

Risk models for monitoring post-operative complication rates after pediatric cardiac surgery

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Abstract

Objectives

As post-operative mortality for pediatric cardiac surgery is very low, we aimed to develop methods for monitoring of post-operative complication rates, given their impact upon children's health and wellbeing.

Methods

We used national registry data to develop and evaluate a suite of risk adjustment models for the outcomes of 6 defined post-operative complications, designed for use in complication monitoring for quality assurance.

Results

There were 23,423 30-day post-operative episodes in children under the age of 18-years undergoing cardiac surgery between 2015-2021 in England and Wales, with 361 (1.5%) deaths <30-days. 257 (1.9%) of 13,556 post-operative episodes in infants (<1 year) involved necrotising enterocolitis; 158 (1.3%) of 12,408 post-operative episodes between 2018 and 2021 involved prolonged pleural effusion; and amongst the full sample of post-operative episodes there were 526 (2.2%) acute neurological events, 446 (1.9%) extracorporeal life supports, 740 (3.6%) renal replacement therapies and 1,006 (4.3%) unplanned reinterventions within 30-days of surgery. The risk adjustment models were developed using clinical factors first defined for mortality monitoring. The models for prolonged pleural effusion, extracorporeal life support and renal replacement performed very well with area under the curve (AUC) statistics >0.85. The performance of the models for necrotising enterocolitis, acute neurological event and unplanned reintervention were less good (AUC statistics 0.74-0.79).

Conclusions

Although complications are more complex outcome measures than mortality, national registry data can be used to capture them and to evaluate methods for risk adjustment of these outcomes. These methods may enable future risk-adjusted monitoring of complication metrics for quality assurance.

Keywords

Cardiac surgery, outcomes, care quality, complications.

Introduction

The 30-day post-operative mortality following pediatric cardiac surgery is <2% in the UK.¹

Mortality is monitored using variable life adjusted display charts² reviewed monthly within all centres, and annually by the United Kingdom and Republic of Ireland National Congenital Heart Diseases Audit (NCHDA). These analyses, based on risk adjusted analyses of 30-day mortality^{3,4}, enable the review of recent trends in benchmarked outcomes, and support prompt action if any worrisome deviations are observed.

In line with international efforts to supplement post-operative mortality monitoring with additional metrics⁵⁻⁷, the national audit started collecting complication outcomes in 2015, and reporting centre level, unadjusted rates in 2020¹. The complication metrics were based on a multi-centre prospective research project that selected⁸, defined⁹, measured¹⁰, and evaluated¹¹ 9 complication outcomes. Prospective study noted these selected complications to be important based on demonstrated links to prolonged hospitalisation, costs, quality of life¹¹ and toddler neurodevelopment¹². Given the feasibility constraints of national audit, mandatory monitoring of complications was restricted to 6 of the 9 metrics, and their definitions refined based on clinician and data manager feedback¹³.

In this study we aimed to develop risk adjustment methods for each of the 6 complication metrics monitored by the national audit, so that future use in local quality assurance and national reporting could take account of case-mix.

Methods:

Data sources

We used all records of cardiac surgeries that occurred in public hospitals in England and Wales between 2015-2021 for patients aged under 18-years. This data submission is mandatory and subjected to annual external validation. In line with post-operative mortality

monitoring¹, we created 22,423 '30-day episodes' that started with a cardiac surgery and ended with the patient's vital status at 30-days. Patients who had only a transcatheter or cardiac support procedure were excluded. Subsequent surgeries for the same patient occurring within a 30-day episode did not count as new 30-day episodes. If a patient had further cardiac surgery >30-days later, this initiated a new 30-day episode. All variables were based on the European Pediatric Cardiac Code version of the International Pediatric Cardiac Code.

Ethical approvals

The study was approved by the North of Scotland National Health Service Research Ethics Committee February 14th 2020 (20/NS/0022) and the Health Research Authority Confidentiality Advisory Group on 12th July 2020 (20/CAG/0027) which permits the use of routinely collected patient data without consent.

Complication outcomes

The outcome measures were the following 6 complications, ascertained <30-days of surgery: **necrotising enterocolitis, prolonged pleural effusion, acute neurological event, extracorporeal life support, renal replacement therapy and unplanned reintervention (comprised any one of; unplanned additional cardiac surgery, interventional catheterisations, permanent pacemaker placements and diaphragm plication procedures).**

The detailed definitions (Supplementary Appendix 1) are in the NCHDA data manual.¹³ The time criteria for prolonged pleural effusion changed from 7 to 10 days after surgery in 2018, hence analysis of this outcome was restricted to post-2018 data. The analysis of necrotising enterocolitis was restricted to children aged under 1-year at surgery given the age distribution of this complication.

Candidate risk factors

Candidate risk factors were based on those identified as important in our previous prospective study of post-operative complications.¹⁰ These were defined by record level codes and followed national audit definitions^{3,4,14} (we provide expanded details in Supplementary Appendix 2 and we provide lists of CHDs and specific operation types in Supplementary Tables 1 and 2).

- Age (in years) and weight (in kg) were included as a continuous term and square root term (the latter to account for the non-linear relationship between age / weight and outcome). Records that had an absolute weight-for-age Z-score of 5 or higher, weights deemed infeasible by a clinician, and missing weights were assigned the average weight-for-age.
- Specific cardiac surgeries (N=58) and congenital heart diseases (CHDs) (N=26) were identified based on clinical codes and national algorithms.
- Additional pre-operative risk factors were identified before surgery from record level codes using national definitions: the presence of functionally univentricular heart (FUH)^{3,4}, acquired comorbidity (e.g.: renal failure)¹⁴, additional cardiac risk factors (e.g.: impaired ventricular function)¹⁴, congenital non-cardiac comorbidity (e.g.: genetic syndrome)¹⁴, congenital cardiac risk factors (e.g.: anomalous coronary artery), Down syndrome, prematurity (<37 weeks birth gestation), increased severity of illness factors present (e.g.: ventilated)¹⁴ and level of operation urgency¹³.

