NEW PERSPECTIVES IN THE MANAGEMENT OF CONGENITAL HEART MALFORMATIONS IN CHILDREN: CLINICAL MONITORING REGISTRY

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Abstract: *Electronic clinical registries represent the key elements in establishing a management strategy in regards to a particular disease, a systematic, multidirectional approach that combines: case management, clinical data for follow-up, therapy related feedback, developing new clinical practice guidelines. The development of a Clinical Registry for Congenital Heart Malformations represents an efficient clinical information system dedicated to disease management. It allows attending physicians to evaluate patients in order to prescribe optimal treatment, offers information over the quality and precision of decisions, elements that can be generalised upon the respective patients' population of origin. Also, it holds the potential of separating patients by different risk categories in order to identify those in most need of therapeutic intervention.*

INTRODUCTION

Considering that congenital heart malformations (CHM) represent one of the main causes of mortality and morbidity in the first year of life, diagnosis and management of these diseases are regarded as key points in public health policies. Some critical CHM are diagnosed early on, after birth due to more obvious symptoms: severe cyanosis refractory to oxygen therapy, signs of heart failure or heart murmurs. Others remain undiagnosed until release from hospital or during the first years of life, needing specialized surgical treatments.(1,2,3)

The diagnosis of critical CHM in the first days of life could reduce mortality and morbidity through proper initiation of corrective or palliative procedures. An important aspect would be prenatal screening of CHM, programme that increases the survival rate of children with CHM by early prenatal or immediate postnatal establishment of adequate treatments.(4)

By diagnosing and monitoring children with CHM we can get information about CHM incidence. The number of children with CHM born in Romania, in hospitals that report minimal patient related data has varied during the 2008-2013, between 900 and 1070 cases.

The concept of an electronic Clinical Monitoring Registry for children with CHM was based on the casuistry of the Emergency Institute for Cardiovascular Disease and Transplantation, Tîrgu-Mureş, recorded between 2013-2014, followed by active enrolment and prospective follow-up of cases, starting with June 2015. This registry represents an active management of CHM and of admission rate for surgical treatment of patients within their first days of life, for a better outcome and prevention of potential complications.

PURPOSE

The purpose of this registry is: to develop a template of a Clinical Monitoring Registry within the Emergency Institute for Cardiovascular Disease and Transplantation, Tîrgu-Mureş, to generate a patient-related information database with an associated software, to define the minimal data set needed for developing such a database and to maximize the data collected in order to identify sustainable methods of institutionalization and scaling this to national level.(5,6)

MATERIALS AND METHODS

The Clinical Monitoring Registry for children with CHM was conceived in two steps, regarding data collection:

- firstly, retrospective collection of data (casuistry of the Emergency Institute for Cardiovascular Disease and Transplantation from 2013), in order to determine the admission rate per specialized treatment unit and establishing the accessible data categories.
- secondly, active, prospective collection of data from the eligible patients.

The registry observes the legal guidelines of personal data confidentiality.

Inclusion criteria: all patients 0 to 1 year old at the moment of CHM diagnosis International Classification of Disease 10 Australian Modification - ICD 10 AM-(Q20.0-Q28.9), with characteristic symptoms, with echocardiographic confirmation of diagnosis and the written agreement of parents or legal guardians annexed to the clinical chart, along with the families' compliance to periodic follow-ups.

Exclusion criteria: age of diagnosis outside the first year of life, no characteristic symptoms, absence of agreement to enrol or failure of compliance to periodic follow-ups due to patients' parents or respective family.

Structuring the data regarding CHM patients was done according to international, recognized nomenclature, with the covering of minimal core indicators (as requested at international level), observing case complexity evaluation mechanisms, validation and verification of data mechanisms, with the goal of maximizing information given by data already collected for an easier integration within the current streams.(6,7,8)

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The collected data was grouped in a Microsoft Access 2010 database, which was imported to SQL Server 2005, in order to create a versatile, internationally compatible, user interface for data collection and analysis.

RESULTS

An electronic clinical registry of CHM is in fact a database comprising information regarding children between the ages of 0 and 16, with CHM, diagnosis and therapeutic procedures, in particular surgical ones. It also offers data regarding certain care patterns, progression and prognosis of these diseases, the evaluation of efficiency and effectiveness of medical activity related to diagnosis and treatment.(9)

The objectives of this registry are: the definition of Minimal Data Set; the measurement of incidence and prevalence, studying the disease trend through monitoring, identifying population groups the present CHMs, respectively of those types of patients with interventional or surgical treatment indications at certain ages, according to their diagnosis; measuring the quality of medical services offered and identifying means of improvement, including health programmes; determining clinical efficiency and cost/benefit, cost/efficiency analysis of treatments; estimation of quality of life and survival rate.(10,11,12) Development of different electronic data sources – necessary for the functioning of medical care centres – is useful in completing registration of CHM and contributes to the diverse control stages of case numbers, diagnosis and treatment methods, surveillance and quality of life. By referencing the data collected to the standards of international CHM systems we defined the Minimal Data Set. This set was structured in two main chapters, as follows:

