

# Randomized Controlled Trial of a Novel, Digital, Chest Drainage System in Cardiac Surgery Patients

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## Research article

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## Abstract

Background: A new, self-contained, digital, continuous pump-driven chest drainage system is compared for the first time in a Randomized Control Trial to a traditional wall-suction system in cardiac surgery.

Methods: 120 adult elective cardiac patients undergoing CABG 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 BSA 1.92 vs. 1.91 m<sup>2</sup>. Additionally, a satisfaction assessment score 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 post-operative phase ( $p = 0.006$  and  $p = 0.01$ ) due to continuous suction compared to 11.5 minutes off-suction time in the control group. Blood, cell saver transfusions and post-operative 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.

Conclusion: The new, self-contained, digital, continuous pump-driven drainage system showed better early drainage of the chest cavity and was as reliable as conventional systems. Quicker drain removal might impact on 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. This Randomized Control Trial was retrospectively registered on June 7, 2019 under ISRCTN 14884587. <https://doi.org/10.1186/ISRCTN14884587>

## Background

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 [1,2,3]. There is a great variety of drainage systems and chest tubes and their sizes range from the classical Argyle to more sophisticated tubes such as Blake in order to increase the drainage fluid and reduce the drainage time [4]. Some limitations include a bulky 3-chamber container with a water seal requiring that the system remains upright and making mobilization and ambulation of the patient difficult. Additionally, wall suction is recommended and the system is quite noisy.

In recent years research efforts have developed new self-contained chest drainage systems to replace the wall suction. Such a system has the advantage to be 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 [5,6,7,8]. In order to assess the new and CE-marked drainage system for cardiac surgical patients we planned a large single-centre study. Prior to enrolling patients the physicians and nursing staff of the departments of cardiac surgery, anaesthesiology and intensive care underwent a teaching phase which included several patients for assessing clinically the drainage system and the feasibility to carry out a large-scale study.

The aim of our study was to assess the efficacy of such a novel, self-contained, digital, continuous pump-driven chest-drainage system, compared to a conventional drainage system, in a randomized controlled study (RCT).

## Methods

*Study Plan:* The THOPAZ<sup>+</sup> 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. It was carried out (including randomization, data retrieval, computer entry, assessment, statistics and writing of a final report and a publication) by the cardio-surgical team of the University of Verona. The study planning and statistical evaluation were carried out with the help of the University of Geneva. The protocol was approved by the Ethics Committee of the University of Verona (No. 584CESC) on 28.07.2015. All patients were informed personally by the treating physician that they were enrolled in an RCT comparing the Medela chest drainage system, which had been used in thousands of patients for thoracic drainage, to the conventional drainage system. All patients received an information sheet and signed a dedicated consent form. This Randomized Control Trial was retrospectively registered on June 7, 2019 under ISRCTN 14884587.  
<https://doi.org/10.1186/ISRCTN14884587>

All the chest drainage systems and THOPAZ<sup>+</sup> pumps for the Medela group were provided by Medela, Switzerland. The teaching for using the new THOPAZ<sup>+</sup> pumps by the medical team (physicians and nurses) of Verona was carried out by a trainer from Medela.

*Randomization:* Patients were allocated to either the traditional suction system ( $n = 60$ ) or the THOPAZ<sup>+</sup> ( $n = 60$ ) using block randomization, with blocks of 4 or 6 (block size is also random). Group allocation were put into sealed envelopes, and opened after surgery, just before the OR nurse opened the drainage system. Thus, the surgical team were blinded to the suction system during the surgery.

