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Is Conventional Bypass for Coronary Artery Bypass Graft Surgery a Misnomer?

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Abstract: Although recent trials comparing on vs. off-pump revascularization techniques describe cardiopulmonary bypass (CPB) as "conventional," inadequate description and evaluation of how CPB is managed often exist in the peer-reviewed literature. We identify and subsequently describe regional and center-level differences in the techniques and equipment used for conducting CPB in the setting of coronary artery bypass grafting (CABG) surgery. We accessed prospectively collected data among isolated CABG procedures submitted to either the Australian and New Zealand Collaborative Perfusion Registry (ANZCPR) or Perfusion Measures and outcomes (PERForm) Registry between January 1, 2014, and December 31, 2015. Variation in equipment and management practices reflecting key areas of CPB is described across 47 centers (ANZCPR: 9; PERForm: 38). We report average usage (categorical data) or median values (continuous data) at the center-level, along with the minimum and maximum across centers. Three thousand five hundred sixty-two patients were identified in the ANZCPR and 8,450 in PERForm. Substantial variation in equipment usage and CPB management practices existed (within and across registries). Open venous reservoirs were commonly used across both registries (nearly 100%), as were "all-but-cannula" biopassive surface coatings (>90%), whereas roller pumps were more commonly used in ANZCPR (ANZCPR: 85% vs. PERForm: 64%). ANZCPR participants had 640 mL absolute higher net prime volumes, attributed in part to higher total prime volume (1,462 mL vs. 1,217 mL) and lower adoption of retrograde autologous priming (20% vs. 81%). ANZCPR participants had higher nadir hematocrit on CPB (27 vs. 25). Minimal absolute differences existed in exposure to high arterial outflow temperatures (36.6°C vs. 37.0°C). We report substantial center and registry differences in both the type of equipment used and CPB management strategies. These findings suggest that the term

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"conventional bypass" may not adequately reflect real-world experiences. Instead of using this term, authors should provide key details of the CPB practices used in their patients.

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The vast majority of cardiac surgical operations involve the use of cardiopulmonary bypass (CPB) (1). Although the risk of adverse postoperative outcomes has invariably decreased over time, patients continue to be exposed to a number of sequelae, including acute kidney injury (2,3), stroke (4,5), and infections (6). In many instances, investigators implicate the use of CPB as a major contributing source for these morbid events.

In the modern literature, there is a paucity of data describing, let alone evaluating, the contribution of CPB equipment and practices in the care and outcomes of cardiac surgery patients. Indeed, many reports involving CPB contain little if any specific detail regarding the many different aspects of what broadly constitutes "current" CPB practice; yet, the authors often use the term "conventional bypass" to describe the manner in which the patient was managed while on CPB. Peer-reviewed journals, both within and outside the perfusion specialty, do not stipulate minimum reporting requirements for the conduct of CPB to ensure reproducibility of findings. As an example, studies evaluating outcomes of conventional CPB vs off-pump coronary artery bypass grafting (CABG) surgery often provide few if any details concerning the equipment used; e.g., roller vs. centrifugal pump, cardioplegia strategies, volume management, blood management, and glucose management (7–9). Thus, opportunities to 1) evaluate the science underlying the published literature and 2) improve the practice of CPB are hindered.

We analyzed two large multi-center perfusion databases to identify and describe regional and center-level differences in the techniques and equipment used for conducting CPB in the setting of CABG surgery.

MATERIAL AND METHODS

This study was approved by the Institutional Review Board of the University of Michigan (HUM00129282) and by the Southern Adelaide Clinical Human Research Ethics Committee (386.15).

Patient Population

The perfusion measures and outcomes (PERForm) Registry: The PERForm Registry developed in 2010 by the International Consortium for Evidence-Based Perfusion (a committee of the American Society for ExtraCorporeal Technology [AmSECT]) is now organizationally structured within the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVS-QC). The PERForm Registry, which is AmSECT's official registry, contains information related to the care and conduct of cardiovascular perfusion practices. In turn, the PERForm Registry recognizes AmSECT as its official societal partner. A list of fields and definitions may be found at http://www.performregistry.org. Participating sites are subject to audits for data validity and accuracy as part of the MSTCVS-QC audit system (10).

