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Prehospital use of hemostatic dressings in emergency medical services in the Netherlands: A prospective study of 66 cases

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ABSTRACT

Background: Uncontrolled haemorrhage is the leading cause of potentially preventable death in both civilian and military trauma patients. Animal studies and several case series have shown that hemostatic dressings reduce haemorrhage and might improve survival. One of these products is HemCon ChitoGauze®. The objective of this study was to determine the effectiveness and safety of ChitoGauze in achieving hemostasis in massive traumatic bleeding in civilian emergency medical services.

Methods: From June 2012 to December 2014, all ambulances of two emergency medical services in the Netherlands were equipped with ChitoGauze. The dressing was used according to protocol; if conventional treatment (gauze dressing with manual pressure) failed to control external traumatic bleeding or if conventional treatment was unlikely to achieve hemostasis. The ambulance personnel filled in an evaluation form after each use.

Results: A total of 66 patients were treated with ChitoGauze during the study period. Twenty-one patients were taking anticoagulants or suffered from a clotting disorder. The injuries were located in the extremities ($n = 29$), the head and face ($n = 29$), or the neck, thorax and groin ($n = 8$). In 46/66 patients, the use of ChitoGauze resulted in cessation of haemorrhage. In 13/66 patients, Chitogauze application reduced haemorrhage. ChitoGauze failed to control haemorrhage in 7/66 patients, whereby user error was a contributing factor in 3 of these failures. No side effects have been observed during treatment or transport of the patients and no adverse effects have been reported in discharge letters.

Conclusion: This is the largest prospective study in civilian healthcare and the second largest case series with prehospital use of hemostatic dressings. It demonstrated that ChitoGauze is an effective and safe adjunct in the prehospital treatment of massive external traumatic haemorrhage.

Introduction

Trauma accounts for a significant proportion of annual mortality world-wide. The World Health Organization estimated that 5.1 million people died of injuries in the year 2012, accounting for 9.2% of global annual mortality [1].

Uncontrolled haemorrhage is the second leading cause of death in civilian trauma [2] and the most important cause of death in military setting [3,4]. Recent analysis suggests that 15% of deaths on today's battlefields are preventable, with 82% of these deaths resulting from uncontrolled haemorrhage [3]. It is imperative to stop bleeding, because severe blood loss can quickly lead to the lethal triad of death (hypothermia, acidosis and coagulopathy) and hypovolemia which eventually leads to multiple organ failure and mortality [5].

Due to the global war on terror and recent conflicts in Afghanistan and Iraq, several new products have been developed to achieve a quicker hemostasis in patients with severe external haemorrhage. This includes hemostatic devices like the Combat Ready Clamp and the Abdominal Aortic Tourniquet, but especially hemostatic dressings, which are widely used in the military setting. These dressings have variable mechanisms of actions: products that concentrate the patient's own clotting factors by an exothermic reaction or a rapid fluid absorption, products that contain materials that adhere to erythrocytes in order to create a firm clot and products containing clotting factors to promote clot formation [6]. The National Association of Emergency Medical

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Fig. 1. HemCon ChitoGauze®.

Technicians advises that each soldier should carry a hemostatic agent in his personal medical equipment for use in first aid [7].

Hemostatic dressings have also been introduced in the civilian prehospital healthcare. A large systematic review concluded that hemostatic dressings would be useful for civilian prehospital care [6] and recently the American College of Surgeons published a guideline for prehospital treatment of external haemorrhage in which they advise using a hemostatic dressing when standard gauze and direct pressure are insufficient to control haemorrhage [8].

One of the hemostatic dressings is HemCon ChitoGauze® (Fig. 1), a 10 cm × 375 cm Z-folded gauze produced by HemCon Medical Technologies, Inc. (Portland, Oregon, USA). The gauze is based on the biological polysaccharide chitosan, derived from exoskeletons of crustaceans. The positively charged chitosan forms a strong clot with the negatively charged erythrocytes that covers the damaged surface. This reduces bleeding time and in theory forms a barrier to bacteria. Chitosan also leads to local vasoconstriction and platelet activation, enhancing further wound closure [9].

Numerous animal studies [10–17] and some clinical case series [18–20] have demonstrated the effectiveness of HemCon products in controlling haemorrhage from both arterial and venous sources as well as in coagulopathic or hypothermic patients. No adverse effects have been reported with the use of chitosan-based dressings [9,21].

The objective of this study is to analyse the effectiveness, usability and safety of ChitoGauze in the treatment of traumatic external haemorrhage in civilian emergency medical services in the Netherlands.

Patients and methods

Study location

This study was conducted in Gelderland-South and Gelderland-Middle, a region in the Netherlands that encompasses an area of 2200 square kilometers (≈850 square miles) with a population of 1.2 million people. The region is served by two emergency medical service (EMS) providers, which respond to over 42,000 medical emergency calls annually.

Study protocol

All ambulance personnel of both EMS regions were trained, using a multimedia presentation and a hands-on training in the use of ChitoGauze. All patients with massive traumatic haemorrhage who fulfilled the inclusion criteria (Table 1) between June 2012 and December 2014 were included and treated with ChitoGauzed.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Massive traumatic haemorrhage with one of the following: -Failure of conventional treatment to control haemorrhage within 5 min -Haemorrhage unlikely to be controlled with standard treatment (penetrating injury, difficult to reach with dressing, large laceration or amputation) -Life-threatening haemorrhage	Non-traumatic haemorrhage

The conventional treatment of external haemorrhage consisted of application of a gauze dressing, manual pressure and elevation of the bleeding area. For this study we modified the standard ambulance protocol and developed a protocol with clear indications when to use ChitoGauze (Supplemental digital content 1). This protocol is based on the Battlefield Advanced Trauma Life Support UK (BATLS protocol, JSP 570), which has been implemented in the Royal Netherlands Army since 2006. All receiving hospitals were notified of the use of this product and had received written information about the removal process (irrigating the dressing with a saline solution). A discharge letter was requested. The medical ethical committee of the Radboud University Medical Center at Nijmegen approved the study and indicated that written informed consent was not needed.

Data collection

After each use, the ambulance personnel filled in a digital evaluation form (Supplemental digital content 2). These data included the location and type of the injury, the effect of ChitoGauze application and the evaluation of the use of ChitoGauze. Patient demographics were collected retrospectively from the EMS records.

Outcome measures

The primary outcome measure was the effect of ChitoGauze on the bleeding (cessation, reduction, recurrence or persistent). Secondary outcome measures were time to cessation of haemorrhage, ambulance personnel satisfaction with the result and user friendliness. Persistent or recurrence of haemorrhage was considered to represent failure of the dressing.

Statistical analysis

Patient characteristics were reported and descriptive statistics were calculated for all variables of interest. Categorical variables were expressed as numbers with percentages. Continuous variables were analysed for Gaussian distribution and expressed as mean ± standard deviation or medians (interquartile ranges). The effect of ChitoGauze application was calculated. Subgroup analysis was performed to determine if the effect of ChitoGauze is influenced by coagulopathy, failure of conventional treatment, the location of injury or the type of haemorrhage. All statistical analyses were performed using IBM SPSS Statistics software version 20 (IBM Corp., Armonk, NY, USA). A p-value of ≤ 0.05 was considered statistically significant.

Results

Study population

ChitoGauze was used a total of 66 times in the 2.5-year study period. Complete data from all cases on the primary outcome were