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A prospective, single-blind, randomized controlled trial of petroleum jelly/Vaseline for recurrent paediatric epistaxis

S. LOUGHRAN,* E. SPINOU,* W.A. CLEMENT,* R. CATHCART,* H. KUBBA† & N.K. GEDDES*

**Department of Otolaryngology Head and Neck Surgery, Royal Hospital for Sick Children, Yorkhill, Glasgow, and †Department of Otolaryngology, Great Ormond Street Hospital, London, UK*

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The aim of the study was to determine if petroleum jelly was an effective treatment for paediatric epistaxis. A single-blind, prospective, randomized controlled trial was undertaken in an otolaryngology outpatient clinic of a paediatric hospital from March 2001 to March 2002. A total of 105 children referred with recurrent epistaxis were randomized into the study, 52 into the treatment arm and 53 into the control arm. Children in the treatment arm applied Vaseline twice a day bilaterally for 4 weeks and were monitored for any bleeds for the next 4 weeks. Children in the control arm were simply given an 8-week appointment and the number of bleeds were monitored for the 4 weeks prior to their appointment. The outcome measure was the proportion of children in each group without nosebleeds in the preceding 4 weeks. Both groups were equally distributed in age, duration of symptoms and duration of each bleed. Fourteen of 51 (27.5%) patients of the treatment arm and 18 of 53 (34%) of the control arm did not bleed in the 4 weeks before review (chi-square test, $P = 0.472$). It can be concluded that Vaseline alone confers no benefit over simple observation in recurrent childhood epistaxis.

Keywords *epistaxis* *child* *petroleum jelly* *randomized controlled trial*

Epistaxis in children is an extremely common condition, occurring in up to 56% of children aged 6–10 years.[1] The natural history of the problem is one of intermittent, recurrent, usually minor bleeds that can alarm parents and children significantly. The usual site of the bleeding is the anterior septum in the region of Little's area, which is particularly prone to drying effects and to digital trauma. The majority of children are adequately managed by their parents; however, a proportion with more troublesome bleeds who present to their family doctor may in turn be asked to refer for a specialist opinion. Although bleeding is usually the result of the combination of trauma, nasal drying and crusting, occasionally it may be the presenting feature of a more worrisome condition. Unrecognized haematological diseases may present with nosebleeds. It has also been noted that the prevalence of nosebleeds is greater in children with allergic rhinitis. The bleeds may also be caused by lesions within the nose, for example, pyogenic granuloma, juvenile angiofibroma.[2,3]

Correspondence: Sean Loughran, 3 Deanston Avenue, Barrhead, Glasgow G78 2BP, UK (e-mail: sean@ihr.gla.ac.uk).

The Hippocratic method of controlling nosebleeds is a tried and tested means of controlling nosebleeds, and involves pinching the soft tissue of the nose thereby tamponading the vessel. Unfortunately, there is still widespread confusion among patients and medical staff alike regarding the suitable area of pinching the soft tissue.[4] There is sparse evidence in the literature on how best to manage and prevent recurrent bleeds. Little is known about the natural history of the disease; however, in a recent study it appears that there may be a high resolution rate.[5] Treatment options available to the medical practitioner include wait and see, topical medication such as Naseptin, Bactroban or Vaseline (petroleum jelly), chemical and electric cautery, or a combination of all of them. Previous randomized trials have compared cream and cautery showing equivalent results with either treatment, and in a study from this institution comparing cream against no treatment, there was a significant increase in resolution in the treatment arm.[5–7] Many practitioners prefer to prescribe topical nasal Vaseline placed with a cotton bud as a simpler, cheaper alternative. It is hypothesized that most nasal medication is an emollient preventing drying and crusting.

The increased concern over peanut exposure in young children, and the fact that the most commonly used cream contains peanut oil is another factor that may lead to greater interest in the use of Vaseline. There is however, no evidence that Vaseline is an effective treatment. We compared the efficacy of topical nasal Vaseline against no treatment in controlling recurrent nosebleeds in children.

