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Novel, digital, chest drainage system in cardiac surgery

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Abstract

Background: A new, self-contained, digital, continuous pump-driven chest drainage system is compared in a randomized control trial to a traditional wall-suction system in cardiac surgery.

Methods: One hundred and twenty adult elective cardiac patients undergoing coronary artery bypass graft and/or valve surgery were randomized to the study or control group. Both groups had similar pre/intra-operative demographics: age 67.8 vs 67.0 years, Euroscore 2.3 vs 2.2, and body surface area 1.92 vs 1.91 m^2. Additionally, a satisfaction assessment score (0-10) was performed by 52 staff members.

Results: Given homogenous intra-operative variables, total chest-tube drainage was comparable among groups (566 vs 640 mL; ns), but the study group showed more efficient fluid collection during the early postoperative phase due to continuous suction ($P = .01$). Blood, cell saver transfusions and postoperative hemoglobin values were similar in both groups. The study group experienced drain removal after 29.8 vs 38.4 hours in the control group (ns). Seven crossovers from the Study to the Control group were registered but no patient had drain-related complications. The Personnel Satisfaction Assessment scored above 5 for all questions asked.

Conclusions: The new, digital, chest drainage system showed better early drainage of the chest cavity and was as reliable as conventional systems. Quicker drain removal might impact on intensive care unit (ICU) stay and reduce costs. Additional advantages are portable size, battery operation, patient mobility, noiseless function, digital indications and alarms. The satisfaction assessment of the new system by the staff revealed a higher score when compared to the traditional wall suction chest drainage system.

KEYWORDS

cardiac surgery, chest drainage, postoperative care

Abbreviations: ACT, activated clotting time; CABG, coronary artery bypass graft; CPB, cardio-pulmonary bypass; ITT, intention to treat; ICU, intensive care unit; OR, operating room; PP, per protocol; POD, post operative day; RCT, randomized control trial.

This work was presented in the meetings: ATCSA 2017, Melbourne: Do We Still Need Wall Suction for Chest Drainage? and ESCVS 2018, Strasbourg: Benefits for Patients & Healthcare Providers Using a Novel, Self-Contained Chest Drainage System Assessed in a RCT.

1 | INTRODUCTION

Chest drainage has been introduced historically after the first pioneering pulmonary and cardiac operations and since then the water seal chest drainage system has been used without major improvements especially in cardiac surgery. Most patients undergoing cardiac surgery will receive one or more chest tubes to drain the blood of the pericardial and pleural cavities and therefore reduce morbidity and mortality.[1-3] Some limitations include a bulky, noisy 3-chamber container with a water seal requiring wall suction making mobilization and ambulation of the patient difficult.

In recent years research efforts have developed new self-contained chest drainage systems which are battery-operated, therefore providing continuous suction from the operating room to chest-tube removal thus improving patient mobilization. Additionally, air leaks and fluid levels are recorded digitally, alarm functions such as tube clotting or massive air leak have also been included and finally the draining tube is flushed by air on a regular basis to prevent stagnant blood or clotting. This system has been widely used in over 1 million patients worldwide following thoracic surgery with excellent results and positive feedback from patients and professional healthcare providers.[4-6]

The aim of our study was to assess the efficacy and safety of this novel, self-contained, digital, continuous pump-driven chest-drainage system, compared to a conventional drainage system, in a randomized controlled trial (RCT) with the following end-points: (a) postoperative chest drainage; (b) drainage-related complications; (c) patient's mobilization and outcome; (d) personnel's satisfaction evaluation.

2 | MATERIALS AND METHODS

2.1 | Study plan

The THOPAZ$^+$ self-contained drainage system from Medela, Switzerland, was used (study group) and compared to the conventional wall suction chest drainage systems from Argyle Aqua-Seal, Covidien, USA (control group) which was the standard of care at the University Hospital in Verona. The study duration ranged from surgery to discharge from the cardiac ward.

