Comparison between closed drainage techniques for the treatment of postoperative mediastinitis

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Comparison Between Closed Drainage Techniques for the Treatment of Postoperative Mediastinitis

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Background. **It is not clear which closed drainage technique is preferred as initial therapy for mediastinitis as soon as it is detected after cardiac surgery. A comparison is made between a continuous irrigation system and vacuum drainage using redon catheters.**

Methods. **A retrospective cohort study of patients undergoing cardiac surgery between January 1, 1989 and January 1, 1997 was made. Patients who developed a deep surgical site infection at the sternotomy site and who were treated with one of the two closed drainage techniques were included. Patient characteristics and procedure-related variables were analyzed. Also, variables related to the drainage procedure were included. Outcome parameters were treatment failure, total hospital stay, postoperative hospital stay and in-hospital mortality.**

Results. **The study population consisted of 11,488 patients, of whom 102 developed a deep surgical site infection (0.89%). The final study population consisted of 60 patients who fulfilled the inclusion criteria. From those, 29 were treated with continuous irrigation and 31 were treated with vacuum drainage. Both groups were comparable for patient characteristics and procedure-related variables. Treatment failure was more than three times as likely in the continuous irrigation group (relative risk: 3.2, 95% confidence interval: 1.3 to 7.7). Also, postoperative ($p = 0.03$) and total hospital stay ($p = 0.03$) were significantly longer in the group treated with continuous irrigation (mean prolongation of 14 and 13 days, respectively). After correcting for confounding, using multivariate analysis, the treatment method employed was found to be an independent and statistically significant variable associated with treatment failure ($p = 0.04$).**

Conclusions. **Closed drainage using vacuum-drainage system is the initial therapy of choice for patients with mediastinitis after cardiac surgery, because it is associated with significantly less treatment failure and a shorter stay in hospital.**

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Nowadays cardiac surgery is performed regularly on a large scale. In Europe nearly 250,000 cardiac operations were performed in 1993 [1]. The median sternotomy is the most commonly used incision in cardiac surgery. This technique was first used at the end of the 19th century [2], and became generally known after its introduction in 1957 [3]. Despite the use of modern surgical techniques, perioperative antibiotics prophylaxis and careful wound treatment, surgical site infections remain a feared complication of cardiac surgery with a reported incidence of 1% to 8% [4–6]. If a surgical site infection of the sternotomy wound extends into the mediastinum, this results in a mediastinitis. The consequences of these infections can be severe and include physical suffering, increased length of stay [4, 7], high costs, and significant mortality (10% to 29%) [5, 8, 9].

The initial treatment of mediastinitis comprises aggressive debridement of all infected tissue, including sternal necrosis, followed by a drainage technique. This is combined with prolonged systemic antibiotic treatment [10, 11]. Drainage can be done in several ways: (1) closed drainage with continuous irrigation, or (2) closed drainage using redon catheters. These techniques can only be applied as soon as mediastinitis is detected (usually within 2 weeks [12]). If mediastinitis exists for a long time or is detected in a late phase, there is every chance that the mediastinitis is extended and osteomyelitis with necrosis of the sternum has occurred, so that it is not possible to apply a closed drainage technique. However, in an early phase of mediastinitis, a closed drainage technique is the treatment of choice.

Bryant and colleagues introduced continuous irrigation in 1969 [13]. Since then, this has been the initial therapy for acute mediastinitis in most centers for cardiothoracic surgery. This technique is a rapid and effective procedure. Initially, the irrigation solution was a mix of sodium chloride and antibiotics. Currently, the mediastinum is irrigated with povidone-iodine [12]. In 1989, Durandy and coworkers introduced a new closed technique with a vacuum suction system using redon catheters [14]. After meticulous debridement of the wound, all "dead" retrosternal spaces are obliterated by sucking healthy tissue onto infected areas. This technique is simple and comfortable to the patient.

