Early experience with the Thopaz⁺ chest drainage system – is this a new era in the management of post-cardiotomy bleeding?

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Abstract

Introduction: Monitoring postoperative drainage is a key aspect of patient assessment in the early postoperative period. Accurate assessment of drainage allows rapid diagnosis of postoperative bleeding, preventing excessive hemoglobin drop and cardiac tamponade. However, traditional methods of mediastinal drainage appear to be inaccurate and measurement can often be subjective, delaying the procedure.

Aim: To demonstrate our initial experience with a digital chest drainage system that can be used to closely monitor postoperative drainage.

Material and methods: The Thopaz⁺ system allows manual regulation of negative pressure in the chest. The digital system analyzes the current and long-term values of the drainage, which facilitates therapeutic decisions. The advantage of the system is its mobility, without the need for built-in vacuums in the hospital wall. This allows early rehabilitation of the patient, which is crucial in the perioperative period. The Thopaz system has been used in 42 consecutive patients in all types of cardiac surgery procedures with good key results.

Results: We did not observe any complications with the system and the learning curve of the staff was very fast, both for the physicians and the operating room nurses, intensive care nurses and postoperative nurses.

Conclusions: The first experiences with the Thopaz⁺ system were very positive. The system brings a lot of safety and comfort to the cardiac surgical care we provide. These conclusions are consistent with data published in randomized trials.

Key words: chest drainage, postoperative bleeding.

Introduction

Currently, there are 36 cardiac surgery centers in Poland, where about 20 000 procedures are performed every year. Based on data from Polish National Cardiac Surgery Registry, the number of cardiac surgical procedures is systematically increasing [1–3]. Every procedure requires postoperative drainage to avoid complications due to accumulation of fluid, serum and blood [4–6]. New developments in this field have been limited for decades, as the simple drainage systems we have used in the past have worked well and satisfactorily.

As the world has changed a lot and the cardiac surgical procedures are much more advanced and less invasive nowadays [7], there was a great need to improve the extremely old and archaic drainage systems [8, 9]. One of

the latest systems available on the market is the Thopaz⁺ system (Medela, UK), which offers very advanced management of patient safety and mobility.

The claimed overall benefits of the Thopaz⁺ system are shorter chest tube duration, shorter hospital stay, improved chest tube management, fewer patient complications, lower costs, high comfort for medical staff, less pain, and high patient satisfaction. It also provides much better prediction of patient outcomes and less wastage of consumables.

Aim

This manuscript presents our first experiences with the Thopaz⁺ system in the early phase of its implementation in the Cardiac Surgery department of one of the largest hospitals in Poland.

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Material and methods

The Thopaz⁺ system (Medela Inc UK) is a portable digital chest drainage system that creates a precisely regulated negative pressure near the patient's chest. It also continuously monitors the patient's current status by recording any air leaks and the amount of fluid drainage.

The Thopaz⁺ system has a built-in rechargeable battery that allows unrestricted patient mobility without the need to interrupt pressure at any time. It features a precisely controlled suction pump with a digital display that shows all important information and can be connected to any standard chest drainage catheter. The Thopaz⁺ system also includes a disposable fluid collection reservoir and multiple sensors built into the device to ensure accurate pressure readings and the highest level of safety.

In this evaluation the Thopaz system was used in 42 consecutive patients who received all types of standard cardiac surgery procedures. The system was kept for 1–2 days postoperatively, and removed with standard recommendations for all other types of drainage systems. No change of the blood container was needed as the one used was the largest, 2 l. There are 0.3 l, 8 l and 2 l available.

Results

The pilot program to use the Thopaz system in the Cardiovascular Surgery and Transplantology Department lasted one month. During this time, 20 operating room nurses, 16 surgeons, 14 intensive care unit (ICU) nurses, and 28 postoperative nurses received appropriate training. The Thopaz⁺ system was used in 42 patients. Familiarization with the Thopaz⁺ system took 20 minutes in each professional group.

The Thopaz⁺ pilot program was used only in elective surgery (100%), with 20 cases involving aortic valve replacement (41.6%) and the development of coronary aortic bypass surgery (58.4%). The average duration of use of the system in a patient was 1–2 days. During this time, we did not observe any complications or adverse activity of the system. There was no need to change containers in these patients as the containers we used were 2 l. The system also did not require a switch to a conventional drainage system. There were small problems with this system such as the alarm starting for an unknown reason in the cases of a few early subjects and problems directly related to staff errors that were easily and quickly identified and corrected.