Data processing

To avoid model overfitting, we considered that the number of events in the dataset should be 10-times larger than the number of parameters¹⁵ therefore we collapsed the 58 cardiac procedures and 26 CHDs into broader groups. Thus, for each complication outcome we

created 10 specific cardiac operation groups and 8 CHD groups ranked in prevalence order for the relevant complication. For prolonged pleural effusion where there was a lower event number, we limited this to 7 specific cardiac operation groups and 5 CHD groups. All groups were checked by clinical experts to ensure face validity and we report details of these in Supplementary Tables S1 and S2. We marked up 8/348 (2.3%) specific cardiac operation and complication outcome combinations with zero events: these 8 were moved into the mid from the lowest risk band based on clinical opinion that the event number in wider practice is not zero.

Statistical analysis

We reported missing values and the prevalence of each candidate risk factor by complication outcome, with the relevant Chi square p-value for the whole dataset, inclusive of deceased patients. Because death could be a competing event with the occurrence of complications, we calculated the interval in days between the index surgery and death, finding a median of 11-14 days (first quartile 4-5 days) at death in the absence of any of the 6 complication outcomes. The interval from index surgery to complication onset was obtained from a prior, prospective study¹⁰ (median (IQR) days): acute neurological event 6 (3,14), prolonged pleural effusion 6 (3,10), extracorporeal life support 1 (0,2), necrotising enterocolitis 6 (4,18), unplanned reintervention 9 (3,17) and renal replacement therapy 2 (1,2). The short time interval between surgery and onset for extracorporeal life support and renal replacement therapy meant that death was not considered a competing event, hence in these risk models, all records were included. For the other four risk models, we removed the records of patients who died without this complication occurring.

When developing the risk adjustment models, we undertook a complete case analysis. For each outcome we conducted univariate logistic regression (with standard errors estimated

clustering by centre) for all candidate risk factors and selected for inclusion those with $p < 0.2$ in univariate analysis; then multivariate logistic regression backward selection was applied (with p value threshold $p < 0.2$ and standard errors clustering by centre). We thus generated a prospective multiple variable risk model for each outcome. Receiver operating characteristic (ROC) curves, model calibration slope and calibration-in-the-large and Brier scores were calculated across 25 5-fold cross-validation repeats.

Results

There were 23,423 30-day post-operative episodes with 361 (1.5%) deaths <30-days. A total of 47 included records involved an imputed weight. Descriptive analyses of complication prevalence involved up to 94 records with a missing value, and included all records involving death within 30-days: details for each complication outcome are shown in Tables 1 and 2.

Complication prevalence

The event number and rate for each complication outcome was necrotising enterocolitis: 257 (1.9%) of 13,556 post-operative episodes in children <age of 1-year; prolonged pleural effusion: 158 (1.3%) of 12,408 post-operative episodes between 2018 and 2021; and amongst the full sample of 23,423 post-operative episodes there were: acute neurological event 526 (2.2%), extracorporeal life support 446 (1.9%), renal replacement therapy 740 (3.6%) and unplanned reintervention 1,006 (4.3%).

Cardiac risk factors and complications

The ranked 'risk groups' into which we collapsed 26 CHDs and 58 specific cardiac operations for each complication prevalence and for use in the modelling are reported in Supplementary Tables S1 and S2. For each stated complication, the cardiac operations at highest risk were:

- Necrotising enterocolitis (cardiac conduit replacement, totally anomalous pulmonary venous connection repair and arterial shunt, biventricular pacemaker placement).

- Prolonged pleural effusion (congenitally corrected transposition repair, Rastelli-REV procedure, Fontan operation).
- Acute neurological event (implantable cardioverter defibrillator operation, totally anomalous pulmonary venous connection repair and arterial shunt, arterial switch and aortic arch obstruction repair).
- Extracorporeal life support (totally anomalous pulmonary venous connection repair and arterial shunt, heart transplant, truncus and interruption repair).
- Renal replacement therapy (truncus and interruption repair, Senning operation, Norwood stage one operation).
- Unplanned reintervention (Rastelli-REV procedure, tricuspid valve replacement, congenitally corrected transposition repair).

Presence of a functionally univentricular circulation was associated with much higher risk of all complications.

Additional risk factors and complications

Younger age, smaller size, and urgent compared to elective operation were associated with much higher risk of all complications except prolonged pleural effusion ($p < 0.001$ for all).

Prolonged pleural effusion was more common in older, larger children and was unrelated to operation urgency.

Strong evidence for an association ($p < 0.001$ for all) was found for:

- Pre-operative acquired comorbidity with acute neurological event, renal replacement and unplanned reintervention.
- Additional cardiac risk factors with acute neurological event, extracorporeal life support and unplanned reintervention.

- Congenital comorbidity with acute neurological event, extracorporeal life support and unplanned reintervention.
- Congenital cardiac risk factors with pleural effusion and unplanned reintervention.
- Downs, with extracorporeal life support.
- Pre-operative critical illness with acute neurological event, extracorporeal life support, renal replacement and unplanned reintervention.

With preterm birth, there was much lower risk of renal replacement therapy.

We present additional demographic information in Supplementary Tables S3 and S4.