In 1989, the vacuum drainage system was introduced in the thoracic center of our Hospital. Since then, both

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closed drainage techniques are practiced here. However, it is not clear which technique is to be preferred with regard to the outcome for the patients. To find out if the outcome depended on the drainage technique which was performed, a retrospective comparison was made between both techniques.

Patients and Methods

Study Population

In the Ignatius Hospital, Breda, about 1,500 cardiac operations are performed each year. The study population consists of patients who underwent a cardiac operation between January 1, 1989 and January 1, 1997. In this period, 11,488 patients were operated upon. All patients who were treated with one of the two types of closed drainage, continuous irrigation (CI) and vacuum drainage (VD), were included. The medical records of all patients who underwent reoperation with application of a drainage system were traced. To be included in the study, patients had to meet the following requirements: (1) the patient had a mediastinitis as described in the criteria of the Centers for Disease Control and Prevention (CDC) [15]. (2) The patient had a closed drainage therapy (CI or VD) as initial treatment. All patients were placed in the group of the initially preferred drainage technique according to an intention to treat analysis. Information about the study patients was collected retrospectively from the medical records.

Mediastinitis: Classification and Treatment

The patients had type I to IVa mediastinitis according to the definition described by El Oakley and Wright [12]. This classification differentiates between time of presentation and presence of preoperative risk factors. The severity of the infection was classified based on the report of surgery in mild, advanced, and extensive mediastinitis. These definitions were as follows: *Mild:* minimal indications of an active mediastinitis. No pus or fluid collections substernal. No necrosis or active infection of the sternum. *Moderate:* presence of pus or fluid collections substernal. No necrosis or infection of the sternum. *Severe:* necrosis or active infection of the sternum.

In all patients of the study group, complete debridement of the sternum was performed. This comprised removal of fibrotic material and coagulations, as well as removal of all necrotic bone by removing 2 mm of the sternal edge using a saw. With a sharp spoon, the complete area of the wound was cleaned and an edge of cutis and subcutis was removed, so that a good blood supply of the wound surface was created. Then the wound surface was flushed with povidone-iodine and a closed drainage technique was applied.

During the entire study period, there were six cardiac surgeons. In 1989, the VD technique was introduced. Two surgeons used this technique routinely, since then. The other four surgeons did not use it routinely. Both techniques were performed over the entire study period. The techniques were performed as described below.

CI. After complete debridement of the sternum, the sternum is closed over two to four thick suction drains which are brought in around the heart and, when the pleurae are opened, into the pleurae. Furthermore, a thin input drain is applied just beneath the sternum. The sternal wires are left in upright position; the skin and subcutis are left open, so that the wound healing is by secundary intention. During the postoperative period, the mediastinum is irrigated with two liters of 0.5% povidone-iodine solution per 24 hours continuously and, at the same time, an equal amount is drained with a little suction over the thick drains. This procedure is continued for at least 1 week. Thereafter, the drains are removed when culture of the drain does not show any bacterial growth. The wires must be removed several months after this procedure.

VD. After complete debridement of the sternum, excision is done of the skin and subcutis edges. The skin and subcutis are mobilized to lateral. All necrotic bone is removed by removing 2 mm of the sternum using a saw. Three to six small redon catheters are placed to the left and right, underneath and above the heart, in such a manner that the grafts are not near the drains. Then, the sternum is closed. The subcutis is closed with absorbable dexon suture after one or two redon catheters are brought in beneath the subcutis. The skin is then closed with knotted nylon suture. Redon catheters are small, flexible, multiperforated tubes which are connected (with a luer lock) to a vacuum system after closing the sternum and the skin. Within the vacuum system, a strong negative pressure is created (−300 to −600 mmHg), so that the mediastinum cavity is sucked vacuum. The collecting bottle has a capacity of 600 ml and is replaced when it is full. This procedure is continued for at least 1 week. The complete system is removed only when culture of the drains does not show any bacterial growth.

