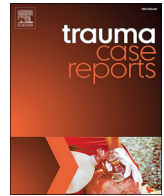


Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Trauma Case Reports

journal homepage: www.elsevier.com/locate/tcr

Case Report

Use of the EVARREST patch for penetrating cardiac injury[☆]

Gustavo Romero-Velez^a, Jody M. Kaban^b, Edward Chao^c, Erin R. Lewis^d,
Melvin E. Stone Jr^c, Sheldon Teperman^e, Srinivas H. Reddy^{c,*}

^a Montefiore Medical Center, Bronx, NY, United States of America

^b Albert Einstein College of Medicine, Division of Thoracic Surgery, Jacobi Medical Center, Bronx, NY, United States of America

^c Albert Einstein College of Medicine, Division of Trauma & Critical Care Services, Jacobi Medical Center, Bronx, NY, United States of America

^d Department of Surgery, Jacobi Medical Center, Bronx, NY, United States of America

^e Albert Einstein College of Medicine, Trauma & Critical Care Services, Jacobi Medical Center, Bronx, NY, United States of America

ARTICLE INFO

Keywords:

Trauma
Cardiac injury
Fibrin patch
EVARREST

ABSTRACT

Penetrating cardiac injuries have a pre-hospital mortality of 94% with a subsequent in-hospital mortality of 50% among initial survivors (Leite et al., 2017 [1]). The Western Trauma Association (WTA) guidelines recommend resuscitative thoracotomy (RT) for patients with penetrating torso trauma and less than 15 min of cardiopulmonary resuscitation (CPR) (Burlew et al. (2012) [2]). Penetrating cardiac injuries are classically repaired using skin-stapling devices and/or suture repair with or without pledgets (Wall et al., 1997 [3]). In this study, we present a case of penetrating cardiac injury where all the aforementioned techniques failed, and a new approach was explored. A fibrinogen/thrombin patch was used in this clinical setting, which is an off-label use of the product, we here present our encouraging outcome.

Case presentation

A 30-year-old male presented as a level 1 trauma activation after sustaining multiple gunshot wounds. En route to the hospital, vital signs were lost, and high-quality CPR was initiated in the ambulance. Upon arrival to the emergency department (ED), the patient remained pulseless. Advanced Trauma Life Support (ATLS) principles were followed; the airway was secured, large-bore venous access obtained, and the massive transfusion protocol initiated. During the resuscitation, a RT was performed and upon opening the left thoracic cavity a large amount of blood was encountered and subsequently - upon opening the pericardium - more blood was found, presumably causing cardiac tamponade. Following these interventions, there was return of spontaneous circulation. Two large injuries to the left ventricle (LV) were identified which were manually compressed to slow the brisk, pulsatile bleeding. Upon careful inspection, there were two holes in the LV which looked to be a through-and-through injury near the apex of the heart ([Image 1](#)). The bullet appeared to have entered the LV posteriorly and exited anteriorly. The anterior wound was larger, cavitary with greater myocardial destruction approximately 1.5 cm in size and could not be controlled with the skin-stapler in the ED. Direct pressure was maintained as the patient was emergently brought to the operating room (OR). In the OR, cardiorrhaphy was again attempted with skin-staples and pledgeted suture repair [3]. Given the extensive myocardial damage to the LV caused by the bullet,

[☆] We confirm this work has not been presented or will be presented in any conference and has not been published before.

* Corresponding author at: Albert Einstein College of Medicine, Division of Trauma & Critical Care Services, Jacobi Medical Center, 1400 Pelham Parkway South, Bronx, NY 10461, United States of America.

E-mail addresses: gromero@montefiore.org (G. Romero-Velez), jody.kaban@nychhc.org (J.M. Kaban), edward.chao@nychhc.org (E. Chao), lewise8@nychhc.org (E.R. Lewis), melvin.stone@nychhc.org (M.E. Stone), sheldon.teperman@nychhc.org (S. Teperman), srinivas.h.reddy@nychhc.org (S.H. Reddy).

