

The Efficiency of Ankaferd Blood Stopper During the Dental Surgery in Hemorrhagic Diathesis: Case Series

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ABSTRACT

Dental surgery in patients with hemorrhagic diathesis represents a great clinical challenge regarding the bleeding and complicated infections. There are various methods and materials for haemostasis of these patients. One of them is ABS (Ankaferd Blood Stopper), which has been approved for the clinical management of external post-surgical and dental surgery bleedings in Turkey. ABS could be effectively used both in individuals with normal haemostatic parameters and in patients with deficient primary hemostasis and/or secondary hemostasis. In this case series, total 11 patients who have various illnesses especially hemorrhagic diathesis are presented. ABS application demonstrated successful clinical management of the patients with various types of hemorrhagic diathesis.

Keywords: ABS, hemorrhagic diathesis, Dental surgery

ÖZET

Hemorajik Diyatezli Olgularda Dental Cerrahi Sırasında Ankaferd Blood Stopper'in Etkinliği

Hemorajik diyatezi bulunan diş cerrahi hastalarında ciddi kanama ve komplike enfeksiyonlar başta olmak üzere birçok sıkıntı görülebilir. Bu tip hastaların hemostazını sağlamak amaçlı çeşitli yöntem ve materyal mevcuttur. Bunlardan biri olan ABS (Ankaferd Blood Stopper), Türkiye'de eksternal kanamalarda kullanım için onay almıştır. ABS hem normal hemostatik parametreleri olan hastalarda hem de primer ve/veya sekonder hemostaz bozukluğu olan hastalarda etkin bir şekilde kullanılabilir. Bu vaka serisinde, çeşitli hemorajik diyatezi bulunan toplam 11 hasta sunulmuştur. Çeşitli kanama bozuklukları bulunan bu hastalarda ABS kullanımı başarılı klinik sonuç göstermiştir.

Anahtar Kelimeler: ABS, Hemorajik diyatez, Dental cerrahi

INTRODUCTION

Bleeding can cause significant morbidity and mortality in any clinical setting. Dental extractions and other similarly invasive procedures can be managed safely at the community dental practice in most situations.¹⁻² However, serious problems can be encountered during and after tooth extraction procedures with medically compromised bleeding-prone patients. Particularly, blood coagulation problems due to acquired or hereditary defects including advanced uremia without dialysis, platelet counts of less than 50000/mm³, liver failure, aplastic anemia and high dose cancer therapy and patients with multiple coagulopathies could need pre-surgical preparations.¹⁻³ Hemorrhage, therefore, can be a major complication of routine dental treatments in patients with bleeding disorders.

There are various standard local hemostatic methods that are being used for the management of dental bleeding. Likewise, there are published reports about unsuccessfulness of the management of dental bleeding with the available methods.⁴⁻⁵ Studies about improvement of the hemostatic agents are continuing.

ABS is a standardized herbal extract obtained from five different plants *Thymus vulgaris*, *Glycyrrhiza glabra*, *Vitis vinifera*, *Alpinia officinarum* and *Urtica dioica*.⁶ ABS has been approved for the clinical management of external post-surgical and dental surgery bleedings in Turkey. ABS represents its unique hemostatic effect by promoting the very rapid (<1 second) formation of a protein network which acts as an anchor for vital physiological erythrocyte aggregation, covering the classical cascade model of the clotting system without independently acting on coagulation factors and platelets without disturbing individual coagulation factors.⁶ Phase-1 clinical study in order to demonstrate the safety of ABS is concluded as ABS is safe and efficient for humans.⁷ There are clinically successful reports about hemostasis of the cases with hemorrhagic diathesis.⁸⁻¹¹

This case series, demonstrated successful clinical management of the patients with various types of hemorrhagic diathesis.

PATIENTS

Total 11 patients who have various illnesses especially hemorrhagic diathesis are presented. Patients' biochemical and hematologic levels were evaluated by the hematologist who also gave written permissions for the extraction procedures. Essential findings of the patients are depicted in Table 1. Written

informed consent was obtained from each subject for using ABS for the management of the bleeding. Bleeding control recorded by consecutive control of the sponge. Bleeding controlled over 3 minutes only in two of the patients. For other patients bleeding control time was 1-3 min or lower than 1 minute. No delayed type bleeding was recorded for teeth extractions. For the patients with further spontaneous gum bleeding, repetitive doses of ABS were recommended beside oral health improvement.

DISCUSSION

Dental surgery in patients with hemorrhagic diathesis represents a great clinical challenge regarding the bleeding and complicated infections. Patients who have bleeding disorders undergoing dental interventions can have postoperative excessive bleeding complications.² In this paper, we reported retrospective observations regarding the topical use of ABS hemostatic agent during dental surgery in the presence of hemorrhagic diathesis. Table 1 summarizes clinical status, type of hemorrhagic diathesis, and dental intervention in our patient cohort prone to bleeding.