Methods

Following ethical approval, 105 consecutive referral letters from general practitioners were selected and randomly allocated to a treatment arm or observation arm. The referred patient had to be between 1 and 14 years of age with recurrent nosebleeds. Those with known bleeding disorders or suspected intranasal masses were excluded. Randomization was performed using a computer generated random list, which was placed in sealed opaque envelopes, shuffled and sequentially numbered. Fifty-two children randomized to treatment were sent an explanatory letter, consent form, epistaxis diary, a tube of Vaseline and an appointment for 8 weeks at the outpatient clinic. The letter gave clear instructions on how to apply Vaseline for 4 weeks, and instructed the parents to keep the diary until the appointment. Fifty-three children randomized to the observation arm of the study received all the above apart from Vaseline and were simply asked to keep their diaries and attend the clinic. Earlier during the study, as there were problems in using diaries, it was decided to rely on the report of nosebleeds from the parent and the child in the preceding 4 weeks as the outcome measure.

The member of the medical staff who reviewed the patients in the clinic was blinded to the randomization and specifically avoided asking questions about treatments used until the end of the assessment. A review data sheet, created at the beginning of the study, in which age, sex, frequency of bleeds, duration of episodes, presence of crusting and abnormal vessels were all documented. All patients who did not attend were contacted by telephone and offered another appointment. In addition, data were collected over the phone on the occurrence of bleeds.

Statistics

The true spontaneous resolution rate is unknown, but may be of the order of 29%. The resolution rate with Naseptin cream is approximately 50–55%.[5,7] We regarded an absolute difference of 25% as being of sufficient clinical importance to justify the use of Vaseline in treating epistaxis. Power analysis calculations were performed and these demonstrated that for a trial to have a power of 75% and to be able to exclude a difference of this magnitude at the 5% significance level, a total of 100 children would be required, 50 in each arm.

Results

One hundred and five children between 1–14 years of age with a median of 9 years were entered into the trial. Fifty-two were randomized to the treatment arm and 53 to the control arm. There were 68 boys and 37 girls. One child was excluded from the analysis because a pyogenic granuloma was the cause for his bleeding. The sex distribution between the two arms was equal (chi-square test, $P = 0.639$). The duration of symptoms was between 2 and 84 months with a median of 12, and the duration of bleeds was between 2 and 120 min with a median of 5. Age, duration of history and duration of bleeds were assessed with Mann–Whitney *U*-test and revealed no difference between the two groups ($P = 0.176$, 0.164, 0.524 respectively).

Figure 1 shows the progression of children through the trial. Fourteen children failed to attend and were all contacted by phone. Seven belonged to the control and seven to the treatment group. Patients who did not attend were no more likely to have stopped bleeding than those who did (five of seven from the control and four of seven from the treatment group).

Visible vessels on the septum were seen in 42 children, 10 on the right side, 16 on the left and 26 on both sides. Two children had visible vessels on the side opposite to that of bleeding. Twenty-nine had crusting, of which four on the right, 11 on the left and 14 on both sides. Visible vessels were seen in 21/44 of the treatment group and 21/46 from the control but this did not have a statistical significance (chi-squared test, $P = 0.843$). Crusting was seen in 11/44 *versus*

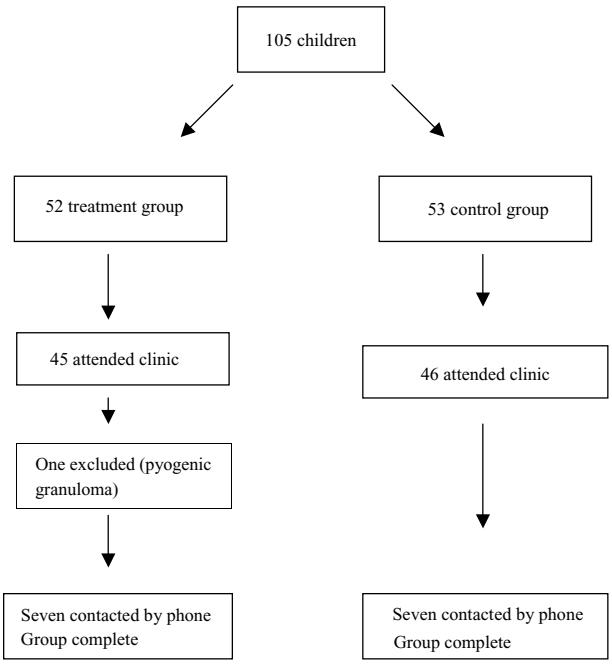

Figure 1. Progression of patients through trial.

