A pilot experimental study of a catheter to facilitate treatment for penetrating cardiac injury

Mahmut TOKUR[1], Mehmet ERGİN[2,]*, İbrahim Can KÜRKÇÜOĞLU[3], Zerrin Defne DÜNDAR[2]

[1]Department of Thoracic Surgery, Faculty of Medicine, Kahramanmaraş Sütçü İmam University, Kahramanmaraş, Turkey
[2]Department of Emergency Medicine, Meram Faculty of Medicine, Necmettin Erbakan University, Konya, Turkey
[3]Department of Thoracic Surgery, Faculty of Medicine, Harran University, Şanlıurfa, Turkey

Background/aim: Penetrating heart injuries result in high mortality. We designed a new catheter to facilitate the treatment of penetrating cardiac injuries and provide more effective initial bleeding control and fluid replacement.

Materials and methods: The cardiac injury model was applied to 8 female 1-year-old Sus domesticus pigs. Subjects were grouped according to whether a Foley catheter or a newly designed catheter was placed into the heart through cardiac lacerations. Changes in systolic blood pressures, mortality, and problems encountered during surgery and other intraoperative findings were recorded.

Results: There were higher mean blood pressure measurements in the newly designed catheter group during stages IV to VII. All subjects had tamponade and cardiac activity after completion of the repair of all lacerations in the catheter group, whereas in the other group only one subject did. Intraoperative direct fluid infusion to the heart through the catheters in the diastole was performed in all subjects of both groups. However, regurgitation from the cardiac cavity in the systole was seen only in the Foley catheter group. All of the intraoperative complications were seen in the same group.

Conclusion: The newly designed catheter can provide effective initial bleeding control, better initial vital sign stabilization, and fewer intraoperative problems during primary repair of cardiac lacerations.

Key words: Cardiac injury, hemorrhage control, penetrating injury

1. Introduction

Penetrating cardiac injuries generally occur due to penetration with sharp objects or gunshot wounds, and rarely by penetration of fractures of the sternum or ribs. The degree of cardiac injuries may vary from myocardium injuries to full-layer pericardium penetration. Although less common than other penetrating traumas, they result in high mortality. Clinical findings may also vary, from situations with stable vital signs to cardiopulmonary arrest. This variability depends on the type of injury, time between injury and arrival at the trauma center, amount of intravascular volume loss, and presence of cardiac tamponade (1,2).

Despite the advances in prehospital emergency services, the majority of patients with cardiac injuries die before reaching hospital (3). In Turkey it is not always possible to transport victims to a center with cardiac surgery capacity. Thus, emergency physicians and general or chest surgeons sometimes perform interventions (4).

We designed a new catheter to facilitate the treatment of penetrating cardiac injuries, to provide more effective initial bleeding control and fluid replacement and to allow more time when extracorporeal circulation is needed. The catheter is basically similar to a Foley drainage catheter, but it is not yet mass produced. Our patent application for the design is pending approval. Our aim here was to research the effectiveness of this newly designed cardiac catheter experimentally.

2. Materials and method

2.1. Parts of the catheter

The catheter is composed of a body and 2 end sections (Figure 1). The body of the catheter contains 2 channels, one within the other. One of these channels ends has a balloon and the other has a hole, situated distally. While inflating the balloon via one of these channels, fluid or blood can be inserted through the other. There are valves with nonreturn mechanisms at the proximal endings of

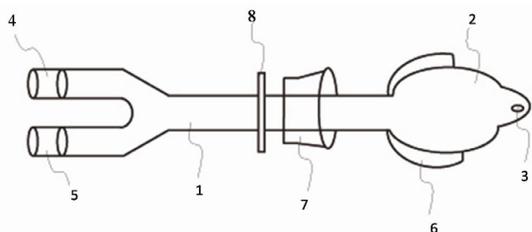* Correspondence: drmehmetergin@gmail.com

Figure 1. The parts and features of the catheter **1**- Body, **2**-Balloon, **3**- Hole, **4** and **5**- Channels, **6**- Layer, **7**- Lid, **8**- Clip.

both channels. The bidirectionally sliding lid is located on the body of the catheter at the back of the balloon. A clip is placed further back on the lid and this serves to secure (lock) the lid.

There is a protective layer around the balloon at the distal end. This layer is hard enough that a needle cannot tear the balloon even if the needle is stuck in the inflated balloon during suturing.

2.2. How to use the catheter

1. After locating the rupture in the heart, the finger is inserted.
2. The front part of the catheter is placed in a cardiac access next to the finger through the rupture.
3. The balloon is inflated to cover the rupture and is secured permanently and tightly by pulling it outwards.
4. and 5. After placing the exterior lid on the outer surface of the rupture, the cardiac muscle is pressed between the balloon and the lid through the clip and secured. By doing this, the bleeding in the rupture area can be stopped. Following initial bleeding control, either rupture repair or extracorporeal circulation may be performed.
6. If needed, direct fluid and blood replacement can be done through the other channel of the balloon (Figures 2A–2C).

