilcoxon signed ranks test).

Conclusions: Rapid Rhino Mannheim packs do not confer a benefit over Netcell Series 5000 packs after routine nasal surgery.

Key words: randomised trial, nasal surgery, nasal packing, pain

INTRODUCTION

Nasal packing is used routinely in nasal surgery to stop post-operative haemorrhage. The major disadvantage of packing is patient discomfort, which is often particularly acute as the pack is removed⁽¹⁾.

In our unit, we routinely use the Netcell pack (Netcell series 5000 tampon, Network Products) following elective nasal surgery. This pack consists of an 8 cm sponge tampon similar to the well-known Merocel pack, enclosed within a plastic sheath to reduce friction and ease removal. A competitor product, the Rapid Rhino Mannheim 8.0 cm (Cat. No. 800) pack (Forth Medical), has recently been introduced. This is a shaped piece of absorbent sponge with a cellulose-based cover, designed to become slippery when moist, and is a larger version of the Goodman and Riemann packs used in previous studies^(2,3). It should be noted that these packs differ from the Rapid Rhino epistaxis tampons, which have a central inflatable section that is injected with air to cause tamponade^(4,5). This study compares the Netcell Series 5000 and Rapid Rhino Mannheim 8 cm packs (Figure 1) after routine nasal surgery.

MATERIALS AND METHODS

Study Design

The study design was discussed at a departmental meeting prior to drafting the protocol. Surgeons were found to have dif-



Figure 1. Photograph of dry nasal packs. Rapid Rhino Mannheim 8 cm pack above, 8 cm Netcell Series 5000 pack below

ferent practices for nasal packing depending on the type of nasal operation performed. It was considered that the particular operation might influence both the background level of post-operative pain, and the degree to which packing contributed to this pain. It was therefore decided that only patients undergoing both septal surgery and bilateral trimming of the inferior turbinates would be eligible for inclusion in the study, as all consultants in the unit routinely pack both sides of the nose after this procedure. The local Research Ethics Committee approved the study.

Packing

The two packs were compared by inserting one of each into the nose, so that participants acted as their own controls. We randomised which side of the nose received each pack, and always removed whichever pack was in the left side of the nose first. This aimed to minimise the possibility of bias caused by the side of the incision, or whether removal of the first pack could influence how painful the second pack was to remove.

Patients and treatment

Adult patients were recruited, with an upper age limit of 65 due to possible changes in pain perception with greater age, and the exclusion criteria were as follows:

- Revision surgery
- Bleeding tendency, prescribed anticoagulants
- History of sino-nasal trauma
- Systemic / sino-nasal disease eg Wegner’s granulomatosis, sarcoidosis, fungal sinusitis

Randomisation took place at the end of the operation, when the surgeon made the decision to pack both sides of the nose. Randomisation was via sequentially-numbered, opaque, sealed envelopes. The slip of paper inside specified which side of the nose was to be packed with Rapid Rhino, with Netcell by default used for the other side. Block-randomisation ensured a roughly equal recruitment into each arm of the study as it progressed, and the block size was varied between 4 and 8 to ensure that it was not possible to crack the code. Patients were blind to the type of pack inserted into each side of the nose.

The standard protocol for nasal surgery in Exeter is for the nursing staff to remove packs at 7 AM the day after surgery. The nurses therefore took responsibility for administering the visual analogue score (VAS) sheets, which clearly stated that pain before removal and pain caused by removal were the outcomes of interest. They always removed the left pack first.

Statistics

Data from a previous study with a similar design ⁽²⁾ (using patients with a different pack up each nostril) was used as the basis for a power calculation for this study. The power calculation considered the primary outcome measure of pain on pack removal.

A difference of 1 on a 10 point VAS was chosen as the minimum for significance based on department consensus. With a standard deviation of 2 at the 5% significance level, calculation showed 42 patients were needed to show 90% power. These statements apply to parametric data, however, and the data from the Arya et al. study ⁽²⁾ was not parametric. For non-parametric tests, our sample size provides 80% power to detect the stated difference.

RESULTS

Results were analysed after 39 patients had participated in the trial. 32 completed the study successfully. The reasons why 7 participants failed to complete the study are given in Table 1.

Two patients required re-packing. For one of these patients the side that was bleeding contained a Netcell pack. The other patient was taken back to theatre and re-packed. Unfortunately, the notes for this patient do not record which side of the nose was bleeding, or why the patient was managed in theatre rather than the ward.