18/46 of the children. Although there was a slight increase of crusting in the control group, it was not found to be statistically significant (chi-squared test, $P = 0.151$).

Fourteen of 51 (27.5%) in the treatment group and 18/53 (33.9%) in the control group had no bleeds in the previous 4 weeks (chi-squared test, $P = 0.472$).

All the children in the treatment group had received and used the petroleum jelly although not always as specified in our instructions. In the control group, one child had been to the GP and received Naseptin while on trial, but in view of the intention to treat analysis, the child remained in the control arm.

Discussion

Although perceived by many as a relatively minor problem, recurrent childhood epistaxis is distressing and causes inconvenience to the child and parents and results in a significant number of referrals to ENT outpatient clinics. Appropriate effective non-interventional methods of treatment are ideally suited to the population involved and the disease process itself. The evidence base for these treatments is however limited. The most commonly used treatment is the antiseptic cream Naseptin. This cream has been used in a number of studies and has been shown to be as effective as chemical cautery, and more effective than any other treatment.[5–7] Petroleum jelly (Vaseline) has been used by otolaryngologists for many years as a safe, cheap treatment for epistaxis. The presumed mode of action is the emollient effect Vaseline has on the nasal mucosa, preventing drying and crusting which may reduce the propensity to bleed; indeed many postulate that this is how all nasal creams and ointments have their effect in treating epistaxis. One concern voiced by a number of practitioners and parents is the presence of peanut oil in the most commonly used nasal cream Naseptin. All patients who are prescribed Naseptin should be questioned if they are allergic to peanuts. There has been mounting evidence that any exposure to nut antigens at a young age increases the subsequent chance of developing nut allergy.[8] Vaseline is perceived as a safe treatment by all, and indeed has few reported side-effects. There have been rare case reports of the development of myospherulosis, a condition representing foreign body reaction to petroleum-based products, which occurs after nasal packing with Vaseline, impregnated gauze.[9] However, there has been no evidence linking topical application with this complication. Nevertheless, evidence for the beneficial effects of Vaseline is anecdotal.[10] This study is the first prospective randomized controlled study to look at the effectiveness of Vaseline in treating childhood recurrent epistaxis.

Randomization at the GP referral stage has advantages and disadvantages. The advantage is that it allowed the normal outpatient wait to act as a natural observation period for the control arm. It would have been difficult to get ethical or parental approval to assess a child and then send them away without treatment. The disadvantages are that occasionally the referral letter may be misleading or even incorrect in its assumptions, and the fact that compliance rates may be higher if patients are initially seen at the clinic and the trial fully explained, and there is a chance to ask questions.

The inclusion of Vaseline in the treatment with an initial contact letter makes it more likely that patients will actually use the same. Difficulty was mentioned in introducing the ointment into the child's nose, despite instruction in the information leaflet. This did not affect a significant number of the participants. Nevertheless, it may be a potential reason as to why there was no difference between the two arms, because unlike Naseptin, Vaseline does not come with a handy nozzle for easy introduction. It was decided before the trial began that the treatment arm should reflect current practice and instillation methods.

As no true placebo was available, it was decided that one of the arms should be an observation arm. Obviously this prevents blinding of the participants and may be a source of bias. Secondly, the blinding of the assessing doctor at the first clinic visit is not without its potential problems as it may be evident which arm the patient had been in, despite the assessors best efforts.

A problem that became evident very early in the study was the use of epistaxis diaries. The completion rate was very low and indeed was often forgotten when attending the clinic. These problems are common in any study involving diary completion. Therefore, it was decided to rely on parental and child report as to the presence of nosebleeds in the preceding 4 weeks, this in itself is prone to problems but was the only method available.

The reason for the majority of the non-attendees was social circumstances. They were contacted by telephone and questioned. If it were found that a significant number of the treatment arm patients did not attend because they had stopped bleeding, then this would significantly bias the results. However, this was not the case, as analysis of the results showed no difference in resolution rates for non-attendees.

It may be that Vaseline could now act as a placebo for future trials in epistaxis. It would be interesting to compare Vaseline to a pharmacologically active ointment such as Bactroban. In the same way it would be potentially interesting to compare a pharmacologically active cream such as Naseptin to a simple carrier cream.

Despite the weaknesses of our study we feel that current practice and administration of topical nasal Vaseline alone confers no advantage over simple observation in the treatment of recurrent childhood epistaxis.

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