

HAEMOSTATIC EFFECT OF ANKAFERD BLOOD STOPPER® SEEN DURING ADENOIDECTOMY

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Abstract

In Turkey, Ankaferd Blood Stopper® (ABS) has been approved for the management of external haemorrhages and bleedings occurring during dental surgeries (Goker et al., 2008). Ankaferd comprises a standardized mixture of plants, including *Thymus vulgaris*, *Glycyrrhiza glabra*, *Vitis vinifera*, *Alpinia officinarum*, and *Urtica dioica*. This study aimed to evaluate the efficacy of ABS tamponade in the control of intra-operative bleeding occurring during adenoidectomy performed in children under the age of 12. Sixty children were randomized to receive 1 to 5 minute-tamponade with either ABS or topical gauze sponges soaked in saline solution (SS) during their adenoidectomy. Time-to-haemostasis and the number of packs required were recorded. A visual analog scale was used by the operating surgeon to record subjective data, including the rate of bleeding following the first adenoid pack removal (0= none, 3=brisk). Compared to the children in the SS group (n=30), time-to-haemostasis seen in ABS patients (n=30) was significantly shorter (mean \pm standard deviation, 1.93 ± 1.39 min vs 3.20 ± 1.50 min; $p < 0.0001$); they required a lower number of packs (mean, 1.93 vs. 3.20), and appeared to bleed less (53.3% vs 6.7%; $p = 0.0001$). ABS aids in the control of intra-operative bleeding and reduces the number of packs required to achieve haemostasis, so that it can be recommended for tamponades performed during paediatric adenoidectomies.

Key words: Ankaferd, adenoidectomy, children, bleeding, haemostasis.

Introduction

Ankaferd Blood Stopper® (ABS) is a medicinal plant extract which has previously been used in the Turkish traditional medicine as a haemostatic agent (Huri et al, 2009; Kurt et al, 2008). Previous reports as to the safety and efficacy of this product have indicated its sterility and non-toxicity (Cipil et al, 2009; Goker et al, 2008; Bilgili et al, 2009; Kurt et al, 2009). In this study, the efficacy of ABS tamponade undertaken to control bleeding during adenoidectomy, was compared against that of the traditional tamponade achieved by topical application of gauze sponges soaked in saline solution.

Materials and Methods

A prospective, non-randomized, non-blinded observational study was conducted in 60 consecutive children who underwent adenoidectomy between March 2009 and May 2009. The study was approved by the local Board of Ethics. A written consent was obtained from the parents of all patients prior to their inclusion. Each child was assigned either to the ABS or the SS group in order of appearance on the surgical waiting list. The patients were subjected to the intended procedure if having an upper airway obstruction due to adenoid tissue. Children younger than 3 or older than 12, and/or those suffering from haematological disorders, were excluded from the study.

All surgeries were performed by the same surgeon (H.Y.) under general anaesthesia achieved by endotracheal intubation. According to our study protocol, each patient was placed in the Rose position; a Davis-Boyle mouth gag supported by Draffin bipods was inserted into the mouth. A tongue retractor of a suitable size was used depending on the patient's age. Adenoidectomy was then performed using a curette and the operative site was packed with either an ABS tamponade or a saline-soaked sponge gauze for 1 min. Following a gentle removal of the tamponade, the bleeding control efficacy was evaluated by the operating surgeon by means of a visual analog scale (0= none, 3= brisk). The tamponade was switched at 1 min intervals, as required. Children who persistently bled despite a 5 minute-tamponade were considered for additional haemostatic procedures (e.g. electrocauterisation).

Following the attainment of an absolute haemostasis, Davis-Boyle mouth gag was removed and the patient was extubated. Acetaminophen was recommended for pain relief and administered as required. No antibiotics were prescribed routinely. The children were examined for bleeding and discharged on the first postoperative day. Data were analyzed by means of Chi-squared and Mann-Whitney-U tests using SPSS 15 software.

Results

No statistically significant differences in age and sex of the children constituting the two groups ($p>0.05$) were revealed; the mean ages of the 30 children (19 male, 11 female) in the ABS group and the 30 children (16 male, 14 female) in the SS group were 7.83 ± 3.17 yrs and 6.30 ± 2.56 yrs, respectively. In 16 ABS (53.3%) and two SS patients (6.7%), intra-operative haemostasis was achieved after a single pack application ($p=0.0001$, Table 1). In 88.9% members of the ABS group and 11.1% members of the SS group, time-to-haemostasis equalled to 1 minute, which is statistically significant ($p=0.0001$; Table 2). The mean number of packs used in the ABS group and the SS group was 1.93, and 3.20, respectively ($p=0.0001$). Electrocauterisation was used to achieve haemostasis in one child in the ABS group, and three children in the SS group. No major complications had been seen during or after the surgery in either group; the same goes for early or late postoperative bleedings or infections.