The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR): Details concerning the ANZCPR (previously called the Perfusion Downunder Collaborative Database) database have been previously described (11,12); the ANZCPR, established in 2007, uniquely integrates intra-operative data from the Data Management System (Stockert, Munich, Germany), CONNECT™ (LivaNova PLC, London, United Kingdom), and JOCAP (Maquet, Wayne, NJ) heart lung machine data collection software, including patient and blood gas monitoring systems. All perfusion-related factors and temperature measurements are collected electronically in a continuous manner at 20–60-second intervals. Clinical data definitions are based on those reported by the Australian and New Zealand Society of Cardiothoracic Surgeons database (13); the ANZCPR Australian New Zealand Clinical Trials Registry number 12614000832673 (http://www.anzctr.org.au/, accessed August 27, 2018).

For this analysis, we included 12,012 patients undergoing isolated CABG surgery between January 1, 2014 and December 12, 2015, in the ANZCPR (3,562 patients, nine centers) and PERForm (8,450 patients, 38 centers) registries.

Measures

We report variability across centers in the choice of equipment components reflecting the conduct of CPB (Tables 1–3). These measures were chosen to exemplify important elements related to CPB in the current era.

Statistical Analyses

We calculated all measures at the center and registry levels. Specifically, for continuous measures, we calculated a median value for each center, and reported the median value across centers, along with the minimum and the maximum. For categorical variables, we calculated the percentage of overall use for each center, and reported the median value across centers, along with the minimum and the maximum.

RESULTS

Variation existed both within and across registries in nearly all aspects of CPB equipment, Table 1. Not all equipment types were tracked uniformly across both

Table 1. Variability in CPB equipment.

	ANZCPR	PERForm
Procedures per site	353 (109, 971)	166 (36, 1,127)
Number of sites	9	32
Arterial filter pore size (micron), % yes		
<30	31.9% (0%, 100%)	7.9% (0–100%)
30–36	NR	40.8% (0–100%)
≥37	67.9% (0%, 100%)	51.3% (0–100%)
Arterial filter integrated	17.3% (0%, 100%)	NR
Autotransfusion device used for the collection of shed blood?	30.3% (.4%, 100%)	NR
% Roller pump vs. centrifugal	85.4% (.0%, 100.0%)	64.2% (.0%, 100%)
% Pulsatile perfusion	.06% (0%, .3%)	.50% (.0%, 13.3%)
Biocompatible surface coating, % yes		
Tip-to-Tip	.0% (0%, 0%)	.77% (.0%, 29.3%)
All but cannula	96.4% (0%, 100%)	91.2% (.0%, 100.0%)
% Open reservoir	100% (.0%, 100.0%)	99.8% (95.8%, 100.0%)
Venous augmentation, % yes		
None	NR	67.6% (.0%, 100.0%)
Vacuum	NR	32.3% (.0%, 100.0%)
Kinetic	NR	.11% (.0%, 4.2%)
Continuous blood gas monitoring	44.7% (0%, 72.8%)	NR

Data for continuous measures are presented as the median value for each center, and reported as the median value across centers, along with the minimum and the maximum, for categorical variables Data are presented as the percentage of overall use for each center, and reported as the median value across centers, along with the minimum and the maximum center values.
NR, not recorded.

registries (e.g., integration of arterial filters was tracked in the ANZCPR exclusively). Arterial line filters with pore size ≥37 micron were the most commonly used, as were roller pumps, non-pulsatile perfusion, extensive (i.e., all but cannula) biocompatible surface coatings, and open reservoirs. Roller pumps were more commonly used in the ANZCPR vs. PERForm (85.4% vs. 64.2%, respectively).

Variation existed both within and across registries in nearly all aspects of CPB management, Tables 2 and 3.

Table 2. Variability in volume and blood management during CPB.

