An innovative technique to control bleeding with vacuum device

Karen Guerrero, Alexandre Moreau-Gaudry, Paolo Porcu, Dominique Blin

Abstract

Bleeding is one of the major problems during surgery as well as in cases of accidental vascular injury. Control of bleeding can be life threatening in two surgical circumstances: when the wound is difficult to expose, and when the tissue is too fragile to suture. Following more than 100 animal tests, we developed an innovative vacuum-based suction device, which enables us to address this challenge. We set up a proof-of-concept protocol in humans and report here our first clinical experience.

Keywords: Bleeding; Haemostasis; Medical device; Vacuum; Suction cup

1. Introduction

During elective surgery or during emergency surgery in both civilian or war circumstances, surgeons can face major bleeding, life threatening by either its extent or its persistence. The control of bleeding can be particularly difficult in two surgical circumstances: the wound is difficult to expose because of its anatomical location, for example, it is deep (thorax, pelvis, abdomen, or video surgery), difficult to visualize (on the posterior side of an organ) or close to vital structures (nerves, and coronary arteries). The wound can also affect tissue that is difficult to suture because of its fragility, such as liver or spleen. Furthermore, the skills or resources necessary to treat the wound are not always available within the medical team in charge of the patient. In such circumstances, conventional surgical techniques (compression, electro-coagulation, ligature, suture, pro-coagulating materials and glue) [1,2], can fail to achieve haemostasis leading to morbidity or mortality.

2. Concept

Application of vacuums to tissue is increasingly frequent in clinical practice (foetal extractions [3], and wound treatment [4]). For example, in off-pump coronary surgery [5], we commonly apply a vacuum of –700 mmHg to the epicardium without significant deleterious effects. Our approach relies on an innovative medical device (IMD) consisting of a pillar pressed on the source of bleeding by a vacuum chamber, mimicking the surgeon’s finger (Fig. 1(A)).

3. Materials and methods

3.1. Innovative medical device (IMD)

This is composed of two chambers: a peripheral vacuum chamber, connected to an external aspirating device, supports a central chamber. When the vacuum is created (–600 to –700 mmHg), the central chamber gets pulled onto the wound and stems the bleeding (Fig. 1(B)).

3.2. Animal experiments

In previous animal experiments, 150 wounds were treated in 60 sheep. Final haemostasis was obtained after three steps. First, the bleeding was immediately stopped in all (100%) cases (heart, lung, liver, spleen, muscle, and major vessels). Second, on removal of the IMD, the bleeding had completely stopped in 80% cases. Third, seven sheep were followed-up at 3 months after wounds had been consolidated by an additional lattice of glue. The histological control showed perfect healing (Fig. 2) for all wounds.

3.3. Clinical setting

To demonstrate the efficiency of this IMD in humans, we designed a prospective, open, non-randomised clinical study.

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* Corresponding author. Address: Cardiac Surgery Department, CHU A. Michallon BP 217, 38043 Grenoble Cedex 09, France. Tel.: +33 4 76 76 55 75; fax: +33 4 76 76 52 81. E-mail address: DBlin@chu-grenoble.fr (D. Blin).
testing the haemostasis of wounds caused by cannulation at ascending aorta and right atrium sites during conventional cardiac bypass surgery.

The protocol is schematically divided in six steps:

1. At the end of bypass surgery, the aortic cannula and then the right atrium cannula are removed without securing the purse-string sutures; the device is immediately placed on each wound and vacuum is applied.

2. The control of the bleeding is checked at two levels: first, external bleeding, that is, blood escaping from the device is evaluated (main goal); second, the amount of blood aspirated into the vacuum line is measured (secondary goal).

3. The device is removed while the patient is still fully heparinised.

4. In case of persistent bleeding (common in uncoagulable patients), the device is immediately reapplied for a short time in the same position and for the same time, the usual dose of protamine is given to the patient.

5. The device is again removed and bleeding re-evaluated (secondary goal).

6. At the end of the protocol, the purse-string sutures were secured according to conventional techniques.

4. Results

Two patients out of 30 are enrolled in the protocol to date. The online video confirms that the device immediately controls bleeding at the aortic site. The main objective was reached for both patients: for both aortic and atrial wounds, no visible bleeding occurred either outside the outer chamber or outside the inner chamber once the suction cup had been correctly applied to the target. Besides, the device left a minimal footprint (see online Video 1). Both patients had simple operating outcomes.

5. Discussion

The medical use of vacuums is not a new concept. A similar approach has already been described by Vander Salm [6] for stopping bleeding in a transversal sinus using a single aspirative drain. By contrast, the approach proposed in the present work addresses haemorrhaging wounds by applying a haemostatic pillar maintained in place by a vacuum chamber around the wound.

To develop techniques adapted to most situations encountered, we continue to test new devices in vitro and on animals before human use. The present device achieves rapid, easy and safe control of most bleedings. It can also prevent some complications of the conventional techniques. After this immediate control of bleeding, the definitive and permanent treatment of the initial wound has naturally to be discussed.

6. Conclusion

The first experimental and clinical results obtained with this new vacuum device look extremely promising. This
innovative concept proposes a simple and convenient solution for surgeons facing bleeding for which they can sometimes lack resources. Nevertheless, it will be necessary to confirm these preliminary results by completing this first study and by performing a prospective multicentre study [7].

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References


Appendix A. Supplementary data

Supplementary data associated with this article (Video 1) can be found, in the online version, at doi:10.1016/j.ejcts.2010.09.047.