Table 1: Subjective data recorded by the operating surgeon with regards to the rate of bleeding after the removal of the first pack. $n=30$ in both groups; $p=0.0001$ between both groups, Chi-squared tests). ABS: Ankaferd Blood Stopper®; SS: saline solution.

Bleeding rate	ABS group n(%)	SS group, n (%)	Total, n (%)
None	16 (53.3)	2 (6.7)	18 (30)
Mild	8 (26.7)	9 (30)	17 (28.3)
Moderate	2 (6.7)	11 (36.7)	13 (21.7)
Brisk	4 (13.3)	8 (26.7)	12 (20)

Table 2: Comparison of time-to-haemostasis established in the two groups ($p=0.0001$, Chi-square test). ABS: Ankaferd Blood Stopper®, SS: saline solution.

Time –to- Haemostasis (min)	ABS group n(%)	SS group, n (%)	Total, n (100%)
1	16 (88.9)	2 (11.1)	18
2	8 (47.1)	9 (52.9)	17
3	2 (15.4)	11 (84.6)	13
4	1 (50)	1 (50)	2
≥5	3 (30)	7 (70)	10
Total	30 (50)	30 (50)	60

Discussion

Adenoidectomy is one of the most commonly performed procedures in children, but bleeding following adenoidectomy may pose a challenge to a surgeon and may require the placement of a posterior nasopharyngeal pack followed by a subsequent prolonged hospitalisation (Mathiasen and Cruz, 2004). Therefore, improvements in currently used techniques and innovations that enable a more efficient bleeding control during and following adenoidectomy would be welcomed.

An ideal haemostatic agent can be applied quickly, conveniently and accurately. It should work to stop even rapid bleeding from a vessel or organ without causing local injury or systemic effects. Furthermore, it should work equally well on the anticoagulated and non- anticoagulated patients. Traditional electrical and mechanical means are still the mainstay of haemorrhage control, but new haemostatic technologies continue to emerge (de la Torre et al, 2007). Mechanical and active topical sealants and haemostatic agents are now available in different forms; these agents can be used in a variety of settings as adjuncts to the control of surgical bleeding (Spotnitz et al, 2007; Jo et al, 2007; Mathiasen and Cruz, 2004).

As an adjunctive treatment undertaken to the end of haemorrhage control, ABS can be used only topically, and not systemically. It induces a rapid formation of a unique protein network in both plasma and serum (Cipil et al, 2009, Kurt et al, 2008). Therefore, this unique mechanism of action provides ABS with the advantage over other haemostatic plant extracts. ABS can be effective in subjects with normal haemostatic parameters, as well as in those with primary and/or secondary haematological disorders (Cipil et al., 2008). In addition to the physiological haemostatic process, ABS exposure appears to enable an increased tissue oxygenation without affecting any individual clotting factor (Goker et al, 2008). Shortening of the bleeding duration achieved by the application of topical ABS, suggests that the extract functions, at least partly, via modulation of platelet functions (Cipil et al, 2008). Other possible mechanisms of its action require further elucidation.

In our study we observed a statistically significantly shorter duration of bleeding and a statistically lower number of packs required to achieve ABS tamponade-induced haemostasis during adenoidectomy as compared to saline-soaked gauze sponge application. However, there were certain limitations to this study. Firstly, ABS tamponade is a pack soaked by 10 ml of ABS solution, which was applied in all adenoidectomy cavities. The optimal dosage of ABS is not certain. Secondly, ABS ampoules that contain 2 ml of the agent may be more beneficial topically within the surgical field as a higher proportion may

be appropriately delivered in a more cost-effective manner. Thirdly, ABS is available in form of haemostatic spray which could be useful for surgeries such as adenoidectomy. In conclusion, further clinical studies are recommended in order to demonstrate any long-term haemostatic effects or potential toxicities of ABS.

Acknowledgements

We would like to thank Dr Alper Yenigun and Dr Zehra Donmez for their assistance with the study, and Funda Necare for her help with the statistical analysis.

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