

**NEW APPROACHES AND PERSPECTIVES ON THE MANAGEMENT OF
SURGICALLY TREATED CONGENITAL CARDIOPATHIES IN CHILDREN.
CONGENITAL HEART MALFORMATIONS REGISTRY**

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INTRODUCTION

In Romania, like other countries in the world, congenital heart malformations represent the main cause of infant morbidity and mortality. The incident of 6 cases in every 1000 new borns is equal worldwide. The hospitalization rate in Romania is around 8, 1‰, in conformity with the global trend of this indicator.

Congenital heart malformations incidence, determining factors and evolution offers vital information for allocating resources within the health system, improves treatment procedures quality through the possibility of their evaluation, allows the development of prevention programmes through a better understanding and control of risk factors, offers comparable data at an international level and allows cost estimates regarding hospitals and the affected population.

The main issues in CHM management are the lack of data regarding real incidence on a populational level, lack of globally uniform diagnostic and reporting standards, as well as gaps in prognosis and postoperative recovery monitoring. In Romania there are only local attempts of developing a malformations registry. In these conditions, information about Romanian children affected by these diseases can only be extrapolated through percentages found in specialty literature, resource allocation is not evidence based and the prognosis and risk factors are difficult to follow and identify due data shortage. Moreover, there is no prospective, cohort study conducted on CHM patients that is able to collect data for estimating prognosis of surgery and control of risk factors.

OBJECTIVES

The purpose of this study is to approach CHMs through the perspective of integrated management in order of developing a registry, by achieving the following:

- a) Highlighting general and particular aspects of CHM epidemiology, their correlation with the degree of adreability to medical resources, the estimate of incidence and prevalence through hospitalized morbidity, respectively;
- b) The evaluation of indications, results and complications of current surgical and interventional therapies, comparing of advantages and limitations of percutaneous methods opposite surgical methods, for an appropriate selection of factors that determine the moment and type of treatment;
- c) Assessment of the quality of medical services in CHM surgery, determined by the complexity of these interventions, summing indicators for mortality rate, morbidity and the estimated degree of technical difficulty of the surgery itself;
- d) Analysis of the medical services offered as secondary prophylactic methods in CHM, cost-benefit analysis, cost-efficacy, cost-efficiency.

MATERIAL AND METHOD

Through accessing the database of the Tg Mureș Emergency Institute of Cardiovascular disease and Transplant, we have contoured a registry of patients 0 to 18yo diagnosed with congenital heart malformations that underwent surgery. Between 2005-2015, 2354 surgical interventions were conducted on a total of 1771 patients.

The database was constructed retrospectively by creating a specific electronic application, PedMCC, with integrated software, by correlating data included in the clinical observation sheets and records in the Diagnosis Related Groups (DRG) database, the latter created through the DRG National application.

Data analysis methods comprised of:

- determining epidemiological characteristics: demographics, clinical and evolution data, respectively the calculation and estimation of hospital incidence and prevalence of CHMs, in the context of national natality rate with implications in determining the rate of adreability and logistic possibilities of internment and treatment;
- the analysis of the complexity of surgical interventions specific to CHM by achieving a cumulative score through summing indicators regarding mortality rate, morbidity and the estimated degree of technical difficulty of the surgery;
- the analysis of direct costs of CHM cases in children that required surgery;
- the integration of our database in the "PedMCC" application, which allows longitudinal and vertical analysis of the study cohort.

RESULTS

Morbidity, in our case, hospitalized morbidity, is characterized by 2 indicators: incidence – the frequency of new cases respectively the prevalence – the frequency of all cases (both new as first admission for a certain pathology as well as subsequent admissions for the same pathology) in hospitalized patients. In particular reference to our study, the prevalence of CHM in 0 to 18yo children was 16,6 cases to every 100 admitted patients, with an incidence of 11,43 %.

Taking in account the logistic capabilities of the IUBCVT, the rate of internment for surgical treatment is of 214 admissions/year. The most frequent pathologies admitted (over 10%) are ventricular septal defect, persistent arterial duct, coarctation of the aortic isthmus, atrial septal defect. Fallot tetralogy and common atrio-ventricular canal represent around 5-10% of cases. The transposition of large vessels represent about 5% of cases that underwent surgery. The congenital aortic valve stenosis, double orifice of the right ventricle, aorto-pulmonary septal defect and corrected transposition represent between 2 and 5%.

Most surgical interventions, classified as priority type 1, were those for the closing of ventricular septal defects (287), closing of atrial septal defects (248), suture of persistent arterial duct (243), palliation of systemic-pulmonary shunts, correction of Fallot tetralogy and large vessel transposition. By establishing a hierarchy of interventions by mortality rate, Intensive Care stay and CHM specific complications, respectively the estimated difficulty of the intervention through extracorporeal circulation time, the most difficult interventions proved to be: the Norwood procedure, large vessel transposition correction and surgically corrected large vessel transposition, Ventricular Level Repair procedure (VLR), correction of interrupted aortic arch and correction of Ebstein's anomaly.

By processing data covering costs of surgical interventions, we estimated sums for cases which required surgery through a level 1 priority procedure. The costs of these cases ranged between 858 USD and 35132 USD. The most expensive intervention was attributed to large vessel transposition surgery, double orifice ventricle correction, palliation of complex CHM and Fallot tetralogy.

We developed and are currently running the experimental phase of the PedMCC electronic registry, 3rd version, with a case enrolment rate of 25 cases per month.

CONCLUSIONS

The "PedMCC" registry, constituted up to this point only by data regarding hospitalization episodes of patients that underwent surgery, must be regarded as an integrative registry which we will be developing through modules regarding all clinical activities, paraclinical data (including pathology), diagnostic and therapeutic activities involved in the "Congenital Heart Malformations" concept, with the possibility of multiple users, ranging from primary medical care, secondary and tertiary, coming as a response to the need for integrated health services in the management of congenital heart malformations, services with an appropriate cost-effectiveness level.

There is a need to quantify the response of integrated medical services in the management of congenital heart malformations, objectivizing the type of response our health system gives towards the needs of patients and healthcare professionals alike.

PedMCC comes as an institutional registry solution with the urge of an unitary approach to these disease, but far from a definitive solution. The perspectives offered by our database, in correlation to centralizing the registry, represent our future directions.

Keywords: congenital cardiac malformations monitoring, clinical registry, cardiology, cardiovascular surgery