ORIGINAL ARTICLE

Hemorrhage Control in Penetrating Cardiac Injury: A New Device Put to the Test in the Advanced Trauma Operative Management (ATOM) Course

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Abstract

Objective: We recently developed a new device to temporize bleeding from penetrating cardiac injuries. To further understand the usefulness of the device, we put it to the test by less experienced physicians.

Methods: General surgery residents participating in the "Advanced Trauma Operative Management (ATOM)" course tested the device. Each participant had to control bleeding from a cardiac injury in a swine. A questionnaire was completed and analyzed.

Results: The number (*n*) of participants is 20; 95% of the participants stated that the device controlled the bleeding, 100% considered it easy to use, 80% of the participants had previously seen a cardiac injury, and 35% had experience using a hemorrhage control device in a human heart. Only 15% of the participants had sutured a human heart and 55% an animal heart; 90% responded that would use the new device clinically.

Conclusion: The new device was easy to use and effectively controlled bleeding in penetrating cardiac injuries regardless of the level of experience of the physician.

Keywords: Cardiac, Device, Hemorrhage control, Trauma.

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Abstrato

Objetivo: Recentemente, desenvolvemos um novo dispositivo para controlar o sangramento de lesões dos ventrículos cardíacos. Para entender melhor a utilidade do dispositivo, colocamos à prova os médicos menos experientes.

Métodos: Residentes de cirurgia geral do curso "ATOM" testaram o dispositivo. Cada participante, atuou utilizando o dispositivo em uma lesão padronizada em porcos. Um questionário foi preenchido após o procedimento.

Resultados: *N* = 20 participantes; 95% afirmaram que o dispositivo controlou a hemorragia e 100% considerou-o de fácil uso, 80% tinham visto uma lesão cardíaca antes e 35% havia utilizado algum outro dispositivo para controle de sangramento coração humano. Somente 15% havia suturado um coração humano e 55% um coração animal. 90% responderam que utilizariam o dispositivo na prática clínica.

Conclusão: O novo dispositivo é de fácil de uso e controla o sangramento em lesões cardíacas penetrantes efetivamente, independentemente do nível de experiência do médico.

Palabras clave: Dispositivo, Hemorragia, Hemostasia, Lesões Cardíacas.

Introduction

Penetrating cardiac injuries cause death through exsanguination, cardiac tamponade, and fulminant cardiac failure.[1] Ballistic trauma and stab wounds are the most common mechanisms involved in penetrating wounds to the heart. Studies of unselected series of patients with penetrating cardiac injuries show a death on the arrival rate of 80 to 90%; 18% were considered salvageable cases if the right treatments were available.[2,3] Consequently, expeditious management of these injuries and immediate hemorrhage control are critical to the improve survival rate. The ideal way to control the hemorrhage is to digitally occlude de injury followed by suture. However, a procedure like this is difficult to perform in the emergency department. Additionally, the lack of physician experience in the treatment of these injuries increases the rate of poor outcome. The first heart suture was successfully attempted in 1882 by Block in a rabbit model.[4] The first attempt in a human was in 1896 by Cappelen.[5] He had to repair a left ventricular laceration and ligate the coronary artery; the patient died in the postoperative period. Rehn of Frankfurt is credited with the first successful repair of a penetrating cardiac injury in 1896, operating on a wound in the right ventricle.[6] Several reports followed that successful repair. Dr Rehn published additional 124 events with 60% successful outcomes.[7] During World War II, Dr Harken from the

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United States reported the removal of 13 projectiles from the heart with no fatalities.[8] A few years later, new tools were developed to help surgeons overcome the challenges of open heart surgery. The most important one was bypassing the heart from the circulation. This problem was tackled with the work of Walton Lillehei on cardiopulmonary bypass using controlled cross-circulation between two humans.[9] A few years later, Dr John Gibbon created a machine to "replace" the functions of the heart and lungs.[10] The first use of cardiopulmonary bypass in the trauma setting was reported only in 1962.[11] However, in the trauma setting, the surgeon does not have enough time to put the patient in bypass given the need for immediate hemorrhage control. Strategies aimed at temporary control of the bleeding in cardiac injuries prior to definitive suture of the wound have a critical impact on improving patient survival. The use of skin staples has been described for that purpose.[12] However, the stapler technique can be ineffective in deep wounds and in injuries near the coronary arteries. Moreover, the need to remove the staples for definitive suture could aggravate the injury.[2]