<https://doi.org/10.1016/j.tcr.2020.100324>

Accepted 26 June 2020

Available online 27 June 2020

2352-6440/© 2020 Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license

(<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

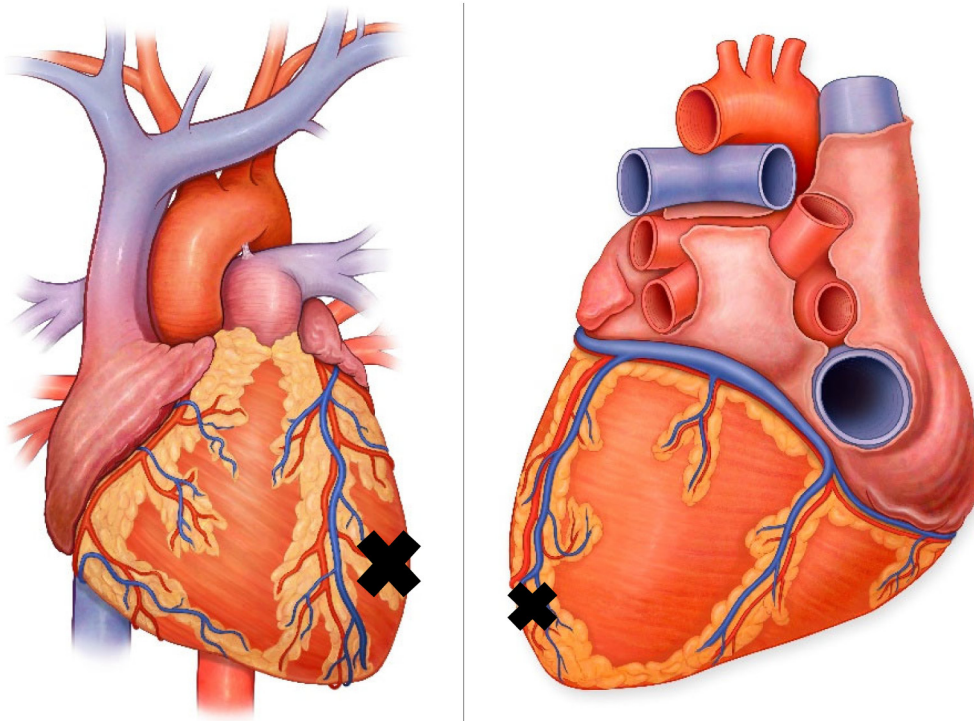


Image 1. Illustration depicting location of cardiac injuries.

both techniques were unsuccessful. Without the possibility of cardiac bypass at our institution, remaining options for controlling the hemorrhage were limited. At that point, as a temporizing measure, an EVARREST (Ethicon, Inc. Somerville, NJ) patch was placed directly over both cardiomyotomies and direct pressure held for 10 min. With this maneuver, complete hemostasis was successfully achieved. The patch remained firmly adherent to the myocardial defect, hemostatic, and was observed for over 30 min. We then proceeded to loosely close the pericardium with the patch in place. During the time of observation of the cardiac repair, the other thoracic injuries - which included a diaphragmatic injury and left upper and lower lobe lung injuries - were all performed. An exploratory laparotomy was also performed and injuries to the rectum, bladder, small bowel, transverse colon, stomach and liver were addressed. After careful trajectory analysis, it appeared that the bullet penetrated from the right gluteal fold and traversed the entire torso ending up lodged in the left scapula.

The patient experienced a prolonged hospital recovery given the extensive nature of his injuries. However, from a cardiac perspective, he remained stable without any obvious sequelae. He has undergone several transesophageal echocardiograms, - the latest 8-weeks postoperatively - demonstrating normal cardiac function and anatomic structure. The patch was no longer visible, and no pericardial effusion or ventricular aneurysm was identified. As part of his follow up, a cardiac CT angiogram was also obtained; the patch was not appreciated in this study either, but some of the original staples placed were visualized ([Image 2](#)). The patient has otherwise recovered well - with intact neurologic function, off mechanical ventilation, nutritional support and independent ambulation - and was discharged to home.

Since intraoperative images were unable to be obtained given the acuity and severity of the initial presentation, an analogous porcine model of the cardiac trauma was created to demonstrate the effectiveness of the EVARREST in an experimental setting. After protocol approval, a single livestock pig (*Sus scrofa*, 50 kg), receiving humane care in compliance with the guidelines outlines in the Guide for the Care and Use of Laboratory Animals and local Institutional Animal Care and Use Committee, was selected. A median sternotomy was performed, and a stab wound to the right ventricle was created ([Image 3-A](#)). A piece of EVARREST was then placed over the injury and direct pressure held per manufacturer recommendations ([Image 3-B/C](#)). After 10 min, the patch had firmly adhered to the heart and successful hemostasis was achieved; these outcomes were similar to those experienced during the case presented in this report ([Image 3-D](#)).