Risk Models

Up to 94 records that involved a missing value, and records involving death <30 days without the specified complication (necrotising enterocolitis (n=284), prolonged pleural effusion (n=190), acute neurological event (n=306), and unplanned reintervention (n=301)) were removed. The univariate analysis is presented in Supplementary Table S5 and the multi-variable risk models are presented in Table 3, with the total contributing records in first row. The risk models for prolonged pleural effusion, extracorporeal life support, and renal replacement therapy performed very well with area under the curve (AUC) statistic >0.85. The performances of the risk models for necrotising enterocolitis, acute neurological event and unplanned reintervention were slightly less good (AUC statistics 0.74 to 0.79) (see Table 3 and figure 1 for details).

Discussion

We aimed to develop a suite of 6 risk adjustment models for routine quality assurance processes in pediatric cardiac surgery when assessing complication rates. Hence, to make interpretation as clear as possible for users, we used a similar data management and statistical approach across all 6 of the models. Although complication outcomes are more

complex metrics than 30-day mortality, it was feasible to develop risk models for case mix adjustment that could be taken forwards by the national audit. The outcomes that could be clinically ascertained most consistently had the best performing risk models (prolonged pleural effusion, extracorporeal life support, and renal replacement therapy). Ascertainment of necrotising enterocolitis, acute neurological event and unplanned reintervention entail consideration of several complex clinical parameters, potentially contributing to their weaker model performances.

Context

The Society of Thoracic Surgery Congenital Heart Surgery Database monitors a range of complication metrics closely matching those selected by NCHDA (unplanned reinterventions inclusive of diaphragm plication and permanent pacemakers, renal replacement therapy and new neurological deficits), and has stressed the importance of these metrics in quality assurance^{6,7}. The Pediatric Cardiac Critical Care Consortium (PC4) successfully demonstrated that reporting and review of complication metrics (which include cardiac arrest, mechanical circulatory support, unplanned cardiac reintervention, neurologic complications, chylothorax) can lead to improved outcomes of mortality and length of stay⁵. The success of PC4 and our alignment with some PC4 metrics, supports the hypothesis that our study has potential to benefit future patients in England and Wales. The near real time monitoring of risk adjusted 30-day mortality rates of paediatric cardiac surgery has been helpful to clinical teams in the UK, and we hope to test a similar process for complication monitoring.

Strengths and limitations

We present unique descriptive information about the rates and risk factors for selected important complications linked to pediatric cardiac surgery, including complication prevalences with specific operations. However, we are aware that complication definitions are more variable and open to interpretation than 30-day mortality. We note that the

national complication definitions have been subject to refinements to improve clarity: this might mean outcome ascertainment was imperfect. The selected complications used for national audit in the United Kingdom and Republic of Ireland do not capture every possible metric: for example, complications considered important by clinicians that were not included were tracheostomy because this is very rare in our population; surgical site infection because this was not reliably captured; and post-operative cardiac arrest, which was recently added as a national metric.

Conclusions and next steps

These methods may enable future risk adjusted monitoring of complication metrics for quality assurance. If the risk models are used for risk adjusted routine monitoring of these outcomes, then submitted data quality is likely to improve.

Data sharing

The study data are held and can only be analysed based on a current and valid data sharing agreement with the National Congenital Heart Diseases Audit and National Health Service Digital.

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Conflicts of interest

None.

Author contributions

Study design was undertaken by KB, CP, SC FP, GA; data analysis by HM FP; data management by JS, JT, FP; clinical methods by KB, RF, CVD, SS, VT; all authors wrote and approved the paper HM, FP RF, GA, JS, JT, CVD, SS, VT, CP, SC, KB.

Figures legends

Graphical Abstract

Figures depict the Receiver Operating Characteristic (ROC) curves for two example complication risk prediction models, showing the different levels of performance.

Figure 1

Figure 1 depicts the Receiver Operating Characteristic (ROC) curves for each of the 6 complication risk prediction models that were developed using a sample of national registry data pertaining to 23,423 pediatric congenital cardiac surgeries. Each of the 25 5-fold cross validation ROC curves is plotted using a light blue thin line (the darker the colour the bigger the overlap between ROC curves). The ROC curve with median Somer's Area Under the ROC value is represented with a black wide line.

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Table 1 Prevalence of risk factors based on post-operative complications ascertained in selected samples

$p \leq 0.05$ and $>0.01=*$, $p \leq 0.01$ and $>0.001=**$ and $p \leq 0.001=***$.

	Necrotising enterocolitis			Prolonged pleural effusion		
Risk factor	Total	No	Yes	Total	No	Yes
All records in sample	13,556	13,299	257	12,408	12,250	158
Weight and age:						
Weight (Kg) median (IQR)	4.3 (3.2-6.1)	4.3 (3.2-6.1)	3.3 (2.9-4.1)***	7.1 (3.9-15.0)	7.0 (3.9-15.0)	14.8 (6.4-18.6)***
Age (Years) median (IQR)	0.2 (0.1-0.5)	0.2 (0.1-0.5)	0.1 (0.0-0.2)***	0.6 (0.2-3.9)	0.6 (0.2-3.9)	3.5 (0.4-5.4)***
Age band:			***			***
Neonate(<28-days)	4,027 (30%)	3,895 (29%)	132 (51%)	2,154 (17%)	2,133 (17%)	21 (13%)
Infant(28-days-1-year)	9,529 (70%)	9,404 (71%)	125 (49%)	4,987 (40%)	4,951 (40%)	36 (23%)
Child(>1-year)				5,267 (42%)	5,166 (42%)	101 (64%)
Sex:						
Male	7,643 (56%)	7,506 (56%)	137 (53%)	6,997 (56%)	6,912 (56%)	85 (54%)
Female	5,910 (44%)	5,790 (44%)	120 (47%)	5,409 (44%)	5,336 (44%)	73 (46%)
Missing	3 (0%)	3 (0%)	0 (0%)	2 (0%)	2 (0%)	0 (0%)
Clinical factors:						
Acquired Comorbidity	2,047 (15%)	1,999 (15%)	48 (19%)	2,017 (16%)	1,998 (16%)	19 (12%)
Additional Cardiac Risk	987 (7%)	964 (7%)	23 (9%)	939 (8%)	928 (8%)	11 (7%)
Congenital Comorbidity	2,669 (20%)	2,606 (20%)	63 (25%)*	2,671 (22%)	2,631 (21%)	40 (25%)
Congenital Cardiac Risk	179 (1%)	172 (1%)	7 (3%)*	155 (1%)	147 (1%)	8 (5%)*
Downs Syndrome	1,355 (10%)	1,341 (10%)	14 (5%)*	1,003 (8%)	989 (8%)	14 (9%)
Premature	2,485 (18%)	2,451 (18%)	34 (13%)*	1,680 (14%)	1,667 (14%)	13 (8%)*
Severity of illness	2,861 (21%)	2,790 (21%)	71 (28%)*	1,661 (13%)	1,647 (13%)	14 (9%)
Functionally univentricular heart	1,869 (14%)	1,797 (14%)	72 (28%)*	1,754 (14%)	1,667 (14%)	87 (55%)*
Procedure urgency:			***			
Elective	6,959 (51%)	6,873 (52%)	86 (33%)	8,522 (69%)	8,402 (69%)	120 (76%)
Urgent	6,547 (48%)	6,376 (48%)	171 (67%)	3,848 (31%)	3,810 (31%)	38 (24%)

