

Bismuth subgallate – its role in tonsillectomy

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Abstract

There have been many attempts at identifying substances and describing methods that would assist the surgeon and be of benefit to the patient undergoing a tonsillectomy. The use of bismuth subgallate as a haemostatic adjunct during tonsillectomy has only been described previously in retrospective studies. A controlled prospective randomized trial of 100 paediatric patients, in which 50 patients had a tonsillectomy performed using bismuth subgallate as a haemostatic agent and in which the remainder did not have any associated haemostatic substance, is presented here.

Data on 72 patients was analysed, 39 patients belonging to the bismuth subgallate group and the remaining 33 to the control group. The time for haemostasis was three to 18 (mean 7.8) minutes in the bismuth group. It was four to 16 (mean 9.9) minutes in the non-bismuth group. These figures are statistically significant.

The range of ties used in the bismuth group was none to three (mean 1.5) ties and one to seven (mean 3.4) ties in the non-bismuth group. These figures are also statistically significant. The remainder of the recorded parameters did not differ significantly.

It was found that bismuth subgallate/adrenaline paste decreases operating time by significantly reducing the haemostasis time and the number of ties required but does not decrease post-operative morbidity.

Key words: Tonsillectomy; Haemostasis, surgical; Bismuth subgallate

Introduction

Bismuth subgallate is an insoluble compound that has been used in the treatment of varying disorders in the past including Vincent's angina, syphilis and in reducing colostomy odour.

The use of bismuth subgallate (BSG) in tonsillectomy was first described by Maniglia *et al.* (1989) in a retrospective study of their experiences with it during a 20-year period. They used a combination of bismuth subgallate, adrenaline and normal saline to form a paste which was applied on a swab to each tonsil fossa after the tonsil had been removed. The extremely low incidence of post-operative haemorrhage (0.28 per cent) in their series was attributed to the use of bismuth subgallate/adrenaline paste.

The aims of this study were to see if firstly bismuth subgallate reduces operating time and secondly if it reduces post-operative morbidity.

Methods

One hundred paediatric patients were randomly selected. Fifty children underwent tonsillectomy using the bismuth subgallate/adrenaline paste as described by Maniglia *et al.* (1989). Bismuth subgallate and adrenaline paste is made by adding 26 gm of bismuth subgallate (BSG) powder to 20 ml normal saline and 0.7 ml of

1:1000 adrenaline until a toothpaste-like consistency is obtained. The remaining 50 patients had tonsillectomy performed without any adjunctive haemostatic agent. Each tonsillectomy was performed by dissection and ligation. Diathermy was not used. The procedures were carried out by either a Consultant or a Registrar.

The age of each patient was noted. The tonsillectomy time, which was the time interval between the first incision to the placement of the pack in the contralateral tonsillar fossa and the haemostasis time, which was the time interval between the placement of the second pack and the removal of the Boyle–Davis gag were recorded. Linen ties were used for haemostasis and the number of ties required was documented. Statistical analysis was applied using a two-sample *t*-test to compare the haemostasis time and the number of ties used in both cohorts. A Fisher's exact test was used to compare the proportion of patients in each group requiring ties. A post-operative morbidity questionnaire was given to the parents of each patient and all of the children were reviewed as outpatients a fortnight after their procedure. This questionnaire (Table I) had been described by Linden *et al.* (1990) in a previous paper and was modified slightly for our study.

Post-operative antibiotics were not prescribed for either group.

Results

The data for 28 patients was not sufficient for analysis,

TABLE I
TONSILLECTOMY QUESTIONNAIRE (AFTER LINDEN *ET AL.* (1990)
MODIFIED)

(1) How many times did your child require pain relief in the first five days after surgery?	Day 1	Day 2	Day 3	Day 4	Day 5
0					
1-2					
3-4					
5-6					
(2) Did your child complain of nausea after surgery?	Yes/No				
(3) How fussy was your child after surgery?	No. of days				
0-normal	_____				
1-cried occasionally, made attempt at play	_____				
2-fussy	_____				
3-cried constantly, inconsolable after surgery	_____				
(4) Did your child complain of ear pain after surgery?	Yes/No				
(5) On what day did your child return to eating a regular diet?					

and therefore the results of 72 patients were tabulated and assessed. Thirty-nine patients belonged to the bismuth subgallate group and the remaining 33 to the control group. The age range in the bismuth subgallate cohort was two to 12 years (mean 7.3 years) whereas the range in the non-bismuth cohort was two to 15 years (mean 7.33 years).

Tonsillectomy time in the bismuth group ranged from three to nine minutes with a mean of 5.12 (SD 1.97) minutes and the range for the non-bismuth group was two to nine minutes with a mean of 4.45 (SD 1.87) minutes. The figures for age and tonsillectomy time between the two groups were not statistically significantly.

The time for haemostasis was within three to 18 minutes in the bismuth group with a mean of 7.8 (SD 3.1) minutes. It was within four to 16 minutes in the non-bismuth group with a mean of 9.9 (SD 2.7) minutes. These figures were statistically significant, $p = 0.005$, with a 95 per cent confidence interval of 0.7-3.5 for the difference between the two means.

