National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT325 - Thopaz+ portable digital system for the management of chest drains

Consultation comments table

Final guidance MTAC date: 8 December 2017

There were 8 consultation comments from 4 consultees:

- 1 manufacturer representative
- 3 healthcare professionals

The comments are reproduced in full.

#	ID	Role	Page	Sec	Comment	Response
1	1	Health professional (within NHS) on behalf of specialist society	-	-	There is only one small RCT in pneumothorax management which is for specific patients (continuing air leak) and managed a certain way (wall suction versus Thopaz suction) and therefore extrapolation to all patients with pneumothorax would be incorrect and risky. We support downgrading the evidence for pneumothorax management.	Thank you for your comment. The Committee considered both published and unpublished evidence, including audit data submitted during consultation (see comment 8), and expert advice. Its considerations are summarised in section 4.2 of the guidance. **The committee considered this comment carefully and decided not to change the guidance.**
2	2	Health professional (within NHS) on behalf of specialist society	-	-	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Thoracic Society (BTS).	Thank you for your comment. Please see the response to comment 1.
3	3	Company	-	1.1	The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve clinical decision-making through continuous, objective monitoring of air leaks and fluid loss. We believe the evidence is strong enough to change this last sentence to ; ''hopaz improves clinical decision-making continuous through objective monitoring of air leaks and fluid loss.'' The consulted experts have all stated it does and the evidence clearly shows that it does. We do not believe this should be considered to be anecdotal and the word «may» is a little weak considering this.	Thank you for your comment. The Committee considered the published evidence and received extensive advice from experts who have used Thopaz+. Although there are indications that management and decision making around chest drain use are improved using Thopaz+, the Committee felt that definitive evidence was currently lacking to make a conclusive statement on this. **The committee decided not to change the guidance.**

4	3	Company		1.2	Thopaz+ should be considered for people who need chest drinage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than standard wall suction. It is unneccessary to limit the use to ‘‘pulmonary resection or because of a pneumothorax’’ it can be used wherever a traditional chest drain would be used. Thopaz+ is essentially a chest drain and it seems a unfair and illogical to only recommend it’s use in these two indications. The advantages apply to any patient with an air leak or fluid draining from the pleural space. Please see also evidence by Rathinam attached " benefits also included utility in wards without wall suction" Rathinam attachment: https://cardiothoracicsurgery.biomedcentral.com/articles/10.1186/1749-8090-6-59 (link added by NICE)	Thank you for your comment. Evidence on other clinical conditions requiring chest drainage was considered in section 4.4 of the draft guidance. This stated that, although the experts acknowledged that staff from other clinical specialities did use their Thopaz+ units successfully, they did not have direct experience of these uses. Published evidence to support clinical or system benefits in other clinical conditions is currently lacking. The Committee concluded that extension of the guidance to other clinical conditions was not appropriate. The EAC confirmed that all included evidence was for the use of Thopaz+ in patients requiring chest drainage following pulmonary resection or for patients with pneumothorax only. The EAC stated that the paper by Rathinam et al. (2011) was excluded as it focussed on an end-user assessment of Thopaz+ which was outside of scope. The paper did not include outcomes for staff time. Qualitative patient views were presented in one small paragraph with no explanation of how this opinion was obtained. **The committee decided not to change the guidance.**
5	3	Company	-	1.3	Cost modelling indicates that Thopaz+ is cost saving compared with standard wall suction in people who need chest drainage after pulmonary resection. The estimated saving is £111.33 per patient over their stay in hospital. These savings are mainly achieved through reduced length of stay in hospital The advantages shown in the evidence are in comparison to traditional water seal chest drains whetеher they are attached to wall suction or not. There is an advantage over wall suction because the suction is regulated but this is only one aspect of Thopaz+ and relates to saftey not reduced costs. The advantage of objective data, mobility and alarm systems are all relevant in a comparison to traditional chest drains whether they are using wall suction or not and these are the advantages that impact patient stay, reduced xrays and therefore costs.	Thank you for your comment. The published evidence for Thopaz+ was on its use with powered suction. Clinical experts added anecdotal evidence that staff did use the device without suction to measure fluid loss and gas leakage in preference to water seal chest drains which do not offer objective, quantitative measurement. As the evidence for use was anecdotal, the Committee felt it appropriate to limit recommendations to those supported by the published evidence on powered suction use only. **The committee decided to change section 1.3 to further clarify the wording “wall suction” to “conventional chest drain”.**

