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Original Article

The assessment of complexity in congenital cardiac surgery based on objective data

David R. Clarke,[1] Francois Lacour-Gayet,[1] Jeffrey Phillip Jacobs,[2] Marshall L. Jacobs,[3] Bohdan Maruszewski,[4] Christian Pizarro,[5] Fred H. Edwards,[6] Constantine Mavroudis[7]

[1]*The Children's Hospital, University of Colorado Denver School of Medicine, Aurora, Colorado;* [2]*The Congenital Heart Institute of Florida (CHIF), Division of Thoracic and Cardiovascular Surgery, All Children's Hospital and Children's Hospital of Tampa, University of South Florida College of Medicine, Cardiac Surgical Associates (CSA), Saint Petersburg and Tampa, Florida, United States of America;* [3]*Drexel University College of Medicine, Philadelphia, Pennsylvania, United States of America;* [4]*The Children's Memorial Health Institute, Department of Cardiothoracic Surgery, Warsaw, Poland;* [5]*Alfred I. duPont Hospital for Children, Wilmington, Delaware, United States of America;* [6]*The University of Florida, Gainesville, Florida, United States of America;* [7]*Children's Memorial Hospital, Northwestern University School of Medicine, Chicago, Illinois, United States of America*

Abstract When designed in 2000, the Aristotle Complexity Score was entirely based on subjective probability. This approach, based on the opinion of experts, was considered a good solution due to the limited amount of data available. In 2008, the next generation of the complexity score will be based on observed data available from over 100,000 congenital cardiac operations currently gathered in the congenital cardiac surgery databases of the Society of Thoracic Surgeons and the European Association for Cardio-Thoracic Surgery.

A mortality score is created based on 70,000 surgeries harvested in the congenital databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. It is derived from 118 congenital cardiovascular operations, representing 91% of the operations and including 97% of the patients. This Mortality Index of the new Aristotle Complexity Score could further be stratified into 5 levels with minimal within-group variation and maximal between-group variation, and may contribute to the planned unification of the Aristotle Complexity Score with the Risk Adjustment for Congenital Heart Surgery system.

Similarly, a score quantifying morbidity risk is created. Due to the progress of congenital cardiac surgery, the mortality is today reduced to an average of 4%. No instrument currently exists to measure the quality of care delivered to the survivors representing 96% of the patients. An objective assessment of morbidity was needed. The Morbidity Index, based on 50,000 operations gathered in the congenital databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, is derived from 117 congenital cardiovascular operations representing 90% of the operations and including 95% of the patients. This morbidity indicator is calculated on an algorithm based on length of stay in the hospital and time on the ventilator.

The mortality and morbidity indicators will be part of the next generation of the complexity score, which will be named the Aristotle Average Complexity Score. It will be based on the sum of mortality, morbidity, and subjective technical difficulty. The introduction of objective data in assessment of mortality and morbidity in congenital cardiac surgery is a significant step forward, which should allow a better evaluation of the complexity of the operations performed by a given centre or surgeon.

Keywords: Congenital heart disease; mortality; morbidity; complications; surgical outcomes; registry; database

Correspondence to: Francois Lacour-Gayet, MD, Professor of Surgery, University of Colorado School of Medicine, The Children's Hospital in Denver, 13123 E. 16th Avenue. Aurora. CO80045, United States of America. Tel: +1 720 777 3376; Fax: +1 720 777 7271; E-mail: lacour-gayet.francois@tchden.org

Background

The Aristotle Basic Complexity Score defines the complexity of an operation through three factors:

- potential for mortality,
- potential for morbidity, and
- technical difficulty of the operation.

When designed in 2000, the Aristotle Complexity Score was entirely based on subjective probability. This approach, based on the opinion of experts, was considered a good solution due to the limited amount of data available at that time. In 2008, two large multi-institution databases are available for studying outcomes of congenital cardiac surgery:

- The Congenital Database of The Society of Thoracic Surgeons, and
- The Congenital Database of The European Association for Cardio-Thoracic Surgery.

The goal of this paper is to discuss the feasibility of using data from these two registries to create new empirically-based mortality and morbidity components for the Aristotle Basic Complexity Score.

