DOI: 10.5114/kitp.2014.45683

A novel high vacuum chest drainage system – a pilot study*

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Kardiochirurgia i Torakochirurgia Polska 2014; 11 (3): 311-320

*This paper was presented during a meeting of the Polish Society for Cardiothoracic Surgery in 2010: Mrówczyński W, Tille JC, Khabiri E, Giliberto JP, Courvoisier DS, Kalangos A, Walpoth BH. Novel high vacuum chest drainage system. Experimental study. Kardiochir Torakochir Pol 2011; 8 supl. 1a: S54. 4th Joint Congress of Cardiac Surgeons of Poland and Cardiovascular Surgeons of Ukraine. Rzeszów, Poland, 9-11 June 2011.

Abstract

Aim: To assess the safety and feasibility of use of a novel high vacuum chest drainage system (HVCDS) and its influence on the cardiovascular system compared to a conventional system (CCDS).

Material and methods: Five anesthetized pigs underwent a median sternotomy. Three drains were placed in retrocardiac, retrosternal and left pleural positions. The animals received a HVCDS (22 Fr with 180 2-mm holes, *n* = 2) or a CCDS (*n* = 2). In the fifth animal off pump coronary artery bypass graft (OPCABG) stabilizers were tested. After chest closure animals had three 30 min runs of artificial bleeding (5 ml/min) under different negative aspiration pressures (–2, –20, –40 kPa) for both groups, followed by standardized surgical bleeding (–40 kPa – HVCDS, – 2 kPa – CCDS). Hemodynamic parameters and each drain's output were registered every 5 minutes and the residual blood was assessed. All catheters, the heart and left lung underwent macroscopic and histopathological examination.

Results: The application of the different pressures showed neither hemodynamic changes nor differences in blood drainage with both systems in two bleeding models. The HVCDS enabled drainage comparable to the CCDS but showed relevant clotting. Application of –20 kPa and –40 kPa caused macroscopic epicardial and pulmonary lesions in all tested devices including OPCABG stabilizers consisting of sub-epicardial or sub-pleural hemorrhage without myocyte or alveolar damage.

Conclusions: The novel and conventional chest drainage systems used at pressures up to 40 kPa induced no hemodynamic instability. Both systems showed adequate equal drainage, despite major HVCDS clotting. High negative pressure drain-

Streszczenie

Cel: Ocena bezpieczeństwa i efektywności wysokopróżniowego systemu drenażu klatki piersiowej (*high vacuum chest drainage system* – HVCDS) oraz jego wpływu na układ krążenia w porównaniu z systemem tradycyjnym (CCDS).

Materiał i metody: Pięć znieczulonych świń poddano sternotomii pośrodkowej. Wprowadzano trzy dreny: zasercowo, zamostkowo i do lewej opłucnej. U zwierząt zastosowano system HVCDS (22 Fr ze 180 2-milimetrowymi otworami, *n* = 2) lub CCDS (*n* = 2). Na piątym zwierzęciu testowano stabilizatory OPCAB. Po zamknięciu klatki piersiowej zwierzęta poddawano trzem 30-minutowym testom sztucznego krwawienia (5 ml/min) o różnych wartościach ujemnego ciśnienia w drenach (–2, –20, –40 kPa) dla obu grup, po których następowało standardyzowane krwawienie chirurgiczne (HVCDS: –40 kPa, CCDS: –2 kPa). Parametry hemodynamiczne i wydajność każdego systemu drenażu odnotowywano co 5 minut. Wszystkie dreny, serce oraz lewe płuco poddano badaniom makroskopowym i histopatologicznym.

Wyniki: Stosowanie różnych wartości ciśnień nie wiązało się ani z zaburzeniami hemodynamicznymi, ani z różnicami w drenażu krwi pomiędzy dwoma opisywanymi systemami w dwóch modelach krwawienia. System HVCDS umożliwiał drenaż porównywalny z CCDS, ale cechował się zaleganiem skrzeplin wewnątrz drenu. Wynikiem stosowania ciśnienia o wartości –20 kPa oraz –40 kPa było powstawanie makroskopowych zmian nasierdziowych i płucnych we wszystkich testowanych urządzeniach, w tym stabilizatorach OPCAB, polegających na krwawieniu podnasierdziowym lub podopłucnowym bez uszkodzenia miocytów i pęcherzyków płucnych.

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age with both systems showed focal sub-epicardial and subpleural hemorrhage. Thus, long-term assessment of high pressure drainage and potential interaction with fragile structures (coronary bypass graft) should be carried out.
Key words: pericardium, pleural disease (incl. drainage), experimental.

Wnioski: Użycie zarówno nowego, jak i tradycyjnego systemu do drenażu klatki piersiowej przy ciśnieniach do 40 kPa nie wywoływało niestabilności hemodynamicznej. Oba systemy wykazywały równie adekwatny drenaż pomimo częstszego zatykania się skrzepami HVCDS. Wysokopróżniowy drenaż powodował ogniskowe krwawienia podnasierdziowe i podopłucnowe w przypadku obydwu systemów. W związku z powyższym należy przeprowadzić długoterminowe badanie drenażu wysokimi ciśnieniami i jego potencjalnych interakcji z wrażliwymi strukturami (pomost aortalno-wieńcowy).
Słowa kluczowe: osierdzie, choroba opłucnej (drenaż), eksperymentalny.

Introduction

Postoperative drainage of pericardial and pleural cavities after cardiac surgery is obligatory in order to avoid life-threatening complications including cardiac tamponade, hemothorax and infection [1, 2]. A conventional chest drainage system (CCDS) uses a negative pressure of 15-20 cm H_20 (from ~–1,5 to –2 kPa) and the size of the drain is patient adjusted (12-34 F or 4-11.3 mm). Removal of the drain can be painful if a bigger chest tube is introduced. For the same reason, drains can sometimes interfere with heart function [3, 4]. Drainage efficacy and completeness are mandatory but can be compromised by clot formation.

In order to address such potential drawbacks of CCDS, a novel high vacuum chest drainage system (HVCDS) has been developed. It can potentially provide the same or eventually superior draining capacity and completeness compared to CCDS while having a smaller cross-sectional diameter, which causes less pain during removal and virtually prevents subcutaneous emphysema [5].

The aim of this study was to investigate the efficacy and feasibility of use of the HVCDS compared to the CCDS as well as the influence of the HVCDS on perioperative hemodynamics in an acute animal model of cardiosurgical intervention via sternotomy.