Missing	50 (0%)	50 (0%)	0 (0%)	38 (0%)	38 (0%)	0 (0%)
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Table 2: Prevalence of risk factors based on post-operative complications ascertained from the full sample

p ≤ 0.05 and >0.01=*, p ≤ 0.01 and >0.001=** and p ≤ 0.001=***.

	Acute neurological event			Extracorporeal life support		Renal replacement therapy		Unplanned reintervention	
	Total	No	Yes	No	Yes	No	Yes	No	Yes
All in sample	23,423	22,897	526	22,977	446	22,683	740	22,417	1,006
Weight and age:									
Weight (Kg) median (IQR)	7.0 (3.9-15.1)	7.0 (3.9-15.2)	5.3 (3.4-10.7)***	7.0 (3.9-15.2)	4.1 (3.2-8.7)***	7.1 (4.0-15.4)	3.6 (3.0-6.2)***	7.0 (3.9-15.2)	5.8 (3.5-13.2)***
Age (Years) median (IQR)	0.6 (0.2-4.0)	0.6 (0.2-4.0)	0.4 (0.1-1.8)***	0.6 (0.2-4.0)	0.2 (0.0-1.1)***	0.7 (0.2-4.1)	0.0 (0.0-0.5)***	0.6 (0.2-4.0)	0.5 (0.1-3.0)***
Age band			***		***		***		***
Neonate(<28-days)	4,027 (17%)	3,887 (17%)	140 (27%)	3,858 (17%)	169 (38%)	3,628 (16%)	399 (54%)	3,766 (17%)	261 (26%)
Infant(28-days-1-year)	9,529 (41%)	9,303 (41%)	226 (43%)	9,367 (41%)	162 (36%)	9,322 (41%)	207 (28%)	9,149 (41%)	380 (38%)
Child(>1-year)	9,867 (42%)	9,707 (42%)	160 (30%)	9,752 (42%)	115 (26%)	9,733 (43%)	134 (18%)	9,502 (42%)	365 (36%)
Sex:									
Male	13,013 (56%)	12,711 (56%)	302 (57%)	12,786 (56%)	227 (51%)	12,588 (55%)	425 (57%)	12,453 (56%)	560 (56%)
Female	10,405 (44%)	10,181 (44%)	224 (43%)	10,186 (44%)	219 (49%)	10,090 (44%)	315 (43%)	9,959 (44%)	446 (44%)
Missing	5 (0%)	5 (0%)	0 (0%)	5 (0%)	0 (0%)	5 (0%)	0 (0%)	5 (0%)	0 (0%)
Clinical factors:									
Acquired Comorbidity	3,559 (15%)	3,376 (15%)	183 (35%)***	3,481 (15%)	78 (17%)	3,405 (15%)	154 (21%)***	3,358 (15%)	201 (20%)***
Additional Cardiac Risk	1,747 (7%)	1,680 (7%)	67 (13%)***	1,664 (7%)	83 (19%)***	1,679 (7%)	68 (9%)	1,630 (7%)	117 (12%)***
Congenital Comorbidity	4,875 (21%)	4,681 (20%)	194 (37%)***	4,754 (21%)	121 (27%)***	4,708 (21%)	167 (23%)	4,602 (21%)	273 (27%)***
Congenital Cardiac Risk	370 (2%)	353 (2%)	17 (3%)**	361 (2%)	9 (2%)	352 (2%)	18 (2%)*	331 (1%)	39 (4%)***
Downs Syndrome	1,842 (8%)	1,811 (8%)	31 (6%)	1,826 (8%)	16 (4%)***	1,806 (8%)	36 (5%)*	1,761 (8%)	81 (8%)
Premature	3,144 (13%)	3,063 (13%)	81 (15%)	3,084 (13%)	60 (13%)	3,074 (14%)	70 (9%)***	3,030 (14%)	114 (11%)*
Severity of illness	3,281 (14%)	3,120 (14%)	161 (31%)***	3,111 (14%)	170 (38%)***	3,070 (14%)	211 (29%)***	3,052 (14%)	229 (23%)***
Functionally univentricular heart	3,333 (14%)	3,184 (14%)	149 (28%)***	3,194 (14%)	139 (31%)***	3,121 (14%)	212 (29%)***	3,046 (14%)	287 (29%)***
Procedure urgency:			***		***		***		***
Elective	15,904 (68%)	15,660 (68%)	244 (46%)	15,755 (69%)	149 (33%)	15,638 (69%)	266 (36%)	15,359 (69%)	545 (54%)
Urgent	7,430 (32%)	7,148 (31%)	282 (54%)	7,133 (31%)	297 (67%)	6,956 (31%)	474 (64%)	6,970 (31%)	460 (46%)