The range of ties used in the bismuth group was none to three ties with a mean of 1.5 (SD 1.07) ties and one to seven ties in the non-bismuth group, with a mean of 3.4 (SD 1.65) ties. Thirty-one of the patients (79 per cent) in the bismuth group required ties whereas all of the non-bismuth group (100 per cent) needed ties, $p = 0.005$. These figures are statistically significant, $p < 0.001$ with a 95 per cent confidence interval of 1.2-2.6.

The pain score and amount of analgesia used were not statistically significant. The mean number of days required to return to normal diet was similar in both groups; 2.9 days in the bismuth group and 2.7 days in the non-bismuth group. Seven patients complained of nausea in the bismuth subgallate group and four in the non-bismuth group. Nineteen patients complained of otalgia in the bismuth group and 17 had otalgia post-operatively in the control group. Eleven patients had post-operative halitosis in the bismuth group. All of the figures for the post-operative morbidity parameters in both groups were not statistically significant.

Post-operative haemorrhage was defined as that which was sufficient to warrant attendance by a doctor. There were no episodes in either group.

Discussion

The search for measures to reduce tonsillectomy time, decrease perioperative bleeding and lessen post-operative morbidity occupies the thoughts and time of many otolaryngologists.

An *in vitro* study by Thorisdottir *et al.* (1988) found that bismuth subgallate activates Hageman factor XII and thereby reduces clotting time.

The only published material on the use of bismuth subgallate/adrenaline paste as a haemostatic adjunct in tonsillectomy is retrospective: Maniglia *et al.* (1989) reviewed 1428 cases where this paste was used. They did not utilize any active measures including diathermy, ties or sutures and relied entirely on packs impregnated with the paste for haemostasis. They did not mention the length of time that each procedure took. It can be argued that if packs without any associated haemostatic agent are left *in situ* long enough primary bleeding will stop of its own accord. The quantity of paste described in 'Methods' satisfies the requirements for approximately 12 tonsillectomies and therefore the amount of adrenaline that each patient is exposed to is 0.08 ml out of 1.1 ml. There have been no controlled studies on the use of bismuth subgallate in tonsillectomy. We felt that by comparing the time for haemostasis, the number of ties needed and post-operative morbidity parameters we could have a much more objective view of the beneficial properties of bismuth subgallate.

A statistically significant reduction in operating time was obtained by including it in the procedure. It was possible to reduce the operating time by up to 3.5 minutes per tonsillectomy which, especially in a paediatric hospital, would allow more cases to be performed during a standard list. This shorter operating time for tonsillectomy is as a result of the use of bismuth subgallate/adrenaline paste and presumably because of the coagulative and vasoconstrictive properties of the paste. Ties were used instead of diathermy to stop the bleeding as they were a more finite way of assessing the extent of active haemostasis required. The activation of Hageman factor XII and the vasoconstrictor ability of adrenaline have a definite influence in that one would expect it to take longer to achieve haemostasis if less ties were being utilized. Phillips and Thornton (1989) demonstrated that the use of diathermy instead of ligation decreased operating time by 26 per cent when they performed a prospective study comparing the two haemostatic modalities. Our trial was performed using a similar format and the combined results would imply that the use of bismuth subgallate and diathermy should reduce operating time even further.

It was felt that the amount of adrenaline that each patient was exposed to was not enough to account for the differences found between our two cohorts. However our intention was to assess the paste as already described by Maniglia *et al.* (1989). We did not attempt to measure total blood loss as studies have shown that the majority of blood loss is related to the dissection of the tonsil itself and not to the type of pack placed in the fossa after its removal (Weimert *et al.*, 1990; Sharp *et al.*, 1991). The use of a haemostatic agent applied to a tonsillar swab should therefore not affect the blood loss significantly.

Maniglia *et al.* (1989) in their retrospective study attributed the very low incidence of post-operative haemorrhage (0.26 per cent) to the use of bismuth

subgallate/adrenaline paste. We did not have any post-operative haemorrhage in either of our cohorts and therefore cannot say that it reduced the incidence of post-tonsillectomy bleeding. It was interesting to note, however, that the number of ties used did not affect the incidence or severity of post-operative pain. Post-operative antibiotics were not used, as Linden *et al.* (1990) found in their study that their use made no significant difference to the patients undergoing tonsillectomy by dissection and ligation.

The use of bismuth subgallate, or the reduction in the number of ties did not decrease the incidence of post-operative nausea, halitosis or time required to return to a normal diet. There is, however, a possible lack of power statistically in this study with respect to post-operative morbidity. It is possible that the study might not have been large enough to pick up any small but real differences that actually existed in the overall morbidity and a larger study might perhaps be justified in the future to analyse this aspect.

The only complication reported in the literature (Tannous *et al.*, 1989) in the use of bismuth subgallate for tonsillectomy is the finding of pharyngeal opacities on a lateral soft tissue X-ray in one patient. We X-rayed 30 patients post-operatively and found no evidence of pharyngeal opacities. A recent study by Cozzi *et al.* (1991) where they injected rats intratracheally with bismuth subgallate paste found that it caused pneumonia in a significant number of them. There were no laryngeal or respiratory complications in any of our patients but it still must be kept in mind that there is a theoretical risk of respiratory problems when using this paste.

Conclusions

We have found in this prospective study that bismuth subgallate/adrenaline paste used as an adjunctive haemostatic measure during tonsillectomy significantly reduces

the time required for the procedure. It does not appear to reduce post-operative morbidity.

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