Material and methods

The experimental protocol was approved by the Animal Experiments Ethics Committee of the University of Geneva and the Veterinary Office of the State of Geneva (Switzerland; No. 1081/3507/I) and carried out in conformance with the Guide for the Care and Use of Laboratory Animals (National Research Council, Washington, DC: National Academy Press; 1996). The funding agencies did not influence data interpretation.

In vitro study

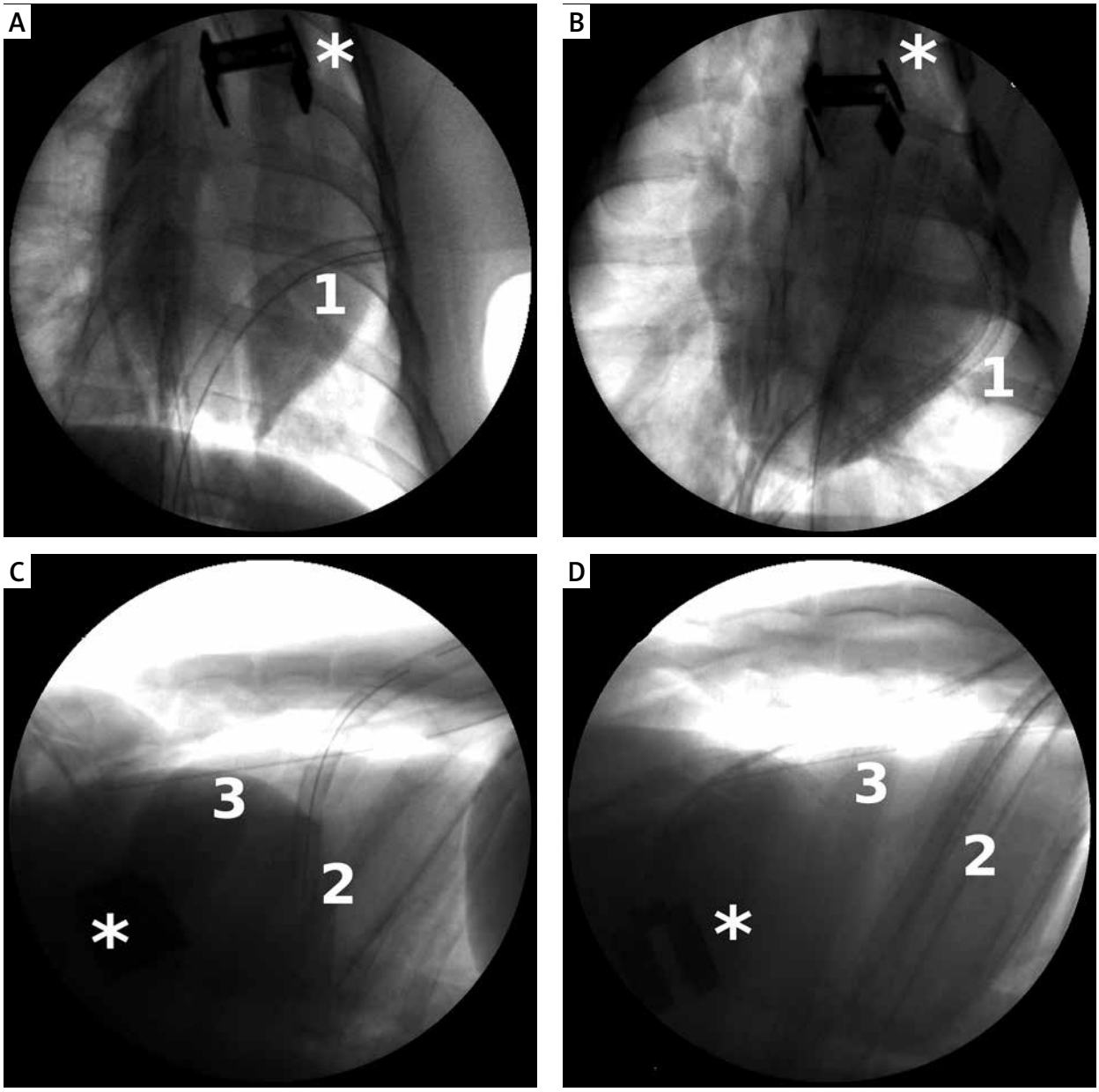
In order to assess maximal liquid flow through both catheters, they underwent a water bucket test under 3 different pressures: –2 kPa, –20 kPa and –40 kPa. The amount of water collected during 1 minute was registered. All tests were repeated 5 times.

Animals, anesthesia, perioperative monitoring and surgery

Five male land race pigs with a mean weight of 38.2 kg (range 35-42 kg) were utilized and assigned to the HVCDS (n = 2) or CCDS group (n = 2). The fifth animal received OPCABG (off-pump coronary artery bypass graft) stabilizers for comparison. They were premedicated with 3 mg/kg azaperone (Stresnil – Roche, Basel, Switzerland) and anesthetized with 2% isoflurane (Isoflurane – Abbott, Switzerland), 4 mg pancuronium bromide (Pavulon – Organon, Pfäffikon, Switzerland) and 0.5 mcg/kg/min fentanyl (Fentanyl – Sintetica, Mendrisio, Switzerland) and intubated. The animals were ventilated with a Servo Ventilator 900D respirator (Siemens, Erlangen, Germany) and monitored using 3-lead ECG, SpO_2, temperature, direct arterial (ABP) and central venous blood (CVP) pressure measurement (Datex AS/3 cardio-monitor – Datex, Helsinki, Finland) and continuous cardiac output by transit time ultrasound Doppler (Cardio-Med CM-4008, Medistim, Oslo, Norway). The animals were heparinized (10 000 IU) to double activated clotting time (ACT) baseline values (Hemochron 401, ITC, Edison, New Jersey, USA). A median sternotomy was performed, followed by longitudinal pericardiotomy. The bleeding from the sternum was controlled using bone wax. Three drains were placed in the retrocardiac, retrosternal and left pleural cavities (HVCDS, n = 2 or CCDS, n = 2). Airtightness was achieved by split sternum reapproximation and skin closure with multiple dressing forceps. The accuracy of drain positions was confirmed by bi-plane X-ray (Fig. 1).

The HVCDS thoracic catheter (Medela AG, Baar, Switzerland) consists of a blind ended outer 22 Fr tube with 180 circular 2 mm perforations (external diameter = 7.3 mm, internal diameter of the outer tube = 5.5 mm; length of perforated segment = 180 mm) and an inner concentric (inner diameter = 2.8 mm) and perforated tube (perforation = 10 × 2.8 mm) serving as a suction (–40 kPa = ~–408 cm H_20) and fluid removal line (Fig. 2A).