Missing	89 (0%)	89 (0%)	0 (0%)	89 (0%)	0 (0%)	89 (0%)	0 (0%)	88 (0%)	1 (0%)
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Table 3: Multiple logistic regression models and model performance measures

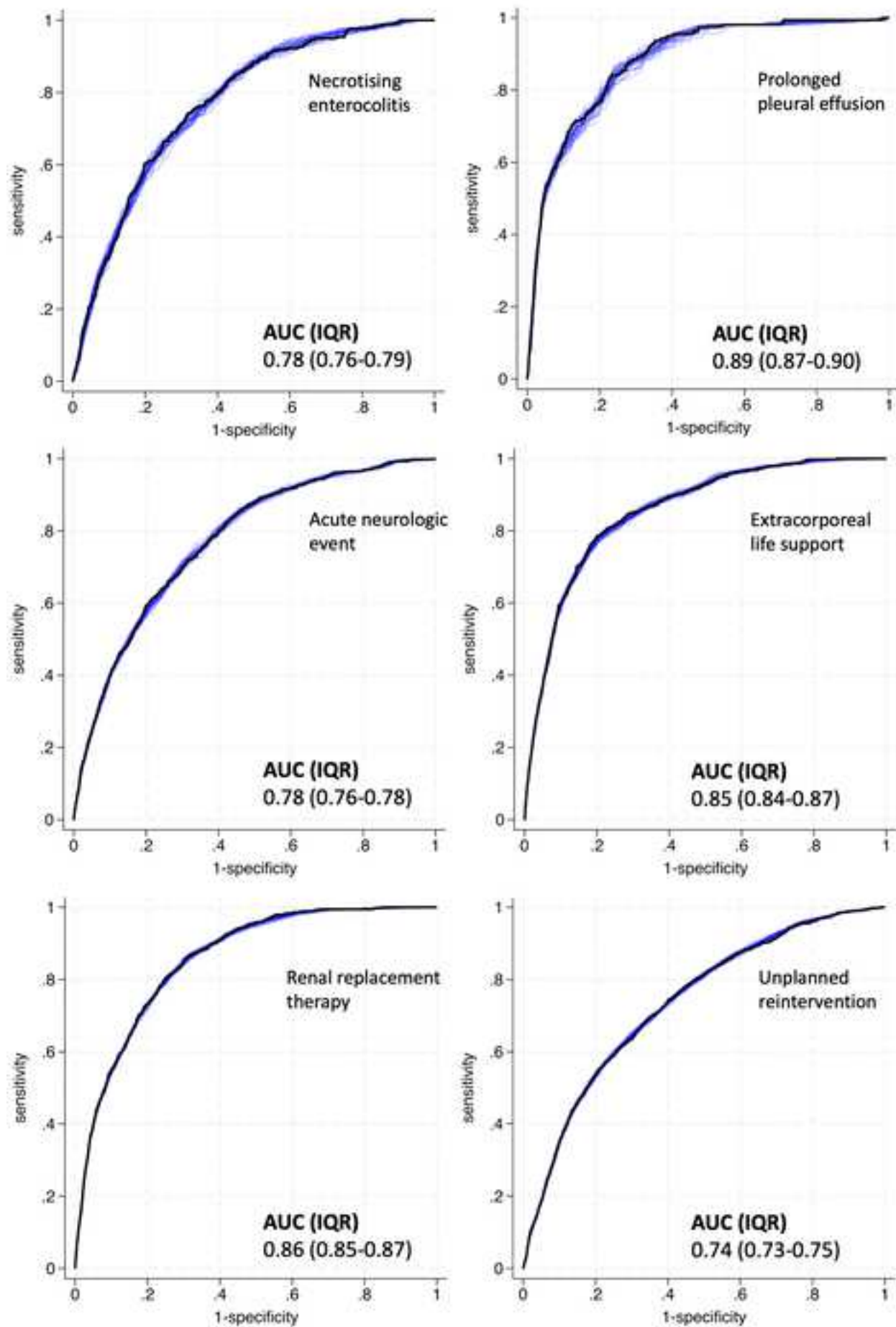
For each complication outcome we present the adjusted odds ratio with 95% confidence interval and p-values as $p \leq 0.05$ and $>0.01=*$, $p \leq 0.01$ and $>0.001=**$ and $p \leq 0.001=***$.

Calibration-in-the-large is assessed by comparing the average predicted risk with the observed event rate: a perfectly calibrated model should have a value of 0.

Brier score is the mean squared difference between predicted probabilities and actual outcomes, with 0 meaning perfect prediction.

