

Sternotomy or Drainage for a Hemopericardium After Penetrating Trauma



A Randomized Controlled Trial

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Abstract and Introduction

Abstract

Objective: To determine if stable patients with a hemopericardium detected after penetrating chest trauma can be safely managed with pericardial drainage alone.

Background: The current international practice is to perform a sternotomy and cardiac repair if a hemopericardium is detected after penetrating chest trauma. The experience in Cape Town, South Africa, on performing a mandatory sternotomy in hemodynamically stable patients was that a sternotomy was unnecessary and the cardiac injury, if present, had sealed.

Methods: A single-center parallel-group randomized controlled study was completed. All hemodynamically stable patients with a hemopericardium confirmed at subxiphoid pericardial window (SPW), and no active bleeding, were randomized. The primary outcome measure was survival to discharge from hospital. Secondary outcomes were complications and postoperative hospital stay.

Results: Fifty-five patients were randomized to sternotomy and 56 to pericardial drainage and wash-out only. Fifty-one of the 55 patients (93%) randomized to sternotomy had either no cardiac injury or a tangential injury. There were only 4 patients with penetrating wounds to the endocardium and all had sealed. There was 1 death postoperatively among the 111 patients (0.9%) and this was in the sternotomy group. The mean intensive care unit (ICU) stay for a sternotomy was 2.04 days (range, 0–25 days) compared with 0.25 days (range, 0–2) for the drainage ($P < 0.001$). The estimated mean difference highlighted a stay of 1.8 days shorter in the ICU for the drainage group (95% CI: 0.8–2.7). Total hospital stay was significantly shorter in the SPW group ($P < 0.001$; 95% CI: 1.4–3.3).

Conclusions: SPW and drainage is effective and safe in the stable patient with a hemopericardium after penetrating chest trauma, with no increase in mortality and a shorter ICU and hospital stay. (ClinicalTrials.gov Identifier: NCT00823160)

Introduction

Only 11% to 20% of patients with a penetrating cardiac injury (PCI) will arrive at the hospital alive^[1–3] and in-hospital mortality rate is reported to be as high as 61% to 65%.^[4,5] The clinical presentation on arrival is classified into: lifeless, critically unstable, cardiac tamponade, thoracoabdominal injury, and benign.^[6] The proportion of patients arriving with a benign PCI ranges from 15% to 30%.^[7–12] More specifically, this cohort is

hemodynamically stable, neurologically alert, and has no signs of cardiac tamponade or active bleeding. The ideal management of these patients [ie, normal physical examination with a positive pericardial ultrasound (US) finding of blood] remains unresolved.

The current internationally accepted management algorithm for a hemodynamically stable patient with a PCI mandates an immediate sternotomy and cardiac exploration.^[13] Experience with performing a mandatory sternotomy in Cape Town, South Africa, was that in many patients, the cardiac injury had sealed. A pilot study conducted in 2001 found that 71% (10 out of 14) of patients had a nontherapeutic sternotomy for a tangential or partial-thickness PCI. Furthermore, the wound had sealed in the 4 patients with a full-thickness PCI.^[14] Subsequently, a further 7 patients with a confirmed hemopericardium were successfully managed by performing a subxiphoid pericardial window (SPW) and drainage of blood in the pericardial sac.

The danger of missing a cardiac injury has been well documented.^[15,16] As a result, all nonsealed major cardiac injuries must be identified and repaired. We have found that by performing an initial SPW, major injuries bleed upon irrigation of the pericardial sac. If bleeding is encountered, sternotomy and repair of the cardiac defect is required. If there is no bleeding, patients can be managed with drainage of the pericardial sac and no sternotomy. A randomized trial was undertaken to test this hypothesis and is the first ever performed on PCI.

Methods

Study Design

This was a single-center parallel-group study with equal randomization conducted in the Trauma Center at the Groote Schuur Hospital from 1st November 2001 through 30th February 2009. All adult patients aged 18 years or older who had (1) sustained penetrating chest trauma, (2) were hemodynamically stable with a hemopericardium confirmed by SPW, and (3) had no signs of active bleeding at SPW were included in the study.

Exclusion criteria included hemodynamic instability, evidence of cardiac tamponade, preoperatively intubated patients, respiratory failure, presence of traumatic septal or valvular defects, delayed presentation of longer than 1 week, and an impaired level of consciousness. The study was approved by the Faculty of Health Sciences Research Ethics Committee of the University of Cape Town and registered at ClinicalTrials.gov NCT00823160.