Ankaferd-induced formation of the protein network with vital erythroid aggregation covers the entire physiological hemostatic process. Mainly there are distinct important components of the Ankaferd-induced hemostatic network. Vital erythroid aggregation takes place with the spectrin and ankrin receptors on the surface of red blood cells.⁶ Bilgili et al. studied the efficiency of ABS in a swine bleeding model. They used ABS spray and tampon forms for hemostasis of superficial and deep skin lacerations, grade II liver and spleen injuries, grade II saphenous vein injury and grade IV saphenous artery injury. They informed about successful hemostasis except spleen model which was temporarily effective. They concluded that ABS was an effective hemostatic agent for superficial and deep skin lacerations and minor/moderate trauma injuries in a porcine bleeding model.¹² Cipil et al. reported their study about hemostatic effect of ABS in rats pre-treated with warfarin. They showed that topical administration of ABS to amputated leg shortened the duration of bleeding significantly corresponding to control group and they recommended ABS hemorrhagic management of patients with deficient primary hemostasis in clinical medicine.¹³ Akgul et al demonstrated the efficiency of ABS over penile cavernosal tissue in rat model and concluded that ABS can be

TABLE 1. Clinical status, underlying hemorrhagic diathesis, the type of dental intervention, and observations regarding the topical ABS administration in the bleeding- prone patients

Patients	Clinical status	Hemorrhagic diathesis	Dental intervention	Observations during/ after topical ABS administration
57-year-old female	End-stage liver failure Hipersplenism Pancytopenia	Defective 1 ^o haemostasis (refractory thrombocytopenia) Defective 2 ^o haemostasis (high INR)	Number 48/24/38 dental extractions	Bleeding controlled in 1-3 min. the presence of the both the defects in primary and secondary haemostasis
62-year-old female (Figure 1)	Platelet secretion defect Activated protein C resistance / venous thrombosis Hyperlipidemia	Defective 1 ^o haemostasis (thrombocyte dysfunction) Concomitant hypercoagulability	Number 36 dental extraction	Bleeding controlled in 1-3 min. in the presence of the defect in primary haemostasis. No thrombotic event.
43-year-old Male (Figure 2)	Severe Haemophilia A	Defective 2 ^o haemostasis (F VIII < 1%)	Multiple dental extractions (total 9 teeth%)	Bleeding controlled in 1-3 min. in the presence of both the defect in secondary haemostasis. (Decreased factor requirement)
55-year-old Male	Heart failure Uncontrolled diabetes	Defective haemostatic disorder and impaired wound healing due to systemic disorders	Total 16 teeth	Bleeding controlled in less than 1 min. in the presence of the defect in secondary haemostasis.
8-year-old Male	Immune thrombocytopenic purpura	Defective 1 ^o haemostasis (refractory thrombocytopenia)	Lower left deciduous molar dental extraction	Bleeding controlled in less than 1 min. in the presence of the defect in primary hemostasis
35-year-old Female	Clonal aplastic anemia	Defective 1 ^o haemostasis (refractory thrombocytopenia) Prone to infection due to leukopenia	Number 38 dental extraction	Bleeding controlled in less than 1 min. in the presence of the defect in primary hemostasis
15-year-old Male (Figure 3)	Glanssmann Disease	Defective 1 ^o haemostasis (thrombocyte dysfunction)	Chronic spontaneous gum bleeding leading to anemia requiring transfusion	Bleeding controlled in less than 1-3 min. in the presence of the defect in primary haemostasis
30-year-old Female	Glanssmann Disease	Defective 1 ^o haemostasis (thrombocyte dysfunction)	Chronic spontaneous gum bleeding leading to anemia requiring transfusion	Bleeding controlled in less than 1-3 min. in the presence of the defect in primary haemostasis
29-year-old	Clonal aplastic anemia	Defective 1 ^o haemostasis (refractory thrombocytopenia) Prone to infection due to leukopenia	Number 12, 22, 31 extractions	Bleeding controlled in less than 1 min. in the presence of the defect in primary hemostasis
20-year-old Female	Thalessemia intermedia Hemochromatosis	Defective haemostatics disorder and impaired wound healing due to systemic disorders	Chronic spontaneous bleeding leading to anemia requiring transfusion	Bleeding controlled in less than 1 min. in the presence of the defect in primary hemostasis
38-year-old Female	Rheumatic heart disease (Mitral valve replacement)	Defective 2 ^o haemostasis (high INR due to chronic warfarin use)	Number 18, 48 dental extractions	Bleeding controlled in less than 1 min. in the presence of the defect in primary hemostasis