*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, re-operation and anti-coagulation or anti-platelet therapy (except aspirin cardio) until surgery. All operations were carried out on cardio-pulmonary bypass (CPB) and were standardized regarding anticoagulation (ACT target: 480 secs), mildly hypothermic temperature management, blood transfusions (trigger <10g/L haemoglobin). Normally Argyl chest tubes size 36–40F were used in the pericardial/retro-sternal space and, if needed, in the pleural space. Patients requiring more than 2 drains was an exclusion criteria to simplify the study. The suction level was set at –20cm H<sub>2</sub>O for both systems. Chest drains were removed on POD 1 (24 –26 hrs after surgery) using the following criteria: fluid loss lower than 120 mls during the last 6 hrs and no air leak. A chest x-ray was performed after chest tube removal.

#### *Data Collection:*

Data concerning CPB, heparin and protamin dosage, blood transfusions, hematologic laboratory values were collected at pre-defined time points (pre-op, post-op, 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. At the end of use of a THOPAZ<sup>+</sup> system (after removal of all chest tubes) the stored data of the Medela system regarding the device and the patient were downloaded onto a computer for review and statistical analysis. Such information ranged from when the drainage canister was changed to the timing and nature of all the alarms.

Intra-operative and post-operative 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.

## **PRIMARY AND SECONDARY OUTCOMES**

The primary endpoint of our study is drainage capacity as measured by total blood in ml accumulated by the drainage systems.

As secondary end points, patient-related complications which might be in connection with the chest drainage, e.g. tamponade, were recorded. Comfort for the patient during mobilization and ambulation was also considered (see below).

## **Satisfaction Evaluation**

User-related data included physicians' and nurses' feedback. 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 data collection; Usefulness during transport of patients; Ability of the patient to move around; Noise reduction; Time saving; Security for patients (e.g. continuous suction); Usefulness of the alarms. Additionally: How frequently do you use milking?; How frequently were the alarms useful?; How useful is the digital information on the screen (e.g. trends)? All analyses were descriptive.

*Sample size:* Based on a pilot study of the new drainage system, we expect the total blood drainage to be 610ml with the new system and 460ml in the usual suction system, with a standard deviation of 260 ml. With an alpha of 5% and power of 80%, 96 patients are required to have an 80% chance of detecting, as significant at the 5% level, an increase in total blood drainage of 150ml.

*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 Mann-Whitney U test otherwise. Categorical endpoints were compared using Chi-square 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, Wilcoxon rank sum test, and graphical analyses. User-reported outcomes (e.g., ease of use of the device) were presented using graphical analyses.

## Results

After the introduction of the new THOPAZ<sup>+</sup> chest drainage system to the personnel of the operating room, ICU and ward, the clinical trial was initiated. 120 Patients were enrolled between September 2015 and June 2016. After 30 Study Group patients, on nurses' and physicians' request, a soft silicone tube was inserted between the chest tubes and the Medela suction tube in order to allow for milking which is standard practice after cardiac surgery. The trial stopped upon completion of the required sample size.

## Prospective Randomized Study

*Patient Demographics:* The majority of all the patients were men with a mean age of 67.8 for the study group and 67.0 for the Control Group. Also BSA values were similar (1.92 vs. 1.91). The Euro Score was relatively low for both groups (2.3 vs. 2.2) and the risk factors were representative of patients requiring cardiac surgery. Half of the patients had anti-coagulation up to two days before surgery (Tables 1 and 1S). 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).

*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. (Tables 1 and 1S).

*Chest-tube Drainage and Haemoglobin 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 ( $p < 0.01$ ). (Tables 2 and 2S, Figure 1). 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, it was noted that the total time of chest drainage was shorter by 9-hours in the Study Group (28.9 vs. 38.4 hrs;  $p = 0.19$ ), which may explain why the total drainage, although not significant, was slightly lower in that Group (536.4 vs. 640.7 ml,  $p = 0.78$ ).

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 (Tables 1 and 1S). The patients' haemoglobin 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 3 patients in the study group had to be re-operated for bleeding. After the re-operation a conventional chest drainage system was used in two of the study group patients that represent cross-overs from the study group to the control group. Additionally, there were 5 crossovers from the study to the control group, 2 for massive air leak (Medela reservoir not connected correctly) and 3 for surgeons' preference. After modification of the chest drainage tubing by inserting a short silastic tubing to allow milking there were no more crossovers in the Study Group. For crossover patients, comparing before and after insertion of the silicone tube, using Fisher exact test, the p-value to test if the change decreased the number of crossovers was 0.01.