Flexible PVC 28 Fr chest catheters were used in a CCDS setting (Atrium Europe, Mijdrecht, The Netherlands). This tube (active part: 9.3 mm outer and 7 mm inner diameter) has 6 big elliptic orifices (9.5 × 4.5 mm) placed on the distal 102 mm of the catheter, whose tip is open.



HVCDS – high vacuum chest drainage system, CCDS – conventional chest drainage system

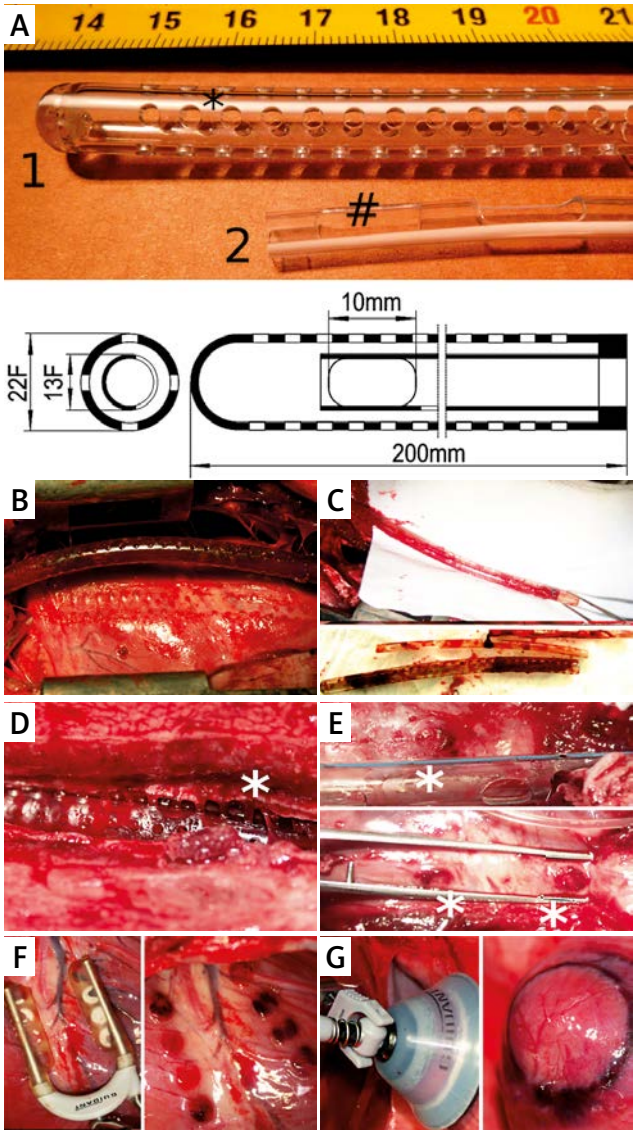
Fig. 1. X-ray control of drain placement after the chest closure and before the bleeding. Three drains of both types are positioned as follows: left pleural cavity (1), retrocardiac position (2), retrosternal position (3). CCDS drains are more rigid than HVCDS and their position in the thorax cavity is slightly different. CCDS: a-p (A) and lateral (C) projections. HVCDS: a-p (B) and lateral (D) projection. Transit time flow measurement probe is visible (*)

Both the HVCDS and CCDS were connected to vacuum pumps (Vario for 2 kPa and Vario 18 for 20 kPa and 40 kPa, Medela AG, Baar, Switzerland) with the pressure set according to the study protocol. Each catheter of both groups was draining into separate reservoirs and quantities of collected blood were pooled.

To simulate bleeding, a 3 mm catheter was positioned at the base of the right atrium close to Waterston's groove. It was connected to an infusion pump (MS-4/6, Ismatec Reglo, Zurich, Switzerland) instilling a mixture of expired human erythrocyte concentrate and fresh frozen plasma (in 1 : 1 proportion) at a rate of 5 ml/min.

Real bleeding was then performed by making a stab incision in the auricle of the right atrium with scalpel no. 11 after placement of a 7-0 Prolene purse string suture around the wound area. This suture was removed by pulling after chest closure in order to initiate the bleeding. All thoracic catheters were exchanged for new ones before the next bleeding session.

The experimental protocol consisted of 30 min artificial bleeding using 3 different negative aspiration pressures (–2, –20 and –40 kPa) performed with the two chest drainage systems. After the 3 runs of artificial bleeding a real hemorrhage was induced using CCDS at –2 kPa and HVCDS



HVCDS – high vacuum chest drainage system, CCDS – conventional chest drainage system, OPCAB – off-pump coronary artery lateral stabilizer

Fig. 2. Diagram of the high vacuum chest drainage system and macroscopic views of both types of drains during the chest re-exploration after the artificial bleeding. A) Diagram of the high vacuum chest drainage system: 1 – outer 22 F blind-ended tube with 180 2-mm round holes (*), 2 – inner 13 F open-ended tube with 4 rectangular orifices (# - 10 × 3 mm). B) HVCDS – the drain is filled with clots. Multiple small hemorrhages (kissing marks) corresponding to drain orifices are visible along the drain position on the right ventricle during 40 kPa suction. C) HVCDS – the drain is partially clotted between its internal and external tubing. D) HVCDS – formation of clot and fibrin bridges (*) between surrounding tissues and HVCDS interior through drain orifices. E) CCDS – the drain is free of clots. Large ecchymosis corresponding to the drain orifice is visible (*) on the right ventricle outflow tract (40 kPa suction). F) Lateral OPCABG stabilizer and kissing marks appearing after its use (–40 kPa). G) Apical OPCABG stabilizer and resulting kissing marks (–40 kPa)

at –40 kPa. The test was carried out until hemodynamic stability could no longer be maintained by volume replacement and catecholamine administration (mean ABP < 25 mmHg). In both bleeding models the following time points were used for hemodynamic monitoring and total drain output volume registration: catheter placement (–15 min), chest closure (–10 min), negative pressure application (–5 min), start of bleeding (0 min), bleeding (every 5 min), end of bleeding (+30 min), end of suction (+35 min), chest reopening (+40 min). Then, the wound and the drains were explored, documented by macro photography and the amount of remaining blood was measured using a calibrated aspiration system.