Management Protocol

Patients with penetrating chest trauma who were hemodynamically stable on arrival or who required less than 2 L of fluids in total for resuscitation and who were otherwise conscious and well were considered for inclusion into the study. A chest X-ray and an electrocardiogram were undertaken. An US of the pericardial space was performed in the resuscitation room by the on-call radiologist shortly after admission. The presence of any fluid in the pericardial sac was considered as positive for blood. Patients with a suspected haemopericardium were admitted to a high care unit for continuous monitoring for a period of at least 24 hours. If a patient became hemodynamically unstable during this period, emergency surgery was mandated and the patient was not randomized.

Patients with a hemopericardium diagnosed on US, or where there was a clinical suspicion of an underlying cardiac injury due to the presence of a pneumopericardium, or

where the US findings were equivocal, underwent a SPW. This was performed after 24 hours of close observation.

Technique of SPW

The SPW was performed under general anesthesia and involved a 5-cm incision below the sternum. The pericardial sac was opened and the presence of any blood was noted either in the form of clots or in blood staining of the pericardial fluid. The pericardial sac was irrigated vigorously with 500 mL of warm saline. If there was active bleeding, then a median sternotomy was performed to repair the laceration in the heart. If no bleeding was identified, patients were randomized to either sternotomy or drainage of the pericardial sac with a soft plastic pericardial drain. Patients who were randomized to sternotomy had the cardiac injury graded according to the Heart Injury Scale of the American Association for the Surgery of Trauma (AAST).^{17]}

Randomization Process

A computerized random number generator was used for the allocation of all patients. At the start of the operation, the intervention (sternotomy or drainage) was transferred to the anesthesiologist in an opaque, sealed envelope. After the SPW had been performed, and the presence of blood in the pericardial sac with the absence of active bleeding confirmed, the envelope was opened by the anesthesiologist and the surgeon was informed of the intervention.

End Points of the Study

The primary end point of the trial was survival to discharge from hospital. Survival to discharge, as opposed to 30-day mortality, was chosen because inadequate patient return for follow-up has been documented in previous trauma studies. Given the implications of a missed cardiac injury, a short time interval for evaluation is also reasonable. The secondary end points were the requirement for admission to the intensive care unit (ICU), the total hospital length of stay, and any complications.

Participants in the study were requested to attend a follow-up clinic 2 weeks after discharge. A research assistant followed up the patients who underwent pericardial drainage alone.

Definition of Terms

Hemodynamic stability was defined as a systolic blood pressure equal to or greater than 100 mm Hg.

Hemopericardium was defined as the finding of any blood in the pericardial sac on US or the presence of blood in the pericardial fluid during the SPW.

A negative SPW was the complete absence of any blood in the pericardial sac at the time of the SPW.

Statistical Analysis

The number of patients needed to treat was calculated at 110 patients for 2-sided tests, with a power of 90% and alpha value of 0.05 to detect a difference in mortality of 60%. This mortality value was considered reasonable based on the current in-hospital mortality rate of PCI. Continuous variables were compared with the use of the *t* test. Chi-square analysis and the Fisher exact test were used for the analysis of categorical variables where appropriate. The Levene test for the homogeneity of variances was used to

determine the comparability of the 2 groups. Confidence intervals were based on the normal approximation to the binomial distribution. *P* values of less than 0.05 were considered to be significant.

Results

During the study period, a total of 348 patients underwent surgery for an obvious or suspected PCI. One hundred fifty-seven patients required either an emergency department thoracotomy or emergency surgery. The remaining 191 of the 348 patients with penetrating chest trauma were hemodynamically stable on presentation or required less than 2 L of resuscitation fluid, and were assessed for eligibility into the study.

Thirty-nine of the 191 patients were excluded from the study for the reasons depicted in . Thirty-six patients did not meet the inclusion criteria, and a further 3 patients refused consent for the study.

Table 1. Reason for Patient Exclusion From the Study

Reason for Exclusion	Number of Patients
Less than 18 years of age	11
Developed hemodynamic instability	6
Septic pericarditis	6
Delayed presentation	4
Respiratory failure	3
Traumatic septal defect	3
Traumatic valvular defect	2
Blunt head injury	1
Declined consent	3
Negative SPW	36
Active bleeding at SPW	5
Total number	80

One hundred fifty-two patients were transferred to the operating room after 24 hours of observation in a high care unit and underwent a SPW. At surgery, 36 patients had a negative SPW (not randomized). Five patients started actively bleeding at the time of performing the SPW and so the SPW was converted to a median sternotomy (not randomized). One patient had a laceration of the superior vena cava, 2 patients had right ventricular injuries, and 2 had wounds of the left ventricle. These perforating cardiac injuries were all suture-repaired.