	ANZCPR	PERForm
Procedures per site	353 (109, 971)	166 (36, 1,127)
Number of sites	9	32
Volume management		
% Retrograde autologous prime	20.3% (.0%, 94.9%)	80.5% (.0%, 100.0%)
Volume (mL)	370 (200, 470)	500 (150, 1,350)
Static prime volume (mL)	1,500 (1,250, 1,600)	1,000 (400, 1,500)
Total prime volume (mL)	1,462 (1,250, 1,635)	1,217 (640, 2,080)
Net prime volume (mL)	1,362 (1,250, 1,625)	722 (415, 1,300)
Total volume (mL)*	NR	996.5 (100, 3,000)
Total colloid volume (mL)	NR	10 (0, 300)
% Ultrafiltration	1.4% (.0%, 2.3%)	25.1% (.0%, 100.0%)
Blood management		
Hematocrit		
Last preoperative	41.7 (36.6, 42.9)	39.9 (36.4, 41.4)
Nadir during CPB	27.0 (25.2, 29.9)	25.3 (21.0, 31.0)
% Autologous blood harvest	.9% (.0%, 3.0%)	16.9% (.0%, 85.9%)
Residual pump volume processing, % yes		
Direct infusion	NR	68.7% (.0%, 100.0%)
Centrifugation	NR	86.2% (1.0%, 100.0%)
Ultrafiltration	NR	5.7% (.0%, 33.3%)
% Unprocessed cardiotomy suction returned to bypass circuit	86.4% (4%, 98%)	58.8% (.0%, 100.0%)
% Autotransfusion	30.3% (.4%, 100%)	99.5% (84.0%, 100.0%)
% Where autotransfusion blood reinfused	60.1% (23%, 100%)	NR

Data for continuous measures are presented as the median value for each center, and reported as the median value across centers, along with the minimum and the maximum, for categorical variables. Data are presented as the percentage of overall use for each center, and reported as the median value across centers, along with the minimum and the maximum center values.
NR, not recorded.
*Includes the total amount of fluid (mL) administered into the bypass circuit during extracorporeal circulation (including crystalloid, colloid, and medications). The total amount does not include any blood products.

Table 3. Variability in myocardial protection and temperature management during CPB.

	ANZCPR	PERForm
Procedures per site	353 (109, 971)	166 (36, 1,127)
Number of sites	9	32
Myocardial protection		
Cross clamp usage, % yes	94% (86.6%, 100.0%)	96.8% (35.1%, 100.0%)
Cardioplegia use		
Yes	95.8% (86.6%, 100%)	96.2% (35.1%, 100.0%)
With ventricular fibrillation	3.4% (0%, 12.4%)	.63% (.0%, 7.9%)
Cardioplegia		
Solution, % yes		
Blood cardioplegia (1:1, 2:1, 4:1, 8:1)	99.7% (99.5, 100%)	49.5% (.0%, 100.0%)
Crystalloid (including HTK)	.1% (0%, .4%)	1.3% (.0%, 4.7%)
Microplegia	.2% (0%, .4%)	15.0% (.0%, 100.0%)
Del nido	.0% (.0%, .0%)	24.7% (.0%, 91.7%)
Other (including variable)	.0% (.0%, .0%)	14.3% (.0%, 100.0%)
Cardioplegia induction temperature, % yes		
Cold (<28)	67% (.7%, 100%)	87.6% (.0%, 100.0%)
Mild hypothermia (28 to <32)		
Tepid (32–25)	22.1% (0%, 96.2%)	1.3% (.0%, 28.5%)
Warm (>35)	10.8% (0%, 63.5%)	11.1% (.0%, 90.0%)
Cardioplegia maintenance temperature, % yes		
Cold	61.2% (0%, 91.8%)	99. 7% (93.9%, 100.0%)
Tepid	8.5% (1.5%, 97.7%)	.08% (.0%, 2.6%)
Warm	30.4% (.9%, 95.9%)	.22% (.0%, 6.1%)
Hot shot, % yes	3.4% (0%, 12.4%)	45.5% (.0%, 100.0%)
Total cardioplegia volume per hour of cross clamp time (mL, median)	NR	1,700.0 (330.7, 3,696.3)
Core temperature management* (celsius)		
Nasopharyngeal temperature		
Highest	36.6 (36.3, 37.1)	37.0 (36.1, 37.6)
Lowest	33.6 (32.1, 34.6)	33.4 (27.5, 35.3)
Bladder temperature		
Highest	NR	36.8 (36.0, 37.1)
Lowest	NR	34.0 (32.0, 36.0)
Rectal temperature		
Highest	NR	36.8 (35.7, 37.2)
Lowest	NR	34.0 (32.7, 36.7)
Esophageal temperature		
Highest	NR	37.0 (36.0, 37.3)
Lowest	NR	33.9 (30.2, 35.5)
Arterial outflow temperature		
Highest	36.8 (36.2, 37.1)	37.0 (36.2, 38.0)
Lowest	31.3 (29.3, 33.6)	NR
% Alpha-stat management	99.9% (99.9%, 100%)	100.0% (100.0%, 100.0%)
Average cardiac index on bypass (L/min/m^2)	2.2 (1.8, 2.5)	NR