ANTIBIOTIC THERAPY. Systemic antibiotic therapy was started after a sample was taken from the mediastinal space during the reexploration of the sternum. Initially, the antibiotic therapy was based on the results from a gram stain. When the type and susceptibility of the causative microorganism(s) was known, antibiotic therapy was further targeted to the most appropriate drug. Antibiotic therapy was administered during the first 2 weeks intravenously (sometimes intravenous therapy was extended) after which it was changed to oral administration. The total duration of the antibiotic treatment was at least 4 weeks.

Outcome and Evaluation Criteria

The primary parameter for the outcome was treatment failure, defined as reexploration of the sternal wound within 60 days after the drainage was applied. Reexploration included any surgical intervention with the intent to treat mediastinitis, such as debridement, reclosure, a different drainage technique or (muscle) flap reconstruc-

tion. Other criteria for the outcome were: total length of stay in hospital (from admittance to discharge), postoperative length of stay in hospital (after closed drainage application), and in-hospital mortality.

The following variables were scored for every patient: age; sex; chronic obstructive pulmonary disease (COPD); underlying diseases; New York Heart Association (NYHA) score; smoking; usage of immunosuppressive drugs; diabetes mellitis (a) insulin-dependent (IDDM), or (b) non-insulin-dependent (NIDDM); body-mass-index defined as weight/(length)^2; preoperative renal failure; previous cardiac surgery; emergency operation; type of operation; number of bypasses; and duration of operation, aorta occlusion, extra-corporal-circulation, and postoperative ICU-stay. The following postoperative complications were included: sepsis, septic shock, renal failure, need of dialysis, infection elsewhere (according to the CDC criteria).

Statistical Analysis

The results were analyzed using the Statistical Package for the Social Sciences (SPSS). The statistical significance of differences was determined using Student's *t* test, Fisher's exact test, or the chi-square test when appropriate. To determine dependence between risk factors, logistic and linear regression analyses were performed. A stratified analysis was performed to control for severity of mediastinitis and for presence of insulin-dependent diabetes. Relative risks and 95% confidence intervals were calculated. Statistical significance was accepted at p less than 0.05 (two-tailed).

Results

Patient Population

Between January 1, 1989 and January 1, 1997, 102 patients (0.89%) underwent reexploration because of a deep surgical site infection. Twenty-eight were excluded because open wound treatment was applied. In these patients, the sternum was completely necrotic and closure was not possible. Of the remainder, 14 additional patients did not fulfill the inclusion criteria (Fig 1). The final study population consisted of 60 patients, 29 who were treated with CI and 31 who were treated with VD (see Fig 1).

Patient Characteristics

Table 1 shows the patient characteristics in both groups. There were no statistically significant differences between the groups.

Surgical Procedures

Table 2 shows the variables related to the initial cardiac surgical procedure. No significant differences were found between both groups. Table 3 shows the variables related to the drainage procedure. In the group of patients treated with VD, there are significantly more patients with a mild mediastinitis (RR: 3.3, 95% CI: 1.2 to 8.8). Mediastinitis caused by *S aureus* was more frequent in the group of patients treated with CI, but the difference was not significant. Furthermore, Table 3 shows all six surgeons and their number and type of drainage procedure compared to the other surgeons. Surgeon D used the VD technique significantly more often compared to the other surgeons. Surgeon E and F used the CI technique significantly more often.

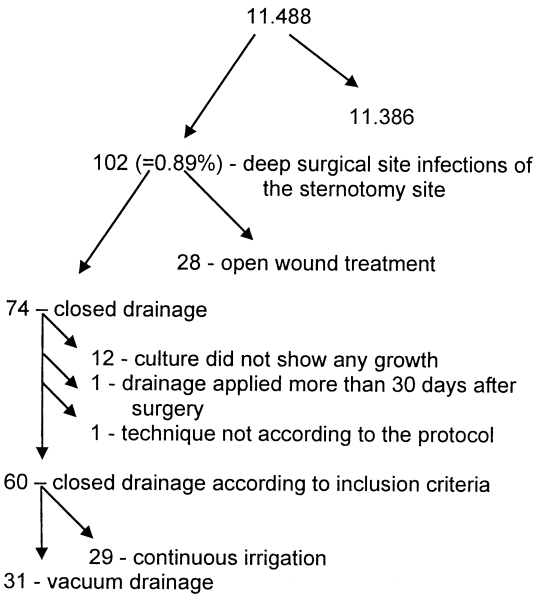

Fig 1. Study population.