2.3. Overview of experimental animal groups

Eight female 1-year-old *Sus* domesticus pigs, each weighing 50–55 kg, were used in this study. All animals were kept under a 12-h light/12-h dark cycle at a constant temperature (22 °C) and allowed free access to food and tap water. All experimental procedures were approved by the Ethical and Experimental Committee of the Faculty of Medicine, Çukurova University. All efforts were made to reduce the total number of animals and to minimize their discomfort. The animals were fasted for 24 h with water until 2 h before the experiment. Vascular access was established from V. auricularis lateralis for 0.9% saline infusion during the experiment. Atropine sulfate was administered in an intravenous dose of 0.2 mg/kg in order to inhibit secretion before the anesthesia. A combination of Rompun at 2 mg/kg intramuscularly and ketamine at 13 mg/kg intramuscularly was administered for anesthesia and intravenously administered intraoperatively. Oxygen support was given throughout the anesthesia. All pigs were noninvasively monitored for blood pressure and oxygen levels in the blood. Immediately after the onset of penetrating thorax injury, animals were randomly assigned to groups. All animals were sacrificed under anesthesia with a high dose of ketamine HCL after all measurements were taken.

2.4. Induction of penetrating thorax injury, insertion of catheters, and the thoracotomy operation

The pigs were divided into 2 groups of 4 pigs each. A Foley catheter was intended for the first group (Group I) for initial bleeding control, and the new catheter design was intended for the second group (Group II). After shaving of the thoracic region containing the sternum and the ribs, asepsis-antisepsis was performed in compliance with disinfection protocols using an iodine solution (Batikon). All pigs received a cardiac injury model by the same surgeon using a scalpel (20 cm long) with 2 penetrating thorax injuries, one through the right paratracheal
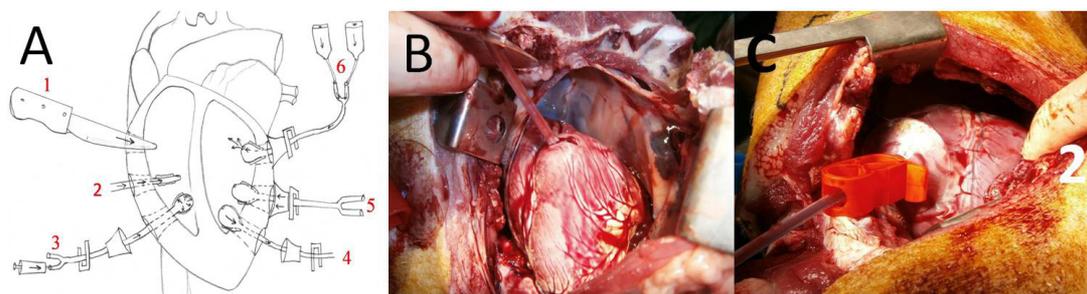

Figure 2. How to use the catheter in cardiac injury. **A) 1**- Penetrating the heart with a knife. **2**- Getting the distal part of catheter through the laceration into the ventricle. **3**- Inflating the balloon from the proximal end of the catheter by a syringe with air or fluid. **4**- Placing the inflated balloon at the ventricular wall internally. **5**- Placing lid and clip tightly to ventricular wall externally. **6**- Rehydrating the patient with isotonic fluids or blood products. **B and C)** Photographs taken during our experiment.

fourth intercostal space (ICS) and the other from the left paratracheal fourth ICS. No medical interventions were made in either group for 5 min following the penetrating injuries (Stage III). The purpose here was to model the duration until the arrival of medical aid following injury. Intravenous 0.9% NaCl administration was started at 200 mL/h after the 5-min period expired.

All surgical interventions were carried out by the same surgeon and operational team. In Group I, after the 5-min waiting time expired, the thoracic cage was incised by Clamshell incision while intravenous hydration to access the heart continued (Stage IV). Both pleural spaces and the pericardium were incised. The bleeding site on the heart was localized and an effort was made to control the bleeding with a pressed finger. A Foley catheter was then placed into the heart through the cardiac penetrating injury, and its balloon was inflated to control the initial bleeding. We waited for 3 min for the blood pressure to rise (Stage V). During this time, 0.9% NaCl was administered at 200 mL/h directly through the Foley catheter in addition to intravenous hydration. After 3 min, cardiac incisions were primarily sutured (Stage VI).