Discussion

Penetrating cardiac injury is one of the most lethal insults to the body with an estimated incidence of 0.16% [1,4]. Clinically, patients may present with hemorrhagic shock, cardiac tamponade and/or cardiac arrest. As with any trauma, initial management is based on ATLS principles and practices. The indication for RT should be tailored based on current guidelines [2].

Once the injury is recognized, there are different techniques for repair. Skin staples are easy to use and can rapidly stem the bleeding. In our experience, this approach is better suited for straight linear lacerations in the thicker ventricular walls. The other

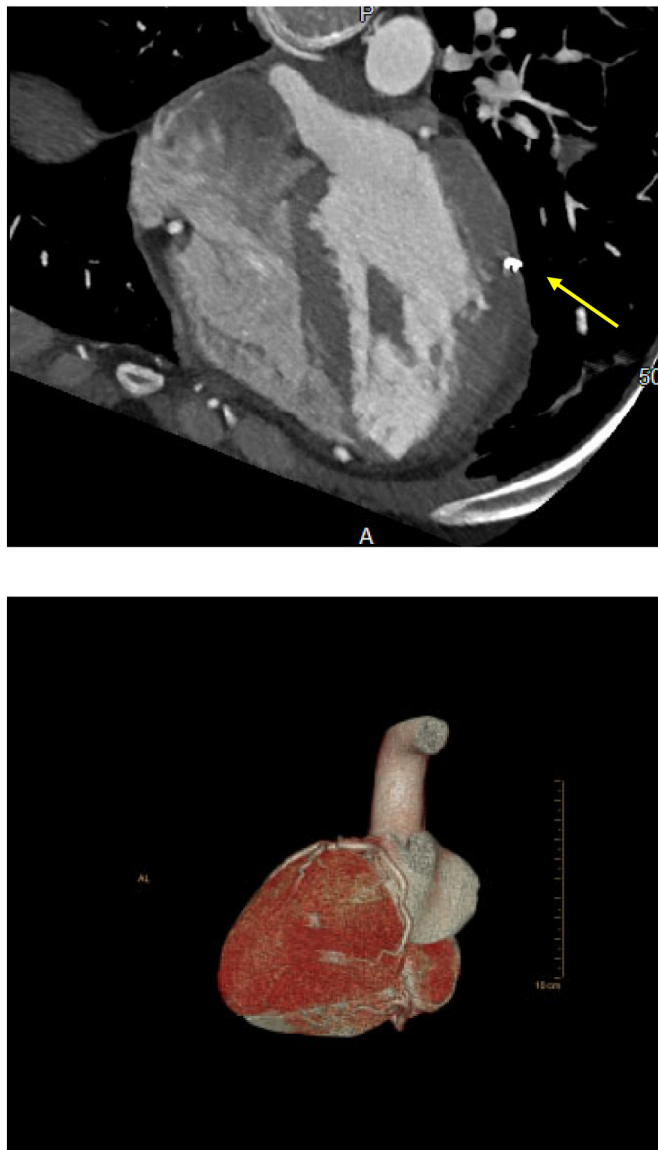


Image 2. CT angio showing staples (arrow), no effusion, no aneurysm, and no mass effect from EVARREST patch.

common modality used is suture repair with or without pledgets, which can be challenging in a beating and exsanguinating heart. In our case - without the benefits of cardiac bypass - we were out of options and, as a last resort, opted to try EVARREST as a hemostatic patch over the cardiac injuries.

EVARREST is a fibrin sealant patch made from human fibrinogen and human thrombin embedded in a cellulose matrix which is degraded after 8 weeks. It achieves hemostasis by creating a fibrin-based clot once its components are activated by hydration. It was approved by the Food and Drug Administration in 2012 as a hemostatic adjunct. In a porcine model, Baker et al. showed equivalent hemostasis with EVARREST compared to Combat Gauze (Z-Medica, LLC, Wallingford, CT) with the advantage of being able to leave the fibrin patch at the surgical site avoiding a second operation [5].

Clinical studies proved EVARREST to have superior hemostasis compared to the standard of care in hepatobiliary surgery with the advantage of having less postoperative collections [6]. Fischer et al. compared EVARREST against Surgicel (Ethicon, Inc. Somerville, NJ) for soft tissue hemostasis in elective abdominal, pelvic, retroperitoneal and non-cardiac thoracic surgery, proving its superiority in mild to moderate bleeding [7]. Even though the fibrin patch is not currently indicated for major arterial or venous bleeding, there are three other case reports where a fibrin patch has been successfully used to control cardiac bleeding otherwise not amenable to suture repair [8–10].