	Necrotising enterocolitis	Prolonged pleural effusion	Acute neurological event	Extracorporeal life support	Renal replacement therapy	Unplanned reintervention
Total contributing records	13,219	12,178	23,023	23,329	23,329	23,028
Risk factor						
Sex girl v boy		1.18 (1.05,1.33)**		1.36 (1.12,1.66)**		
Age in years					1.37 (1.18,1.60)***	1.04 (0.99,1.09)
Age (SQRT)	2.72 (1.04,7.11)*	1.75 (1.25,2.44)***			0.45 (0.25,0.83)*	
Weight in Kg		0.97 (0.96,0.99)**		1.02 (0.99,1.05)		0.99 (0.97,1.00)
Weight (SQRT)	0.13 (0.07,0.24)***			0.76 (0.59,1.00)*	0.64 (0.41,1.02)	
Elective v urgent types			1.58 (1.32,1.90)***	1.92 (1.35,2.74)***	1.40 (1.15,1.70)***	1.44 (1.32,1.56)***
Acquired comorbidity	1.31 (0.99,1.71)		2.42 (1.50,3.91)***		1.57 (1.11,2.21)*	1.26 (0.98,1.63)
Additional cardiac risk				1.90 (1.39,2.59)***		1.25 (1.05,1.49)*
Congenital comorbidity	1.27 (0.93,1.72)	1.33 (1.12,1.59)**	2.10 (1.79,2.47)***	1.44 (1.03,2.00)*		1.28 (1.04,1.57)*
Congenital cardiac risk						1.77 (0.99,3.18)
Downs syndrome						
Prematurity	0.66 (0.46,0.94)*					
Severity of illness			1.68 (1.25,2.26)***	2.15 (1.30,3.55)**	1.33 (1.04,1.71)*	1.51 (1.08,2.11)*
Functionally univentricular heart	1.88 (0.86,4.10)	2.39 (1.44,3.98)***	1.34 (0.93,1.93)	1.34 (0.97,1.86)		
Procedure prevalence groups						
(2 v 1)	1.90 (0.76,4.74)***	5.47 (1.34,22.32)***	1.74 (0.89,3.39)***	5.08 (1.68,15.34)***	4.75 (2.09,10.80)***	1.28 (0.49,3.38)***
(3 v 1)	1.61 (0.46,5.67)***	11.57 (4.59,29.18)***	2.27 (1.35,3.80)***	6.78 (3.65,12.61)***	7.29 (2.73,19.44)***	1.53 (0.56,4.20)***
(4 v 1)	7.46 (3.20,17.37)***	15.08 (4.85,46.82)***	2.68 (0.99,7.24)***	9.94 (5.64,17.52)***	15.38 (5.87,40.29)***	1.29 (0.47,3.56)***
(5 v 1)	3.85 (1.36,10.94)***	25.16 (8.65,73.18)***	3.59 (2.11,6.11)***	11.36 (5.15,25.01)***	25.60 (12.19,53.77)***	2.57 (1.08,6.09)***

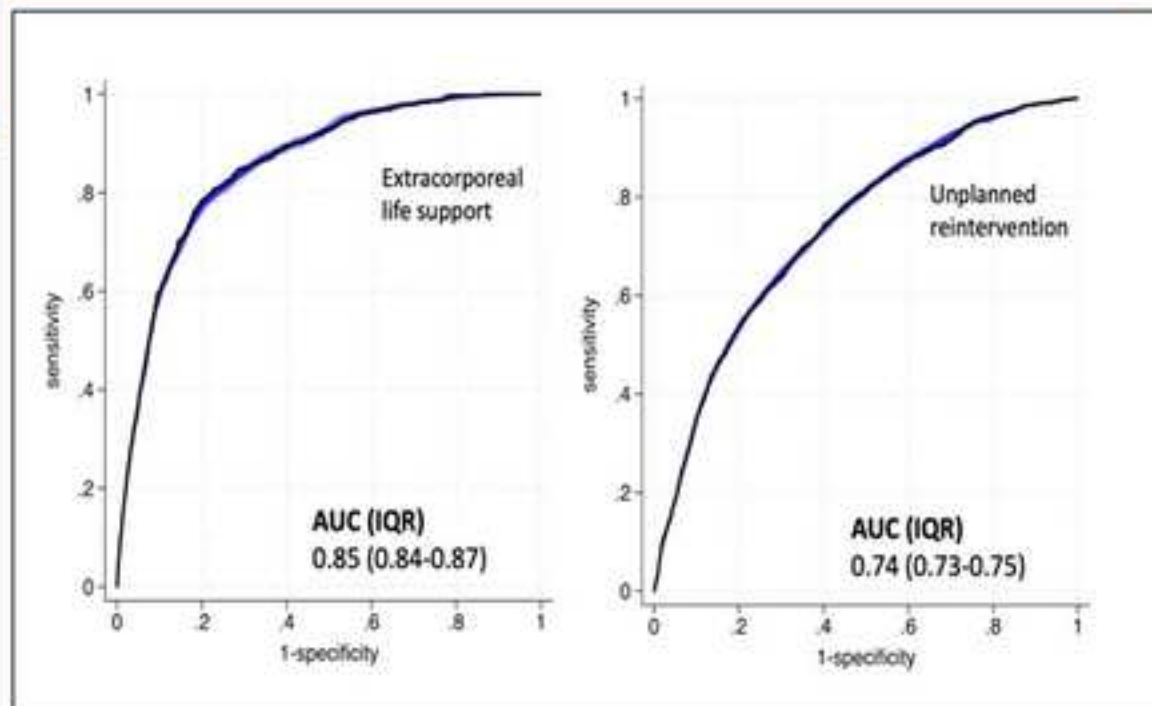
(6 v 1)	4.23 (1.76,10.15)***	35.29 (12.32,101.13)***	4.44 (2.33,8.44)***	11.70 (6.55,20.90)***	40.53 (13.26,123.91)***	1.58 (0.66,3.80)***
(7 v 1)	5.71 (2.84,11.48)***	50.06 (21.41,117.01)***	4.41 (2.19,8.91)***	9.15 (4.70,17.81)***	41.72 (21.99,79.13)***	2.62 (1.05,6.53)***
(8 v 1)	8.24 (4.14,16.37)***	80.63 (25.38,256.22)***	5.38 (2.13,13.57)***	21.36 (9.91,46.02)***	75.56 (42.51,134.31)***	2.82 (1.19,6.66)***
(9 v 1)	7.98 (3.30,19.29)***		6.46 (3.99,10.46)***	23.20 (11.12,48.41)***	123.30 (49.54,306.90)***	3.31 (1.24,8.79)***
(10 v 1)	15.79 (7.06,35.33)***		8.53 (4.15,17.54)***	40.66 (17.79,92.94)***	90.76 (37.70,218.51)***	6.19 (2.39,16.08)***
CHD Prevalence Groups						
(2 v 1)	5.71 (1.99,16.37)***	3.07 (1.22,7.71)***	2.75 (1.05,7.22)***	1.65 (0.46,6.01)***	1.37 (0.60,3.14)***	3.52 (1.25,9.89)***
(3 v 1)	5.56 (2.31,13.36)***	4.38 (1.56,12.30)***	4.29 (1.66,11.04)***	2.79 (0.86,9.08)***	1.87 (0.68,5.17)***	5.65 (1.97,16.18)***
(4 v 1)	7.38 (1.86,29.30)***	3.88 (0.99,15.12)***	5.66 (2.46,12.99)***	3.86 (1.11,13.42)***	2.18 (0.93,5.08)***	6.38 (2.03,20.03)***
(5 v 1)	5.00 (1.68,14.86)***	5.97 (2.06,17.29)***	5.08 (1.68,15.32)***	3.05 (0.94,9.87)***	1.93 (0.82,4.56)***	7.35 (2.98,18.13)***
(6 v 1)	6.55 (2.30,18.62)***	2.83 (1.27,6.34)***	6.44 (2.66,15.60)***	5.22 (1.62,16.84)***	2.70 (1.23,5.92)***	11.32 (4.21,30.45)***
(7 v 1)	12.16 (4.11,35.97)***		8.20 (3.89,17.29)***	5.70 (2.13,15.25)***	1.66 (0.89,3.12)***	13.02 (5.07,33.43)***
(8 v 1)	6.11 (2.86,13.04)***		6.34 (2.43,16.50)***	4.42 (1.47,13.28)***	2.53 (1.14,5.64)***	13.78 (5.12,37.08)***
In-sample validation						
Area under ROC curve	0.79	0.90	0.78	0.86	0.86	0.74
Number of procedures	2654	2443	4607	4632	4666	4608
Cross validation						
Calibration slope median (IQR)	0.90 (0.79,0.99)	0.91 (0.85,1.06)	0.95 (0.89,1.00)	0.94 (0.90,1.02)	0.97 (0.91,1.03)	0.95 (0.89,1.02)
Calibration-in-the-large median (IQR)	-0.010 (-0.12,0.12)	0.015 (-0.15,0.16)	0.004 (-0.09,0.07)	-0.009 (-0.10,0.10)	0.012 (-0.07,0.06)	-0.006 (-0.05,0.05)
Area under ROC curve median (IQR)	0.78 (0.76,0.79)	0.89 (0.87,0.90)	0.78 (0.76,0.78)	0.85 (0.84,0.87)	0.86 (0.85,0.87)	0.74 (0.73,0.75)
Brier score median (IQR)	0.018 (0.02,0.02)	0.012 (0.01,0.01)	0.022 (0.02,0.02)	0.018 (0.02,0.02)	0.028 (0.03,0.03)	0.040 (0.04,0.04)