Outcome

Table 4 shows the outcome in both groups according to the treatment method employed. Treatment failure occurred significantly more frequently in the group treated with CI (RR: 3.2, 95% CI: 1.3 to 7.7). Also, postoperative hospital stay and total hospital stay were significantly

Table 1. Patient Characteristics

	CI		VD		p
Variable	n	%	n	%	Value
Number of patients	29		31		
Sex is male	23	79	25	81	NS[a]
COPD	4	14	5	16	NS
Smoking	10	35	12	39	NS
Immunosuppressive drugs	2	7	2	7	NS
IDDM	6	20	2	7	NS
Underlying disease[b]	2	7	1	3	NS
	Mean	SD	Mean	SD	
Age	64.2	8.5	63.5	9.9	NS
NYHA score	3.3	0.7	3.2	0.8	NS
Body mass index	27.0	2.5	27.7	3.6	NS

[a] $p > 0.05$. [b] Rheumatoid arthritis, malignancy, renal disease.

CI = continuous irrigation; COPD = chronic obstructive pulmonary disease; IDDM = insulin-dependent diabetes mellitis; NS = not significant; NYHA = New York Heart Association; SD = standard deviation; VD = vacuum drainage.

Table 2. Variables Related to the Initial Cardiac Surgical Procedure

Initial Procedure	CI n	CI %	VD n	VD %	*p* Value
Emergency operation	7	24	7	23	NS[a]
Type of operation					
CABG with venous graft	9	31	12	39	NS
CABG with IMA[b]	19	66	16	52	NS
Valve replacement	1	3	2	6	NS
CABG and valve replacement	0	0	1	3	NS
	Mean	SD	Mean	SD	
Number of bypasses	3.3	1.2	3.4	1.6	NS
Duration of surgery[c]	236	84.4	256	99.8	NS
Aorta occlusion time[c]	62	23.3	72	31.9	NS
Extra corporal circulation time[c]	117	53.8	138	74.7	NS

[a] $p > 0.05$. [b] Left or right intermammary artery. [c] Duration in minutes.

CABG = coronary artery bypass grafting; CI = continuous irrigation; IMA = internal mammary artery; NS = not significant; SD = standard deviation; VD = vacuum drainage.

longer in patients treated with CI. There was no significant difference in the incidence of mortality between the 2 groups. Variables which were significantly associated with treatment failure were: *S aureus* as causative pathogen ($p = 0.04$), NYHA score ($p = 0.04$), and severity of mediastinitis ($p = 0.02$). The classification of mediastinitis according to El Oakley and Wright was not significantly associated with treatment failure [12].