The fifth animal underwent a trial with OPCABG stabilizers applied in the standard left anterior descending coronary artery (possessing 8 suction orifices of 6 mm diameter) and apical positions (CTS Axius Guidant Stabilizer system – Guidant Corporation, Santa Clara, CA, USA) during 15 min under –40 kPa of suction (as in our protocol).

Euthanasia

At the end of this acute experiment – after the real bleeding run or after the OPCABG stabilizer trial – all animals were sacrificed by potassium chloride overdose. Their hearts and lungs were harvested for further histological examinations.

Histological study and morphometry

For histology, tissues were fixed in 4% formaldehyde for 24 hours and slices with macroscopic lesion were embedded in paraffin. Histological sections of 4 µm were stained with hematoxylin-eosin (H+E). Histological slides were numerically scanned in their totality at 20x magnification (Mirax Midi, Carl Zeiss MicroImaging GmbH, Jena, Germany) for quantifications with image-processing software (Mirax Viewer, idem). The following measurements were made on the slides: the depth, width and the area of each lesion. A mean of five measurements of distinct lesions in different positions in each animal were registered and associated with the type of device used (HVCDS, CCDS and OPCABG lateral stabilizer).

Statistics

Results of hemodynamic measurements and drain outputs are presented in graphs showing the mean result of 2 animals (if applicable). Since several measures of morphometry and drainage completeness (described by mean, minimum and maximum) were collected per pig, we used mixed linear models, which accounts for repeated measures, with pig as the random effect and group as the fixed effect. The results of *in vitro* tests were presented as the mean and standard deviation. The differences were verified with the Mann-Whitney *U*-test. A two-tailed *p* value less than 0.05 was considered significant in all tests.

Results

In vitro study

Water flow through the chest catheter was statistically significantly higher under all pressure conditions in

the CCDS group – 1744 ± 56 ml/min vs. 2172 ± 39 ml/min (at –2 kPa, $p < 0.001$), 3864 ± 82 ml/min vs. 4816 ± 97 ml/min (at –20 kPa, $p < 0.001$), 5200 ± 126 ml/min vs. 6776 ± 123 ml/min (at –40 kPa, $p < 0.001$).

Surgical procedure

Four animals underwent trials with the HVCDS ($n = 2$) and conventional chest drainage systems ($n = 2$). The second animal in the CCDS group died prematurely due to ventricular fibrillation refractory to several defibrillation trials before completing –40 kPa artificial bleeding and –2 kPa real bleeding trials.

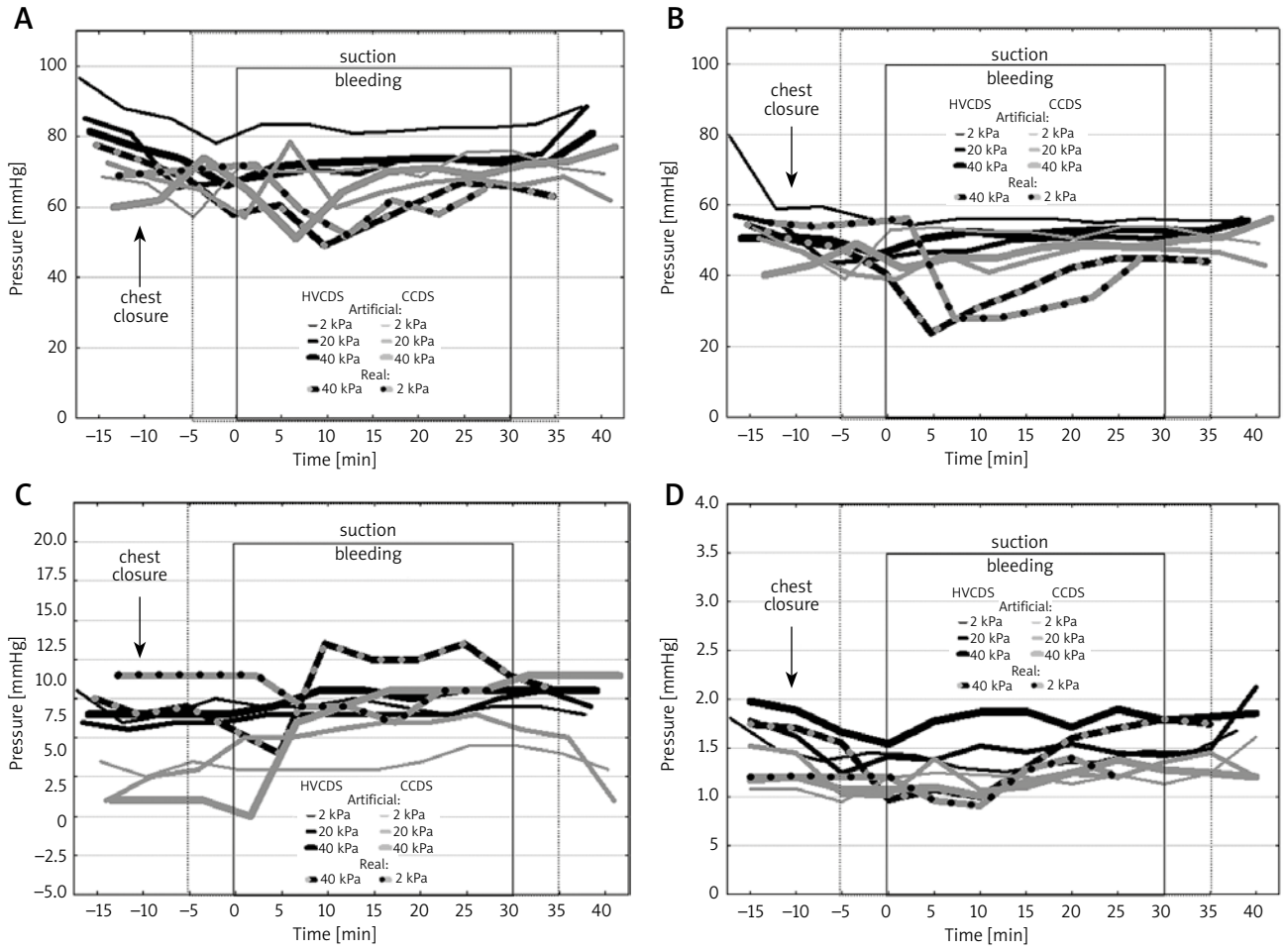
Hemodynamics

The application of different negative pressures during the artificial bleeding did not cause a dramatic drop of systolic ABP in either chest drainage system group. Some fluctuations were visible between the 5th and 10th minute in CCDS animals subjected to –20 and –40 kPa. However, after 15 minutes their parameters stabilized. In both chest drainage groups a decrease of systolic ABP was observed after the 5th minute of real bleeding due to blood loss and was corrected equally by volume replacement and catecholamine administration (Fig. 3A).

