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Evaluation of paediatric cardiosurgical model in Croatia by using the Aristotle Basic Complexity Score (ABC score) and the Risk Adjustment for Congenital Heart Surgery - 1 Method (RACHS-1)

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Abstract:

Objective: The Aristotle Basic Complexity score and the Risk Adjustment in Congenital Heart Surgery-1 method were developed and used to compare outcomes of congenital heart surgery. We used both methods to compare results of procedures done on our patients in Croatian cardiosurgical centres and results of procedures done abroad.

Methods: The study population consisted of all patients with congenital heart disease born to Croatian residents between October 1, 2002 and October 1, 2007 undergoing a cardiovascular operation during that period. **Results**: Of the 556 operations, ABC score could be assigned to 553 and RACHS-1 score to 536 operations. Procedures were performed in 2 institutions in Croatia and 7 institutions abroad. The average complexity for cardiac procedures done in Croatia was significantly lower ($p<0.001$). With both systems, along with the increase in complexity, there is also an increase in mortality prior to discharge and postoperative length of stay. Only after adjustment for complexity are there marked differences in mortality and occurrence of postoperative complications.

Conclusion: Both ABC and RACHS-1 were predictive of in-hospital mortality as well as prolonged post-operative length to stay, and can be used as a tool in our country to evaluate a cardiosurgical model and recognise potential problems.

Keywords: Congenital cardiac surgery, mortality, length of stay, Risk adjustment, Scoring system

Introduction:

The evaluation of the quality of care delivered to patients with congenital heart disease relies heavily on the analysis of outcomes. Simple comparisons of overall mortality rates are not useful because of baseline differences in risk among individuals. Risk adjustment in congenital heart surgery is hard due to great variations in the anatomy and physiology. For paediatric cardiac surgery, case-mix differences between institutions lie in the anatomic variation of the underlying disease and thus in the nature of the surgical procedure required for correction. Lesion-specific approaches have limited precision because even common lesions represent only a small fraction of the annual surgical caseload of a centre.

Despite everything, there is an ongoing effort to improve the techniques and technologies for evaluating the outcomes of congenital heart disease treatments. The rationale for this goal is multifactorial. The importance of the quantitation of complexity centres on the basis that, in the field of paediatric cardiac surgery, analysis of outcomes using raw measurements of mortality, without adjustment for complexity is inadequate. The mix of cases can vary greatly from programme to programme. Without stratification of complexity, the analysis of outcomes will be flawed. For individual centres, quality-improvement efforts can be stimulated with information on how one centre is performing compared to other centres. Evaluations of performance are important because of constant self-evaluation, including benchmarking with similar programs and creating health care improvement strategies.

Four items are necessary to create a meaningful outcome analysis system: a common language or nomenclature, a mechanism for data collection or a database with an established minimal database dataset, a mechanism for evaluating case complexity and a mechanism for verifying data completeness and accuracy [6,12,19].

The common language or nomenclature has been created by the International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, also

known as the Nomenclature Working Group. By 2005, the Nomenclature Working Group crossmaped the nomenclature of the International Congenital Heart Surgery Nomenclature and Database Project of The European Paediatric Cardiac Code of the Association for European Paediatric Cardiology, and thus created the International Paediatric and Congenital Cardiac Code (IPCCC) [8,11]

Two major multi-institutional efforts that have attempted to measure the complexity of congenital heart surgery are the Risk Adjustment in Congenital Heart Surgery-1 method (RACHS-1) and the Aristotle Complexity Score (ABC score). The methodological details of each system are described in the respective references [14,16]. In brief, the Aristotle committee, consisting of experts from 50 centres in 23 countries, developed the ABC Score. Each of 145 procedures was rated with a score of 0.5 through 5 in three areas: potential for mortality, potential for morbidity and technical difficulty. After assigning each procedure with an Aristotle Basic Complexity Score ranging from 1.5 to 15, each procedure was assigned to Aristotle Basic Complexity Level ranging from 1 through 4 based on the Aristotle Basic Complexity Score (basic score of 1.5 to 5.9 = basic level of 1, basic score of 6.0 to 7.9 = basic level of 2, basic score of 8.0 to 9.9 = basic level of 3, basic score of 10.0 to 15.0 = basic level of 4). On the other hand, in the RACHS-1 system, which was developed between 1993 and 1995, congenital cardiac operations were stratified into 1 to 6 categories. The ABC Score and RACHS-1 represent the most widely utilized and accepted methodologies of case mix complexity adjustment in paediatric and congenital heart surgery. Both tools for stratification of complexity are slightly different and each is only an approximation of stratification of complexity and not proper risk-adjustment. With both systems, as the complexity increases, mortality prior to discharge from the hospital also increases. Efforts involving the developers of each system to unify these two systems so as to capitalise on the strengths of both are already underway [7].

In this report, we analysed outcomes of cardiac surgical procedures performed on population with congenital heart defect born between October 1, 2002 and October 1, 2007. The data included in this report were collected in this period of study and represent surgical procedures performed with or without cardiopulmonary bypass. This section contains information on patient, discharge mortality, occurrence of postoperative complications and procedural complexity. Case complexity is presented using both the Aristotle Basic Complexity Score and the Risk Adjustment for Congenital Heart Surgery methodology. Due to the fact that improvements in the medical care of patients with congenital heart disease, including early diagnoses, diagnostic procedures, neonatal care and intensive care units in our country, were not followed by an advance in surgical development, major proportion of cardiac surgeries is still performed in referral centres abroad. Using the widely utilised and accepted methodologies of case mix complexity adjustment in paediatric and congenital heart surgery, we tried to evaluate the performance in our surgical centres, as well as the paediatric cardiac surgery program in our country.