Risk models for monitoring post-operative complication rates after pediatric cardiac surgery

Summary

- National data for 23,423 surgeries was used to develop risk adjustment models for 6 defined post-operative complications.
- Models for prolonged pleural effusion, extracorporeal life support and renal replacement had area under the curve (AUC) statistics >0.85.
- Models for necrotising enterocolitis, acute neurological event and unplanned reintervention had AUC statistics 0.74-0.79.



Figures depict the Receiver Operating Characteristic (ROC) curves for two example complication risk prediction models. Each of the 25 5-fold cross validation ROC curves is plotted using a light blue thin line (the darker the colour the bigger the overlap between ROC curves). The ROC curve with median Somer's Area Under the ROC value is represented with a black wide line.

Real-world experience with Thopaz⁺

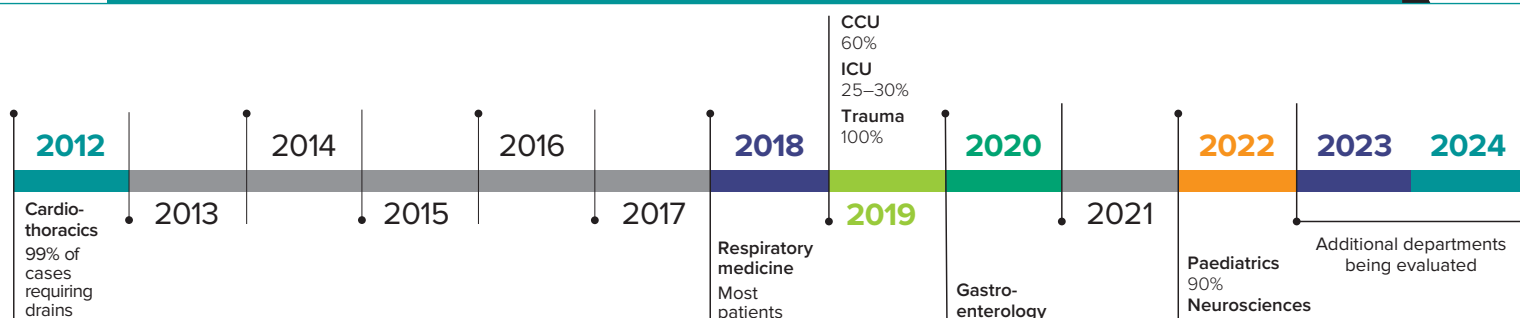
The Oxford University Hospitals
NHS Foundation Trust experience