Correction for Confounding Variables

As shown in Table 3, mild mediastinitis occurred significantly more frequently in the patients treated with VD. Also, *S aureus* was found less frequently in the group treated with VD. These and other variables may have influenced the outcome of treatment as well. To correct for possible confounding, logistic and linear regression analysis were performed. The following variables were entered into the model: surgeon, insulin-dependent diabetes mellitus (IDDM), COPD, severity of mediastinitis, treatment method (CI or VD), sex, age, number of bypasses in the initial procedure, *S aureus* as causative pathogen, and NYHA score. For treatment failure, logistic regression analysis was performed. The only independent, statistically significant variable was the treatment method performed (RR: 11.1, 95% CI: 1.0 to 119.1; $p = 0.04$). For the total duration of hospital stay and the postoperative hospital stay, linear regression analysis was performed. None of the variables was significantly related to prolongation of hospital stay nor to prolongation of postoperative stay. The only variable which approached significance with regard to postoperative stay in the hospital was *S aureus* as causative pathogen ($p = 0.088$). A stratified analysis was done to provide more insight into the effect of the severity of mediastinitis and IDDM. First, in the group with mild mediastinitis, no significant difference in treatment failure was found between CI and VD (25.0% and 14.3% respectively, RR: 1.8, 95% CI: 0.2 to 14.7; $p = 1.0$). In the group of moderate or severe mediastinitis, a significant difference between CI and VD was found, with treatment failure rates of 56.0% and 17.6%, respectively (RR: 3.2, 95% CI: 1.1 to 9.3; $p = 0.024$). The same analysis was performed for patients without IDDM. Two patients in the group with VD had IDDM and none had a treatment failure, whereas 4 of the 6 patients (66.7%) treated with CI had a treatment failure ($p > 0.05$). In the group without IDDM, a significant difference in treatment failure was found between both therapies (47.8% versus 17.2%, RR: 2.8, 95% CI: 1.1 to 6.8; $p = 0.033$).

Comment

Our study shows that the VD system is the initial therapy of choice for patients with mediastinitis as soon as it is detected after cardiac surgery because it results in significantly less treatment failure and a shorter duration of stay in the hospital. In a recent review [12], it is concluded that a closed drainage technique is the therapy of choice for a patient with mediastinitis which develops within 2 weeks after the initial surgical procedure. Which closed drainage technique is to be preferred is not mentioned. Calvat and associates [16] also made a comparison between the two closed drainage techniques CI and VD. In this study, VD had a favorable outcome compared to CI. The mortality in the intensive care unit was significantly lower (17% and 40%, respectively, $p = 0.01$), treatment failure was significantly lower (13% and 53%, respectively, $p = 0.0001$), and mean length of stay in the intensive care unit was comparable (28 and 30 days, respectively, $p > 0.05$). Compared to our study, the failure rates of CI and VD are comparable to that of

Table 3. Variables Related to the Drainage

Variable	CI n	CI %	VD n	VD %	*p* Value
Severity mediastinitis					
Mild	4	14	14	45	0.01[a]
Moderate	21	72	13	42	NS[c]
Severe	4	14	4	13	NS
Result of culture					
S aureus	20	69	14	45	NS
Drainage surgeons					
A	4	14	6	19	NS
B	1	3	4	13	NS
C	4	14	2	7	NS
D	1	3	18	58	< 0.0001[b]
E	7	24	0	0	0.004[b]
F	12	42	1	3	0.003[b]

[a] Mild compared with moderate and severe together. [b] This surgeon compared with all other surgeons. [c] $p > 0.05$.

CI = continuous irrigation; NS = not significant; VD = vacuum drainage.

Table 4. Outcome Associated With Treatment Method

Variable	CI		VD		*p* Value
	n	%	n	%	
Death	2	6.9	2	6.5	NS[a]
Treatment failure	15	52	5	16	0.006
	Mean	SD	Mean	SD	
Postoperative hospital stay[b]	42	21.9	29	26.0	0.03
Total hospital stay[c]	56	22.0	42	26.0	0.03

[a] $p > 0.05$. [b] Days after closed drainage technique. [c] Total number of days of admission in the institute.

CI = continuous irrigation; NS = not significant; SD = standard deviation; VD = vacuum drainage.

Calvat and colleagues, but the mortality in our study group is much lower (less than 7% in both groups).

There are no other comparisons between CI and VD reported in the literature. Molina describes a closed irrigation-suction system [17]. This is a combination of CI and VD. In this study, there was neither mortality nor treatment failure, but there is no information regarding the severity of the infection or the condition of the patient. Therefore, these results cannot be compared with other studies. In a Turkish study, CI is compared to a simple technique, leaving drains in the mediastinum after closure [18]. Hospital mortality was high in both groups, overall 16.4%, and hospital stay showed no significant difference. This study did not correct for confounding. In conclusion, our study confirms the results of the only other study which compared CI and VD, and is the only study which corrected for confounding variables.