We previously reported that the Aristotle Basic Complexity Score was associated with both mortality as well as prolonged post-operative length of stay greater than 21 days.[1] The strength of the association was quantified by calculating the C-statistic in a combined sample of nearly 35,000 patients from the congenital database of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. The C-statistic was equal to 0.70 for mortality and 0.67 for prolonged post-operative length of hospital stay.[1]

When fixed hospital-specific intercepts were added to the logistic regression models along with the Aristotle Basic Complexity Score, the C-statistic was 0.74 for mortality and 0.72 for prolonged post-operative length of hospital stay. The C-statistics of the models containing hospital effects only were 0.63 for mortality and 0.62 for prolonged post-operative length of hospital stay. Thus, adding the Aristotle Basic Complexity Score to a model containing hospital effects appears to improve discrimination.[1]

In an effort to improve further the discriminative ability of the Aristotle Complexity Score, the next generation will take advantage of the available data from over 100,000 congenital cardiac operations currently in the congenital cardiac surgery databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. The Congenital Database Taskforce of The Society of Thoracic Surgeons, working in collaboration with the Joint Congenital Database Committee of the European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, is in the process of developing a new tool: the Aristotle Average Complexity Score. The mortality and morbidity components of the new score will be based primarily on objective data from the congenital databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. Bayesian methods and subjective probability will be used where objective data is lacking. This tool will likely be incorporated into the Congenital Database of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery.

Mortality

The rate of mortality at discharge from the hospital was determined for 130 congenital cardiovascular procedures, using combined data involving more than 70,000 patients undergoing surgery in the years 2002 through 2005, inclusive, who were already present in the congenital cardiac surgical databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. Procedures were excluded if they were classified as thoracic, extracorporeal membrane oxygenation, or ventricular assist device procedures. To ensure that 95% confidence intervals were no wider than $\pm 5\%$, twelve additional procedures were excluded because they had less than 18 occurrences in the combined databases. The remaining 118 procedures represented 90.8% of the primary cardiovascular procedures of interest, and more importantly included 96.7% of the patients. The mortality rates per procedure were plotted and the sorted procedures were divided into five levels using subjectively determined break points (Fig. 1).

Each procedure was then assigned a mortality score between 0.1 and 5.0. Zero mortality was assigned 0.1 and the highest mortality given 5.0. Within each level, intervals of mortality rate were determined according to the slope of the mortality curve to correspond with 0.1 increments in index. The plot of the mortality score is illustrated in Figure 2 and the mean mortality for each level is shown in Figure 3.

This initial development of the mortality index, although interesting, needs refinement using more sophisticated mathematical and statistical methods. In the future, all 145–150 procedures will be included. Mortality rate estimates will be calculated using a Bayesian model that accounts for uncertainty due to rare occurrences and incorporates prior information from an expert panel. Procedures sorted by increasing risk will then be organized into the five data-driven groups of mortality. The groups

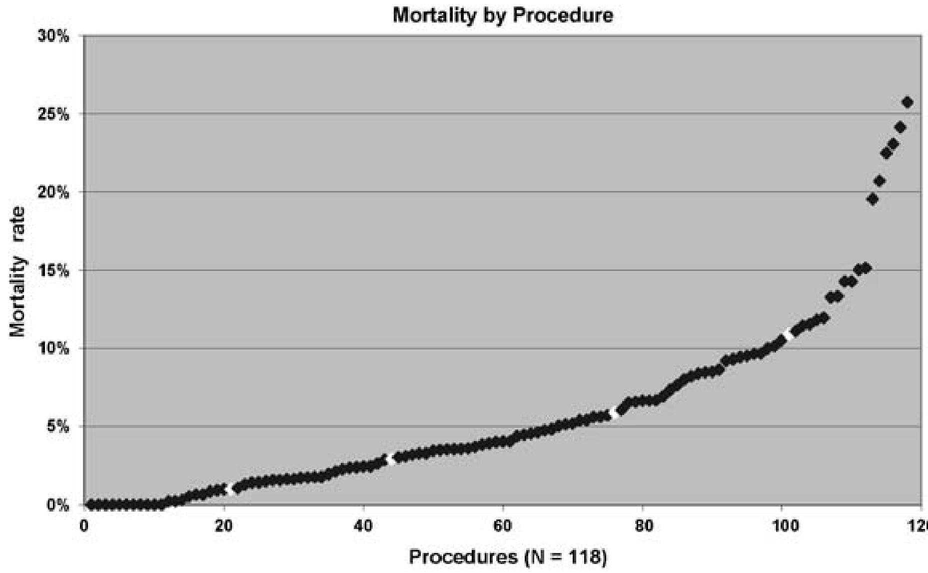

Figure 1.
Mortality rate is plotted in increasing progression for 118 procedures. Light squares indicate data break points.