6	3	Company	-	4.3	The committee considered the use of Thopaz+ in other patients who need chest drainage. None of the experts had experience of using the technology in children, but they did report the use of Thopaz+ in other patients needing chest drainage (such as after cardiac surgery and trauma). The clinical experts explained that if devices are available on wards they may be used safely for a broad range of patients who need chest drainage, but evidence to support clinical or system benefits in these circumstances is currently lacking. There is evidence for paediatric use Costa et.al. 2016 https://www.ncbi.nlm.nih.gov/pubmed/?term=28117476 (The use of this digital system facilitated the decision-making process during the postoperative period, reducing the risk of errors in the interpretation and management of air leaks.). Does the lack of a UK stakeholder exclude the evidence? We accept we may have been remiss in not making the committee aware of this paper. but lacking stakeholder experience in UK why excluded from NICE recommendation? There is also evidence for cardiac use from Barozzi et al 2015 (see attachment) and there will be data from a RCT comparing Thopaz+ and Atrium Ocean presented soon Van Linden et al perhaps before publication. Barozzi et al attachment – from Journal of cardiovascular surgery, abstract from meeting on March 28, 2015 (comment added by NICE)	Thank you for your comment. Please see the reply to comment 4 on use in patients other than those requiring drainage after re-section. The EAC commented that the company did not include the study by Costa et al. (2016) in their submission and was identified by the EAC in their included studies. The paper by Costa et al. (2016) was non-comparative and had a small sample size (n=11). It was a part of the committee's discussion regarding the use of Thopaz+ in other patients, including children who need chest drainage. The EAC said the conference abstract by Barozzi et al. (2015), had only one outcome of interest: fluid loss measurement. Other outcomes are related to cardiac surgery and are outside of the scope. As noted in section 4.3, clinical experts reported the use of Thopaz+ in other patients needing chest drainage (such as after cardiac surgery and trauma). However, the evidence to support this is lacking. The EAC cannot comment on the results from the RCT by Van Linden et al. as this has not been published and is unavailable. **The committee decided not to change the guidance.**

7	3	Company	-	4.13	The committee concluded that using Thopaz+ is likely to lead to significant clinical and system benefits compared with standard drainage using wall suction in people who need chest drainage after pulmonary resection or for pneumothorax. Again, the mention of wall suction is not relevant Additionally, there is evidence of patients needing fewer x-rays, see attached • J Cardiothorac Surg. 2011 Apr 21;6:59; o benefits also included utility in wards without wall suction, reduction in portable x-rays, decreased infection risk and better physiotherapy. • K. Tsakiridis1, T. Marinos2, S. Arikas1, S. Tzamtzis1. Thopaz Medela digital drainage system decreases the need of postoperative chest X-rays. DIGITAL THORACIC DRAINAGE: OUR INITIAL EXPERIENCE IN HUNDRED PATIENTS. Interactive CardioVascular and Thoracic Surgery, Volume 13, Issue Supplement_1, 1 August 2011, Pages S1–S58 • Cir Esp 2010, 87(6):385-9.; Interactive CardioVascular and Thoracic Surgery 2009, 9 (Supplement 1): S31; Multimed Man Cardiothorac Surg. 2009 Jan 1;2009(409): o Thopaz delivers objective information in chest drain management, reduces the number of x-rays and is cost effective Rathinam attachment: https://academic.oup.com/icvts/article/13/Supplement_1/S1/767007#13443748 (article P-066) (link added by NICE)	Thank you for your comment. Please see the reply to comments 4 and 5 on extension of the indication for Thopaz+ and the use of the words 'wall suction'. EAC commented that the clinical experts stated that patients may need fewer chest X-rays with the use of Thopaz+ (section 4.6). The EAC noted that the conference abstract by Tsakiridis et al. (2011) is of poor methodological quality with no quantitative data presented on the number of chest x-rays required. The authors of the paper presented a mean reduction of 30% across all variables (number of chest X-ray required per patient, time to mobilization, duration of the drainage and length of the in-hospital stay) with no individual outcome results presented. **The committee decided not to change the guidance.**
8	4	Health professional (within NHS)	-	-	I have attached the first audit performed. It is self explanatory. << Attachment displayed in Appendix 1 – pg 6 – 18) >>	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