Mean ABP was between 40 and 60 mmHg throughout all artificial bleeding runs in the two study groups. It was influenced neither by negative pressure application (all three values) nor by the blood instillation during hemorrhage simulation. However, during the real bleeding sessions mean ABP dropped to the values of 25-30 mmHg in both groups (Fig. 3B).

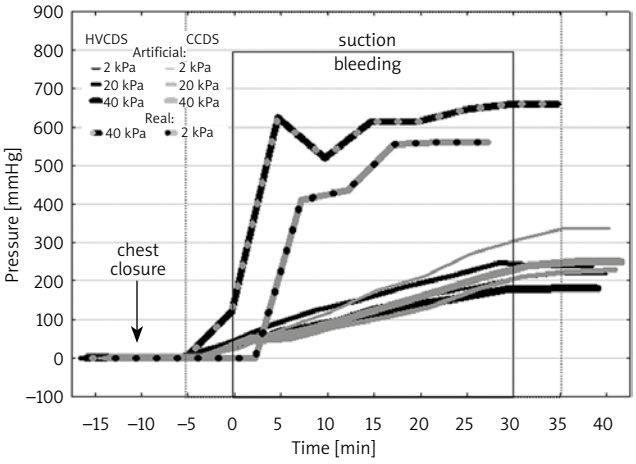
Central venous blood was constant in the HVCDS during all 3 artificial bleeding sessions in the majority of animals (0-9 mmHg), whereas CVP in the CCDS was initially lower and rose to the level of the HVCDS after 5 min after initiation of bleeding in two animals, whereas one animal had a tendency to lower CVP throughout the whole experiment despite volume substitution (Fig. 3C).

Cardiac output (CO) values were constant in both drain groups during artificial bleeding runs regardless of aspiration pressures (Fig. 3D). However, during the real bleeding CO was temporarily depressed after the application of neg-



HVCDS – high vacuum chest drainage system, CCDS – conventional chest drainage system

Fig. 3. Systolic (A) and mean (B) arterial blood pressure, central venous pressure (C) and cardiac output (D) according to suction pressure intensity and bleeding type



HVCDS – high vacuum chest drainage system, CCDS – conventional chest drainage system

Fig. 4. Total drainage according to negative suction pressure intensity and bleeding type

ative pressure in the HVCDS group, but increased between the 15th and 20th minute to baseline value. Cardiac output in the CCDS animal during real hemorrhage was constant.

Draining efficacy was similar in both systems during simulated bleeding in terms of total quantity of drained and received blood (Fig. 4). The same result was observed in the real bleeding trial in both systems (approx. 600 ml drained in 15 minutes). Some animal-derived bleeding was noted from the fluid balance. There was no statistically significant difference (p = 0.25) in the mean amount of blood remaining at the end of the drainage period in the HVCDS (8.9 ml; range: 0-15 ml) compared to CCDS (16.5 ml; range: 5-25 ml).

Wound and drain inspection

Major drain clotting was observed in all cases of HVCDS application (Fig. 2B-D, Table I). Clots were positioned between the two concentric tubes of the HVCDS catheter occupying the majority of the active drain area. Moreover, clots within the HVCDS tube had continuity with surrounding tissues and formed bridges of fibrin clot occluding the drain's orifices (Fig. 2D). Local clotting of the CCDS tube was observed once after the artificial bleeding under –40 kPa aspiration and all the other CCDS catheters remained free of internal residual clots (Fig. 2E).

The use of aspiration pressure higher than –2 kPa always resulted in the macroscopic appearance of confined hemorrhages ("kissing marks") on heart and lung surfaces in contact with the drain orifice of both HVCDS and CCDS tubes (Table I). Lesion sizes corresponded with the position and drain perforation (Fig. 2B and E). Similar lesions were found after application of OPCABG stabilizers (Fig. 2F-G).

Histology

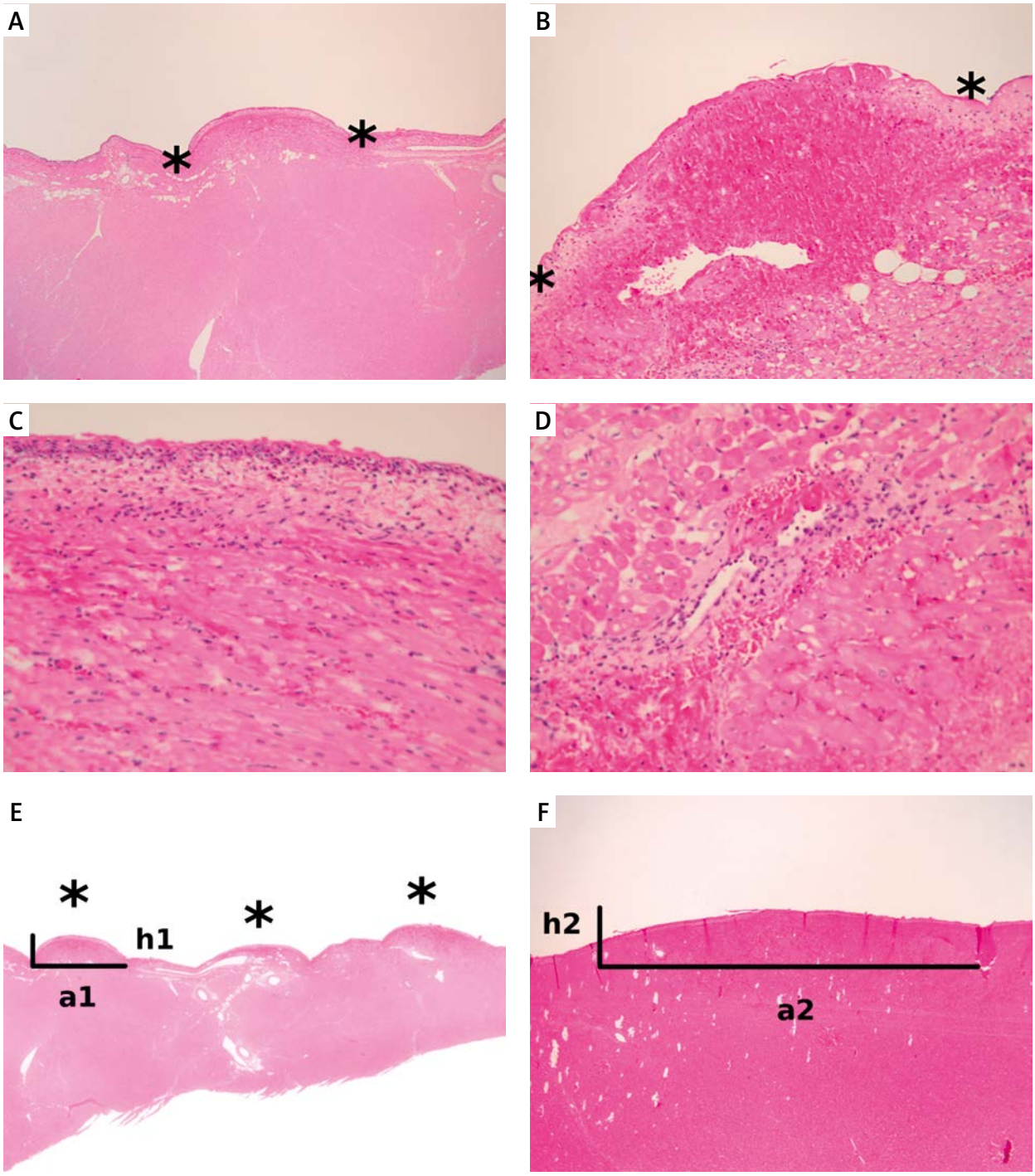
Heart lesions after the use of negative aspiration pressures higher than –2 kPa in both drainage systems were characterized by hemorrhagic suffusion with extravasation of red cells into the epicardial adipose tissue (Figs. 5A-B) or by interstitial bleeding without myocyte damage (Fig. 5D). The mechanism is presumably the capillary vessel lesions sparing the venules and arterioles. A similar type of lesion was found in the case of the OPCABG vacuum stabilizer. In some specimens a fibrinous pericarditis connected with the surgery was visible (Fig. 5C).