Despite concerns over its safety and efficacy, the use of the Foley balloon catheter to gain temporary control of the bleeding from a cardiac injury has not been abandoned, particularly following emergency department (ED) thoracotomies.[2,13] This technique involves the insertion of a Foley catheter through the wound followed by traction tightly positioning the balloon against the wound inside the ventricle. In practice, the method and variations thereof result in suboptimal control of the bleeding and frequently lead to enlargement of the initial injury. Moreover, the balloon inevitably occupies space inside the ventricle, thereby interfering with cardiac function.[13] Therefore, an ideal method for temporary hemorrhage control in cardiac injuries is certainly needed.

We previously published a study on our novel device to temporize hemorrhage in penetrating ventricular injuries.[13] In that experimental study, our new device (Fig. 1) effectively and efficiently controlled hemorrhage from the injuries with minimal interference with cardiac function compared to the Foley catheter. The experiment, however, was performed by a surgeon with vast experience in the treatment of penetrating cardiac injuries.[13]

The aim of the current study is to investigate the performance of Post Graduate Year 4 (PGY4) general surgery residents during the American College of Surgeons Advanced Trauma Operative Management (ATOM) course in temporizing hemorrhage from penetrating ventricular injuries using the new device.[16] The importance of this study resides in the fact that data from an American survey showed that only 62% of doctors working in trauma centers had any experience with cardiac wound repair.[14]

Materials and Methods

The study was approved by the Animal Care Committee of the Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Canada.

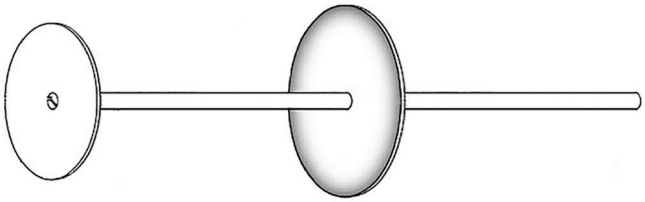

Fig. 1: The new device to control bleeding from penetrating ventricular injuries is depicted in this drawing

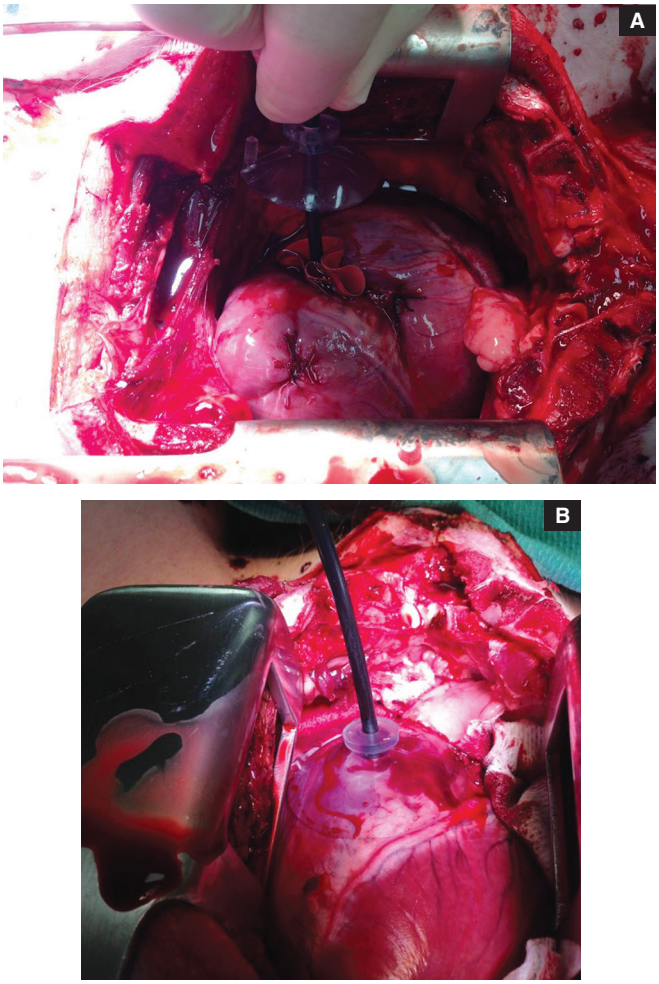

Fig. 2: (A) Photograph of the new device insertion in a penetrating cardiac injury. (B) Photography of the new device in place and bleeding controlled "hands-free"

The new device was introduced to PGY4 general surgery residents during the ATOM course. One of the exercises in the ATOM course is the repair of a cardiac injury in a swine. In this exercise, the sternum is opened to expose the heart. Afterwards, a cardiac injury is created with a scalpel.