Figure 2.
Derived mortality scores for 118 procedures plotted in increasing order. Trend line reveals the linear approximation of the data array.

will be optimized by minimizing the within-group variation and maximizing the between-group variation. The mortality index for each procedure will then be derived by methods similar to the ones used with the preliminary data.

Although individual procedure indices will allow better discrimination, the mortality component of the Aristotle Average Complexity Score will allow for the risk of operative mortality to be easily stratified into 5 levels. These levels may contribute to the planned unification of the Aristotle Complexity Score with the Risk Adjustment for Congenital Heart Surgery system.[2]

Morbidity

Most evaluations of quality of care in cardiac surgery have been based on operative mortality.[3,4] De novo, the Aristotle complexity score, since 2002, has chosen to include morbidity in its definition of complexity.[5] Today, the operative mortality in congenital cardiac surgery, as observed in the congenital cardiac surgical

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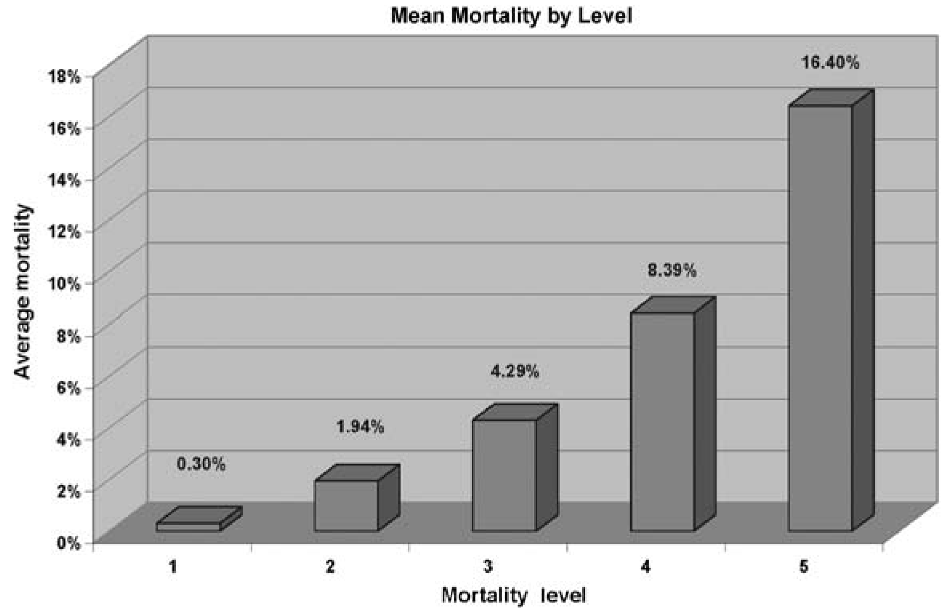

Figure 3.
Average mortality rate for procedures within five mortality score levels.

databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, is approximately 4%. No instrument currently exists to measure the quality of care delivered to the survivors, representing 96% of the patients. An objective assessment of morbidity is needed.[6] The following proposals were discussed in detail within the Society of Thoracic Surgeons Congenital Database Taskforce and also within The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease.

Principles of the objective assessment of morbidity

Morbidity is a state of illness or lack of health, and includes physical, mental, or emotional disability.[7] Survival is the antonym of mortality and is used to describe the rate of freedom from death. Until now, however, no antonym of morbidity has existed. We have coined the term "optivival" to represent freedom from morbidity.[8]

The suffering of patients should be evaluated first, forming the basis of the morbidity assessment. Following surgery, patients suffer temporary or permanent disability which can vary from mild to severe. It is notable that even the best possible surgery includes a period of temporary disability. Therefore zero operative morbidity does not exist.

Morbidity is correlated with utilization of hospital resources, which is the basis for calculation of hospital cost. The evaluation of morbidity must allow correlation with cost.

The disability of morbidity can be temporary or permanent, and can vary from mild to severe.[9] In general, morbidity assessment can be applied to all patients including hospital deaths. This issue, however, remains controversial. Excluding hospital deaths from the morbidity assessment would appropriately focus on the surviving patients. Nevertheless, death does not contradict the definition given above; death is in fact "the ultimate" permanent disability. The risk of death is correlated with increased morbidity,[10] and the morbidity level of the non-surviving patients is important information. From a management standpoint, the patients who die after a long hospitalization generate an important cost that should be known. We will separately quantify two types of morbidity:

- the morbidity of the surviving patients, and
- the total morbidity, which will include the morbidity of all patients including the operative deaths.