One hundred eleven patients were confirmed at SPW to have a hemopericardium without any evidence of active bleeding. Fifty-five of these patients were randomized to sternotomy and 56 to pericardial drainage only. There were no protocol deviations and no exclusions after randomization. The enrollment and outcomes are presented in Figure 1.^[18]

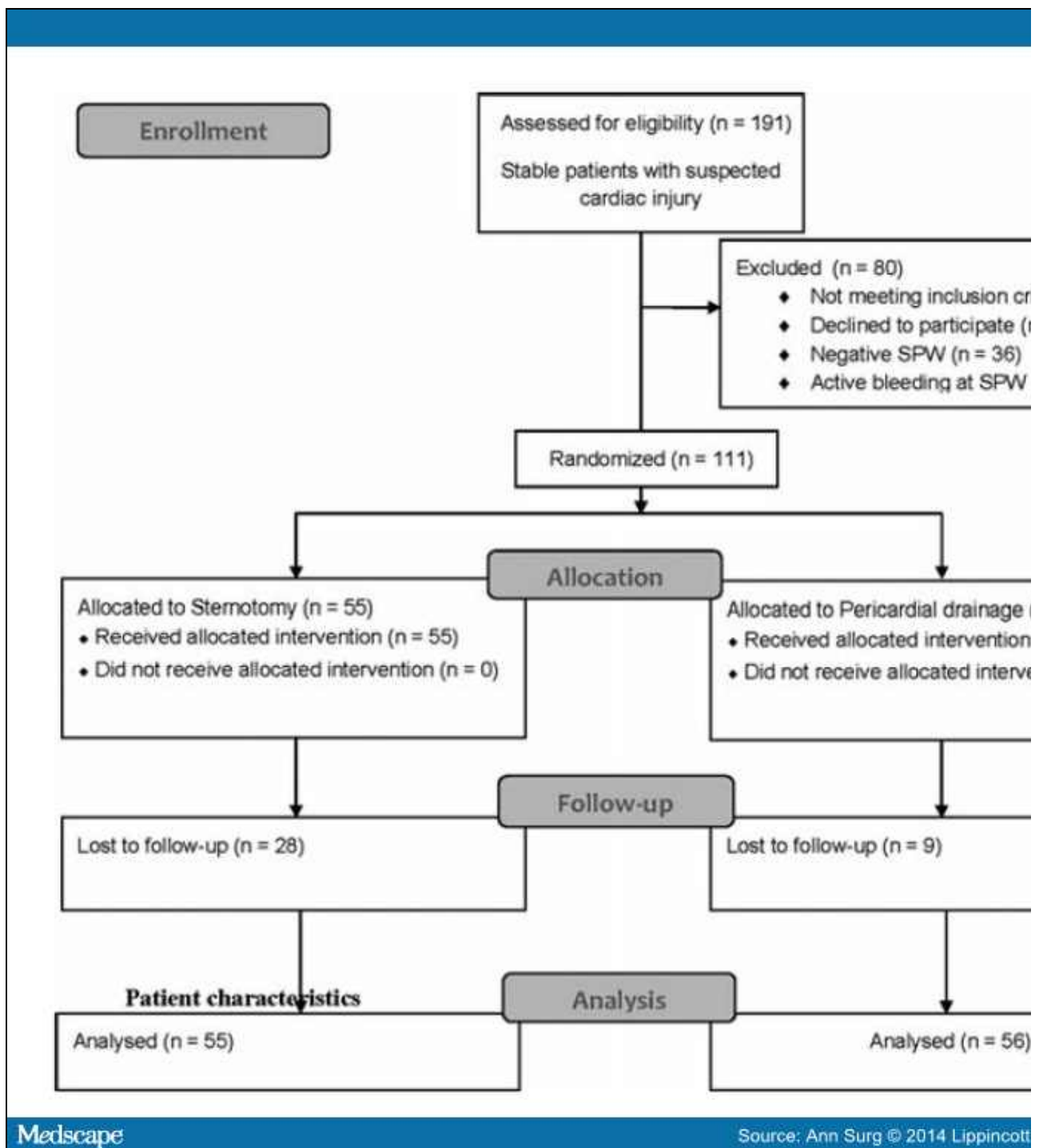


Figure 1.

Enrollment and outcomes.

