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CASE STUDY

Haemostasis action of VELSEAL-T in a haemophilia A patient with external bleeding

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VELSEAL-T is an innovative haemostatic medical device for the control of bleeding. Incorporating a clotting agent (thrombin) and anti-fibrinolytic agent (tranexamic acid), it enables rapid coagulation when blood flows into the dressing, leading to sealing and stabilisation of wound surfaces. A 36-year-old known to have mild haemophilia A presented with profuse bleeding from the forehead after injury following a fall on concrete surface. He attended hospital after 18 hours of injury as bleeding continued as soon as pressure was released from the injury site. A VELSEAL-T patch was applied to the injury site with the patient's full consent. The bleeding stopped after 60 seconds, but the patient was instructed to hold the patch in place for a further 60 seconds. After two minutes of tight pressure application, there was no more oozing of blood from the injury site. This case shows that VELSEAL-T can be used as an aid in stopping external bleeding in haemophilia patients. Further trials should be undertaken to evaluate the safety and efficacy of this product.

Keywords: *VELSEAL-T, Haemophilia, External bleeding, Haemostatic patch*

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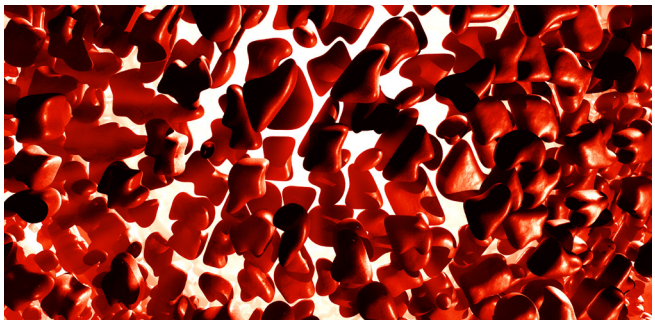

A haemostatic patch incorporating thrombin and tranexamic acid may provide a cost-effective way to manage external bleeding in haemophilia patients

Haemophilia is an X-linked congenital bleeding disorder caused by a deficiency of coagulation factor VIII (in haemophilia A) or factor IX (in haemophilia B) caused by mutations of the respective clotting factor genes. Haemophilia generally affects males on the maternal side, although as many as one third of all cases are the result of spontaneous mutation where there is no prior family history. In the Upper Assam region of North East India, the treatment modality has generally been on-demand, via the administration of an appropriate dose of factor concentrate as soon as possible in the event of bleeding. However, factor concentrates are costly and not easily affordable by all. Prophylactic treatment has been limited to very few selected patients, although there has been a recent drive towards prophylaxis for all people with haemophilia.

VELSEAL-T is an innovative haemostatic medical device for the control of bleeding. Comprising a

Figure 1: Haemophilia patient applying VELSEAL-T patch to the site of external injury.

Figure 2: Bleeding stopped after 60 seconds of application of the VELSEAL-T patch.

clotting agent (thrombin) and an anti-fibrinolytic agent (tranexamic acid), it enables rapid coagulation when blood flows into the dressing, leading to the sealing and stabilisation of wound surfaces. The VELSEAL-T patch can be used as an aid to prevent profuse bleeding in haemophilia patients with external injuries, and hence may be a cost-effective alternative to factor concentrates in the management of external bleeds.

Case Report

A 36-year-old shopkeeper known to have mild haemophilia A (serum factor VIII level 8%) presented with profuse bleeding from the forehead after injury following a fall on concrete surface. His factor IX was within normal limits. The patient was from a relatively poor socioeconomic background and was not on prophylactic treatment due to economic constraints; he visited the haemophilia centre every time he had a bleed for on-demand therapy. He had initially put pressure and ice on the area of injury, to the left temporal area of his forehead. However, the bleeding did not stop, and the injury continued to bleed the moment pressure was released. The patient also developed a periorbital haematoma (black eye) rapidly. He attended hospital 18 hours after injuring himself.

Desmopressin (DDAVP) was unavailable within the hospital at that time due to logistical issues; however, we had access to a novel product called VELSEAL-T in the Department of Medicine. Proper consent was obtained from the patient after explaining the product and its mechanism of action to him in his own language (Hindi). The VELSEAL-T patch was applied to the site of external injury, on the left temporal area of his forehead. The patient was told to hold the patch in place for two minutes; bleeding stopped after 60 seconds, but the patient was asked to hold the patch in place for another 60 seconds. After two minutes of applying pressure using the VELSEAL-T patch, there was no further oozing of blood from the injury site.