From a financial standpoint, total morbidity assessment is most useful.

Calculation of the morbidity core

The calculation of morbidity will be based on an algorithm that includes 3 components of measurable uses of resources of the hospital, and 1 component to represent the occurrences of major complications defined as either a temporary but with severe disability or a permanent disability (Table 1).

Hospital Resource components include:

- Postoperative length of stay in hospital(s) prior to discharge to home

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Table 1. Morbidity score components: $\sum (1+2+3+4)$.

1. Post-operative hospital length of stay (in days)
   +
2. Post-operative time on the ventilator* (in days)
   +
3. Post-operative extracorporeal membrane oxygenation and/or ventricular assist device time** (in days)
   +
4. Major complications***:
   - Re-operation during the same hospitalization.
   - Permanent pacemaker for atrio-ventricular block.
   - Palsy of phrenic nerve, recurrent laryngeal nerve, or peripheral nerve.
   - Permanent neurological lesions present at hospital discharge; including stroke with clinical neurological deficit, choreoathetosis, epilepsy, blindness, deafness.
   - Dialysis dependent chronic renal failure.

*It is intentional that time on the ventilator is counted 2 times.
**It is intentional that assist device time is counted 3 times.
***The numerical value for each complication is not yet defined.

- Postoperative time on the mechanical ventilator, from the start of surgery until the final extubation prior to discharge to home
- Post-operative time on Extra Corporeal Membrane Oxygenation and/or Ventricular Assist Device, from initial cannulation to final decannulation.

Major complications include:

- Re-operation during the same hospitalization (excluding sternal closure and procedures involving Extra Corporeal Membrane Oxygenation and/or Ventricular Assist Device)
- Requirement for permanent pacemaker for atrio-ventricular block
- Palsy of phrenic nerve, recurrent laryngeal nerve, or peripheral nerve
- Permanent neurological lesions present at discharge from the hospital including stroke with clinical neurological deficit, choreoathetosis, epilepsy, blindness, deafness
- Dialysis dependent chronic renal failure.

The numerical values for each component of the algorithm are under development.

Preliminary data

Only preliminary results of the morbidity assessment can be presented at this time because even though extra-corporeal membrane oxygenation procedures, ventricular assist device procedures, re-operations, and major complications are harvested by the congenital cardiac surgical databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, a large amount of data is currently missing in these fields.

The sum of length of stay in the hospital and time on the ventilator was determined for 130 congenital cardiovascular procedures, using combined data involving more than 50,000 patients undergoing surgery in the years 2002 through 2005, inclusive, who were already present in the congenital cardiac surgical databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery. Procedures were excluded if they were classified as thoracic, extracorporeal membrane oxygenation, or ventricular assist device procedures. Thirteen additional procedures were excluded because of insufficient occurrences. The excluded procedures were represented by less than 17 cases in the combined database and exhibited 95% confidence intervals of greater than ±1 day. The remaining 117 procedures represented 90.0% of the primary cardiovascular procedures of interest, and more importantly included 94.9% of the patients. The morbidity values per procedure were plotted and the array was divided into five levels using natural break points and changes in slope (Fig. 4).

Each procedure was then assigned a morbidity score between 0.1 and 5.0. Zero morbidity did not exist but was assigned 0.1, and the highest morbidity value given 5.0. Within each level intervals were determined according to the slope of the morbidity curve to correspond with 0.1 increments in index. The plot of the morbidity score is illustrated in Figure 5 and the average morbidity value for each level is shown in Figure 6.

Further development

This initial development of the morbidity index, although interesting, needs refinement using more sophisticated mathematical and statistical methods. In the future, all 145–150 procedures will be included, and indices will be calculated with additional points added for duration of extra corporeal membrane oxygenation, ventricular assist device usage, and major complications. Morbidity value estimates will then be calculated using a Bayesian model that accounts for uncertainty due to rare occurrences and incorporates prior information from an expert panel. Procedures sorted by increasing morbidity will then be grouped into the five data-driven levels of morbidity. The levels chosen will be optimal in minimizing the within-level variation and maximizing the between-level variation. The morbidity index for each procedure will then be derived by methods similar to the ones used with the preliminary data.