Results were very similar when excluding the 7 crossover patients from the study group. In particular, the randomization remained efficient, with patients and operative characteristics at baseline similar between both groups (Tables 1 and 1S). Similarly, evolution of the clinical characteristics in the PP sample was very similar (Tables 2 and 2S, and Figure 1, dashed line with triangle), though patients who switched from study to control clearly had increased loss of chest fluid (Figure 1, dotted line with plus).

## Satisfaction Analysis

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<sup>+</sup> 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<sup>+</sup> pump for the transport and the noise reduction scored highest (Figure 2).

Two additional questions were asked regarding the frequency of the alarms of the THOPAZ<sup>+</sup> pump which was described by one third of the staff happening once or more per shift. Equally, chest-tube milking was reported by the OR and ICU nurses in more than half of the patients at least once per hour.

## 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 [5,6,7,8]; we now report in this first prospective, randomized study about the comparison between the new, self-contained chest drainage system THOPAZ<sup>+</sup> compared to the conventional system in 120 cardiac surgical patients.

Halfway through the study, on nurses' and physicians' request, a soft silicone tube was inserted between the chest tubes and the Medela suction tube in order to allow for milking which is standard practice in many cardiac centres such as Verona [9]. However, the literature is controversial on this point and some studies come to the indication that manipulation such as milking of mediastinal chest drains does not show any improvement on drainage quantity or on outcome of patients [10,11].

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. However, our study was underpowered to evaluate the effect of our drainage systems on the incidence of tamponade which is varying from 1 - 4% according to the detection method used for tamponade diagnosis [12–13].

The randomized trial confirmed the positive findings of the trial phase insofar as that there were no chest-tube related safety issues for the patients. Five patients required reoperation for bleeding (3 in the Study group and 2 in the Control group), leading to crossovers from the Study group to the Control group in 2 cases ('intention to treat' evaluation: fig.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 [2,14,15]. Froid and Jeppsson conclude that excessive bleeding leading to re-exploration is associated with a 2-fold increased early post-operative mortality rate [3].

A total of 7 crossovers were found in the 60 Study patients; Two, as mentioned above for reoperation for bleeding, 2 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 3 for surgeons' choices, feeling that the drainage of the new system was not adequate. Therefore, halfway through the study we introduced a silastic tube between the chest-tube and the Medela drainage tube to allow for milking which was used similarly as in the Control group following this modification no more crossovers were noted [9,16].

Interestingly, in the Study group we found a non-significant 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 [7,17,18]. Early chest-tube

removal impacts also favorably on pain and pulmonary function [19,20]. 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 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.

Other advantages which were clearly described in the 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<sup>+</sup> pumps [5]. 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. Similarly, the digital fluid recording and trend analysis helps the medical team to make decisions as to when to remove the chest tubes [6]. This effect has been confirmed by the shorter chest drainage duration (9h) in the study group compared to the control (ns).

Finally, the alarms implemented on the THOPAZ<sup>+</sup> 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].

Our study has some evident limitations. First of all, sample size is relatively limited; 120 patients give the study enough power to show significant differences in drainage output, but would be a relatively small sample if the endpoint was showing differences in tamponade recurrence (due to its generally low incidence). Furthermore, the study was completed in a single institution, and we think it would be extremely useful to share and compare data with other Units in order to confirm our evidences.