Patient Characteristics

The 111 patients selected for the study were stable on arrival. There were 54 stab wounds and 1 gunshot wound (GSW) in the sternotomy group, and 55 stab wounds and a single GSW in the drainage group. The baseline characteristics of the 2 groups were comparable with respect to age, Revised Trauma Score, hemoglobin on presentation, initial central venous pressure (CVP) measurement, the size of the pericardial effusion on

US, and the mechanism of trauma ().

Table 2. Patient Characteristics

Variable	Sternotomy, Mean (SD) (n = 55)	Drainage only, Mean (SD) (n = 56)	P
Age, y	29.4 (9.04)	26.7 (7.80)	0.09
Revised Trauma Score	7.813 (0.16)	7.791(0.22)	0.56
Hemoglobin	11.4 (1.57)	11.2 (2.04)	0.54
CVP (cm H ₂ O)	13.5 (6.22)	13.7 (4.94)	0.88
Size of pericardial effusion on US in mm	8.3 (5.88)	8.9 (5.91)	0.57
Mechanism of trauma	SW 54	SW 55	1.00
	GSW 1	GSW 1	

SD indicates standard deviation; SW, stab wound.

Sternotomy Group (N = 55). Thirteen (24%) of the 55 patients who were assigned to sternotomy were found to have no cardiac injury (). Another 38 patients (69%) had tangential wounds. Fifty-one of the 55 patients (93%) who were randomized to sternotomy had either no cardiac injury or a tangential injury. There were 4 patients (7%) with penetrating wounds to the endocardium, and in each of these patients, the wound had completely sealed.

Table 3. Grade of the Cardiac Injury Found at Sternotomy (AAST)

AAST Grade	No. Patients (%)	Description
1	13 (24)	Penetrating pericardial wound without cardiac injury
2	38 (69)	Penetrating tangential myocardial wound not extending to the endocardium
3	0	Penetrating tangential myocardial wound with tamponade
4	3 (5)	Penetrating cardiac injury of RV/RA/LV/LA
5	1 (2)	Left ventricular perforation

LA indicates left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle.

Pericardial Drainage Group (N = 56). A total of 56 patients were randomized to pericardial drainage alone with no sternotomy. Given the lack of direct vision, the grade of the cardiac injury could not be determined in this group.

Morbidity and Mortality

There was 1 death postoperatively among all 111 patients (0.9%). This patient had been assigned to (and underwent) sternotomy, during which time an iatrogenic injury to the left internal mammary artery occurred. After surgery, the patient became hypotensive in the ICU and was returned to the operating theatre for hemostasis. Unfortunately, he

sustained ischemic encephalopathy and died.

The complications recorded in the 2 groups are presented in . There was a single patient who developed sternal sepsis after a sternotomy. This required extensive surgery in the form of a sternal debridement and pectoral flaps. He made a full recovery. There was also a patient in the sternotomy group who had a spontaneous asystolic cardiac arrest when the heart was being inspected for a cardiac wound. This patient responded to internal cardiac massage, intravenous adrenaline, and subsequent defibrillation with successful restoration of a cardiac rhythm. There were an equal number of patients with pneumonia who required medical management ($n = 11$). There was no significant difference between the 2 treatment options for any specific complication or all complications overall ($P = 0.412$). What is evident though from the Clavien-Dindo classification,^[19] which stratifies complications by severity, was the absence of any severe grade 4 or 5 complications in the drainage group.

Table 4. The Clavien-Dindo Classification of the Complications

Grade	Description of Grade	Complication	Sternotomy	Drainage
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions	Atelectasis	6	1
2	Requiring pharmacological treatment with drugs other than such allowed for grade 1 complications	Pneumonia	11	11
		Pulmonary edema	1	2
		Wound sepsis	2	2
3	Requiring surgical, endoscopic, or radiological intervention	Reaccumulation of hemothorax	2	4
4	Life-threatening complication requiring ICU management	Cardiac arrest	1	0
		Sternal sepsis	1	
5	Death of a patient	Death	1	0

Six patients were excluded from the study before randomization because they became hemodynamically unstable during the 24-hour observation period in the high care unit (ie, required emergency surgery). One of these 6 patients died from delayed cardiac tamponade that occurred on day 3 post admission. Surgery had been delayed for 3 days because of a lack of available ICU beds. This 32-year-old man had a sudden delayed tamponade with a cardiac arrest in the high care unit. He was found to have a 1-cm hole in the right atrium, which was sutured. Unfortunately, he died from ischemic encephalopathy and multiple-organ failure 2 days later.

