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Hemostatic sprays to control active nonvariceal upper gastrointestinal bleeding

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ABSTRACT

As nonvariceal upper gastrointestinal bleeding remains a critical health concern, there is a need for ongoing optimization of endoscopic hemostasis modalities. Current methods for endoscopic hemostasis include epinephrine injection, thermal coagulation, and mechanical clips. Although these modalities have proven efficacy, there are limitations to their use, including significant learning curves and the requirement of expert assistants. Moreover, there still remains an ongoing risk of rebleeding after therapy. Therefore, a need exists for a safe and easy-to-use method for endoscopic hemostasis, specifically in the setting where current methods for hemostasis are limited or in the setting when hemostasis has not been achieved despite their application. Hemostatic sprays have emerged as novel methods for achieving hemostasis. Therefore, we sought to appraise the evidence concerning the use of hemostatic sprays. Our review highlights that hemostatic spray is a safe and effective method for endoscopic hemostasis, specifically, when current methods are infeasible, unsuccessful, and in malignant nonvariceal upper gastrointestinal bleeding.

1. Introduction

Nonvariceal upper gastrointestinal bleeding (NVUGIB) remains a critical health concern given its associated morbidity and mortality [1-3]. Moreover, it represents a significant economic burden, secondary to transfusion requirements and hospitalization-related costs [4,5]. This highlights the need for simple and effective methods for achieving endoscopic hemostasis. Currently, there are a number of commonly used options, including (1) injection usually with epinephrine (typically used in combination with another modality), (2) thermal coagulation, and (3) mechanical clips. Although these methods are effective [6,7], it is estimated that rebleeding occurs, despite endoscopic intervention, in approximately 5%-10% of cases [8]. Current methods for endoscopic hemostasis are also hindered in certain difficult-to-reach areas of the upper gastrointestinal tract, by the risk of perforation, as well as the potential to worsen bleeding in the setting of friable bleeding surfaces and coagulopathy. Therefore, a need exists for an easy-to-use, safe, and effective method for endoscopic hemostasis.

In an attempt to address these limitations, hemostatic spray has emerged as a novel endoscopic hemostasis modality, given its ease of use due to its noncontact application, its ability to cover large areas of gastrointestinal mucosa, and its adverse events' profile. There are currently 3 available hemostatic sprays. They are (1) Hemospray (Cook Medical, Winston-Salem, NC), (2) EndoClot (EndoClot Plus Inc, Santa Clara, CA) and (3) Ankaferd Blood Stopper (Ankaferd Health Products Ltd, Istanbul, Turkey). Given this exciting evolution in the management of NVUGIB as well as questions regarding the position of hemostatic sprays within current treatment algorithms, we sought to review the evidence for their use in NVUGIB. For the purpose of this review, as Hemospray is the only hemostatic spray available for purchase in Canada and none of the above sprays are available for purchase within the United States, we have focused our review on the use of Hemospray and refer to it as “hemostatic spray” in our review.

2. Hemostatic spray

Hemostatic spray, also known as Hemospray or TC-325, is currently approved for use in Canada as well as several countries in South America, Europe, and Asia [9]. It is currently not approved for use within the United States.

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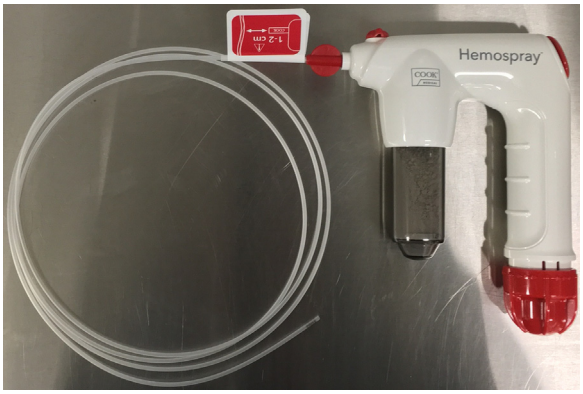

Fig. 1. Hemostatic spray delivery system.