The protocol was approved by the Ethics Committee of the University of Verona (No. 584CESC). All patients were informed by the treating physician, received an information sheet and signed a dedicated consent form.

2.2 | Randomization

Patients were allocated (block randomization) to either the traditional suction system (control group: n = 60), or the THOPAZ$^+$ (study group: n = 60) after surgery, just before the OR nurse opened the drainage system. Thus, the surgical team was blinded to the suction system during the surgery.

2.3 | Patient population

The patient population consisted of 120 adults (18-80 years), elective, first-time coronary artery bypass (CABG), or valve surgeries and/or combined procedures. Exclusion criteria were unstable angina, emergency procedures, off-pump surgery, reoperation, and anticoagulation or antiplatelet therapy (except aspirin cardio) until surgery. All operations were carried out on cardio-pulmonary bypass (CPB) and were standardized regarding anticoagulation (ACT target: 480 seconds), mildly hypothermic temperature management and blood transfusions (trigger < 10 g/L hemoglobin). Normally Argyl chest tubes size 36 to 40F were used in the pericardial/retro-sternal space and, if needed, in the pleural space. Patients requiring more than two drains was an exclusion criteria to simplify the study. The suction level was set at −20 cmH_2O for both systems. Chest drains were removed on POD-1 using the following criteria: fluid loss lower than 120 mL during the last 6 hours and no air leak. A chest x-ray was performed after chest tube removal.

2.4 | Data collection

Data concerning CPB, heparin, and protamin dosage, blood transfusions, hematologic laboratory values were collected at predefined time points (pre-op, post-op, intensive care unit (ICU) arrival and ICU + 6 hours, POD 1, and discharge). Chest drainage was collected rigorously at the following time points: chest closure, end of OR before and after transport (transport with or without suction), on ICU (the drainage level was taken half-hourly for the first hour, then hourly), POD1, and at chest-tube removal.

Chest drain-related events such as air leak, tube disconnection, clotting, fogarty procedure, or exchange of drainage tubes were recorded. Additionally, in the Medela group, alarms (tube occlusion, massive air leakage, massive fluid leakage, canister full, clogged filter, low battery) were also logged.

Intra-operative and postoperative events such as excess bleeding, hemodynamic instability, transfusions, pneumo-thorax, drainage of pleural/pericardial effusions, operation for tamponade, and/or re-operation for bleeding were also noted.

2.5 | Personnel's satisfaction evaluation

User-related data included physicians' and nurses' feedback only for the digital as compared to the conventional chest drainage systems. This was assessed with a short, internet-based visual analog scale (from 0 to 10) which was completed by 52 staff members and included the following questions: Ease of use of the device; Ease of patient care with regard to digital data collection; Usefulness during transport of patients; Ability of the patient to move around; Noise reduction; Time saving; Security for patients (eg, continuous suction); Usefulness of the alarms. The noise reduction was assessed in a few patients who were in isolation rooms on the ICU for the two drainage systems with a decibel sound level meter (I-Phone).

2.6 | Statistical evaluation

The results of the study are expressed as mean values ± standard deviations. The primary and continuous secondary endpoints were compared using *t* test if the distribution is normal and the Mann-Whitney U test otherwise. Categorical endpoints were compared using the χ^2 test or Fisher exact test. Analyses were carried out using intention to treat (ITT) and per protocol (PP). Evolution of clinical characteristics over time was examined using linear mixed models, the Wilcoxon rank sum test, and graphical analyses. User-reported outcomes (eg, ease of use of the device) were presented using graphical analyses.

3 | RESULTS

After the introduction of the new THOPAZ$^+$ chest drainage system to the personnel of the operating room, ICU and ward, the clinical trial was initiated. One hundred and twenty patients were enrolled and after 30 study group patients, on nurses' and physicians' request, a short silicone tube was inserted between the chest tubes and the Medela suction tube to allow for optional milking.