In 2014, Fiore et al. reported a case with RV rupture following catheter ablation where a fibrin/thrombin patch [TACHOSIL (Baxter, Health Care Corporation, Westlake Village, CA)] was used to achieve hemostasis [8]. Feng et al. reported in 2016 the use of

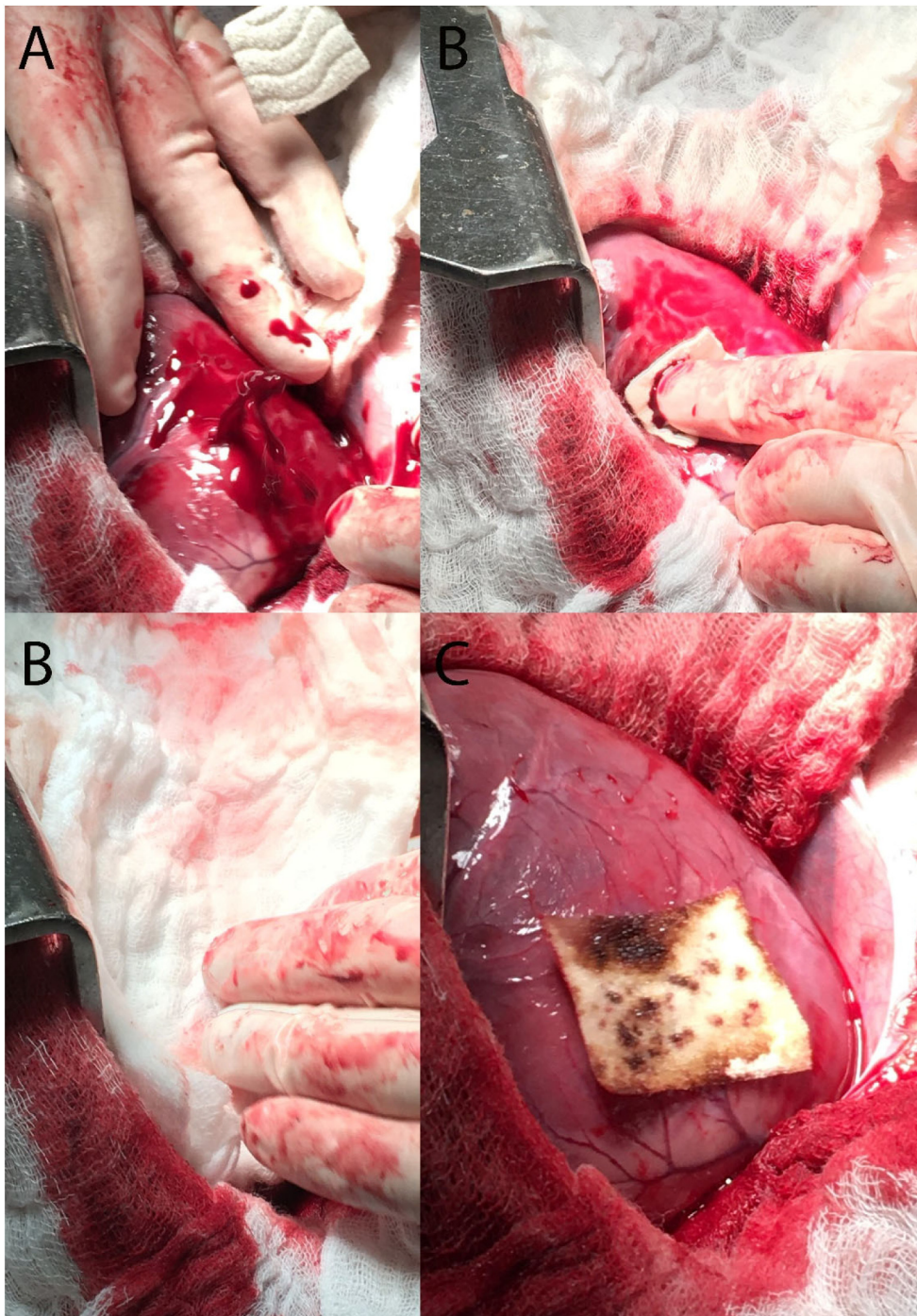


Image 3. A) Stab wound to porcine heart B) Direct pressure held per manufacturer recommendations C) Hemostasis achieved with EVARREST after holding pressure for 10 min.

the same fibrin patch in a LV rupture following a mitral valve replacement, however in their case a bovine pericardium patch was used on top of the fibrin patch [9]. Butts et al. recently reported the use of EVARREST in a stab wound to the RV close to the right coronary artery [10].