## 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 (i.e. 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.

## Abbreviations

ICU: Intensive Care Unit

OR: Operating Room

CABG: Coronary Artery Bypass Graft

ACT: Activated Clotting Time

POD: Post Operative Day

ITT: Intention To Treat

PP: Per Protocol

BSA: Body Surface Area

RCT: Randomized Control Trial

CPB: Cardio-Pulmonary Bypass

## **Declarations**

## **ACKNOWLEDGEMENTS**

The authors would like to thank the team of Medela who provided the material for the study group and the teaching of the THOPAZ<sup>+</sup> system.

## **DISCLOSURE**

Drs. Courvoisier and 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.

## **Ethics approval and consent to participate; Trial Registration**

The protocol was approved by the Ethics Committee of the University of Verona (No. 584CESC) on 28.07.2015. All patients were informed personally by the treating physician that they were enrolled in an RCT comparing the Medela chest drainage system, which had been used in thousands of patients for thoracic drainage, to the conventional drainage system. All patients received an information sheet and signed a dedicated consent form. This Randomized Control Trial was retrospectively registered on June 7, 2019 under ISRCTN 14884587.

## **CONSORT Guidelines:**

The study adheres to CONSORT Guidelines. The CONSORT Checklist is included in the submission as a separate file.

# **Consent for publication**

Not applicable.

## **Availability of data and materials**

The datasets analyzed during this study are available from the corresponding author on reasonable request.

## **Competing interests**

Drs. Courvoisier and Walpeth 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.

## **Fundings**

No funding was necessary to support this study. All the chest drainage systems and THOPAZ<sup>+</sup> pumps for the Medela group were provided by Medela, Switzerland. The teaching for using the new THOPAZ<sup>+</sup> pumps by the medical team (physicians and nurses) of Verona was carried out by a trainer from Medela.

## **Authors' contributions:**

All Authors have read and approved the manuscript

LB: study design, data collection, data analysis, data interpretation, manuscript draft and revision.  
Corresponding author.

LSB: data collection

MM: data collection

DC: data analysis, data interpretation

BW: study design, data analysis and interpretation, manuscript draft and revision

GF: study design, overall study revision

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## Tables

Table 1: Baseline patient characteristics by device (ITT analysis)

N(%) or mean values  $\pm$  (SD)