3.1 | Patient demographics

The majority of all patients were men with a mean age of 67.8 for the study group and 67.0 years for the Control Group. Also, body surface area values were similar (1.92 vs 1.91 m^2). The Euro Score was relatively low for both groups (2.3 vs 2.2) and the risk factors were representative of patients requiring elective cardiac surgery. Half of the patients had anti-coagulation up to 2 days before surgery. Surgery included mainly valves followed by CABG. Interestingly, although not significant, in the Study group there were more patients undergoing double procedures (12 vs 5) (Table 1).

3.2 | Operative procedures

None of the following operation-related findings showed differences between the two groups, i.e. cardiopulmonary bypass and clamping times, core temperature, heparin and protamine dosage as well as cell saver and blood transfusions (Table 1).

3.3 | Chest-tube drainage and hemoglobin values

The size and numbers of chest tubes did not differ between the two groups. There was a significantly higher drainage in the study Group at the end of the operation before transport and on arrival in the ICU ($P < .01$). Thereafter there were no more differences in chest-tube drainage. It should be noted that the mean time during which there was no suction in the Control Group during the transport from the OR to the ICU was 11.5 minutes. Although statistically not significant, the total time of chest drainage was shorter by 9-hours in the Study Group (29.8 vs 38.4 hours; $P = .19$), which may explain why the total drainage, although not significant, was slightly lower in that Group (536.4 vs 640.7 mL; $P = .78$) (Table 2; Figure 1).

The requirement of blood products did not show significant differences between the study and control groups and red blood cell transfusions were required in half of the operated patients. The patients' hemoglobin levels were similar pre-operatively, at the end of surgery and on chest-tube removal. There were no tamponades or chest-tube related complications. Two patients in the control group and three patients in the study group had to be reoperated for bleeding. There were seven crossovers from the study to the control group, two for massive air leak (Medela reservoir not connected correctly), two after reoperation for bleeding and three for surgeons' preference. After modification of the chest drainage tubing by inserting a short silastic tubing to allow optional milking there were no more crossovers in the Study group.

TABLE 1 Patient demographics and operative procedures

Patient demographics			
Characteristics	**Study group N = 60**	**Control group N = 60**	***P***
Sex (male)	46 (76.7%)	36 (60.0%)	.08
Age (y)	67.8 (10.3)	67.0 (10.4)	.77
Euroscore	2.3 (1.9)	2.2 (2.1)	.32
BSA (m^2)	1.92 (0.22)	1.91 (0.20)	.43
Total No of risk factors	2.08 (1.32)	1.93 (1.32)	.46
Anticoagulation, N(%)	31 (51.7%)	30 (50.0%)	.00
Anticoagulation: No. of days stopped before surgery	1.63 (1.94)	1.72 (1.93)	.80
Operative procedures			
Aorta clamping (min)	72.1 (32.9)	75.0 (33.8)	.70
CPB duration (min)	95.1 (38.4)	101.0 (42.1)	.58
Surgery duration (min)	253.0 (65.3)	259.3 (81.5)	.81
Lowest temperature (°C)	35.2 (0.9)	34.9 (1.2)	.10
Total Heparin dose (mg)	322.9 (71.7)	316.1 (70.2)	.65
Total Protamin dose (mg)	287.9 (75.8)	318.3 (86.3)	.08
Cell saver transfusion (mL)	250.1 (208.3)	204.9 (200.1)	.18
RBC transfusion, N (%)	28 (46.7%)	32 (53.3%)	.58
FFP transfusion, N (%)	9 (15.0%)	10 (16.7%)	1.00
PLT transfusion, N (%)	2 (3.3%)	2 (3.3%)	1.00
No. of days until dismissal	8.7 (5.6)	9.2 (4.8)	.60

Note: Intention to treat analysis: N(%) or mean values ± standard deviation.