Specific instructions on the use of the new device were briefly given to the participants. Afterwards, a 1.5-cm full-thickness wound was created on the anterior surface of the right ventricle. The wound was allowed to bleed freely for 5 seconds to simulate the actual challenges involved in the treatment of these injuries. Subsequently, the new device was handed to the resident for hemorrhage control.

The new device was deployed by introducing the collapsible blood flow blocking membrane through the cardiac injury, and subsequently sliding the silicone suction cup down toward the injury on the surface of the heart. Thereby, abutting the membrane to the undersurface of the ventricle wall creating a firm seal[13] (Fig. 2A and B). An international patent application was filed for this device (PCT/IB2016053827).

Finally, the questionnaire sheet shown in Figure 3 was handed to the participants at the end of the exercise; the survey was anonymous. The survey responses were tabulated using Microsoft Excel (www.microsoft.com).

PROTOCOL QUESTIONS (Thank You for Participating!)

Student Number:_____ Specialty:_____(Mark the Box ☐ with an "X")

1- Have you ever seen a penetrating cardiac injury in a human? ☐Yes ☐No

2- Have you ever sutured a penetrating cardiac injury in a human? ☐Yes ☐No

3- Have you ever seen a penetrating cardiac injury in an animal? ☐Yes ☐No

4- Have you ever sutured a penetrating cardiac injury in an animal? ☐Yes ☐No

5- Have you ever attempted temporary hemorrhage control of a penetrating cardiac injury in a human? ☐Yes ☐No

6- Have you ever attempted temporary hemorrhage control of a penetrating cardiac injury using a Foley Catheter? ☐Yes ☐No

7- Have you ever attempted temporary hemorrhage control of a penetrating cardiac injury using any other device then the ones described above? ☐Yes ☐No

8- Do you feel that the cardiac injury device provided temporary hemorrhage control of the penetrating cardiac? ☐Yes ☐No

9- Do you feel that the cardiac injury device was easy to use? ☐Yes ☐No

If No, please explain why:_____

10- Do you have any concerns about the cardiac injury device? ☐Yes ☐No

If Yes, please explain:

11- If the cardiac injury device were approved by Health Canada or the FDA for medical use, would you used it in your clinical practice? ☐Yes ☐No

If No, please explain why:

Fig. 3: Questionnaire given to the participants

Results

A total of 20 questionnaires were collected from the PGY4 residents (Tables 1–3).

To investigate the potential effect of prior experience with cardiac injuries, we divided the questionnaires into two groups: those from participants with experience with temporary hemorrhage control of cardiac injury in humans ($n = 7$) and those from participants without any experience ($n = 13$); based on the answer to question no. 5 of our questionnaire.

The new device was an expeditious and efficient mean for temporary hemorrhage control per 95% ($n = 19$) of the residents. Moreover, all residents ($n = 20$) were of the opinion that the device was easy to use, thus accessible to physicians with any level of training.

Table 1: Overview of the answers to questions 1 to 11

	Distribution of answers (n = 20)			
	Yes, %	*Yes*	*No, %*	*No*
Question 01	80	16	20	4
Question 02	15	3	85	17
Question 03	65	13	35	7
Question 04	55	11	45	9
Question 05	35	7	65	13
Question 06	10	2	90	18
Question 07	5	1	95	19
Question 08	95	19	5	1
Question 09	100	20	0	0
Question 10	55	11	45	9
Question 11	90	18	10	2

Table 2: Answers provided by participants who had no experience in treating cardiac injuries