We report here the successful usage of EVARREST in a near fatal clinical scenario of exsanguinating hemorrhage from gunshot wounds to the heart where the standard repair techniques had failed. The patient is now more than 4 months post-op without any obvious complications encountered with the use of the hemostatic patch. Even though a novel application, this technique proved its efficacy in both animal and clinical studies with outcomes consistent with the published literature [6–10]. These findings support the

need for further studies to identify the optimal circumstances where EVARREST can be safely used.

Author contribution

GRV: Writing-Original draft and visualization. JK: Investigation, methodology and conceptualization. EC: Writing- Review & Editing. ST: Resources. MS: Resources. EL: Writing- Review & Editing and validation. SR: Visualization and supervision.

Funding

There was no funding for the creation of this paper.

Declaration of competing interest

The authors declare no conflict of interest.

Acknowledgement

The authors thank all our trauma staff as the survival of this patient and all of our patients would not be possible without their unwavering support.

References

- [1] L. Leite, L. Gonçalves, D. Nuno Vieira, Cardiac injuries caused by trauma: review and case reports, *J. Forensic Legal Med.* 52 (2017) 30–34, <https://doi.org/10.1016/j.jflm.2017.08.013>.
- [2] C.C. Burlew, E.E. Moore, F.A. Moore, et al., Western trauma association critical decisions in trauma: resuscitative thoracotomy, *J. Trauma Acute Care Surg.* 73 (6) (2012) 1359–1363, <https://doi.org/10.1097/TA.0b013e318270d2df>.
- [3] M.J. Wall, K.L. Mattox, C.-D. Chen, J.C. Baldwin, Acute management of complex cardiac injuries, *J. Trauma Inj. Infect. Crit. Care* 42 (5) (1997) 905–912, <https://doi.org/10.1097/00005373-199705000-00022>.
- [4] D.A. Raptis, S. Bhalla, C.A. Raptis, Computed tomographic imaging of cardiac trauma, *Radiol. Clin. N. Am.* 57 (1) (2019) 201–212, <https://doi.org/10.1016/j.rcl.2018.08.009>.
- [5] J.E. Baker, M.D. Goodman, A.T. Makley, et al., Evaluation of a novel fibrin sealant patch in hemorrhage control after vascular or hepatic injury, *Mil. Med.* 184 (3–4) (2019) e290–e296, <https://doi.org/10.1093/milmed/usy168>.
- [6] J.B. Koea, J. Batiller, B. Patel, et al., A phase III, randomized, controlled, superiority trial evaluating the fibrin pad versus standard of care in controlling parenchymal bleeding during elective hepatic surgery, *HPB* 15 (1) (2013) 61–70, <https://doi.org/10.1111/j.1477-2574.2012.00583.x>.
- [7] C.P. Fischer, G. Bochicchio, J. Shen, B. Patel, J. Batiller, J.C. Hart, A prospective, randomized, controlled trial of the efficacy and safety of fibrin pad as an adjunct to control soft tissue bleeding during abdominal, retroperitoneal, pelvic, and thoracic surgery, *J. Am. Coll. Surg.* 217 (3) (2013) 385–393, <https://doi.org/10.1016/j.jamcollsurg.2013.02.036>.
- [8] A. Fiore, D. Grandmougin, N. Laurent, M. Andronache, T. Folliguet, Efficacy of TachoSil® as a sutureless hemostatic patch to repair a perforation of the interventricular groove during endocardial radiofrequency ablation, *J. Cardiovasc. Surg.* 55 (5) (2014) 4.
- [9] W. Feng, M. Coady, Epicardial tachosil patch repair of ventricular rupture in a 90-year-old after mitral valve replacement, *Ann. Thorac. Surg.* 101 (6) (2016) 2361–2363, <https://doi.org/10.1016/j.athoracsur.2015.07.066>.
- [10] C.A. Butts, A. Hagaman, J. Porter, J.P. Hazelton, Sutureless repair of a full-thickness cardiac stab wound adjacent to the right coronary artery using Evarrest® patch, *Am. Surg.* 85 (8) (2019) e419–e420.