Data for continuous measures are presented as the median value for each center, and reported as the median value across centers, along with the minimum and the maximum, for categorical variables. Data are presented as the percentage of overall use for each center, and reported as the median value across centers, along with the minimum and the maximum center values.
NR, not recorded; HTK, histidine–tryptophan–ketoglutarate.
*Among centers using specific core temperature location.

In terms of volume management, retrograde autologous priming was less commonly used in the ANZCPR (20.3% vs. 80.5%), as was ultrafiltration (1.4% vs. 25.1%). Median static (1,500 mL vs. 1,000 mL) and net (1,362 mL vs. 722 mL) prime volumes were higher in ANZCPR. In terms of blood management, last preoperative hematocrit (41.7% vs. 39.9%) and nadir hematocrit on bypass (27.0 vs. 25.3) values were higher within ANZCPR. Autologous blood harvesting was less commonly performed in ANZCPR (.9% vs. 16.9%), as was the use of autotransfusion (30.3% vs. 99.5%. Subsequently a greater percentage of centers returned unprocessed cardiotomy suction blood to the CPB circuit in the ANZCPR (86.4% vs. 58.8%). The use of blood cardioplegia was much more common within ANZCPR than within PERForm (99.7% vs. 49.5%), driven in part by a greater use of microplegia (.2% vs. 15.0%) and del Nido (.0% vs. 24.7%) within PERForm. Cardioplegia temperature strategies varied by registry, with ANZCPR having higher adoption of tepid and warm cardioplegic techniques for induction or maintenance, whereas hot shots were higher in PERForm (3.4% vs. 45.5%), Table 3. Highest and lowest nasopharyngeal temperatures were qualitatively similar between the registries, as were the highest arterial outflow temperatures.

DISCUSSION

We accessed two prospectively collected, multi-institutional perfusion databases to document variability in the CPB practice. We found center variation in nearly all aspects of the equipment and conduct of CPB in both databases. Further work is needed to quantify the clinical and financial impacts of this variability; nonetheless, these findings suggest the value of structured reporting of elements of CPB practice in the peer-reviewed literature.

A number of investigators, using clinical databases or cross-sectional survey designs, have evaluated variability CPB equipment and practice (15–17). The Northern New England group published findings concerning variability in CPB practice (14); importantly, the group noted wide variability in some aspects of perfusion that served as the nexus for a subsequent multi-center quality improvement project (15). Although surveys provide valuable information concerning practice patterns, especially if performed serially over time, they also are subject to a number of inherent biases. Surveys may be limited in the scope of questions, sample of targeted respondents, or response rates. Some of the most recently cited surveys within our field were published in 2009 and 2010, making the practices far from contemporary (16,17). Furthermore, surveys are subject to recall bias, as they generally rely on the contributor's memory rather than objective data from an institution's clinical registry/database.