This article was funded by Medela AG

Thopaz⁺ is a portable digital chest drainage and monitoring system developed by Medela. It offers continuous objective monitoring of fluid loss and air leaks, which facilitates assessment of patients' progress, as well as standardisation of chest drainage management across different departments.¹ Clinical evidence has demonstrated that Thopaz⁺ is a useful tool in the management of patients that require chest drains and has clear clinical advantages compared with underwater seal drains.¹⁻³

Thopaz⁺ and its predecessor, Thopaz, have been used within the Cardiothoracic Department at Oxford University Hospital NHS Trust since 2012. A report on this experience contributed to [National Institute for Health and Care Excellence \(NICE\) Medical Technology Guidance 37](#).^{1,4} Use of Thopaz⁺ in Oxford has since expanded to other departments within the trust. This document summarises the experience with Thopaz⁺ based on interviews with healthcare professionals (HCPs) at Oxford University Hospital NHS Trust in February/March 2024.

Evolution of Thopaz⁺ use in Oxford: initial introduction by department and current usage*



*Percentage of cases using Thopaz⁺, where known from interviews.

CHEST DRAINAGE PROTOCOLS

Each department has a chest drain protocol based on their use of Thopaz⁺ or underwater seal drains, and whether active suction or physio mode is needed.

MOBILISATION

Improved and earlier mobilisation is a major advantage of Thopaz⁺ in relation to complications associated with immobility.

OBJECTIVE AND CONTINUOUS MONITORING LEADS TO IMPROVED DECISION-MAKING

Continuous monitoring improves chest drain decision-making by providing objective estimates/measurement of leakage. It helps determine when air leaks are resolving (allowing for earlier drain removal and discharge planning) or when further intervention is needed (such as referral to a surgeon).

LENGTH OF STAY

Digital drainage facilitates day-case procedures by giving HCPs confidence that their patients have no persistent air leaks or fluid loss.

RESPIRATORY

70% of patients following pleural intervention and 60% undergoing thoracoscopy return home the same day.

CORONARY CARE UNIT (CCU)

Length of stay of 7 days with Thopaz⁺ compared with 10 days with underwater seal drains.

THROUGHOUT THE PATIENT JOURNEY

Thopaz⁺ can be used throughout a patient's journey, which can reduce the possibility of issues and errors, because drains can become kinked or displaced whenever a device is changed. Suction can be added to a Thopaz⁺ device set up to provide straightforward drainage simply by pressing a button to initiate suction via the device itself.

COSTS AND EFFICIENCIES

The use of the device can lead to improved operational efficiencies and cost savings, which may justify the acquisition costs. From an evidence-based practice project in the USA, a digital air leak detection device after pulmonary lobectomy led to cost savings of \$2,659 per hospital day.⁵

IMPROVED PATIENT SAFETY

Thopaz⁺ is a closed system, reducing incidents, errors, mishaps, and infections. As a dry system, Thopaz⁺ prevents issues with water and device positioning. Non-medical staff can manage Thopaz⁺ if it is knocked over, with no patient impact. Thopaz⁺ has its own suction source, preventing complications with wall suction becoming displaced or unclogged.

STAFF EXPERIENCE

Precise fluid and air leak measurements including time trends, improve clinician confidence and decision-making and facilitate continuity of care. The user-friendly interface makes it easier to track air leaks and fluid output. Nursing time is saved with easy canister replacement, reduced manual monitoring, and visual and audible notifications alert HCPs of issues.

PATIENT EXPERIENCE

Patients can move around freely without nursing or healthcare assistant support. Earlier discharge reduces hospital stay. Patients can monitor their progress in terms of reducing volumes of fluid and air leaks on the display.

Summary of the real-world experience with Thopaz⁺

The experience of HCPs within Oxford University Hospitals NHS Foundation Trust over the past 12 years has shown that Thopaz⁺ has multiple benefits in the right circumstances and should be available for the vast majority of patients requiring a chest drain.

Francesco Di Chiara MD, MS THOR (Hons), FEBTS

Consultant Thoracic Surgeon Oxford University Hospitals NHS Foundation Trust



Overall, our experience at Oxford University Hospitals NHS Foundation trust has shown that Thopaz⁺ is an indispensable asset for HCPs, redefining standards of care and operational efficiency across multiple medical departments. We encourage all units using chest drains to consider making the move from underwater seal drains to Thopaz⁺ in the vast majority of patients requiring chest drainage.

Quotes from interviews with a number of healthcare professionals at Oxford University Hospital NHS Trust:



From the NHS perspective, I think it probably allows us to make earlier decisions about withdrawing chest drains and getting people out of hospital earlier.



There are a number of ways to recoup the costs: efficiencies in the system, less litigation because things don't go wrong, staff sickness due to back injuries, and length of stay if you can get patients home quicker.



References

1. NICE. [Thopaz⁺ portable digital system for managing chest drains](#). Medical technologies guidance 37. London: NICE, 2018 (updated 2022). (assessed March 2025)
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4. Mitchell J. [Adopting Thopaz⁺ portable digital system for managing chest drains on the cardiothoracic ward at Oxford University Hospitals NHS Foundation Trust](#). (assessed March 2025)
5. Patel C *et al.* Use of a digital air leak detection device to decrease chest tube duration. *Critical Care Nurs* 2023;**43**:11–21.

Read the full report:



The summary report has been written by HSJ Advisory on behalf of Medela AG, reflecting the views expressed in interviews with healthcare professionals. Medela AG funded the project and had input into the development of this report.

HSJ Advisory

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Turning Science into Care

Thopaz⁺
#1 reference for digital
drainage*

Read the evidence



*Pioneering the digital chest drainage market since 2007. Market report and data show number 1 market share as of January 2024. Thopaz/Thopaz⁺ being named or referred to in >100 published studies, reports, or publicly available data.