Six surgeons contributed to the data. Individual surgeons were given freedom to choose surgical techniques such as side of

Table 1. Reason for failure to complete study after recruitment.

Reason for failure to complete study protocol	Number of patients
Different operation performed	1
Wrong packs inserted	2
Nurses didn’t give VAS before packs removed	2
Bled: Netcell changed to Meroceel	1
Bled: returned to theatre- BIPP pack inserted	1

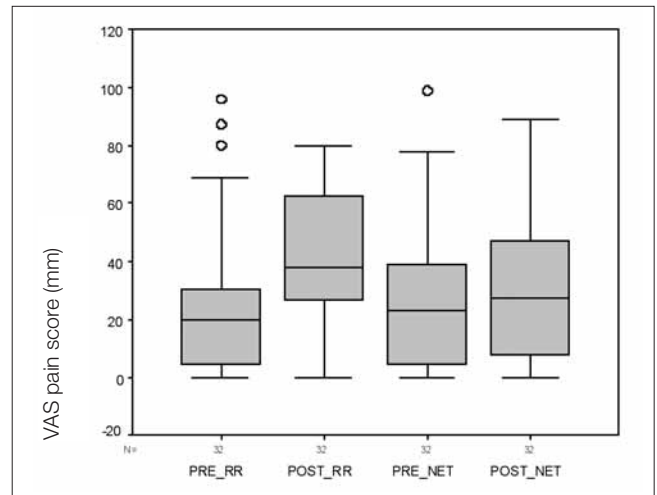


Figure 2. Box plots of VAS pain scores for each pack type, before and during removal. Each plot presents data from an equal number of left and right sides. The y-axis is marked from -20 to +120 for clarity, although the VAS sheets were from 0 - 100mm (no pain to worst pain imaginable). The grey shading indicates the inter-quartile range about the median. The tails on the boxplots are calculated by SPSS (www.spss.com) ignoring the extreme outliers, which are shown as circles. Pre: Before removal; Post: During removal; RR: Rapid Rhino Mannheim; Net: Netcell Series 5000.

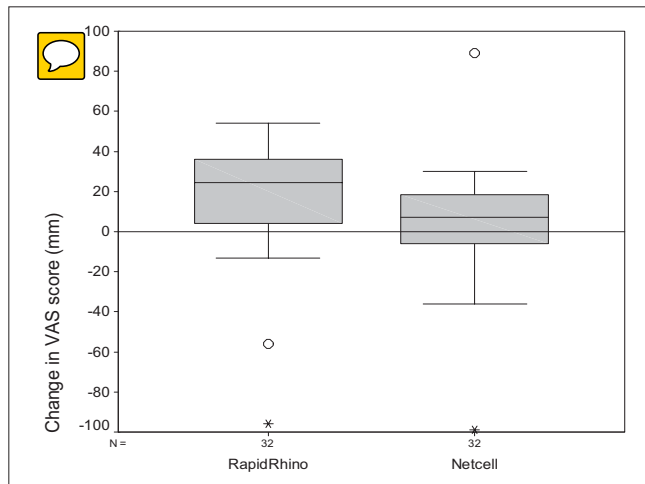


Figure 3. Box plots of change in VAS pain score for each pack type. The p value for the difference between these 2 data sets is 0.008.

Table 2. Side of incision.

Side of Incision	Number of patients
Left Killian’s	27
Right Killian’s	1
Hemi-transfixion	4

incision without coercion. Most incisions were left sided, as shown in Table 2.

Figure 2 shows box plots for the VAS pain scores for the two types of pack, both before and after removal from the nose, for the 32 patients who completed the study

The pre- removal pain scores are very similar for both types of pack ($p = 0.45$, Wilcoxon signed rank test for non-parametric paired data). Comparing the medians pre- and during-removal, it can be seen that both packs are more painful on removal than in situ. However, only the Rapid Rhino shows a significant increase in pain score on removal ($p < 0.001$). The median pain score on removal was 10.6mm higher in the Rapid Rhino Mannheim group than in the Netcell Series 5000 group. Figure 3 is a box plot illustrating the change in VAS scores pre- and during- removal. The fact that there are some negative values shows that some patients found greater discomfort with the packs in situ than when they were being removed.

Rapid Rhino was more painful on removal than Netcell, both compared to the in situ discomfort, and overall.