Appendix 1

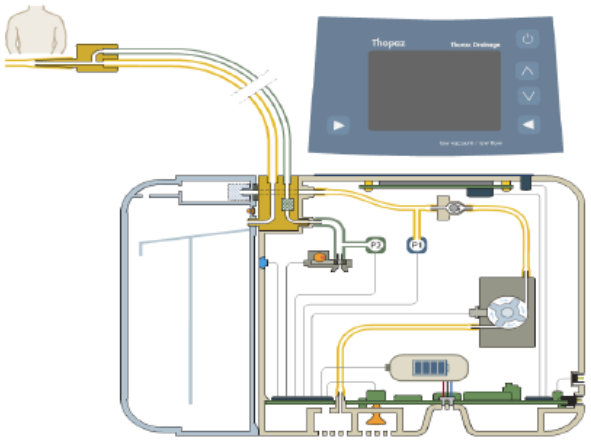
My everyday practice with the Thopaz pump

LEEDS THORACIC SURGERY
St.James's Institute of Oncology
St.James's University Hospital
Leeds. United Kingdom
www.leedsthoracicsurgery.com

Experience

- Used since March 2008
- Over 2500 procedures utilized of which 1100 anatomical lung resections.
- Unit's 'likes':
  one tube
  suction as standard unless contraindicated
  fluid volume has declined as an issue over the years

What was different?



- An entirely new concept; from underwater seal to waterless.
- From visual to digital reading
- From a canister to a digital gadget with real time info and recording capability

The Trial/Audit

- Single surgeon's results to standardise technique
- 430 cases treated between September 08 and September 09
- 250 patients needed tube drainage.
- Trained staff
- Continued support from Medela
- Software updates and improvements
- Feedback on recorded problems from pumps
- Strict protocols followed for all patients

The trial

- Patient safety
- Patient satisfaction
- Ease of handling
- Reliability
- Staff involvement and understanding
- Staff satisfaction
- Cost effectiveness
- Change of practice

Appendix 1 cont.

PROCEDURE	No of patients
Pneumonectomy	18
Lobectomy	86
Lesser resections	16
Lung biopsy	27
Pleurodesis for palliation of lung CA	37
Bullectomy pleurodesis	27
Miscellaneous (hernia, repair, thymectomies, pericardial cysts, pectus repairs, trauma, AF ablations e.t.c.)	39

Procedure subgroups

Results

- Serious events: 2 patients developed severe surgical emphysema post surgery.
- 6 patients switched to underwater seal when transferred to facilities with no experience in this device.

Patient experience- 27 patients had previous experience with 'BUBBLERS'

- More comfortable than classic bottle
- Less noisy when moderate or large air leak present
- Easy and Compact enough to carry
- Easier to handle as it had no attachments
- Allowed early mobilisation and accelerated postoperative recovery with a sense of faster progression to medical discharge.
- Civilised bed space

Nursing experience

- Easy to handle
- Simple to teach
- Guided alarms facilitated error handling
- Facilitated nursing care and patient hygiene
- 'Neat' consumables with reduced risk of infections
- Silent
- Compact
- More reliable than low pressure readings from 'wall' suction.

Surgeon's view

- Confident decisions for drain removal
- Confident decisions for drain management
- Real time recording of leak with no 'estimates'
- Retrospective viewing of drain function and incidences for safety purposes.

Appendix 1 cont.

PROCEDURE	No	Potential gain in hospital days	Percentage of patients with faster discharge	Cost benefits per group
Pneumonectomy	18	0	0%	£0.00
Lobectomy	86	36	41,8%	£13320.00
Lesser resections	16	4	25%	£1480.00
Lung biopsy	27	1	3%	£370.00
Pleurodesis for palliation of lung CA	37	7	19%	£2590.00
Bullectomy pleurodesis for Pneumothorax	27	19	70%	£7030.00
Miscellaneous	39	3	0.8%	£1110.00

Procedure subgroups and subgroup cost analysis

Appendix 1 cont.

How was cost benefit estimated?

- Tubing cost
- Canister cost and number of canisters required per treatment
- Use of saline cost (fluid to prime the traditional systems)
- Number of chest films required per treatment
- Length of stay cost benefit.

Change of practice?

- **Past**
- Several Chest films
- Reliability of Ward round findings
- Controlled by Nursing staff notes
- If in doubt stay one day more for observations

- **Present**
- No need for serial chest films
- Reliability of data/graphs
- No doubt
- Civilized environment
- Mobility
- Nursing experience