2.1. Mechanism of action

Hemostatic spray is an inert, mineral-blend powder that appears to not be absorbed or metabolized by the gastrointestinal mucosa. Upon exposure to moisture, hemostatic spray coalesces and adheres to the bleeding site, thus forming a mechanical barrier. This mechanism was recently proven, through the use of scanning electron microscopy [10], with hemostatic spray showcasing the potential to deform and pack erythrocytes in vivo. Moreover, hemostatic spray significantly reduced the median clotting time and the median plasma prothrombin time, highlighting that hemostatic spray appears to also affect coagulation. Interestingly, hemostatic spray has also been shown to promote re-epithelialization and reduces scar tissue formation [11]. Once hemostasis has been achieved, hemostatic spray sloughs off the gastrointestinal mucosa, commonly within 24 hours [9].

2.2. Method of application

Hemostatic spray (Figures 1-4) is delivered via a preassembled delivery device and catheter (either 7 or 10 Fr), which is introduced through the working channel of an appropriate endoscope. A “built-in” carbon dioxide canister is used to force hemostatic spray out of the catheter onto the targeted area. From our experience, congruent with those noted in the literature [9,12], we recommend positioning the catheter tip approximately 1-2 cm from the target with subsequent delivery of hemostatic spray in short bursts of 1-2 seconds in duration. Longer bursts will tend to obscure the visual field; therefore, to maintain ideal visibility and to ensure appropriate application, short application periods are recommended. Once hemostasis appears to have been achieved, endoscopic visualization is recommended for approximately 5 additional minutes. If further bleeding is seen during the observation period, reapply hemostatic spray until hemostasis is achieved.

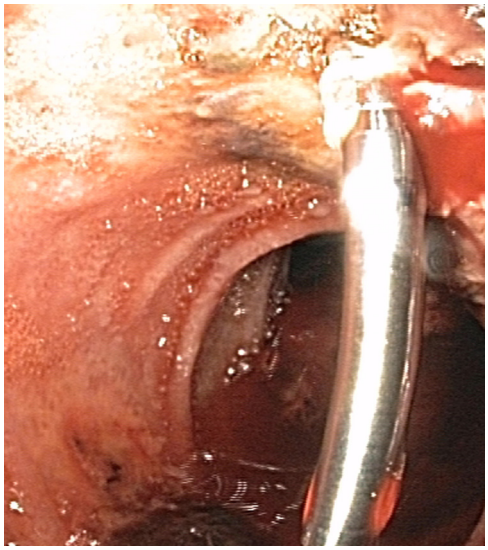

Fig. 3. Persistently bleeding peptic ulcer status after endoscopic clip application.

2.3. Animal studies

In 2011, Giday et al [13] were the first to randomize 10 pigs, after freely exposing the gastroepiploic vessels through a gastrostomy alongside heparinization, to either hemostatic spray or no intervention. In all 10 pigs, spurting arterial bleeding (Forrest IA) was induced. All 5 pigs randomized to hemostatic spray achieved initial hemostasis vs none of the control pigs. Durable hemostasis (after 1 and 24 hours) was achieved in 4 of 5 pigs that received hemostatic spray. In a follow-up study in 2013, Giday et al [14]

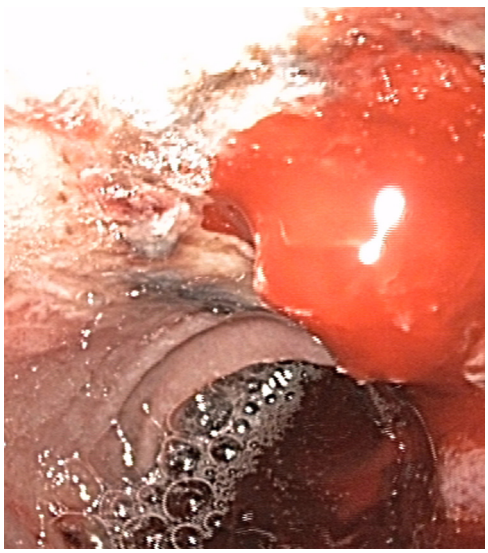

Fig. 2. Posterior duodenal wall actively bleeding peptic ulcer.

Fig. 4. Actively bleeding peptic ulcer status after endoscopic clip application and hemostatic spray application.