EACTS | Adult Cardiac Database / Quality Improvement Programme (QUIP)

The EACTS Quality Improvement Programme: Adult Cardiac Database

Improving quality through international outcome benchmarking

Stephanie Hawksworth, Theo de By and Örjan Friberg on behalf of the EACTS Adult Cardiac Database

The EACTS Adult Cardiac Database (ACD) includes contributions from more than 80 European hospitals and cardiothoracic units, corresponding to more than 120,000 surgical interventions. This expansive collection of data has strengthened the ACD's benchmarking capabilities, providing a sophisticated tool which individual hospitals can use to compare their outcomes with the anonymised data of other hospitals in the database.

The unique characteristics of the ACD benchmarking tool allow a user to:

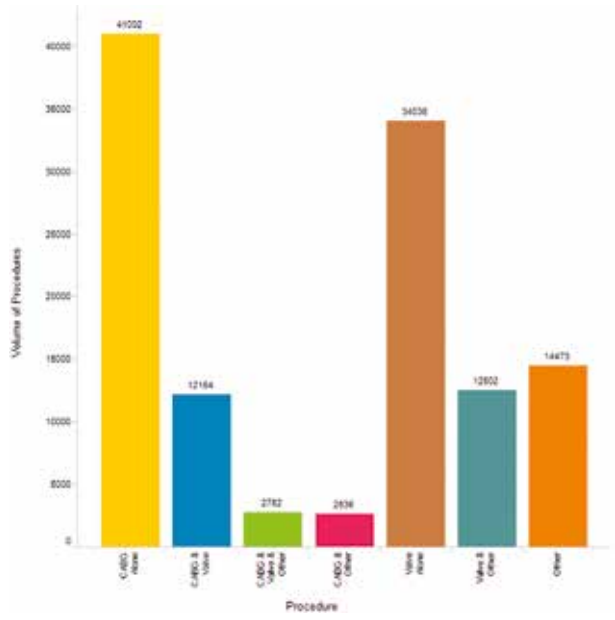
- Access the ACD dashboard and select which hospitals to compare
- Select hospitals with a volume-range of interventions, comparable to their own
- Use many filters, e.g. for patient age, procedures, urgency, logistic EuroSCORE etc.
- Download their hospital's bespoke report, which is automatically updated on a monthly basis, and look for hospital compared to all others
- Monitor results with control charts, offering performance statistics over time

As part of the EACTS Quality Improvement Programme (QUIP), the ACD and its benchmarking possibilities have proven to be a powerful instrument for quality assessment. Firstly, the volumes of various kinds of interventions can be compared, e.g. the number of patients with multiple CABGs, mitral valve operations, etc. What's more, it can reveal on-pump/off-pump statistics, the distribution of patients by urgency and it can confirm areas of professional excellence which are present in every unit. Finally, in some areas, it is able to pinpoint areas of relative weakness, and how they can be improved.

The Quality of outcomes support team

The Quality of Outcomes and Research Unit (QuORU) of the University Hospital in Birmingham collaborates with EACTS to provide support and offers statistical and data analyses services on the highest level.

Importantly, their experienced software developers are able to tease out what kinds of comparisons users are undertaking with the benchmarking tool, helping to better gauge what searches are common, as well as the ultimate quality of those comparative outcomes.



Volume of procedures in Adult Cardiac Database 2018

Bespoke Reports

Participating centres can download their bespoke reports when they log into the Adult Cardiac Database. This report provides a comprehensive overview of the centre's cardiac data and contribution to the Adult Cardiac Database, showing statistical analysis and the comparisons of the following data:

- Completeness of data
- Volume of procedures
- In-hospital mortality rate
- Re-op for bleeding rate
- Average post-op LOS

To find out more about what the ACD Centre Reports can offer you, please go to www.eacts.org/quip or contact quip@eacts.co.uk

"Since 2017 I had the privilege of being Chair of the ACD Task Force. The ACD is growing rapidly in terms of numbers of procedures, participating centres and countries. This is gratifying but also increases the demands for clear and universally adopted data definitions and defined processes of data validation.

"During the last year the Task Force have focused most of our work on the very fundamentals of a database; a thorough revision and update of all included variables with definitions, as well as analysing and trying to define the different steps and means of data validation required for achieving as high validity as possible of the data in the registry.

"A new 'data-dictionary' with the updated list of variables was just finalised and will be publicly available in the coming months. We also hope to soon publish the first Annual Report in 2018, which will reflect the growth of the database, the trends in adult cardiac data and the future developments."

Örjan Friberg
Database Task Force Chair

EACTS | EUROMACS

The EACTS EUROMACS Registry: a source for scientific data

Theo de By
The Hague, the Netherlands

Ever since its conception, the focus of the EUROMACS Registry has been on the promotion of scientific research with respect to the care of patients with end-stage heart failure, and who have received mechanical circulatory support (MCS). The availability of clinical data and long-term follow-up facilitates scientific studies, as anonymous EUROMACS Registry can be harnessed by research groups.