In Group II, the experiment was carried out with 2 differences. Intravenous hydration was started at the end of the 5-min waiting period and, as the first difference, the catheter was moved through the skin incisions to the thoracic space along the tracks (Stage III). This procedure was carried out in order to stop the bleeding before the thoracic cage was incised using the new catheter and to investigate whether fluid could be directly injected into the heart without establishing vascular access. When blood flowed from the distal port of the catheter, the catheter was considered to be at the correct site and its balloon was inflated to fix it. In addition to intravenous hydration, 0.9% NaCl was then started at 200 mL/h from within the catheter. The chest was incised by Clamshell incision and the heart was exposed (Stage IV). The second difference was that the externally placed catheters were localized at this stage. If the heart was lacerated, the catheter was then placed through the laceration. We waited for 3 min after the bleeding was controlled (Stage V). During this time, 0.9% NaCl was started at 200 mL/h through the catheter in addition to intravenous hydration. After 3 min, cardiac incisions were primarily sutured (Stage VI).

2.5. Data gathering process
During the experiment the following data were gathered:
1. Changes in systolic blood pressures throughout the experiment.
2. Results of the operation during the experiment.
3. Problems encountered during the process of primary repair.
4. The intrathoracic positions of catheters intraoperatively placed blindly from the skin incisions to the thorax.

5. The results of fluid hydration as a result of this procedure were observed and recorded for Group II.

2.6. Statistical analysis
Data analysis was performed using SPSS 11.5 for Windows (SPSS Inc., Chicago, IL, USA). While the continuous variables were shown as mean ± standard deviation, the number of cases and percentages were used for nominal data. The mean blood pressures within each measurement time were compared by Student's t-test. Nominal data were analyzed by Fisher's exact test. A P-value of less than 0.05 was considered statistically significant.

3. Results
No statistically significant difference was found between the study groups for preoperative (Stage I), postintubation, and preinjury (Stage II) periods, or at 5 min after the injury (Stage III) in terms of mean blood pressure (P = 0.750, P = 0.670, P = 0.437, respectively; Table 1).

Following thoracotomy, it was seen that, in Group I, there was an injury at the right ventricle of pigs 1 and 3 and the left ventricle of pig 4, whereas injuries were at both ventricles of pig 2. In Group II, pigs 1 and 2 had an injury only at the left ventricle, whereas the others had injuries at both ventricles.

Despite a difference in mean blood pressure between the groups following exposure of the heart by thoracotomy (Stage IV), the difference was statistically insignificant (P = 0.147; Table 1). At this stage, the newly designed catheter was inserted into the subjects in Group II through the wound site. Blood pressure was too low to be measured in pig 1 in Group I.

Despite a difference in mean blood pressure after a 3-min hydration (Stage V) following the intraoperative placement of catheters into cardiac lacerations, the difference was statistically insignificant (P = 0.488; Table 1).

During the primary repair of the lacerations in the heart (Stage VI), blood pressure was too low to measure in pig 1 in Group I and, despite a difference in mean blood pressure of both groups, the difference was statistically insignificant (P = 0.054; Table 1).

After completion of the repair of all lacerations in the heart (Stage VII), pigs 1, 2, and 4 in Group I had no cardiac activity. All pigs in Group II had cardiac activity, with a mean blood pressure of 50.00 ± 4.08 mmHg (Table 1).

A review of postthoracotomy findings showed no statistically meaningful differences (P = 0.143) between the groups for tamponade, despite seeing that all subjects in Group II and only 1 subject in Group I had tamponade. There were also no statistically significant differences (P = 1.000) between the groups in establishing initial bleeding control. Intraoperative direct fluid infusion to the heart through the catheters in the diastolic stage was successfully

Table 1. Blood pressures (mmHg) by measurement times.*

Follow-up**	Group I (n = 4)	Group II (n = 4)	P value †
Stage I	63.75 ± 4.79	65.00 ± 5.77	0.750
Stage II	61.25 ± 4.79	62.50 ± 2.89	0.670
Stage III	51.25 ± 6.29	47.50 ± 6.45	0.437
Stage IV	43.33 ± 5.77	48.75 ± 2.50	0.147
Stage V	48.75 ± 6.29	51.25 ± 2.50	0.488
Stage VI	43.33 ± 5.77	51.25 ± 2.50	0.054
Stage VII	50.00	50.00 ± 4.08	-

†: Student's t-test.

*: Normal blood pressure range: 60-80 mmHg.

**: Stage 1: Preintubation (preoperatively); Stage 2: Period between postintubation and preinjury; Stage 3: 5 min after penetrating injury; Stage 4: Upon exposure of the heart by thoracotomy; Stage 5: After the placement of the Foley catheter (Group I)/newly designed catheter (Group II) and 3 min intravenous infusion of 0.9% NaCl; Stage 6: At the start of primary repair of the heart; Stage 7: Upon completion of the operation (postoperatively).

performed in all subjects of both groups. However, regurgitation from the cardiac cavity in the systolic stage was seen only in subjects of Group I, with a significant difference (P = 0.029) between the groups. Again, a statistically significant difference (P = 0.029; Table 2) was seen between groups for intraoperative complications (blowing up of the catheter balloon).