Intensive Care Unit and Hospital Stay

Thirty-nine of the 55 patients who underwent a sternotomy were managed in the ICU postoperatively. The remaining 16 patients were extubated after surgery and monitored in a high care unit. Nine patients in the drainage group required ICU management. The mean ICU stay for the sternotomy group was 2.04 days (range, 0–25 days) compared with 0.25 days (range, 0–2) for the drainage-only group ($P < 0.001$). The estimated mean difference highlighted a shorter stay of 1.8 days in the ICU for the drainage-only group (95% CI: 0.8–2.7). With respect to the drainage-only group, 84% left the ICU within 1 day compared with only 20% in the sternotomy group.

The mean total hospital stay for the sternotomy group was significantly longer than the drainage-only group (6.5 days vs 4.1 days; $P < 0.001$; 95% CI: 1.4–3.3). In the drainage-only group, all patients were discharged home. No patient required delayed surgery for a cardiac tamponade or a symptomatic pericardial effusion.

Follow-up

Follow-up for the 56 patients who underwent drainage showed that 44 patients were alive and well, with a mean follow-up of 23 months (range, 2 weeks to 5.5 years). There have been 3 documented deaths after discharge. Two patients were stabbed again and died in this second assault. The first patient died 16 months post surgery and the other 8 months. The third patient died in his sleep 10 months post surgery and it has not been possible to locate any autopsy report of his death. The remaining 9 patients were lost to follow-up.

Discussion

It must be emphasized that the subset of patients who were selected for this trial were a highly selected group. More specifically, they represented 111 out of 348 patients (32%) who underwent cardiac surgery. US has proven to be excellent as a screening tool for cardiac injuries,^[20–22] but false negatives can occur in the presence of an undrained hemothorax.^[23] As a result, this trial enrolled only patients who had the gold standard test of a SPW to confirm or refute the presence of a hemopericardium.

The performance of a SPW allows for the identification of major PCIs, which require repair, by the demonstration of bleeding from the pericardial sac during the procedure. The process of irrigating the pericardial sac appears to facilitate bleeding and therefore helps to identify patients with "unstable" clot who require suture repair. Five major cardiac injuries were identified in this manner and all underwent a sternotomy and successful suture repair.

Thirteen patients had no cardiac injury and 38 patients had tangential cardiac wounds at sternotomy. Despite the presence of blood in the pericardium upon SPW, a total of 93% of patients at sternotomy had either no cardiac injury or tangential injuries. In the remaining 4 patients, the injuries had sealed. It was also noted that although a grading system does exist for cardiac trauma, it is very difficult to accurately grade the injuries as tangential or full-thickness without probing the cardiac wounds, and therefore, cause bleeding.

The observation that a large proportion of cardiac wounds in patients presenting in a stable manner have sealed has been previously documented. Harris et al^[11] found that clotted lacerations of the heart were present at sternotomy in 21 out of the 43 patients (48%) who were stable on presentation.

There appeared to be a similar total number of complications between both groups ($P = 0.412$), but the added severity of a cardiac arrest and sternal sepsis imply that the complications within the sternotomy group were more severe. The Dindo-Clavien classification of complications clearly shows that the life-threatening complications occurred in the sternotomy group. The numbers of complications were, however, too small for meaningful statistical comparison. There was an unexpected single death in the sternotomy group, which resulted from a surgical complication. This highlights the reality that a sternotomy is not a benign operation and that deaths related to the procedure will occur even in young trauma patients. The death of a patient prior to randomization highlights the necessity for extremely close observation and the fact that a SPW should not be delayed beyond 24 hours.

The ICU and total hospital stays were significantly shorter in the drainage-only group versus the sternotomy group. Thus, the adoption of this surgical policy would reduce the demand on the ICU and the use of hospital beds.

Almost all preceding studies have recommended immediate surgery and cardiorrhaphy for the management of a hemopericardium in the stable patient after penetrating chest trauma.^[24–29] Recently, a study by Thorson et al^[30] from Miami also questioned whether a hemopericardium after chest trauma mandated a sternotomy. Three hemodynamically stable patients (2 blunt and 1 penetrating trauma) with a hemopericardium identified at SPW were successfully managed without performing a sternotomy.^[30]

The limitations of this study are the lack of follow-up echocardiography, the loss of 9 patients in the drainage-only group to follow-up, and the undetermined cause of death of a patient in the drainage-only group at 10 months post surgery.

Conclusions

In summary, pericardial drainage alone appears effective and safe in the management of a hemopericardium in the stable patient after penetrating chest trauma, with no increase in mortality and a shorter ICU and hospital stay. This policy should be adopted only in trauma centers with significant experience in the management of cardiac injuries and with the immediate availability of an operating room.

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