The Thopaz⁺ system required additional staff training that was not limited to one group of medical experts or to one department only. The use of it started in the operating rooms (OR) where we need both our scrub nurses and surgeons to learn how to connect the system and turn it on. Fortunately it is a very easy system to assemble and use, so the OR staff needed just a few hours to get fully trained. After that all the staff in the ICU proceed to use the system. This is critical point due to the potential for extensive bleeding that might occur after the surgery and needs to be detected as early as possible. This part of the training was surprisingly easy to perform as everyone liked the system,

not only because of its great features, but mainly because it has an automatic alarm system and that it is quiet. We all know how loud the older systems based on the water valve can be on the ICU. Quietness gives the staff much more relief from the overall noises we have to face on the ICU.

The next step was the postoperative ward, which began to use the system and terminated its activity. Training there was also very easy, and it took a few hours during a few days as it was impossible to collect all the staff in place at the same time. Learning was found to be easy for everyone.

All of the members of our hospital staff appreciated the fact that there is no need to connect and disconnect the patient from the wall during transportation from one ward to another and during patient activities. Changing containers is also a trouble-free procedure.

Fortunately, it is very simple to learn how to use it and it requires a very short time.

Discussion

There are already several publications regarding the use of the Thopaz⁺ system from European centers, but so far there have been no manuscripts coming from Polish departments. We already have some reference hospitals currently using this system in Poland, and these are John Paul II hospital in Krakow and hospitals in Poznan, Szczecin-Zdroje and Zakopane, but only in the Thoracic Surgery Department. The total Polish experience reached 260 devices, but the global usage exceeds 100,000 devices.

In patients undergoing cardiac surgery, the pericardial cavity is routinely drained postoperatively by chest drains because of the risk of developing postoperative effusions that can cause tamponade or other hemodynamic problems [4, 5, 10]. The use of a drain is mandatory in any cardiac surgery, including the most common ones such as coronary artery bypass grafting [8, 11, 12], aortic valve replacement [13, 14], mitral valve repair or minimally invasive procedures [15] or even percutaneous procedures using epicardial access [16, 17].

Initial experience with the Thopaz system is very limited compared to European or US experience. There are only 42 devices that have been used in the John Paul II hospital and any problems we have had with this system have been related to a few early subjects and directly to staff errors that were easily and quickly identified and corrected. No serious adverse events were noted.

The Thopaz⁺ system has NICE and ERAS recommendation certificates for thoracic surgery and its use shortens the time in which drainage must be used, which directly leads to shorter hospital stays and lower costs, not to mention the comfort of use, which in our experience is very positive [5, 7]. The other investigators in European departments have observed much lower complication rates in their patients, as well as the very objective assessment of the patient's status from the moment the chest is closed after surgery. It is too early to make a definitive statement based on our experience, but worldwide experience has already demonstrated its undeniable benefit and safety [10, 18].

The published evidence for Thopaz⁺ includes a total of 13 studies with 1,632 patients included. There are also a few randomized controlled trials that have been published [10, 18]. We identified 6 randomized trials with 826 patients enrolled that provided excellent results. There are also many other studies that have been carried out around the world, mainly in Europe and the US. Almost all of them find the Thopaz system very helpful in preventing complications and providing additional comfort for medical staff.

Conclusions

The first experiences with the Thopaz⁺ system were very positive. The system brings a lot of safety and comfort to the cardiac surgical care we provide. These conclusions are consistent with data published in randomized trials.

Disclosure

The authors report no conflict of interest.

