Ankaferd blood stopper in episiotomy repair

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Summary

Background and Objective: Ankaferd blood stopper (ABS) is a new hemostatic agent that is licensed for external hemorrhages. ABS comprises of a standard mixture of Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum, and Urtica dioica which has also been approved in Turkey for the management of bleeding. The authors, aim was to evaluate the efficacy of ABS spray in terms of blood loss during episiotomy repair. *Materials and Methods:* The authors included pregnant women with a term singleton fetus (37-40 wks) in a vertex position, who were at least 18-years-old, had delivered vaginally, and required a mediolateral episiotomy. The patients were randomly assigned to one of the two approaches: 20 (Group 1) to ABS and 20 (Group 2) to isotonic saline solution (0.9% NaCl). The authors applied 4 ml ABS spray solution (1 ml/puff X 4) or isotonic saline solution (0.9% NaCl) (4 ml) topically on a sponge applied on the episiotomy. The sponge was weighed before and after the episiotomy repair to determine the amount of bleeding. Hemoglobin values were also recorded on admission and 12 hours after delivery. *Results:* Both groups were similar in terms of maternal age, parity, body mass index and gestational age. The sponges weighed heavier in Group 2. Baseline hemoglobin values measured on admission showed no significant differences between the groups. Hemoglobin on the first postpartum day was significantly higher in the ABS group ($p < 0.05$). The operative time for episiotomy repair for the two groups was also statistically insignificant. No major immediate or delayed complications were observed in either group. *Conclusion:* In this study group, the application of 4 ml of ABS instead of isotonic saline solution lessened bleeding.

Key words: Ankaferd; Episiotomy.

Introduction

Ankaferd blood stopper (ABS) is a standardized herbal extract obtained from five different plants Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum, and Urtica dioica [1]. ABS has been approved in Turkey for the clinical management of external postsurgical and postdental surgical bleeding, but its mechanism of action remains unknown.

Numerous reports have been published regarding the application of ABS to control bleeding [2-7]. ABS represents a 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, while covering the classical cascade model of the clotting system without independently acting on coagulation factors and platelets [1]. Exposure to ABS seems to provide tissue oxygenation as well as physiological hemostatic process without affecting any individual clotting factor [2-7].

Although the use of episiotomy is often debated, it remains the most common surgical procedure experienced by women [8]. The authors' aim was to evaluate the efficacy of ABS spray in terms of blood loss during episiotomy repair.

Materials and Methods

This research was carried out in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Hospital and by the 7th Ethics Committee. Consent was obtained from all patients after full explanation of the procedure.

The authors included pregnant women with a term singleton fetus (37-40 wks) in a vertex position, who were at least 18-years-old, had delivered vaginally, and required a mediolateral episiotomy. The episiotomy was performed with scissors by the same obstetrician. It was defined as a six-cm incision at a 45-degree angle from the inferior portion of the hymeneal ring.

The authors excluded patients who were taking anticoagulation medications (warfarin, heparin, or enoxaparin), had systemic bleeding disorders (von Willebrand disease and hemophilia) or had systemic conditions that caused coagulopathies (liver disease), or had abnormal biochemical parameters. Patients were randomly assigned to one of the two approaches: 20 (Group 1) to ABS and 20 (Group 2) to isotonic saline solution (0.9% NaCl). A randomized number was assigned by using random allocation software.

ABS is available in spray form and is a registered product of a combination of plant extracts. ABS was obtained from Trend Teknoloji İlac AS, Istanbul (Turkey) as a solution for direct application in the pharmaceutical form of spray.

The authors applied 4 ml of ABS spray solution (1 ml/puff X 4) or isotonic saline solution (0.9% NaCl) (4 ml) topically on a sponge applied on the episiotomy. Based on the manufacturer's recommendation, the sponge was left in place for five min during episiotomy repair for ABS group of patients treated in this study, and another sponge was used to evaluate bleeding. The authors then weighed (scale SKS 4507 Sinbo, made in P.R.C, 2009) the sponge after the procedure to determine the amount of bleeding. Hemoglobin values were also recorded on admission and 12 hours after delivery. All patients' data including demographic parameters, intraoperative blood loss, hemoglobin levels, episiotomy repair time, and postopartum complications were recorded.