	Participants without experience with temporary hemorrhage control of cardiac injury in a human (n = 9)			
	Yes, %	*Yes*	*No, %*	*No*
Question 02	11	1	89	8
Question 06	0	0	100	9
Question 07	0	0	100	9
Question 08	100	9	0	0
Question 09	100	9	0	0
Question 10	67	6	33	3
Question 11	89	8	11	1

Table 3: Answers provided by participants who had previous experience in treating cardiac injuries

	Participants with experience with temporary hemorrhage control of cardiac injury in a human (n = 11)			
	Yes, %	*Yes*	*No, %*	*No*
Question 02	18	2	82	9
Question 06	18	2	82	9
Question 07	27	3	73	8
Question 08	91	10	9	1
Question 09	100	11	0	0
Question 10	45	5	55	6
Question 11	82	9	18	2

Even though the survey showed that 80% ($n = 16$) of the residents stated that they had previously seen a cardiac injury, only 55% ($n = 11$) had any experience in temporizing hemorrhage from these injuries. Furthermore, when asked about whether or not the resident had actually sutured a penetrating injury to the heart, only 15% ($n = 3$) of them had a positive response.

Analyzing the results obtained from the groups of participants without experience with temporary hemorrhage control of cardiac injuries in humans, we found that 67% of them had concerns regarding the cardiac device. The concerns were the following: concerns about removing the device prior to suturing 33% ($n = 2$) and prototype limitations 67% ($n = 4$). Among the experienced surgeons, 45% ($n = 5$) were concerned about the device, all of those concerns were based on current prototype limitations.

Finally, we also assessed the time required by each resident to control the bleeding using the new device, after the 5 second free bleeding period. Our results showed that it took the residents an average of 12.5 seconds (± 2.7 seconds) to control the bleeding with the new device. Residents who reported any previous experience with cardiac injuries required 12.1 ± 2.5 seconds to control the bleeding with the new device, while those without prior experience required 12.6 ± 2.9 seconds; these results, however, were not statistically significant ($p = 0.683$).

Discussion

Surgical treatment of injured patients can be extremely complicated, expeditious and precise actions are frequently required. Therefore, the most critical steps of the surgical procedures performed on severely injured patients are usually done by the most experienced surgeon in the operating room, even in academic hospitals. This could lead to a lack of experience by trainees in managing those complicated cases. The repair of penetrating cardiac injuries is an example of those critical situations.[15,16] To compensate for this deficiency in surgical training, critical lifesaving procedures are frequently taught in courses involving human cadavers and large live animals.

An additional factor that contributes to the lack of experience in the treatment of cardiac wounds is the rarity of these injuries. A review of the National Trauma Databank of the American College of Surgeons showed that the nationwide incidence of cardiac injuries was 0.016%.[17] The impact of surgeon's experience on the outcomes of penetrating cardiac injuries was also corroborated by the results of a recent study involving 260 patients with high-risk cardiac injuries.[18] That study showed that trauma/acute care surgeons were the ideal physicians to treat penetrating cardiac injuries. Moreover, the need for sophisticated procedures in the acute treatment of penetrating cardiac injuries was rare. The most important factors for successful treatment of these injuries were the clinical condition of the patient at presentation and expeditious injury repair. The new device described herein was designed to assist physicians in temporizing hemorrhage from penetrating cardiac injuries, until definitive treatment is performed.

Our findings showed that the new device was easy to use and very effective to temporize bleeding from the injuries. The use of such device could potentially be of significant value for emergency physicians, trauma and non-trauma surgeons, trainees in trauma/acute care surgery, and cardiothoracic surgery. Although participating residents had some concerns regarding prototype engineering, there were no concerns about the basic function of the new technology. Moreover, participating residents who had prior

experience in treating cardiac injuries emphasized the ingenuity and the importance of the new device, and all of them would use the device in their clinical practice.

Lastly, the deficiencies of prototype engineering underlined by the residents can be easily be solved. Developing the prototype up to par with requirements set by regulatory health agencies is a critical step for a final product. Our findings showed that 18 of the 20 participants would use the device if it were approved for clinical use by regulatory agencies. We are currently working on that phase of the development of our technology.

Conclusion

The new device proved to be both effective and efficient to control bleeding from penetrating cardiac wounds even in the hands of PGY4 residents in general surgery. The new device worked appropriately in all cases. The residents would use the new device in their clinical practice when appropriately approved for that purpose.

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