References

- Bartus K, Litwinowicz R, Sadowski J, Filip G, Kowalewski M, Suwalski P, Mazur P, Kędziora A, Jasiński M, Deja M, Kuśmierczyk M, Czup P, Zembala M, Jemielity M, Pawlaczyk R, Tobota Z, Maruszewski B, Kapelak B. Bioprosthetic or mechanical heart valves: prosthesis choice for borderline patients? Results from 9,616 cases recorded in Polish national cardiac surgery registry. *J Thorac Dis* 2020; 12: 5869-5878.
- Bartus K, Sadowski J, Litwinowicz R, Filip G, Jasinski M, Deja M, Kusmierczyk M, Pawlak S, Jemielity M, Jagielak D, Hendzel P, Suwalski P, Tobota Z, Maruszewski B, Kapelak B. Changing trends in aortic valve procedures over the past ten years-from mechanical prosthesis via stented bioprosthesis to TAVI procedures-analysis of 50,846 aortic valve cases based on a Polish National Cardiac Surgery Database. *J Thorac Dis* 2019; 11: 2340-2349.
- Filip G, Litwinowicz R, Kapelak B, Sadowski J, Tobota Z, Maruszewski B, Bartus K. Trends in isolated aortic valve replacement in middle-aged patients over the last 10 years: epidemiology, risk factors, valve pathology, valve types, and outcomes. *Kardiologia Polska* 2019; 77: 688-695.
- Barozzi L, San Biagio L, Meneguzzi M, Courvoisier DS, Walpoth BH, Faggian G. Novel, digital, chest drainage system in cardiac surgery. *J Card Surg* 2020; 35: 1492-1497.
- Engelman DT, Ali WB, Williams JB, Perrault LP, Reddy VS, Arora RC, Rosselli EE, Khojasteh A, Gerdtsch M, Levy JH. Guidelines for perioperative care in cardiac surgery: enhanced recovery after surgery society recommendations. *JAMA Surg* 2019; 154: 755-766.
- Litwinowicz R, Bartus K, Drwila R, Kapelak B, Konstanty-Kalandy J, Sobczynski R, Wierzbicki K, Bartus M, Chrapusta A, Timek T. In-hospital mortality in cardiac surgery patients after readmission to the intensive care unit: a single-center experience with 10,992 patients. *J Cardiothorac Vasc Anesthesia* 2015; 29: 570-575.
- Batchelor TJP, Rasburn NJ, Abdelnour-Berchtold E, Brunelli A, Cerfolio RJ, Gonzalez M, Ljungqvist O, Petersen RH, Popescu WM, Slinger PD, Naidu B. Guidelines for enhanced recovery after lung surgery: recommendations of the Enhanced Recovery After Surgery (ERAS[®]) Society and the European Society of Thoracic Surgeons (ESTS). *Eur J Cardiothorac Surg* 2019; 55: 91-115.
- Abramov D, Yeshayahu M, Tsodikov V, Gatot I, Orman S, Gavriel A, Chorni I, Tuvbin D, Tager S, Apelbom A. Timing of chest tube removal after coronary artery bypass surgery. *J Card Surg* 2005; 20: 142-6.
- Litwinowicz R, Bryndza M, Chrapusta A, Kobielska E, Kapelak B, Grudziński G. Hyperbaric oxygen therapy as additional treatment in deep sternal wound infections – a single center's experience. *Kardiologia Polska* 2016; 13: 198-202.
- Ramos Dos Santos PM, Aquaroni Ricci N, Aparecida Bordignon Suster É, de Moraes Paisani D, Dias Chiavegato L. Effects of early mobilisation in patients after cardiac surgery: a systematic review. *Physiotherapy* 2017; 103: 1-12.
- Light RW, Rogers JT, Moyers JP, Lee YC, Rodriguez RM, Alford WC Jr, Ball SK, Burrus GR, Coltharp WH, Glassford DM Jr, Hoff SJ, Lea JW, Nesbitt JC, Petracek MR, Starkey TD, Stoney WS, Tedder M. Prevalence and clinical course of pleural effusions at 30 days after coronary artery and cardiac surgery. *Am J Respir Crit Care Med* 2002; 166: 1567-1571.
- Litwinowicz R, Kapelak B, Sadowski J, Kędziora A, Bartus K. The use of stem cells in ischemic heart disease treatment. *Kardiologia Polska* 2018; 15: 196-199.
- Bartus K, Litwinowicz R, Bilewska A, Stapor M, Bochenek M, Rozanski J, Sadowski J, Filip G, Kapelak B, Kusmierczyk M. Intermediate-term outcomes after aortic valve replacement with a novel RESILIA(TM) tissue bioprosthesis. *J Thorac Dis* 2019; 11: 3039-3046.
- Bartus K, Litwinowicz R, Bilewska A, Stapor M, Bochenek M, Rozanski J, Sadowski J, Filip G, Kusmierczyk M, Kapelak B. Final 5-year outcomes following aortic valve replacement with a RESILIA[™] tissue bioprosthesis. *Eur J Cardiothor Surg* 2021; 59: 434-441.
- Bryndza M, Litwinowicz R, Kapelak B, Filip G, Piątek J, Konstanty-Kalandy J, Kędziora A, Bartus K. Recurrence of atrial fibrillation ten years after thoracoscopic transdiaphragmatic epicardial radiofrequency ablation. *Kardiologia Polska* 2018; 76: 1733-1735.
- Litwinowicz R, Bartus M, Kapelak B, Suwalski P, Lakkireddy D, Lee RJ, Bartus K. Reduction in risk of stroke and bleeding after left atrial appendage closure with LARIAT device in patients with increased risk of stroke and bleeding: long term results. *Catheter Cardiovasc Interv* 2019; 94: 837-842.
- Litwinowicz R, Bartus M, Malec-Litwinowicz M, Michalski M, Banaszkiwicz K, Kapelak B, Lakkireddy D, Bartus K. Left atrial appendage occlusion for secondary stroke prevention in patients with atrial fibrillation: long-term results. *Cerebrovasc Dis* 2019; 47: 188-195.
- Hofmann S, Awad G, Asch S, Saha S, Bireta C, Niehaus A, Baraki H, Kutschka I, Friedrich M. The influence of dynamically regulated, intermittently regulated active chest drainage units compared to conventional vacuum-driven systems on the early postoperative outcome after cardiac surgery. *Thorac Cardiovasc Surg* 2018; 66: S1-S10.