How can participating centres obtain data?

Any contributor of data can approach the EUROMACS Director who will send a standard form. The form should summarise the data that is necessary from the EUROMACS Registry, as well as the strategy of the publication.

Evaluation of the proposal will then take place by a EUROMACS sub-committee using criteria such as:

- Is it a good research question; is it original?
- Is the research design appropriate?
- Are the methods rigorous and feasible?
- Are the specific objectives clear?
- Is the background and significance scholarly and pertinent?
- Are the methods appropriate for the research study?
- Is the proposal clear, concise and well organised?

A proposal can be rejected based on one or more of the following arguments:

- If the researcher's hospital doesn't contribute data to the EUROMACS Registry
- If the subject is already "taken", i.e. another researcher has received approval and data from EUROMACS to work on the same or very similar hypotheses.

How many study proposals were received, and what is their status?

Twenty-eight proposals were registered between 1 January 2016 and 1 October 2018. Of these 28 proposals:

- Five were rejected
- Two studies are pending
- 10 studies are ongoing
- Four projects are in their last stage (writing before submission to a journal)
- 1 study has been submitted to the *EJCTS* and is presently under review
- Seven studies with EUROMACS data have been published in the past two years
- Contributions to two IMACS reports have been provided.
- Two proposals have recently been submitted and are in the process of approval by the sub-committee

Publications are made available on the EUROMACS website: **www.euromacs.org/downloads/scientific-articles**

Expected developments

Presently, each participating centre can download its data from the EUROMACS Registry on a daily basis. The aim of EACTS is to offer its members a software tool with which they can administrate and analyse the clinical data of their own patients and compare their data with the entire registry. For this reason, a tool has been developed through which local data can be benchmarked on an international level. By using filters and selections of patient categories, more precise comparisons can be made. While the EUROMACS team is working on a possible migration of software, the benchmarking tool can be installed once the software migration has taken place.

Come join us at the EUROMACS Focus Session this morning, 08.15–09.45!

Availability of research data in EUROMACS contributes to quality improvement

Alexander Bernhardt is responsible for the heart transplant and the mechanical circulatory support programmes at the University Heart Centre in Hamburg, Germany. *EACTS Daily News* caught up with Dr Bernhardt to talk about his perspectives on EUROMACS, past, present and future.

Dr Bernhardt, you're one of the surgeons who has participated in EUROMACS since the beginning of the Registry. What motivates you to keep on providing data for so many years?

My colleagues and I enter data from our patients on mechanical circulatory support into the EUROMACS Registry on a structural basis. There are two main reasons to do so: First, we contribute consistently to a database that serves our own purpose, to administrate all relevant clinical data for these patients; secondly, by contributing to EUROMACS, we are able to obtain anonymised data from all participants for scientific study projects.

The leading principle is that you can't manage it when you can't measure it; that keeps us motivated to register relevant therapeutic data.

The EUROMACS registry has quite a lot of data fields – does that discourage you and your data manager?

Treating patients who are on a VAD requires the observation of many factors that play a role in their wellbeing. Given the fact that most centres are relatively small, it's only natural that we accumulate data on an international level so that large quantities of variables become available for analyses.

Do your patients object to sharing their de-personified data internationally?

No, very few patients object. I think the reason is that we have shown that these data are used for increasing the insights into the strengths and weaknesses of mechanical circulatory support therapy. Moreover, the EUROMACS Registry is owned by the EACTS, which is a non-profit charity and impartial.

Which insights have you gained from EUROMACS?

First of all, I must say that you can always ask any questions from EUROMACS and you promptly get the answers. Over the years, this service has been very helpful. Secondly, and most important are the possibilities to obtain data for scientific projects. The results of these projects have given us insights into the consequences of therapeutic treatments as we practise them.

Can you be more specific on that?

We've been following several publications with EUROMACS data over the years. At our Hamburg University Heart Center, we've been able to obtain data from EUROMACS that has made it possible to do analyses on factors such as gender differences and the outcomes of isolated RVAD implantations in patients with right heart failure. These data have been published in peer reviewed journals. Currently, we're working on a comparative study between European and US data.

Finally … the EUROMACS data are shared with the IMACS registry in an anonymous way, and we find it very important to know that our data are included in an endeavour to aggregate insights on a global level.

If you look at the possibilities for EUROMACS, what do you envisage?

It's good to hear that more centres are in the process of joining. A further increase of data will strengthen the base for future analyses. Additionally, I have learned that the EACTS has contracted a university-based processor that can offer us state-of-the-art software with which we can benchmark our data on a daily basis. The availability of such a tool will enable all participants to identify areas for improvement. The greatest benefit of gained insight is for our patients, because at the end of the day, [improvement in their care] is the aim we all strive for.