A major point of criticism on this retrospective study is the comparability of the two groups. The favorable outcome of the patients treated with VD may be caused by other factors than the treatment method employed. Ideally a prospective, randomized, double-blind study should be performed. However, this would take a long time to include sufficient numbers of patients. Moreover, a double-blind study is not possible. Therefore, a retrospective study was performed. To improve the value of the analysis, a number of baseline characteristics, surgical procedures, and other possible confounders were included and corrected for. Furthermore, objective outcome variables were choosen. In the univariate analysis, treatment failure was more than three times as likely in patients treated with CI compared to those treated with VD. Also, patients treated with CI had a significantly longer total duration of hospital stay and postoperative duration of hospital stay. Therefore, the conclusion is that VD is to be preferred over CI. However, other variables were also associated with treatment failure and prolongation of hospital stay. The severity of the infection at the time of reoperation was significantly associated with treatment failure. Moreover, moderate to severe mediastinitis were statistically significant more frequently in the group treated with CI. Therefore, the observed better outcome of patients treated with VD may have been caused by a difference in the patient groups rather than a difference in the effect of the therapy employed. Similarly, IDDM is a known risk factor for a severe course of infections, in general. In the group treated with CI, there were more patients with IDDM, although not statistically significant. These and other variables may have influenced the outcome of this study. Therefore, multivariate analysis using logistic and linear regression analysis was performed. This analysis revealed that the treatment method employed was the only statistically significant, independent variable associated with treatment failure. After correction for confounding, none of the variables was significantly associated with total, or postoperative, hospital stay.

Multivariate analysis is a good and reliable method to correct for possible confounders. However, for many people it is still a "black box" of statistics. To provide more insight into the effect of the severity of mediastinitis and IDDM, a stratified analysis was performed on the group of patients with a mild mediastinitis only, and on those with moderate or severe mediastinitis. It is clear from this analysis that the effect of the treatment method employed is of no, or minor, importance for patients with a mild mediastinitis. On the other hand, the effect is even stronger for patients with moderate or severe mediastinitis. The analysis performed for patients with, and for patients without, IDDM showed that IDDM may modify the effect of the treatment method employed but, even in patients without IDDM, there was a significant difference in favor of VD. Therefore, the conclusion is that VD is to be preferred over CI because it is associated with a significantly better outcome.

If a closed drainage therapy fails or if mediastinitis presents in a late phase at least 2 weeks after primary cardiac surgery when the sternum is completely necrotic, only a few therapeutic options are left. Open wound treatment with frequent change of povidone-iodine packings is a possible treatment. Open wound treatment is a simple technique, but is not preferred because of the major associated risks, including superinfection, fatal hemorrhage, and prolonged hospital stay [19, 20]. Delayed closure with muscle or omental flap can be done. Flap reconstruction reduces morbidity, mortality, and hospital stay, but is associated with chronic pain, numbness, and weakness in 30% to 50% [21].

The overall rate of deep surgical site infection or

mediastinitis in our population was low (0.89%). Other studies have reported deep surgical site infection rates up to 5% [4–6, 22, 23]. The mortality was also low (6.7%) compared with previous reports (10% to 29%) [5, 8, 9]. The mean duration of hospital stay in patients with mediastinitis was 42 days in patients treated with VD and 56 days for patients treated with CI. In patients without infection, the mean duration of hospital stay was 8 days [23]. Therefore, mediastinitis is a rare complication after cardiac surgery in our institute but its consequences are serious. Although the mortality is relatively low, the prolongation of hospital stay and its associated costs are impressive (34 days with VD, and 48 days with CI). Therefore, it is important to improve prevention of mediastinitis and its treatment methods. This study shows that the VD system is the therapy of choice for patients with mediastinitis, especially those with moderate and severe mediastinitis. It is a fast and simple method. At the same time, the comfort of the patient is better and it has a good cosmetic result.

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