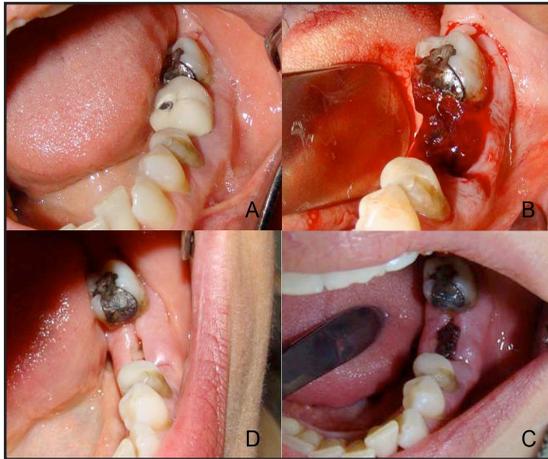


Figure 1. A: Tooth number 36 that going to be extracted
B: ABS applied extracted socket.
C: wound healing of the socket after 24 hours
D: wound healing of the socket after 5 days

used in cavernosal surgeries due to its haemostatic and anti inflammatory effects.¹⁴ Further, a number of clinical case reports have demonstrated successful bleeding management by ABS applied topically over uncontrolled bleedings.^{11,15-17} Those findings suggested that ABS has a strong potential of usage in medical practice, particularly in dentistry.

ABS could be effectively used both in individuals with normal haemostatic parameters and in patients with deficient primary hemostasis and/or secondary hemostasis. The safety and efficacy of ABS in dental surgery and bleedings have been shown previously in 25 patients with normal hemostasis.¹⁸ There was no statistically and clinically significant difference



Figure 3. A: Spontaneous bleeding especially from interdental papilla region
B: bleeding from 15,16 teeth region
C: ABS applied and in seconds hemostasis achieved
D: 24 hours later of ABS application

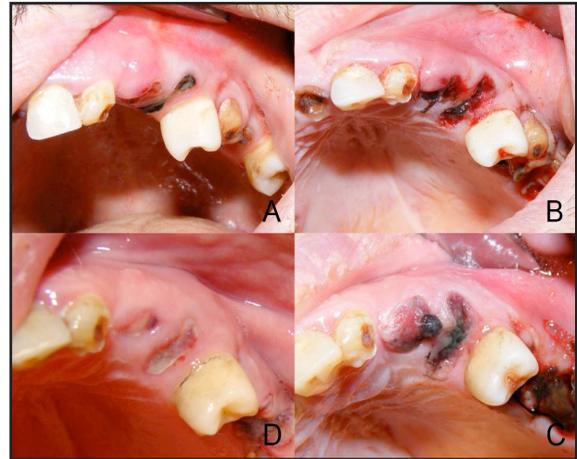


Figure 2. A: Tooth number 23 and 24 that going to be extracted
B: After seconds of immediately applied ABS
C: 24 hours later after the extraction
D: 4 days later after the extraction

between the pre- and post treatment values of the serum levels of blood urea nitrogen, creatinine, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, total and direct bilirubin, total protein, albumin, uric acid, creatinine kinase, cystatin C, sodium and potassium levels. Hemostatic efficiency without any toxicity of ABS in patients with hemorrhagic diathesis was also observed in this study.¹⁸ Hemostasis was successful and they healed uneventfully. In this study, postoperative evaluations regarding hematological, biochemical, hepatic and renal functions had not been performed.

Ak et al. reported teeth extraction of 5 hemophilic patients. They used ABS for the management of bleeding and reported that ABS reduced hemorrhage after treatment which is similar to our case series.¹⁰ Leblebisatan et al., used ABS for 12 pediatric patient with hemorrhagic diathesis and reported that ABS had stopped bleeding successfully except one patient. They concluded that, ABS was effective for clinical usage of such patients.⁸ Cakarar et al, evaluated bleeding time of 25 patients who were on anti-thrombotic therapy and needed simple extractions. Bleeding time for ABS group was statistically lower according to control group.⁹ Turgut et al., reported 8 cases which have haemorrhagic diathesis and had dental or external bleedings.¹¹ They achieved bleeding control of all cases and concluded that these results were promising for the usage of ABS in anti-coagulated patients and hereditary bleeding disorders such as clotting factor deficiencies.¹¹

These published reports which are listed over and this case series are important as exhibiting the effectiveness of ABS over external bleedings of dental patients who have hemorrhagic diathesis. Further investigations on the exciting features of ABS as a hemostatic, wound healing accelerator, and anti-infective agent are still in progress.

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