A. General socio-demographic data

Table no. 1. Minimal data set – general demographic and personal history data. New perspectives in the management of congenital heart malformations in children: clinical monitoring registry

Demographic data	
Last name	
First name	
Personal identity number	
Date of birth	
Gender	
Domicile	
Urban / Rural	
Contact data	
Mothers' age	
Fathers' age	
Clinical and personal history data	
Date of diagnosis	
Methods of diagnosis	Echocardiography (Yes/ No)
	Pulse oximetry (Yes/ No)
	Electrocardiography (Yes/ No)
Prenatal diagnosis	Yes/ No
Family history of CHM	Yes/ No
Mothers' age (under 16 or over 40)	Yes/ No
Inclusion date	
Symptoms at admission	Cyanosis (Yes/ No)
	Heart failure (Yes/ No)
	Prostaglandins Treatment(Yes/ No)

Table no. 2. Minimal data set – mother and pregnancy related data. New perspectives in the management of congenital heart malformations in children: clinical monitoring registry

Risk factors during pregnancy	
Risk factors during pregnancy	Rubella (Yes/ No)
	Measles (Yes/ No)
Medication of toxic substances used during pregnancy	Yes/ No
Use of teratogenic medication during pregnancy	
Chronic disease of the mother	Diabetes (Yes/ No)
	Collagen disease (Yes/ No)

Table no. 3. Follow up data collection – starting point – New perspectives in the management of congenital heart malformations in children: clinical monitoring registry

State at release	
Stationary	
Improved	
Cured	
Deceased	
Deceased during surgery	

Table no. 4. Follow up data collection – monitoring – New perspectives in the management of congenital heart malformations in children: clinical monitoring registry

Monitoring	
Date	
Stationary	
Improved	
Worsened	
Deceased	

B. Information regarding diagnosis, surgical techniques and related data

1. Information regarding the admission diagnosis, main diagnosis at discharge, complications and other related data, encoded as to correspond to international nomenclature
2. Surgical, interventional and life support techniques

Data regarding the surgical treatment (procedure encoding according to the up-to-date RO.vi.DRG 2010), the date of the intervention, surgery performed through cardio-pulmonary by-pass, maintenance by means of extracoroporeal oxygen-therapy (ECMO), cumulated time (in hours) of continuous respiratory support, interventional cardiology techniques, date of re-intervention – where the case arises, the possibility of scheduling a surgical re-intervention.

Table no. 5. Surgical treatment monitoring – New perspectives in the management of congenital heart malformations in children: clinical monitoring registry

Data related to surgical procedures	
Main surgery (Code)	
Date of main surgery	
Associated surgery (Code)	
cardiopulmonary bypass (CPB)	Yes/ No
Extracorporeal Membrane Oxygenation (ECMO)	Yes/ No
Extracorporeal circulation	Yes/ No
Overall hours of continuous assisted ventilation	
Date of re-intervention	
Programmed re-intervention	Yes/ No

DISCUSSIONS

The structure of the Clinical Monitoring Registry for children with CHM was established according to the International Nomenclature for CHM Surgery, determined by the need of an easy integration within international databases. A common, standardized language is necessary in order to attain a good connection between diagnosis and therapeutic arsenal. The coding of diagnosis and procedures was done using ICD 10 AM with case mapping in accordance to Romanian DRG classification of Diagnosis related groups by major diagnostic category 2011 edition. For data collection, the registry uses the Minimal Data Set, thus ensuring a unique reference system with identical data sets for all patients. Each variable is well structured, using standardized parameters and coding lists. The database will allow data entries in safe conditions, in specific forms, enabling longitudinal monitoring. Collected data will ensure estimation over the incidence of surgical curable CHM, based on different diagnosis groups, age distribution, comorbidities, type of surgical procedure, complications and short term results; these can be presented as a whole in software-generated reports. With the Clinical Monitoring Registry, we aim to develop a cohort type study characterized by the enrolment of patients at the time of diagnosis, followed by active monitoring, at preset intervals, through contact and interview, by qualified personnel from the Emergency Institute for Cardiovascular Disease and Transplantation, Tîrgu-Mureş. This way, we will be gathering data that can be set into temporal series, allowing longitudinal analyses over disease evolution and risk factors. This approach also sets ways to identify those patients who are sometimes lost from clinical follow-up due to different reasons and also gives the opportunity for detailed study of self-reporting information (socio-economic background, behavioural elements, economic burden, social and psychological pathology, treatment etc.).(13,14,15,16,17)

CONCLUSIONS

The analysis of the data within the Clinical Monitoring Registry for Children with CHM offers a detailed profile of CHM patients, allowing transverse prevalence analysis, multifactorial analysis of risk factors, study of the distribution of cases in terms of social background, identification of determinants of early diagnosis, evaluation of diagnosis impact over the family of the patient and the acceptance of medical treatment. Monitoring the incidence, determinants and evolution of CHM is important for the proper allocation of health resources, improving the quality of treatment by possibility of evaluation, helping developing prevention programmes by understanding and controlling the risk factors and facilitating contouring global strategies by offering international comparable data.

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