The evaluation of quality of care in our complex specialty is a work in progress. The minimal dataset

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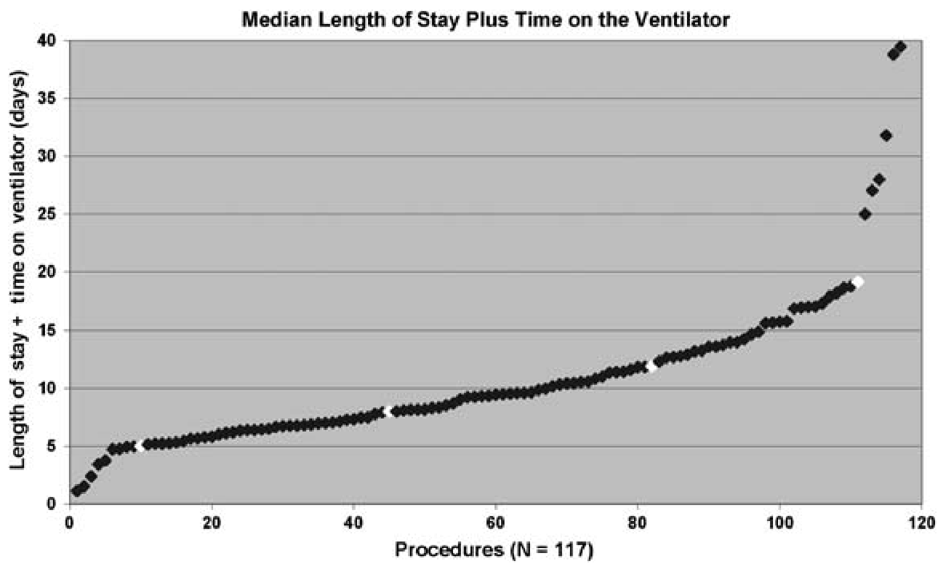

Figure 4.
Median hospital length of stay plus median time on the ventilator in days is plotted for 117 procedures in ascending order. Light squares indicate data break points.

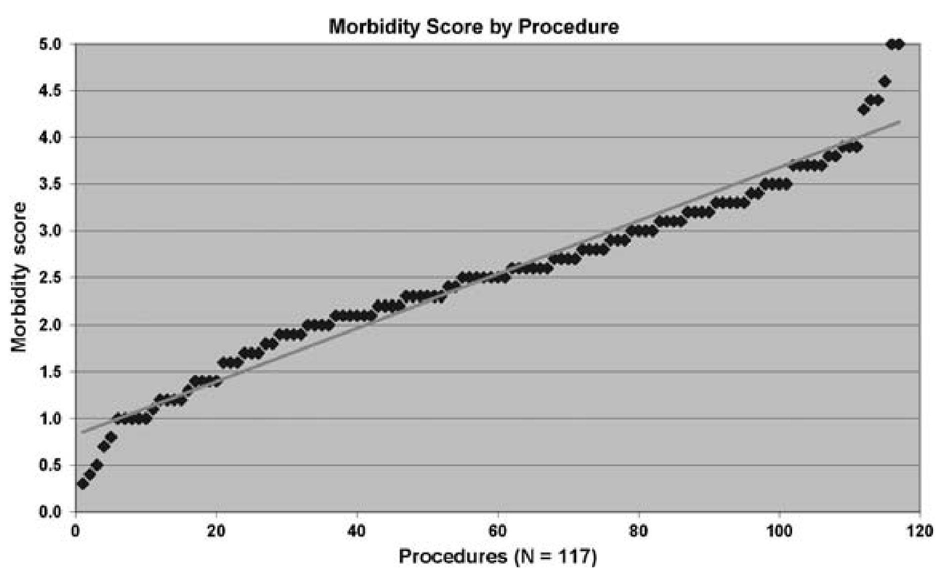

Figure 5.
Derived morbidity scores for 117 procedures plotted in increasing order. Trend line reveals the linear approximation of the data array.

used in the congenital cardiac surgical databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery will be modified in 2010 in an attempt to capture all elements of data needed for the calculation of the morbidity index. The first significant values for the complete morbidity index are not expected before 2011.