Abbreviations: BSA, body surface area; CPB, cardio-pulmonary bypass; FFP, Fresh Frozen Plasma; PLT, Platelets.

TABLE 2 Chest drainage & hemoglobin levels

Chest drainage & hemoglobin levels			
Characteristics	**Study Group N = 60**	**Control Group N = 60**	***P***
Chest drainage (mL): End OR	24.8 (36.6)	14.8 (25.0)	.06
Chest drainage (mL): Before transport	55.6 (60.7)	33.3 (45.3)	.006
Chest drainage (mL): ICU arrival	81.1 (78.6)	55.0 (60.2)	.01
Chest drainage (mL): ICU + 6 h	280.2 (218.7)	254.5 (298.3)	.12
Chest drainage (mL): ICU + 24 h	476.1 (275.4)	508.8 (483.1)	.45
Total chest drainage (mL)	536.4 (321.8	640.7 (675.3)	.78
Duration of chest drainage (h)	29.8 (15.2)	38.4 (23.7)	.19
Hemoglobin pre-op	13.5 (2.0)	13.5 (1.5)	.61
Hemoglobin post-op	10.2 (1.3)	10.1 (1.3)	.66
Hemoglobin at ICU + 6 h	11.5 (1.2)	11.6 (1.2)	.55
Hemoglobin at chest-tube removal	11.4 (1.3)	11.3 (1.8)	.83

Note: Intention to treat analysis: N(%) or mean values ± standard deviation.
Abbreviation: ICU, intensive care unit.

Results were not statistically different when excluding the 7 crossover patients from the study group as shown in Figure 1 (dashed line with triangle), though patients who switched from the study to the control group clearly had increased loss of chest drainage (dotted line with plus).

3.4 | Personnel satisfaction evaluation

The web-based Satisfaction Assessment Questionnaire was carried out halfway through the prospective randomized study by 52 healthcare professionals of the Verona Team, namely: 12 ICU nurses, 10 OR nurses, 16 ward nurses, 8 surgeons, and 6 cardiac anesthetists. The satisfaction with the THOPAZ$^+$ pump was overall high and did not differ much across professions though the nurses were a little less positive. Interestingly, the use of the THOPAZ$^+$ pump for the transport and the noise reduction scored highest. The decibel sound level of patients in isolation in the ICU ranged around 35 dB for the THOPAZ+ and around 65 dB for the conventional chest drainage system with wall suction (Supporting Information file) (Figure 2).

4 | DISCUSSION

In the perioperative care of cardiac patients, chest-tube drainage plays an important role for avoiding pneumo-thorax and/or tamponade. For the last 50 years no significant improvements have been made to the 3-chamber suction system until digital drainage systems were introduced into thoracic surgery[4-6]; we now report in this prospective, randomized study about the comparison between the new, digital chest drainage system THOPAZ$^+$ and the conventional system in 120 cardiac surgical patients. This study compared 60 patients in each group and was able to answer several questions, but other larger studies would be needed to conclude that this device is very helpful with the postoperative chest tube drainage.