There were no mortalities in Group II in Stage VII, but all subjects died in Group I except for pig 3. However, no statistically significant difference (P = 0.143; Table 2) was found between mortality rates in the groups.

4. Discussion

While 10.4% of trauma incidents requiring urgent surgical intervention are thoracic injuries, only 1% of those are cardiac injuries. Most of the patients referred to emergency services with complaints of penetrating cardiac injuries were hemodynamically unstable and their mortality rates were quite high (5). The time between cardiac injury and arrival to the hospital is vital, because a great majority of patients with cardiac injuries are lost even before they can make it to the hospital (3). In Turkey, just 3.5% of patients are still alive on arrival (6). Mortality, which varies within a range of 3%–94%, depends on the severity of injury, general health of the patient, and whether the patient has additional organ injuries (7–10).

Hypotension, deep heart sounds, and jugular venous distension are clinical indicators of pericardial tamponade, and the existence of these symptoms is associated with Beck's triad (11). Moreover, it has also been reported that tamponade has a positive impact on survival in injuries involving a cardiac cavity; however, its mechanism is still unknown (12,13). There were no cases of mortality in our study in subjects suffering tamponade. We consider that the catheters intraoperatively placed blindly from the skin incision to the thorax in Group II also contributed to tamponade formation.

Table 2. Other clinical findings.

Variables	Group I (n = 4)	Group II (n = 4)	P-value †
Tamponade	1 (25%)	4 (100%)	0.143
Initial bleeding control	3 (75%)	4 (100%)	1.000
Regurgitation from cardiac cavity in the systolic stage	4 (100%)	0 (0%)	0.029
Fluid infusion during the diastolic stage	4 (100%)	4 (100%)	-
Intraoperative complications	4 (100%)	0 (0%)	0.029
Exitus	3 (75%)	0 (0%)	0.143

†: Fisher's exact test.

Treatment in cardiac injuries has several stages. The first stage is replacing the blood volume that the patient has already lost and covering the puncture that is bleeding. Subsequently, a permanent repair of the puncture is performed (10,14). Although a statistically insignificant level of difference was found, blood pressure values in the group using the newly designed catheter were higher than in the Foley catheter group. Furthermore, no subject died in the newly designed catheter group when all cardiac lacerations were repaired. We think that these differences are associated with the catheter contributing to the formation of tamponade, as well as its establishing a better fluid resuscitation and intraoperative bleeding control.

Median sternotomy in stable patients and anterolateral thoracotomy in patients whose general health states are particularly critical and who are in agony can be performed (14,15). Subsequently, the pericardium should be incised and the heart should be exposed if tamponade is present. Initial bleeding control (temporary bleeding control) and effective fluid replacement that will increase cardiac output must be performed simultaneously in a swift manner. Having ensured vital stabilization, incision repair (permanent bleeding control) must be carried out (15,16). The catheter designed in this study was as successful as the Foley catheter in initial bleeding control and direct fluid infusion into the heart. It was also found to be far superior to the Foley catheter in preventing fluid regurgitation from the heart during the systolic stage.

Serious problems can occur during the initial bleeding control. After having ensured initial bleeding control by finger during incision repair, problems including a needle sticking into the finger and gloves or slight or partial rebleeding may be experienced when removing the finger during suturing. However, during the incision repair stage, massive bleeding and volume loss due to the needle piercing the balloon and time loss experienced during the replacing of the catheter increase mortality. In larger incisions it may be necessary to inflate the Foley catheter excessively in order to stop bleeding; however, this may

result in a decrease in filling volume and cardiac output (16). In our study, intraoperative balloon deflation was seen in the Foley catheter group, with no such experience in the catheter-placed group.

In conclusion, this study demonstrates that in using the newly designed catheter:
1. Effective bleeding control was provided during the repair of the cardiac rupture.
2. Better immediate vital stabilization was attained via the catheter through direct fluid and blood replacement to the heart.
3. The rupture repair became not only much easier but also swifter and more effective as there was no balloon problems caused by the needle.

We think that the newly designed catheter can provide more effective bleeding control and could improve surgical success in patients admitted to the emergency units following cardiac injuries. This can be particularly important in hospitals with limited cardiac surgery capacity and lacking adequate equipment to deal with such incidents.

Pigs were chosen due to the difficulty of working on an experimental animal with a suitably sized cardiac structure for placing the newly designed catheter. We think that the lack of any other studies that could serve as examples for our study and the number of animals allowed as per the decision of the ethical committee in question affected the finding of no statistical significance despite a difference between the mean values of blood pressure and other parameters.

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