DISCUSSION

This study shows that there is no significant difference between the discomfort caused by the 2 types of pack whilst *in situ*, but that Rapid Rhino Mannheim 8.0 cm is significantly more painful on removal than *in situ*. There was one adverse bleeding event with an 8 cm Netcell Series 5000 pack and one where the type of pack was not recorded. No conclusion can therefore be drawn about the comparative efficacy of the two packs at preventing post-operative bleeding.

At the time of writing a Rapid Rhino Mannheim 8.0 cm pack is approximately 3 times more expensive than a Netcell Series 5000 pack, which itself costs approximately 20% more than a Merocel pack. This study therefore suggests that the Rapid Rhino tested is not superior to the Netcell pack currently favoured in our unit.

The study design attempts to minimise the systematic bias that can occur in studies involving subjective reporting of pain. Adult patients were studied who underwent the same operation, and had packs removed in a specified order, early on the first post-operative day. It looked at the *in situ* pain as well as pain on removal, and randomisation of pack to nostril side ensured that there was an equal chance of either pack being removed first. Patients were not shown the packs before the study, and so even if they could detect a difference they would have been blind to which was which.

A limitation of the study is that it was stopped following recruitment of 39 patients due to logistical difficulties caused by two of the researchers moving on to work in another hospital. Data was available for 32 of these patients, which falls short of the target of 42 patients suggested by the power calculation. The statistical significance of the result suggests that a type II error is unlikely to have occurred, however.

A potential weakness of asking patients to compare the level of pain on each side the nose is that the close proximity of these areas makes it difficult to distinguish exactly where the pain is coming from. We feel that this problem is partially overcome by removing the packs one at a time.

Pain associated with nasal packing may be related to how long the packs are kept in situ. In our study we maintained the unit practice of removing packs early on the first post-operative day, which may influence how generalisable our results are.

A variety of experimental designs have been used in the literature on the comparison of nasal packs^(2,6,7), with more recent studies favouring a similar design to our study. Previous authors have documented that nasal packs are more painful on removal than in situ⁽¹⁾. Arya et al.⁽²⁾ found the well-established and inexpensive Merocel pack to be significantly more painful than the Rapid Rhino Goodman pack on removal (the Goodman pack is the same shape as the Mannheim pack, but measures 5.5 cm in length). They recruited 14 patients, who had a variety of elective nasal operations, and recorded pain on pack removal using a VAS. A mean difference of 4.0 on a 10-point scale was recorded, which would only have required 7 patients to demonstrate significance. For our study, the differences in pain on removal of the two types of pack were expected to be smaller, and therefore the sample size needed to be larger.

Subsequent studies have similarly compared new packing materials with Merocel^(8,9). These studies both found that the new packs, the Spiggle foam pack⁽⁸⁾ and the Algostéril calcium alginate pack⁽⁹⁾, were as effective at stopping post-operative bleeding, but were less painful to remove than Merocel.

Recently, work investigating other Rapid Rhino products has been published⁽³⁻⁵⁾. Moumoulidis et al.⁽⁴⁾ and Badran et al.⁽⁵⁾ have compared Merocel with Rapid Rhino for the treatment of epistaxis. The Rapid Rhino epistaxis pack has a central cavity that is filled with air by the inserting clinician to create a tamponade effect. Air is aspirated before pack removal, making the pack much slimmer than the Mannheim pack we used. Cruise et al.⁽³⁾ compared the Rapid Rhino Riemann pack with Telfa packs following FESS, using patients as their own controls. The Riemann pack used was 4 cm long but otherwise similar to the Mannheim pack. They found that the Riemann pack caused significantly less pain on removal compared with Telfa. It is interesting to speculate whether the larger dimensions of the Mannheim pack may cause greater pain on removal.

Although many ENT surgeons prefer either to avoid packing, or to use absorbable packs, a survey of 370 UK ENT consultants showed that the majority continue to use packs that must be removed on the ward post-operatively (Sadr et al., unpublished data). The supposed advantage of this practice is to control oozing of blood into the naso- and oropharynx, which could increase the risk of aspiration during recovery from general anaesthesia. For those who do favour packing, our results show that there is a small difference in the pain caused by removal of Netcell Series 5000 and Rapid Rhino Mannheim 8 cm packs, with patients preferring Netcell.

The authors are aware that not all ENT surgeons favour the practice of trimming the inferior turbinates, but we feel that the results of this study should be generalisable to other operations.

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