Bismuth subgallate: a safe means to a faster adenotonsillectomy

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Abstract

Tonsillectomy, with or without adenoidectomy, is one of the most commonly performed surgical procedures and as such contributes significantly to the surgery performed by GPs and ENT surgeons. In this randomized controlled study we compared the use of a compound bismuth subgallate (BSG) during adeno-tonsillectomy with the standard operations.

Two hundred and two tonsillectomies were randomized into two groups. BSG was used in 90 patients while the other 112 patients were used as controls. The mean operating time was reduced from 11.5 to 9.9 minutes, the number of swabs from 4.5 to 3.7 and number of ties from 3.4 to 2.1. All these reductions were significant (*p*-values all <0.05). There were no post-operative complications in either group. Thus the use of BSG during adeno-tonsillectomy or tonsillectomy alone significantly decreases the operating time and results in less intraoperative haemorrhage with fewer ties and swabs being required.

Key words: Tonsillectomy; Bismuth subgallate

Introduction

Adeno-tonsillectomy and tonsillectomy are the most commonly performed major surgical procedures in the USA (Brodsky, 1989). Many articles have been written where surgeons have tried haemostatic substances (Handler *et al.*, 1986), different surgical techniques (Roy *et al.*, 1976; Mann *et al.*, 1984; Maniglia *et al.*, 1989) and post-operative antibiotics (Telian *et al.*, 1986) attempting to reduce the operative time and post-operative morbidity without notable success. Although antibiotics have been found to reduce the overall post-operative morbidity by reducing pain, lassitude and mouth odour, they had no effect on post-operative haemorrhage (Telian *et al.*, 1986).

Bismuth subgallate (BSG) was first introduced by Maniglia *et al.* (1989) who suggested that the use of BSG may allow adenoidectomy and/or tonsillectomy to be performed as an outpatient procedure as opposed to the standard inpatient procedure without influencing adversely the incidence of post-operative haemorrhage or general patient care.

BSG is a poorly soluble heavy metal with astringent qualities. Its mode of action was demonstrated by a group of haematologists, Thorisdottir *et al.* (1987), who showed that BSG activated the Hageman factor (factor XII) of the clotting cascade and thus accelerated coagulation. As recommended by Maniglia *et al.* (1989) we combined the BSG with 1 : 1000 adrenaline for its vasoconstrictor qualities which we believe improves BSGs haemostatic qualities. BSG is poorly absorbed and no toxic effects have been described when used as a haemostatic agent despite its use for over 20 years (Maniglia *et al.*, 1989).

The purpose of this study was to assess the effectiveness of BSG in controlling intra-operative haemorrhage and reducing operative time.

Materials and methods

A total of 202 patients were included in this trial. Patients who were under three years of age, not medically fit, or with a previous peritonsillar abscess were excluded. The patients were randomized to receive BSG according to theatre lists. The BSG group had 90 patients while the control group had 112 patients. The male to female distribution was 1 : 1.2 and the mean age 13.1 years. They were the same for both groups.

BSG paste is made up by adding 0.7 ml of 1 : 1000 adrenaline to 30 mg of BSG powder and mixing this with normal saline (20 to 40 ml) to obtain a paste the consistency of toothpaste. The cost per patient in South African rands is R4.00 (US dollar: \$1.30); the powder is obtainable from Merck Pharmaceuticals.

TABLE I									
RESULTS	OF	THE	BSG	GROUP	AND	THE	NON-BSG	GROUP	WITH
				REGARD TO TIME [*]					

	Mean time	STDV	95% Confidence interval 9.31 to 10.5 min 10.7 to 12.2 min	
BSG non-BSG	9.9 min 11.5 min	3.0 min 4.1 min		

**T*-test: t(200) = 2.9; p < 0.005; STDV = standard deviation.

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 TABLE II

 RESULTS OF THE BSG GROUP AND NON-BSG GROUP WITH REGARD TO

 NUMBER OF SWABS USED*

	Mean no. of swabs	STDV	95% Confidence interval		
BSG	3.7	1.3	3.4 to 4.0		
non-BSG	4.5	1.8	4.2 to 4.9		

**T*-test: *t* (200) = 3.3; *p* < 0.005; STDV = standard deviation.

There were similar numbers of adeno-tonsillectomy (BSG: non-BSG = 57:71) and tonsillectomy (BSG: non-BSG = 33: 41) in both groups. Adenoidectomy was performed using curved Shambaugh curettes while tonsillectomy was performed using the Gwynn-Evans blunt dissector with a cold snare to remove the inferior pole of the tonsil. Operative time was measured from the first incision into the anterior tonsillar pillar to when the Boyle-Davis mouth gag was removed. Haemostasis was achieved in the non-BSG group with linen ties and swabs. The number of swabs and ties used was independently monitored by the scrub nurse. In the BSG group swabs were smeared with BSG and placed in the adenoidal bed and tonsillar fossae. After two to three minutes the swabs were removed and any bleeding in the tonsillar fossae tied with linen ties. Excess BSG was removed from the tonsillar fossae and the nasal passages were cleaned with a fine suction catheter prior to removal of the mouth gag. Due to the usage of BSG, possible surgical bias could not be controlled.

Results

The results are presented in Tables I, II and III. The statistical analysis was done using Student's T-test for independent groups. The means, standard deviations, 95 per cent confidence intervals for the means and p-values are presented.

No post-operative complications other than minor fever, pain and mouth odour occurred in either group with no incidence difference between the two groups. There were no primary or secondary haemorrhages in either group.

Discussion

The beneficial qualities of BSG have been advocated in the literature but the need to compare the use of BSG with a normal adeno-tonsillectomy or tonsillectomy in a ran-

TABLE III								
RESULTS	BETWEEN	THE	BSG	GROUP	AND	NON-BSG	GROUP	WITH
REGARD TO NUMBER OF TIES USED*								

	Mean no. of ties	STDV	95% Confidence interval
BSG	2.1	1.4	1.8 to 2.4
non-BSG	3.4	1.8	3.0 to 3.7

*T-test: t(200) = 5.2; p < 0.005; STDV = standard deviation.

domized and controlled way is necessary. In this study the use of BSG when compared to the standard operation has resulted in a reduction in operating time and intra-operative haemorrhage. Although these differences may appear small, they are significant and could increase the productivity of both the surgeon and the theatre staff. The additional cost of BSG could outweigh its advantages if the paste is mixed for only one patient, but when used on a list of adeno-tonsillectomies or tonsillectomies, it is not significant. Although our numbers were not sufficient to allow a meaningful comparison between the two groups as to the incidence of post-operative haemorrhage, Maniglia et al. (1989) stated that their incidence of 0.28 per cent in 1428 patients in which they used BSG was lower than the accepted incidence of between 0.7 and 7 per cent (Handler et al., 1986). Day-case surgery is becoming increasingly popular as this reduces the costs of medical care and Maniglia et al. (1989) state that consideration should be given to doing these procedures as day-cases in otherwise healthy patients as most of the serious complications occur within the first hour after the operation. However, poor social circumstances, lack of transport facilities and poor access to emergency medical care can put these patients at risk. BSG appears to have a beneficial effect when used in adeno-tonsillectomy and tonsillectomy primarily due to its haemostatic qualities. The small additional cost is warranted when account is taken of the reduction in both the operative time and in the amount of intra-operative haemorrhage.

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