Introduction  Congenital malformations are still a major cause of morbidity and mortality in newborns in Romania. The significant incidence and the difficulties of the management of this pathology are a reality which requires more attention and efforts.

Objective  The aim of the study was to determine the incidence of congenital cardiac malformations (CCM) between 2000–2010, the risk factors and distribution of the CCM.

Material and method  It was a retrospective study which included all the newborns with CCM who were admitted in our hospital. We had proceeded: clinical exam, laboratory tests, ECG, echocardiography.

Results  From a total of 105968 children, 863 had congenital cardiac malformations (0.81%). The main risk factors were: teratogenic factors (diabetes mellitus and alcoholism), chromosomal defects, multifactorial transmission. The most frequent malformations were noncyanotic as atrial septal defects and ventricular septal defects (88.06%) vs cyanotic defects (11.95%). In most of the cases the diagnosis was established after birth and only 1.73% (n=15 cases) had prenatal diagnosis. The outcome of children was: 504 newborns (58.40%) had needed medical treatment but no surgical corrective procedures, 223 (25.54%) had had palliative or corrective surgical treatment and 136 (15.75%) had died because of complications or of the impossibility of a proper surgical treatment.

Conclusions  The diagnosis of cardiac malformation is not a problem anymore due to echocardiography but, unfortunately, prenatal diagnosis is still difficult. The most cases are noncyanotic malformations. The outcome is related with the type of CCM, complications and possibility of a proper treatment.