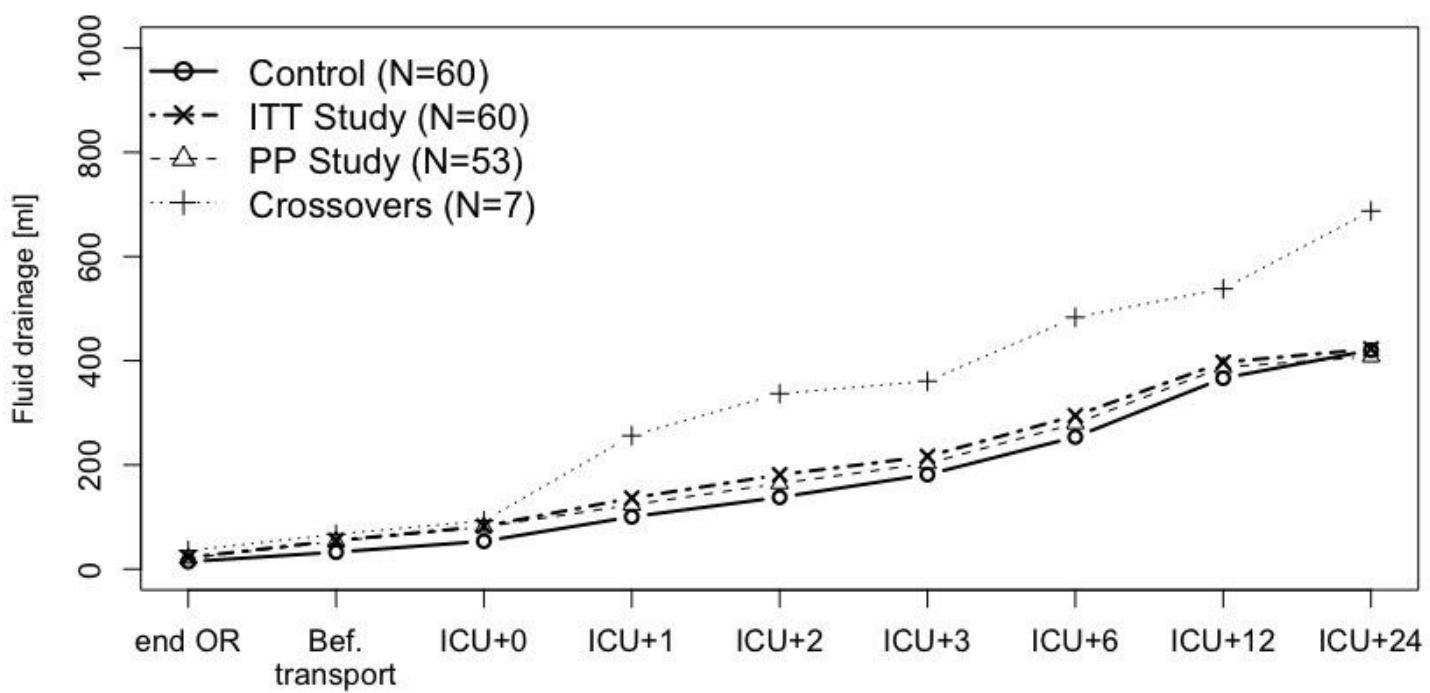
Patient Demographics			
Characteristics	Study Group N = 60	Control Group N = 60	P
Sex (Male)	46 (76.7%)	36 (60.0%)	0.08
Age	67.8 (10.3)	67.0 (10.4)	0.77
Euroscore	2.3 (1.9)	2.2 (2.1)	0.32
BSA (m <sup>2</sup> )	1.92 (0.22)	1.91 (0.20)	0.43
Total N° of risk factors	2.08 (1.32)	1.93 (1.32)	0.46
Anticoagulation, N(%)	31 (51.7%)	30 (50.0%)	1.00
Anticoagulation: N° days stopped before surgery	1.63 (1.94)	1.72 (1.93)	0.80
Operative Procedures			
Aorta clamping (min)	72.1 (32.9)	75.0 (33.8)	0.70
CPB duration (min)	95.1 (38.4)	101.0 (42.1)	0.58
Surgery duration (min)	253.0 (65.3)	259.3 (81.5)	0.81
Lowest temperature (°C)	35.2 (0.9)	34.9 (1.2)	0.10
Total Heparin dose (mg)	322.9 (71.7)	316.1 (70.2)	0.65
Total Protamin dose (mg)	287.9 (75.8)	318.3 (86.3)	0.08
Cell saver transfusion (ml)	250.1 (208.3)	204.9 (200.1)	0.18
RBC transfusion, N(%)	28 (46.7%)	32 (53.3%)	0.58
FFP transfusion, N(%)	9 (15.0%)	10 (16.7%)	1.00
PLT transfusion, N(%)	2 (3.3%)	2 (3.3%)	1.00
N days until dismissal	8.7 (5.6)	9.2 (4.8)	0.60

**Table 2: Clinical characteristics over time by device**

N(%) or mean values ± (SD)