Surgical difficulty

The evaluation of quality of care in congenital cardiac surgery needs a technical difficulty score so that the skill and effort of the surgical team is appropriately included in the evaluation of quality. It can be argued that although the time required to perform an individual operation is not a meaningful measurement; the overall average time to perform the same operation across the entire database may constitute an objective surrogate for the average technical difficulty of the operation relative to other procedures. This argument has not yet achieved consensus support.

It may be that the "skin to skin time" may need adjustment. For example, some procedures done

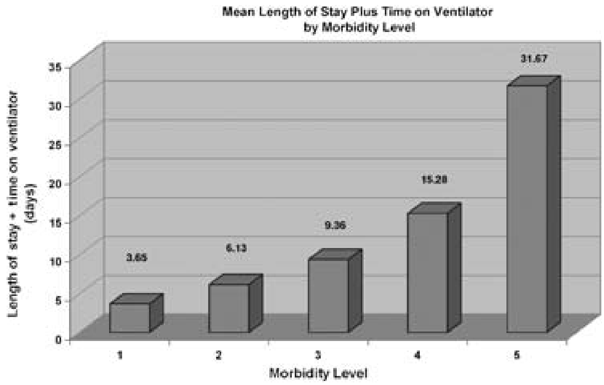

Figure 6.
Average hospital length of stay plus time on the ventilator within five Morbidity Score levels.

without the use of cardio-pulmonary bypass are clearly more difficult than some simple open cardiac procedures which take as long or longer to perform. Perhaps additional time added to the duration of closed cardiac procedures would compensate for this perceived inequity. The authors are pursuing their investigation to find a valid technical difficulty index. Until a reasonable measurable parameter is settled upon, the technical difficulty score derived from subjective probability will serve as the surgical difficulty index.

Comments

The newly created assessments of mortality or morbidity associated with congenital cardiac surgery are compliant with the recommendations of The Society of Thoracic Surgeons and respect the criteria of the quality score published by the Quality Measurement Task Force of The Society of Thoracic Surgeons.[11,12] These scores are also compliant with the recommendations of governmental agencies that assess and measure the quality of health-care. The National Quality Forum,[9] the Agency for Healthcare Research and Quality, and the Institute of Medicine[13,14] recommend a standardized taxonomy for quality and safety and a precise methodology to evaluate performance. These recommendations were followed.

Evaluation of quality of care in congenital cardiac surgery is a work in progress and a learning process. This long enterprise has only been possible because of the creation of an International Nomenclature for Congenital Heart Surgery by Constantine Mavroudis and colleagues.[15] The administrative databases using the coding systems of the International Classification of Diseases and Current Procedural Terminology are insufficient to draw significant conclusions regarding mortality, morbidity, epidemiology, cost, and centre performance.[16] The development of a cost index seems needed in the future. It will include all components of the morbidity calculation and an additional factors causing significant hospital cost increase.

The mortality score will be the first developed because of the concrete nature of the statistic and the availability of data about mortality prior to discharge from the hospital. A useable index will be available during 2008. The index will remain, however, a work in progress and will be updated when sufficient data about 30 day mortality is gathered.

The assessment of morbidity is a concept recently introduced in the evaluation of quality of care in our specialty. The Aristotle Complexity Score is the first benchmark of evaluation of quality of care in our specialty that includes morbidity.[2–4] It is no longer possible to ignore the quality of care delivered to the 96% of patients surviving surgery. With the prospect of pay-for-performance and cost evaluation looming, a quantification of morbidity is clearly needed. Since it is likely that it will be some time before the databases have enough data to produce the completed morbidity index, in the short term, in 2008–2011, we would propose use of available data in the registries such as post-operative length of stay and time on the ventilator, as a an objectively derived assessment, as shown in Figures 4, 5 and 6. Although not conceptually ideal, it may represent a reasonable surrogate for morbidity, and may well be a better quantitative indicator of true relative morbidity than the subjectively derived morbidity score currently in use.

Although the majority of the contribution of adverse events to morbidity is adequately reflected in the measurements of the different post-operative stages, some major complications with severe temporary disabilities, and permanent disabilities, represent a degree of patient suffering that is beyond the morbidity measured by hospital resources utilization. We chose to consider only major complications in order to simplify the score, following the example of the quality score of the adult cardiac surgeons that addresses coronary artery bypass surgery.[11] In reality, the less important complications are already measured through the utilization of hospital resource components. In calculating the hospital resource components, it is intentional that a period of time is counted two or three times, in an effort to weight the index relative to degree of patient suffering and utilization of resources. For example, the time on the ventilator is counted twice as it is also included in the hospital length of stay. Considering the cost of the intensive care unit and the suffering of the intubated patient, weighting this time twice seems justified. Similarly, the time of extra-corporeal membrane oxygenation and ventricular assist device will be counted three times; this calculation was considered justified for the same reasons. If a patient is extubated while on a ventricular assist device, then this time period will only be counted twice.