EACTS enables first EUROMACS Paediatric Report

Structural support for statistics and informatics has been consolidated

Martin Schweiger, Theo de By and Oliver Miera

There are substantial differences between adults supported with ventricular assist devices (VAD) and children, especially the very young. Thanks to the structural support provided by the EACTS, an increasing number of hospitals have contributed data from their patients on mechanical circulatory support (MCS) to the EUROMACS Registry. This has made it possible to accumulate clinical data to such an extent that a first EUROMACS Paediatric Report has now been published in the *EJCTS*.[1]

Theo de By The Hague, the Netherlands
Martin Schweiger Zurich, Switzerland
Oliver Miera Berlin, Germany

Statistical support

Statistical support was provided by the Quality and Outcomes Research Unit (QuORU) of the University Hospital Birmingham (UK). The aims of QuORU are to provide the specification for, and oversee, the development and implementation of appropriate quality outcome metrics.

Recently, the EACTS has entered into an agreement with the UHB to provide expertise in the areas of clinical research, statistics and informatics.

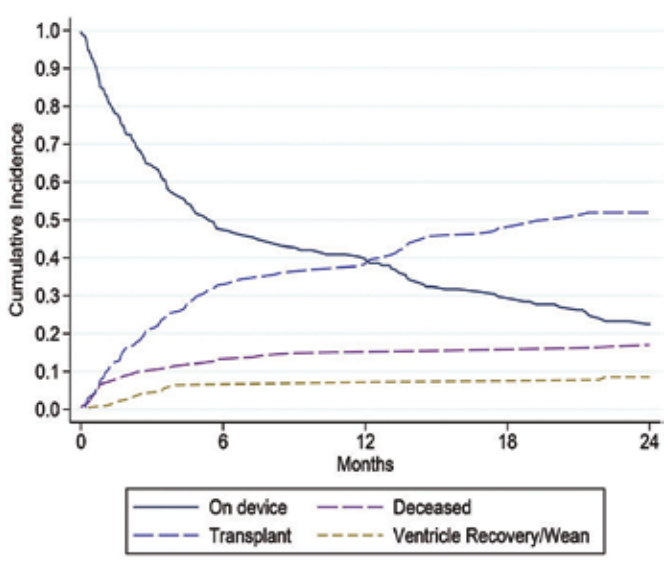


Figure 1.

Highlights of the report

Data from 237 durable device implantations in 210 patients (81 female), originating from 25 European centres in 14 countries could be analysed. In a unique collaboration throughout the analytic process, all contributing clinicians were willing to provide additional data, supply missing data and corrections whenever needed.

A summary of the data shows that:

- Mean support time was 11.6 months (+ 16.5 SD)
- 51% (n = 107) received a transplant at two years post VAD implantation
- 82.4% (n = 3) of the children

survived to transplant, recovery, or are at ongoing treatment until the last follow-up.
- 17.6% (n = 37) died at two years. Cerebro-vascular accidents were the main cause of death (24.3% of the deceased)

Competing outcomes

In the analysis, a patient is considered at risk until explantation due to transplant, weaning from the device, has died or is alive. To determine these values, cumulative incidences were calculated using competing outcomes methods. To avoid any censored individuals, only patients with a follow-up period of two years were considered for the competing outcome analysis. Figure 1 shows those competing outcomes.

Devices

In this first Paediatric Report, the relation between pulsatory and rotary/centrifugal devices was 46.8% versus 53.2%, respectively. Not surprisingly, this differed significantly from the adult cohort where only 3% of patients had a pulsatory durable VAD.

Conclusions

The one-year survival rate seems to be satisfactory in this first EUROMACS Paediatric Report. Device malfunctions, including pump-chamber changes due to thrombosis, were the most frequent adverse event.

A comparison between registries shows that outcome data differ with, for example, the Pedimacs report (North-America data[2]). One of the most striking differences is the waiting time for a heart transplant. Whereas permanent support has long become a reality for adults, bridge to transplantation or transplantability still remains the highest percentage in intention-to-treat patients within the paediatric population. Whereas almost 50% of the paediatric patients in North America had a transplant within the first six months after a VAD implant, in Europe, only 33% at six months and 38% patients at 12 months had a transplant. These numbers reflect the lack of suitable donor organs in Europe, which leads to significantly longer support times.

Continued interest and increase of data

Many questions remain to be addressed, e.g. discharge, additional specifics in anticoagulation management, a focus on congenital heart disease and much more, all of which were beyond the scope of this first EUROMACS Paediatric Report. The publication of the EUROMACS Paediatric report has led to renewed interest from colleagues who hadn't joined EUROMACS yet. With an increasing number of contributors, we are reaching pan-European coverage step by step.

As many questions remain to be addressed, the additional data will hopefully enable stronger analyses and improved insight. Further focused EUROMACS paediatric reports are planned.

Acknowledgements: On behalf of all co-authors we acknowledge all contributors of data, and Hina Waheed, Statistical Intelligence Analyst from QuORU, for her contribution to the success of this EUROMACS Paediatric Report.

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