Lung lesions related to the use of both the HVCDS and CCDS at high negative pressures (HNP) consisted (similarly to the heart damage) of hemorrhagic suffusions due to the mechanical injury of capillary vessels of the subpleural space (Figs. 6A and C) and caused by congestion of capillary vessels of the alveolar septa (Fig. 6B). In some places intra-alveolar hemorrhages were found (Fig. 6D). The mean depth of the suffusions was 534 ± 376 µm. Histopathologically these findings resembled focal subpleural atelectasis.

Tab. I. Activated clotting time and post-drainage blood and drain clotting for HVCDS (H) and CCDS (C)

Bleeding type		Artificial bleeding						Real bleeding	
Applied vacuum		2 kPa		20 kPa		40 kPa		40 kPa vs. 2 kPa	
Drainage system		H	C	H	C	H	C	H	C
Variable									
ACT [s]		283	239	191	136	173	147	130	120
		225	261	228	186	183	–	262	–
	Mean	254	250	209.5	161	178	147	196	120
Remaining blood [ml]		12	15	12	25	5	25	0	12
		10	17	7	5	10	–	15	–
	Mean	11	16	9.5	15	7.5	25	7.5	12
Drain clotting		Yes	No	Yes	No	Yes	No	Yes	Yes
		Yes	No	Yes	No	Yes	–	Yes	–
Macroscopic tissue hemorrhage		No	No	Yes	Yes	Yes	Yes	Yes	No
		No	No	Yes	Yes	Yes	–	Yes	–

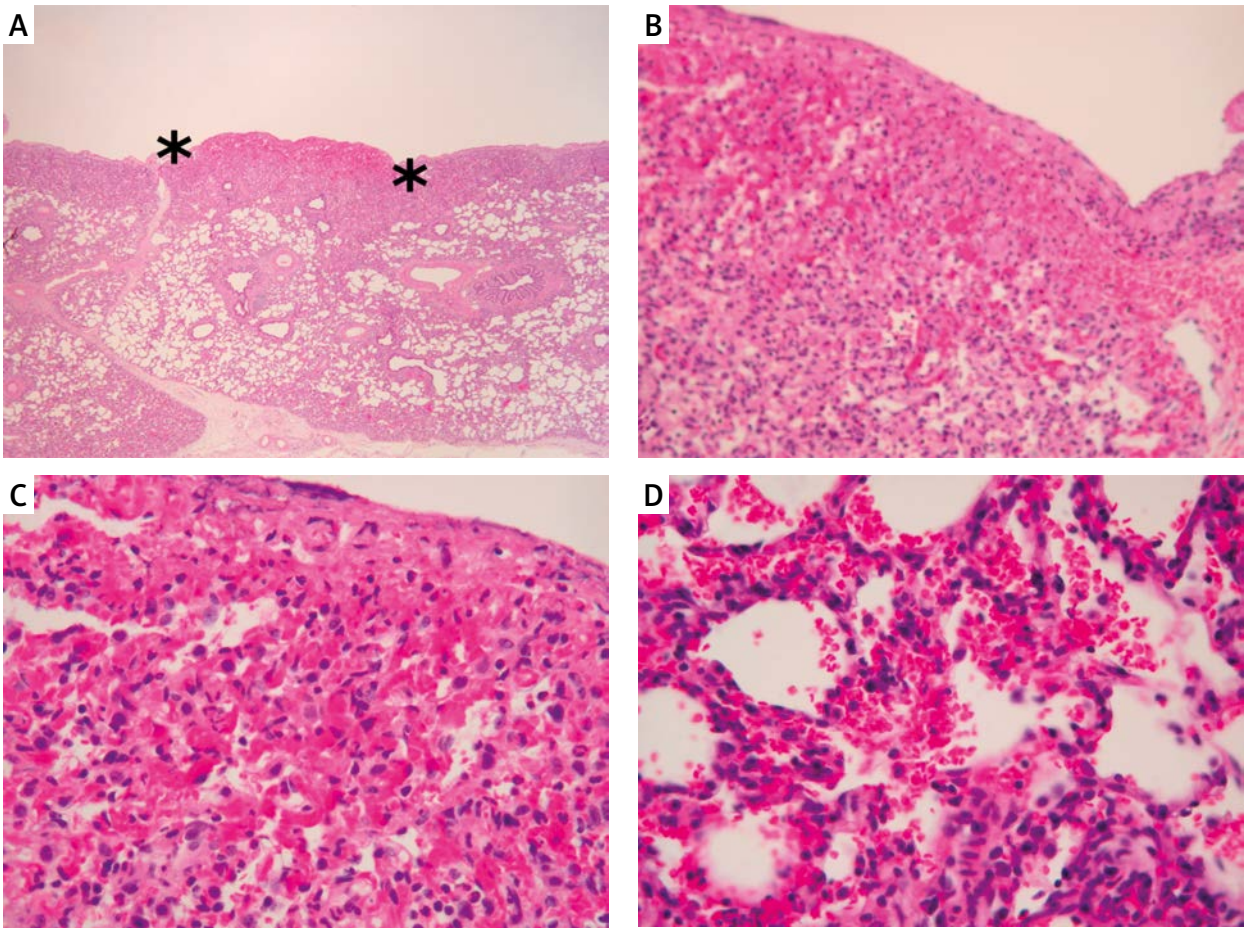
Numbers in columns represent the result of a single animal. The mean value of two measurements is shown for each drain type in every pressure and bleeding category.
ACT – activated clotting time, C = CCDS – conventional chest drainage system, animal 2, 4, H = HVCDS – high vacuum chest drainage system, animal 1, 3