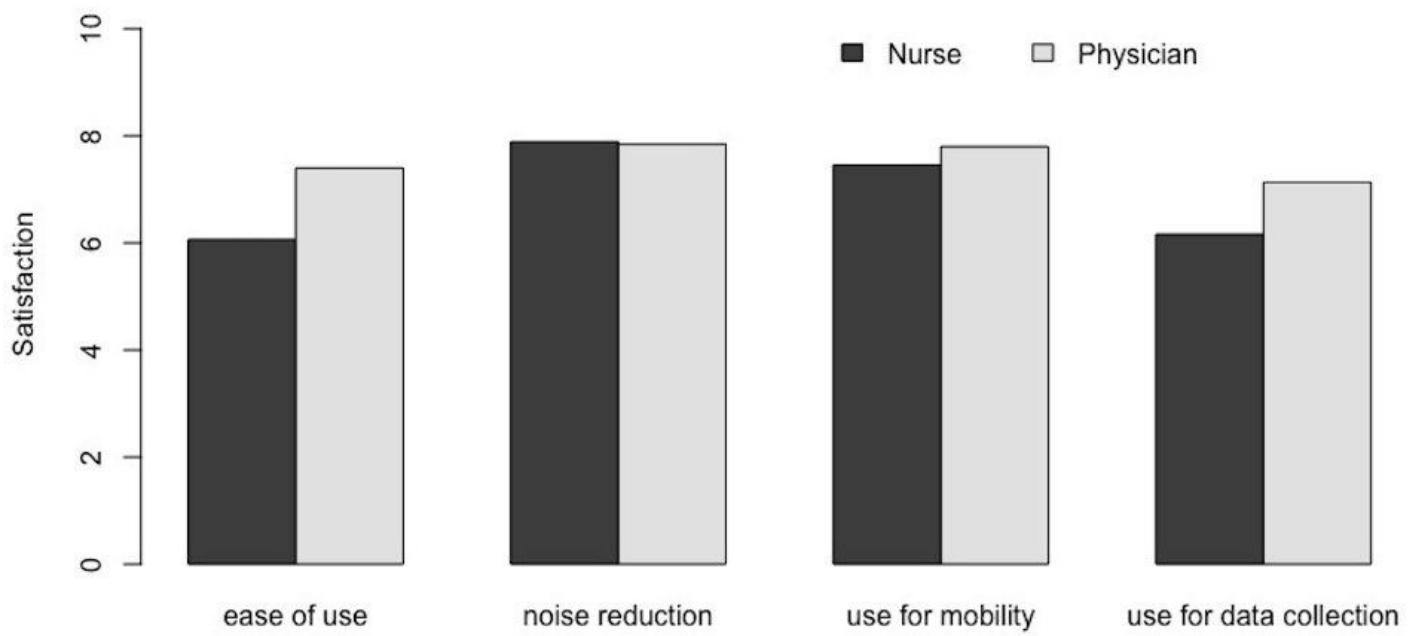
Chest drainage & Haemoglobin levels			
Characteristics	Study Group N = 60	Control Group N = 60	P
Chest drainage (ml): End OR	24.8 (36.6)	14.8 (25.0)	0.06
Chest drainage (ml): Before transport	55.6 (60.7)	33.3 (45.3)	0.006
Chest drainage (ml): ICU arrival	81.1 (78.6)	55.0 (60.2)	0.01
Chest drainage (ml): ICU+6 h	280.2 (218.7)	254.5 (298.3)	0.12
Chest drainage (ml): ICU+24 h	476.1 (275.4)	508.8 (483.1)	0.45
Total chest drainage (ml)	536.4 (321.8)	640.7 (675.3)	0.78
Duration of chest drainage (h)	29.8 (15.2)	38.4 (23.7)	0.19
Haemoglobin pre-op	13.5 (2.0)	13.5 (1.5)	0.61
Haemoglobin post-op	10.2 (1.3)	10.1 (1.3)	0.66
Haemoglobin at ICU+6 h	11.5 (1.2)	11.6 (1.2)	0.55
Haemoglobin at chest-tube removal	11.4 (1.3)	11.3 (1.8)	0.83

## Figures



**Figure 1**

Chest-tube drainage for the Control (n=60) and Study (n=60) groups of the ITT analysis during the first 24 hours. Also shown are the Study group (n=53) and the 7 crossovers of the PP analysis.



**Figure 2**

Satisfaction analysis (0-bad, 10-optimal) for the main questions asked according to the professional health status (nurses and physicians; (n=52)).

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SITables.docx](#)
- [CONSORT2010Checklist.doc](#)