Several professional perfusion societies have published minimum requirements for the conduct of safe, effective, and reliable CPB (18–22). These documents provide a framework for perfusion departments to define local practice standards. In some cases, these local standards are based on regulatory requirements and/or science (evidence-based). The development of these local standards may be useful for comparing practices at one's center to an external benchmark. Likewise, data from our present study may help guide our profession by identifying unwarranted variability in practice across multiple centers and registries. While unclear at this time, our team is investigating determinants (e.g., financial, access, and provider preference) of differences in cardiopulmonary practice patterns across centers participating in these two databases. Although variability is considered the bane of quality in health care, such variation offers opportunity for quality improvement through outcomes research (23).

Our findings highlight the contrast between real-world practices and the peer-reviewed literature (24,25). Although investigators and journals continue to publish articles describing perfusion practices as being conducted "conventionally," such claims may be unsubstantiated. Journal editors may wish to consider developing and implementing protocols for reporting CPB equipment and practice, akin to those required for reporting randomized trials (26) or perfusion-related contributions to red blood cell transfusions (27). An initiative to support standardized reporting was trialed by Poulis et al. Although well intentioned and reasoned, its adoption has not been broadly accepted. As stated in their editorial concerning standardized reporting in perfusion literature, "*Generation of standards for reporting aspects of perfusion will undoubtedly improve the quality and relevance of new science concerning the practice of perfusion*" (9). Furthermore, our findings suggest that there are few instances in which there is general consensus regarding how best to manage a patient while on CPB. As has been advocated within the setting of anesthesiology, there is a critical need to 1) understand the role that processes of care (and equipment) have in contributing to overall clinical outcomes and 2) identify opportunities for standardizing best practices across centers (28). Our report highlights the value of registry participation and the role of perfusion in the reporting of CPB practice.

These findings highlight the dilemma faced by clinicians and hospital administrators when evaluating the need to balance cost and proven benefit. The results presented demonstrate wide variation in practice. If institutional costs had been assigned to CPB equipment and components, we would anticipate large center variation in cardiac surgery expenditures. Can or should we continue to accept such variation in practice and expenditure in the absence of established efficacy data? Our present study may be used to help target future areas of evaluation to maximize value to patients, payers, and society.

We recognize the following limitations to our present study. First, although we acknowledge that we may have missed some important aspects of equipment (e.g., monitoring of blood flow, including distal to all shunts) and conduct of CPB (e.g., transfusion trigger), this study may serve as a foundation for developing consistent reporting for future studies. Second, we acknowledge differences in the manner of data collection between the two registries, with the ANZCPR uniquely collecting electronic perfusion data gathered through the heart–lung machine. It is difficult to estimate the impact of these differences; nonetheless, although exposure to the median values of highest arterial line temperatures was quite similar between the two registries (ANZCPR: 36.8°C vs. PERForm: 37.0°C), there was greater deviation from arterial outlet >37.0°C in PERForm at the 75% interquartile range (ANZCPR: 37.1°C vs. PERForm: 38.0°C). Development of greater integration of electronic perfusion data into perfusion registries would facilitate clearer understanding of the variation of physiological variables such as arterial pressure and flow rates. Third, we recognize that our findings may not be broadly generalizable outside the centers included in this report; nonetheless, our findings are contemporaneous and represent 47 centers and 12,012 isolated CABG procedures. Fourth, we have not evaluated the impact of variation in the equipment

and conduct of CPB with regard to clinical outcomes. It is unlikely that many of the areas noted in this report are attributed to differences in patient characteristics across centers; rather, these differences are likely driven by provider preferences or institutional tradition. Nonetheless, the variation across these registries highlights areas that could benefit from standardization of both practice and reporting, that are worthy of investigation (i.e., through trials), and that should be evaluated in terms of cost effectiveness and/or provider preference.

CONCLUSION

In this large, multi-institutional experience comprising two registries, we report variation in the equipment used and in the conduct of CPB for isolated CABG surgery. Our findings suggest that "conventional bypass" is a misnomer. There is a need to develop and implement minimal criteria for reporting on the equipment and practice of CPB to strengthen the existing evidence base.

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