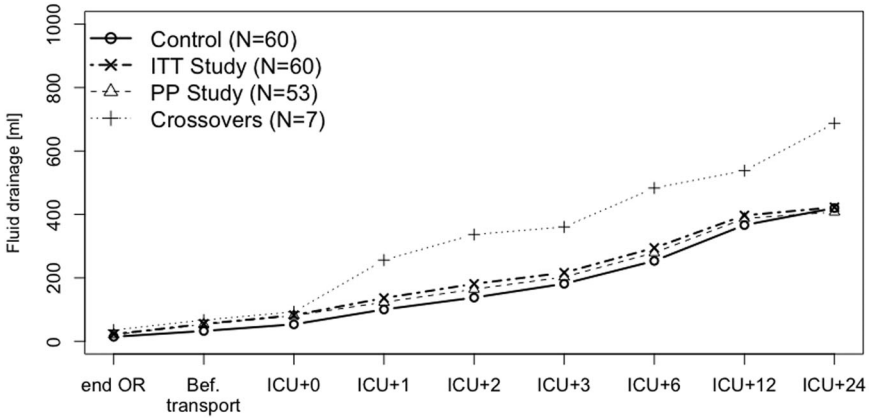

FIGURE 1 Chest-tube drainage for the Control (n = 60) and Study (n = 60) groups of the intention to treat (ITT) analysis during the first 24 hours. Also shown are the Study group (n = 53) and the 7 crossovers of the per protocol (PP) analysis. x-axis: time points in hours; y-axis: cumulative chest drainage quantity

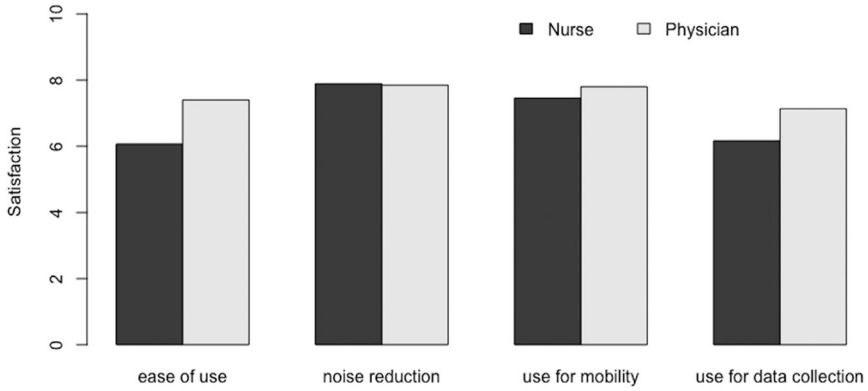

FIGURE 2 Personnel satisfaction evaluation was only performed in the digital (study group) as compared to the conventional (control group) chest drainage system. Results are expressed for the visual analog scale as: 0-bad, 10-optimal for the following questions asked according to the professional health status (nurses and physicians; n = 52): Ease of use of the device; Noise reduction; Ability of the patient to move around; Ease of patient care with regard to digital data collection

The drainage capacity of both systems was equal. However, during transportation the study group showed a significantly higher blood drainage due to its continuous drainage until arrival on the ICU. This was not the case with the conventional system since the suction was interrupted for a mean time of 11.5 minutes, meaning that some patients had much longer duration without chest tube suction after surgery. Even the small drainage volume differences may have a significant impact on the patient since clots can form in the pericardial sac leading, in the worst case, to tamponade. In a recently published retrospective study, including 265 patients, there was also a significantly higher drainage with the digital device during the first 6 postoperative hours.[7] However, our study was underpowered to evaluate the effect of our drainage systems on the incidence of tamponade which is varying from 1% to 4% according to the detection method used for tamponade diagnosis.[8,9]

Our randomized trial confirmed the positive findings that there were no chest-tube related safety issues for the patients. Five patients required reoperation for bleeding (three in the study group and two in the control group), leading to crossovers from the study group to the control group in two cases ("intention to treat" evaluation: Figure 1). The incidence of reoperation for bleeding was therefore 4% which is comparable to the literature that also shows a negative impact on the outcome, which was not the case in our patients.[2,10,11] Froid and Jeppsson[3] conclude that excessive bleeding leading to re-exploration is associated with a twofold increased early postoperative mortality rate.

A total of 7 crossovers were found in the 60 study patients; Two, as mentioned above for reoperation for bleeding, two suffering massive air leak due to lack of proper device handling between the Medela pump and the collecting reservoir which was signaled by an alarm, and three for surgeons' choices, feeling that the drainage of the new system was not adequate. Therefore, halfway through the study we introduced a short silastic tube between the chest-tube(s) and the connector of the Medela drainage tube to allow for optional milking which was used similarly as in the control group, thus the THOPAZ$^+$ venting of the drainage line was still operational; following this modification no more crossovers were noted.[12] Saha et al[7] reported in their retrospective study a significantly higher incidence of blood clotting mainly at the level of the connector from the chest tube to the THOPAZ$^+$ drainage tube (6.5%; $P < .04$). We observed no blood clotting in the tubing in our study group and this might be due to the optional milking of the silastic tubing.