The SPSS (Version 11.5; SPSS Inc., Chicago, IL) statistical software was used for analyzing patient data. Normal distribu-

Revised manuscript accepted for publication April 30, 2012

Table 1. — *Demographic and clinical characteristics of the two groups.*

	Control group (n = 20)	Study group (n = 20)	*p*
Age (years)	23.7 ± 3.9	21.1 ± 3.1	0.153
Gravidity	1 (1-2)	1 (1-4)	0.463
Parity	0 (0-1)	0 (0-1)	0.300
Gestational age (days)	278 (261-285)	276 (260-287)	0.849
Baseline hemoglobin (g/dl)	12.3 ± 1.05	12.6 ± 1.2	0.528
Postpartum hemoglobin (g/dl)	10.7 ± 1.2	11.6 ± 1.4	0.04
Weight of sponge (g)	56.2 ± 39.0	31.1 ± 35.01	0.039

tion of the collected data was verified using the Kolmogorov-Smirnov test. When the Kolmogorov-Smirnov normality test revealed normal distribution, the independent sample t test for comparing the differences between two groups was used. When the test failed, the Mann-Whitney U test was used to compare the differences between the two groups. The level of significance was set at $p < 0.05$.

Results

In Table 1 the authors report demographic characteristics of the patients enrolled. Both groups were similar in terms of maternal age, parity, body mass index, and gestational age.

Baseline hemoglobin values measured on the admission showed no significant differences between the groups. The operative time for episiotomy repair for the two groups was also statistically insignificant. The weights of the sponges were heavier in the control group (56.2 ± 39.0 g vs 31.1 ± 35.01 g). Hemoglobin on the first postpartum day was significantly higher in the ABS group ($p < 0.05$). Hemoglobin on the first postpartum day was 11.6 ± 1.4 g/dl for the ABS group and 10.7 ± 1.2 g/dl for the control group (p = 0.04) (Figure 1). No major immediate or delayed complications were observed in either group.

Discussion

Hemostatic agents have become increasingly employed across all surgical fields. Topical hemostatics are recommended for the management of low-volume bleeding rather than major hemorrhage. A plant extract, Ankaferd, was registered in Turkey as a "hemostatic agent" in 2007. ABS is a topical hemostatic agent and can be an alternative to manage external bleeding.

Several studies have been carried on to investigate the hemostatic capacity of Ankaferd in experimental traumatic bleeding models. It ensures a statistically-significant reduction in hepatic parenchymal bleeding [9]. Cipil *et al*. [10] evaluated in vivo hemostatic effect of ABS in rats pretreated with warfarin and found that ABS was indeed beneficial as a topical hemostatic agent.

ABS was also found to be safe and efficient in decreasing intraoperative bleeding when compared to the traditional hemostatic methods after cold-knife dissection tonsillectomy [6]. The same group also showed the efficacy of ABS in adults who suffered from epistaxis [4].

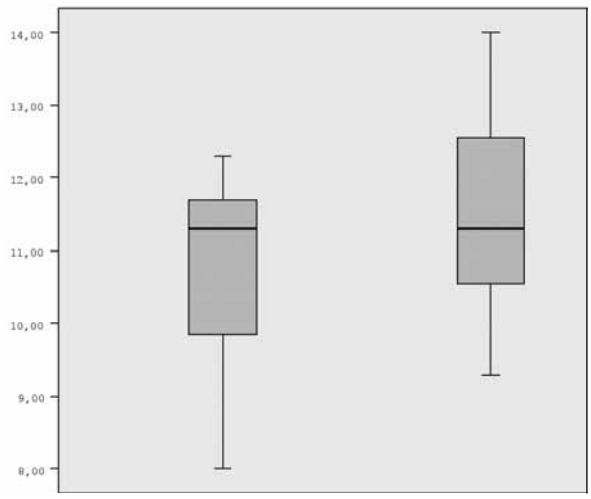

Figure 1. — Comparison of postpartum hemoglobin values in the two study groups.

In this study, the hemostatic efficacy of ABS was investigated during episiotomy repair. To the authors' knowledge, this is the first study evaluating the efficacy of ABS spray in terms of blood loss during episiotomy repair. In the study group, an application of 4 ml of ABS instead of isotonic saline solution lessened bleeding.

The present study revealed a positive effect of the topical application of ABS tested for bleeding reduction. The indications for topical ABS seem to increase in clinical settings. Nonetheless, like other hemostatic agents, ABS is expensive so that its use in episiotomy repair is controversial. Additional prospective studies with a larger number of patients are required to confirm these results.

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