**heart lesion – between asterisks

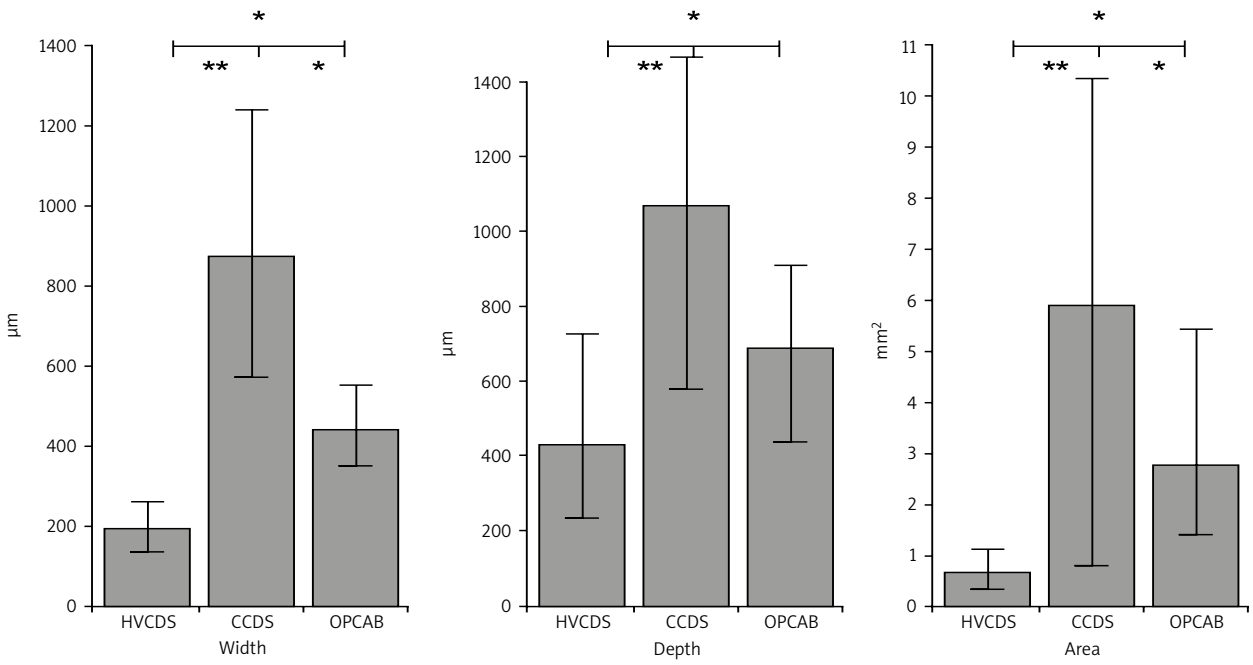
Fig. 5. Microphotography of myocardial vacuum lesions (at –40 kPa) for both types of catheters. A) Magn. ×20 – pericardial lesion (between asterisks). B) Magn. ×100 – hemorrhagic lesion in the pericardium and the myocardium (between asterisks). C) Magn. ×200 – fibrinous pericarditis. D) Magn. ×200 – intramyocardial hemorrhage with preservation of the arterioles. E) Magn. ×20 – lesions caused by 3 small orifices (*) – HVCDS, h1 = 534 ± 215 µm, a1 = 1937 ± 357 µm. F) Magn. ×20 – lesion of big orifice cut in the short axis – CCDS, h2 = 921 ± 227 µm, a2 = 8028 ± 1723 µm

Both drainage systems and the OPCABG stabilizer differed significantly in terms of width, depth and cross-sectional area of suction lesions showing the same histological pictures (Fig. 7). The depth of injury was significantly smaller in the HVCDS than in the CCDS and the stabilizer (Figs. 5E and F). However, there was no difference between CCDS and the cardiac stabilizer. The width of the hemorrhage corresponded to the diam-



**pulmonary lesion – between asterisks

Fig. 6. Microphotography of lung vacuum lesions (at –40 kPa). A) Magn. ×20 – pulmonary lesion (between asterisks). B) Magn. ×400 – capillary congestion. C) Magn. ×200 – visceral sub-pleural hemorrhage. D) Magn. ×400 – intra-alveolar hemorrhage



*p < 0.05, **p < 0.01
HVCDS – high vacuum chest drainage system, CCDS – conventional chest drainage system, OPCAB – off-pump coronary artery lateral stabilizer

Fig. 7. Mean (min and max) width, depth, and area of tissue lesions according to the causative device

eter of the drain orifice. The mean area of tissue damage was 0.64 mm^2 (0.31-1.1) vs. 5.9 mm^2 (0.8-10.33) vs. 2.7 mm^2 (1.39-5.41) respectively for the HVCDS, the CCDS and the stabilizer.

Discussion

The current study assesses the safety and efficacy of a novel chest drainage system as well as giving a new insight into the drainage-related acute hemodynamic changes. It shows that the application of different negative aspiration pressures (–2, –20, –40 kPa) during combined mediastinal and pleural drainage after experimental sternotomy does not compromise the hemodynamics of the animal, regardless of the catheter type used (HVCDS or CCDS or suction applied). This is in accordance with a randomized clinical trial reporting the use of high vacuum drains in pediatric cardiac surgery (Redivac) where no early postoperative hemodynamic complications due to a very HNP were mentioned [6].