The mortality and morbidity scores will be part of the next generation of the Aristotle Complexity Score. The new complexity score will be named the Aristotle Average Complexity Score, which will be based on the sum of objective mortality, objective morbidity, and subjective technical difficulty scores.[1,8,17]

Conclusion

The introduction of objective data in assessment of mortality and morbidity in congenital heart surgery is a significant step forward which will allow a better evaluation of the complexity of the procedures performed by a given centre or surgeon. The ultimate goal is the ability to equitably evaluate performance in our complex speciality.

Acknowledgement

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References

1. O'Brien SM, Jacobs JP, Clarke DR, et al. Accuracy of the Aristotle Basic Complexity Score for classifying the mortality and morbidity potential of congenital heart surgery procedures. Ann Thorac Surg 2007; 84: 2027–2037. PMID: 18036930.
2. Jenkins KJ, Gauvreau K. Center-specific differences in mortality: preliminary analyses using the Risk Adjustment in Congenital Heart Surgery (RACHS-1) method. J Thorac Cardiovasc Surg 2002; 124: 97–104.
3. Edwards FH, Grover FL, Shroyer LW, Schwartz M, Bero J. The Society of Thoracic Surgeons National Cardiac Surgery Database: Current risk assessment. Ann Thorac Surg 1997; 63: 903–908.
4. Welke KF, Shen I, Ungerleider RM. Current assessment of mortality rates in congenital cardiac surgery. Ann Thorac Surg 2006; 82: 164–171.
5. Lacour-Gayet FG, Clarke DR, Jacobs JP, et al. and the Aristotle Committee. The Aristotle Score: a complexity-adjusted method to evaluate surgical results. Eur J Cardiothorac Surg 2004; 25: 911–924.
6. Lacour-Gayet F, Jacobs ML, Jacobs JP, Mavroudis C. The need for an objective evaluation of morbidity in congenital heart surgery. Ann Thorac Surg 2007 ; 84: 1–2.
7. Jacobs JP, Jacobs ML, Mavroudis C, et al. What is operative morbidity? Defining complications in a surgical registry database: a report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. Ann Thorac Surg 2007; 84: 1416–1421.
8. Lacour-Gayet FG, Jacobs JP, Clarke DR. Evaluation of quality of care in congenital heart surgery: contribution of the Aristotle Complexity Score. Adv Pediatr 2007; 54: 67–83. PMID: 17918467.
9. [http://www.qualityforum.org/], accessed January 7, 2008.
10. Benavidez OJ, Gauvreau K, Del Nido P, Bacha E, Jenkins KJ. Complications and risk factors for mortality during congenital heart surgery admissions. Ann Thorac Surg 2007; 84: 147–155.
11. Shahian DM, Edwards FH, Ferraris VA, et al. Quality measurement in adult cardiac surgery: Part 1 – Conceptual framework and measure selection. Ann Thorac Surg 2007; 83: S3–S12.
12. O'Brien SM, Shahian DM, DeLong ER, et al. Quality measurement in adult cardiac surgery: Part 2 – Statistical considerations in composite measure scoring and provider rating. Ann Thorac Surg 2007; 83: S13–S26.
13. To err is human. Building a safer health system. Institute of Medicine. National Academy Press; 2006.
14. Performance management. Accelerating improvement. Institute of Medicine. National Academy Press; 2006.
15. Mavroudis C, Jacobs JP (eds). International Congenital Heart Surgery Nomenclature and Database Project. Ann Thorac Surg 2000; 69 (Suppl 1): 1–372.
16. Welke KF, Peterson ED, Vaughan-Sarrazin MS, et al. Comparison of cardiac surgery volumes and mortality rates between the Society of Thoracic Surgeons and Medicare Databases from 1993 through 2001. Ann Thorac Surg 2007; 84: 1538–1546.
17. Jacobs JP, Lacour-Gayet FG, Jacobs ML, et al. Initial application in the STS congenital database of complexity adjustment to evaluate surgical case mix and results. Ann Thorac Surg 2005; 79: 1635–1649.

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