Proper consent was obtained from the patient to publish his case history and photograph the bleeding site, including his face. This was also recorded in his native language (Hindi).

Discussion

Bleeding disorders reportedly affect 1 in 1,000 men and women globally [1]. Haemophilia A and B, and von Willebrand disease, make up the most prevalent types of bleeding disorders [2-6], with haemophilia A affecting 1 in 5,000 men [7-9], and haemophilia B estimated to affect 1 in 30,000 male births [10]. As the second most populated country in the world, it can be expected that there are a large number of people with haemophilia in India. However, as a developing country with significant resource constraints, most of these patients do not have access to factor concentrate and hence bleed profusely even with minor trauma.

Figures for India were reported by the Hemophilia Federation (India) in a global survey of haemophilia and bleeding disorders conducted by the World Federation of Hemophilia (WFH) in 2011 [11-12]. In the global population,

Table 1: Five countries reporting the highest numbers of patients of bleeding disorders and haemophilia [11,12]

	DISTRIBUTION OF COUNTRIES WITH BLEEDING DISORDERS	REPORTED CASES OF BLEEDING DISORDERS	DISTRIBUTION OF COUNTRIES WITH HAEMOPHILIA A	REPORTED CASES OF HAEMOPHILIA A
1	United States of America	32,496	United States of America	13,276
2	United Kingdom	23,459	India	11,586
3	Brazil	17,350	China	8,921
4	India	14,618	Brazil	8,839
5	China	10,280	United Kingdom	5,420
	Global total	**268,030**	**Global total**	**167,110**

268,030 people were reported as having a bleeding disorder: 167,110 people with haemophilia were identified, 69,729 people with von Willebrand disease, and 31,191 people with other bleeding disorders. 134,354 had haemophilia A, and 26, 821 had haemophilia B. 3,387 people with haemophilia A and 183 people with haemophilia B had clinically identified inhibitors. The data showed that, in 2011, India reported 14,718 patients with bleeding disorders and 11,586 patients with haemophilia A.

A study at Assam Medical College and Hospital reported 45 haemophilia-related cases over a one-year period, from July 2014 to July 2015 [13]. 33 patients were known to be haemophilic and 9 cases were newly diagnosed during the study period. Most of the patients were below 20 years of age. Factor VIII deficiency was most common, accounting for 36 (81%) of the patients.

A second study at Assam Medical College and Hospital reported 79 haemophilia-related cases between 1 October 2015 and 31 March 2017 [14]. Again, haemophilia A was most common, accounting for 63 (79.7%) of the patients. Joint bleed was the most common clinical feature, present in 57 patients (72%) and intramuscular bleed was present in 19 patients (24%). Other clinical presentations included teeth and gum bleeds, epistaxis, trauma, burns, and superficial cuts and bruises.

In all patients, factor is given on an on-demand basis only, when they report to the hospital with bleeding. This is helpful in controlling acute bleeds; however, it does not prevent musculoskeletal damage, which can only be achieved through primary or secondary prophylactic treatment.

Although most of our haemophilia patients have musculoskeletal symptoms, in a setting where prophylaxis is far from reality and most patients are on on-demand therapy, we see a significant number of cases of bleeding following trauma and injury. Most patients with external bleeding bleed profusely if the bleeding is not controlled by pressure, and require treatment with factor concentrate or blood transfusion.

The VELSEAL-T device is manufactured in Haryana, India, and has been used in the control of bleeding in patients without bleeding disorders. However, even in patients with a low concentration of clotting factor, the haemostatic action of the VELSEAL-T device is evident, as the coagulation process of blood entering the matrix of the patch is enhanced by the presence of clotting factors. Its use in haemophilia patients may significantly reduce morbidity, and may provide a cost-effective treatment modality for minor trauma in a setting where factor concentrate is prohibitively costly and not widely available.

Conclusion

This case shows that VELSEAL-T can be used safely and is a cost-effective treatment in stopping external bleeding in haemophilia patients. It is a useful treatment modality for all patients with external bleeding, but in the treatment of haemophilia patients may significantly reduce the requirement for costly factor concentrates. Further large trials should be undertaken to evaluate the safety and efficacy of this product.

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VELSEAL™-T is manufactured by Datt Mediproducts Pvt. Ltd., New Delhi, India: https://dattmedi.com.

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Informed consent has been obtained from the individual reported in this case study.

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