The current work is also the first to describe the performance of the HVCDS in a model of simulated and real, surgical intrathoracic bleeding. The simulation of 30 min hemithorax bleeding has already been performed by Niinami, who explored the behavior of a small caliber Blake drain [7]. However, neither thoracotomy nor sternotomy was performed in his study. Until now, the only experimental data on the HVCDS concern pleural drainage, and the study was focused mainly on drain placement and surveillance of post-interventional pneumothorax [5]. Similarly, preliminary experiences with HVCDS placement in a clinical setting were described in adult patients undergoing bilateral thoracoscopic sympathectomy [8].

The second important finding is the similar draining capacity seen in the 2 types of chest drainage catheters regardless of both applied pressure and bleeding type and despite clot formation in the HVCDS. Contrary to our *in vitro* tests, CCDS did not perform better in the case of catastrophic real bleeding. The influence of applied suction pressure intensity was not seen. This finding is corroborated by the outcomes of small caliber Blake drains (19F) applied in pleural positions in pigs where a sufficient drainage capacity in an *in vivo* setting was observed [7]. However, *in vitro* this small silastic drain has a drainage capacity 9 times smaller than a conventional chest tube serving as a control (28 F) [7]. This is obviously a result of its smaller physical dimensions and was confirmed in our *in vitro* study in which flow through the HVCDS was 1.24-1.3 times smaller than flow in the CCDS, depending on pressure conditions.

There was no significant difference in the completeness of drainage between the HVCDS and CCDS groups in our study. However, a potential better completeness of drainage in the HVCDS group could be attributed to the bigger total suction area compared to the conventional one (5.7 cm^2 vs. 2.4 cm^2) and by the use of more negative aspiration pressures. Such an observation was reported by Newcomb *et al*., who documented a significantly lower incidence of residual pleural effusions after cardiac operations when the high vacuum system was used [6].

High negative pressures conditions were used in our study. Despite the existence of accumulated practical experience, the management of chest tubes and accompanying devices remains completely undefined [9], and there are no data to guide an evidence-based decision concerning the negative suction pressure limit [10]. Generally, it is acknowledged that HNP can cause possible tissue damage of intra-thoracic organs even if it is not applied continuously by a vacuum source, but only exerted temporarily by manipulation such as drain milking or stripping [11, 12]. Moreover, potentially dangerous negative pressures can be generated by ordinary drainage systems when not properly adjusted and/or meticulously surveyed [13].

To the best of our knowledge, the pathological aspect of this study is one of the first that clearly evidences and characterizes the tissue damage caused by the application of HNP (between –2 kPa and –20 kPa). The tissue damage is not dependent on the type of catheter used and is localized and limited to the area of the direct contact of the negative pressure environment with surrounding tissues – via drain perforations. The extent of these pressure-dependant lesions in terms of depth is similar in CCDS and OPCABG stabilizers and is only 41% smaller in HVCDS, as seen in our morphometric study. Thus, the potentially protective role of multiple small perforations of the HVCDS catheter cannot be totally accepted as advocated by Wakabayashi [5, 8]. In our opinion, no matter what diameter the perforation, the adhering tissue is always exposed to the same negative pressure with all its subsequent consequences. The suction force applied to a unit of area under a given pressure is always the same and only pressure dependent ($F = P \times A$). In the case of a wider orifice, a higher suction force is distributed over a bigger area – because the pressure must be constant ($P = F/A$). That is why all lesions caused by CCDS and by OPCABG stabilizers were similar despite the difference of the orifice diameter. We explain more superficial HVCDS injuries at equal negative pressure by substantially higher flow resistance of its small perforations causing non-laminar flow conditions and possibly the fact that most holes were thrombosed. We have found that the mean cross-sectional area of tissue damage within one "kissing-mark" is the smallest in the HVCDS, but if multiplied by the number of orifices, the total area of injury is much bigger than in the case of the CCDS (115.2 mm^2 vs. 35.4 mm^2).

In the current study we were not able to observe the effect of high suction pressure on the reduction of bleeding theoretically caused by the collapse of the open cut surfaces due to HNP (A. Wakabayashi – oral communication). The reason may be that our real bleeding induced by right atrium stab incision was too great to be stopped in the manner previously described.

The miniaturization of the HVCDS catheter and the presence of significantly smaller orifices can create certain drawbacks. The presence of clot bridges obstructing drain perforations as well as partial clotting of the space

between two coaxial tubes was demonstrated in our study. This could be a major drawback in the clinical setting of a prolonged postoperative phase, even leading to a cardiac tamponade. Additionally, HNP can promote a blockage of drain orifices by tissues entering from outside, as observed also in the case of conventional chest tubes with an inadvertent, too high suction pressure.

Study limitations

This study is limited by the small number of animals used, as allowed by the Swiss veterinary Ethics Commission. It makes it impossible to perform any inter- or intragroup statistical comparisons concerning the hemodynamic and drainage parameters.

Another limitation is connected with the short time of aspiration and bleeding. As it is an acute study, no recovery assessment of the wound and especially heart muscle and lung after the removal of the drain could be performed. Thus, the real clinical significance of encountered heart and lung lesions remains unknown. However, the result of, for example, coronary artery bypass graft or other fragile implant impairment could be easily extrapolated.

In this study no cardio-pulmonary bypass was instituted and no cardiac arrest was used. Thus, the functioning of the cardiovascular system was not altered and potentially it was less sensitive to high vacuum conditions introduced experimentally.

Our short period study (30 min of bleeding) also impeded the assessment of the sequel of clogging, especially in the HVCDS.

Conclusions

Novel and conventional chest drainage systems were used for pericardial and pleural cavity drainage under different pressures up to 40 kPa. Application of high pressure drainage has no persistent influence on perioperative hemodynamics. The HVCDS showed adequate drainage capacity comparable to the CCDS. However, the novel drainage system is prone to internal clotting. Additionally, pressures higher than –2 kPa resulted in focal sub-epicardial and sub-pleural hemorrhages, no matter which system was used. The presence of multiple small orifices in the design of the HVCDS does not totally protect the surrounding tissues from negative pressure lesions. This tissue damage does not seem to influence the overall or regional cardiac muscle function; however, an assessment of potential interaction of this novel HNP device with fragile structure such as a CABG graft should be carried out.

Acknowledgments

We would like to express our gratitude to Mrs. Melodie Kaeser for her help in the correction of this manuscript and to Mrs Unn Lutzen for histological specimens processing.

Disclosures

The cost of laboratory animals and chest drainage catheters was covered by Medela AG, Switzerland.

Sources of funding

Institutional funds of Cardiovascular Research Group.

Medela AG, Switzerland covered the costs of laboratory animals and chest drainage catheters.

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