Interestingly, in the study group we found a nonsignificant time difference of 9 hours in the ITT and 6 hours in the PP analysis to chest-tube removal compared to the Control group. This has certainly a major impact on the patients' recovery since mobilization and ambulation is earlier.[4,13,14] Early chest-tube removal impacts also favorably on pain and pulmonary function.[15,16] Additionally, this could also have an impact on the cost especially by reducing the time on ICU. Many centers keep patients under ICU conditions until chest tube removal. However, this was not the case in Verona since patients are transferred to the ward with chest tubes and there was no significant difference in length of hospitalization of both groups. This may also be an advantage when using the THOPAZ$^+$ drainage system since no wall suction is required and alarms are provided. Van Linden et al[17] reported in a similar study to ours of a significant time difference in chest drainage duration of 16 hours (digital: 49 vs analog: 65 hours; $P < .01$), but no difference in drainage volume, hospital or ICU length of stay. They found however a reduction of drainage-associated complications such as a lower incidence of chest x-rays to detect air leaks with the digital drainage system.[17]

Other advantages which were clearly described in the personnel Satisfaction Assessment were ease of use, benefits during transport and mobilization and the comfort for the patient and staff due to the silent operation of the THOPAZ$^+$ pumps.[6] The digital recording of air leaks, which are seldom after cardiac surgery, is of major importance and can guide the therapy and save cost and time for performing serial chest X-rays.[17] Similarly, the digital fluid recording and trend analysis helps the medical team to make decisions as to when to remove the chest tubes.[5] This effect has been confirmed by the trend of a shorter chest drainage duration (9 hours) in the Study group compared to the Control Group and other authors.[17]

Importantly, the alarms implemented on the THOPAZ$^+$ system (tube occlusion, massive air leakage, massive fluid leakage, canister full, clogged filter, low battery) can be life-saving for the patient,

especially when considering a disconnection of the tubing with a massive air leak or a drainage tube occlusion with the possibility of clot formation leading to a tamponade.[8]

Finally, in view of the current COVID-19 pandemic, several issues about the viral aerosol spread of patients who require chest tubes have been raised through CTS Net: COVID-19 Chest Drains with Air Leak—The Silent "Super Spreader?" [https:www.ctsnet.org]. After checking with the manufacturing company of THOPAZ$^+$ we were informed that the above mentioned problem should be reduced since the device has an integrated bacterial filters. However, filtering out of all virus particles is not guaranteed.

5 | CONCLUSION

The new, self-contained, digital, continuous pump-driven drainage system showed more efficient drainage of the chest cavity during transportation from the OR to the ICU and was as reliable as conventional systems. Quicker drain removal might impact on ICU stay and reduce costs. Additional advantages are portable size and autonomous battery operation (ie, allowing earlier patient mobility), noiseless function, digital indications, and alarms. The satisfaction assessment of the new system by the staff revealed a higher score when compared to the traditional wall suction chest drainage system.

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CONFLICT OF INTERESTS

Delphine S. Courvoisier and Beat Walpoth have a consultancy agreement with Medela AG, Switzerland. The authors had freedom of investigation and full control of the design of the study, methods used, outcome parameters and results, analysis of data, and production of the written report.

AUTHOR CONTRIBUTIONS

LB: study design, data collection, data analysis, data interpretation, manuscript draft and revision. LSB: data collection, MM: data collection, DC: data analysis, data interpretation. BHW: study design, data analysis and interpretation, manuscript draft and revision. GF: study design, overall study revision. All authors have read and approved the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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