Materials and Methods

The study population consisted of all patients with congenital heart disease born to Croatian residents between October 1, 2002 and October 1, 2007 undergoing a cardiovascular operation during that period. Information about the patients was obtained from medical records collected by a paediatrician cardiologist. The data were collected from the Croatian database, the base that had been created as population and hospital – based register and which included all children with congenital heart disease born between October 1, 2002 and October 1, 2007, a year with demographic and in-hospital variables (Table 1). A resident was considered to be anyone who had lived in Croatia for a year or longer. All diagnoses and procedures were coded according the International Paediatric and Congenital Cardiac Code (IPCCC).

Syndromes and malformations were subdivided into major and minor malformations following guidelines set out by registries of European Concerted Action on Congenital Anomalies and Twins (EUROCAT).

Cardiac surgical procedures performed with or without cardiopulmonary bypass are included in the report. The primary procedure for an operation is the procedure with the highest Aristotle Basic Complexity Score with two exceptions: in the event of simultaneous bidirectional Glenn and pulmonary artery arterioplasty, the bidirectional Glenn is the primary procedure and in the event of a primary diagnosis of atrial septal defect, Sinus venosus with procedures of partial anomalous pulmonary venous connection repair and atrial septal defect repair, patch, the second will be considered the primary procedure. If the two procedures within a given operation share the highest ABC Score, the procedure designated as primary by the participant will be used.

The mortality is achieved using a patient admission–based mortality calculation with a numerator of the number of deceased patients and a denominator of the number of cardiac surgical patient-admissions. Mortality that occurs for an admission with multiple operations is assigned to the first cardiac operation (that is the first operation with operation type cardiovascular bypass or no cardiovascular bypass cardiovascular) of that admission.

This initial cardiac operation of the hospitalisation is considered the index operation of the hospitalization. Mortality status at discharge is the chosen measure of mortality for this report. Patients weighing less than or equal to 2 500 g undergoing persistent arterial duct ligation as their primary procedure will not be included in the mortality calculation due to the fact that the vast majority of deaths in this patient population are multifactorial and largely unrelated to the surgical procedure in time and by cause [3]. Case mix complexity adjustment is performed by using both the Aristotle Basic Complexity Score (ABC Score) and the Risk Adjustment for Congenital Heart Surgery (RACHS-1) methodology. The ABC Score, ABC level and

RACHS-1 are calculated at the patient admission level. For each patient cardiac admission, the ABC Score, ABC Level and RACHS-1 are determined by the component procedure of highest complexity for the index operation. Ten complications reported after cardiosurgical procedure were included and measured in this report, unplanned reoperation, cardiac arrest, atrioventricular block requiring permanent pacemaker, sternum left open, acute renal failure requiring dialysis, reoperation for bleeding, mediastinitis, neurological deficit persisting at discharge and new onset seizures, prolonged stay in intensive care unit. The postoperative complications were presented as prolonged length of stay (more than 21 days).

Statistical methods: For all relevant findings, we primarily used descriptive statistics. Difference in average complexity for cardiac procedures done in Croatia and the ones done abroad according to Basic Score and according to RACHS-1 methodology was tested by nonparametric Mann-Whitney U test. Association of mortality and registration of postoperative complications with the place of operation was tested with Fisher's exact test. Association of ABC score and RACHS-1 distribution with mortality and postoperative complication was tested with Pearson's Chi-square test, and the degree of association between variables was assessed with Cramer's V coefficient. All analyses were conducted using Statistical Package for Social Sciences version 13.

Results:

Of the 556 operations, ABC score could be assigned to 553 operation and RACHS-1 score to 536 operations. Operations that were assigned ABC or RACHS-1 and with known discharge mortality status were used in all subsequent analysis. Among 553 cardiac surgeries performed which could be scored by ABC score, 202 were done in Croatia and 351 were done abroad, among 536 procedures classified by RACHS-1 methodology 336 were done abroad and 200 in Croatia. Procedures were performed in 2 institutions in Croatia and 7 institutions abroad.

The overall mortality rate among procedures analysed by ABC score was 4.3% with the rate of complications reported after cardiosurgical procedure being 24.1%. The overall mortality rate among procedures classified by RACHS methodology was 4.5% with the rate of complications reported after cardiosurgical procedure being 24.3 % (Table 2). 84.1 % of procedures were done before the age of one year. The average complexity for cardiac procedures done in Croatia according to the Basic Score was is 6.1 and the average complexity for procedures done abroad according to the Basic Score was 9.2 with statistically significant difference ($p<0.001$). The average complexity for cardiac procedures done in Croatia according to the RACHS-1 methodology is 2.2 and the average for procedures done abroad according to the RACHS-1 methodology is 3.1 with statistically significant difference ($p<0.001$). In Croatia, only 5 procedures in RACHS-1 category 4 were performed and no cases in category 5 or 6, also, there were only 4 procedures placed in ABC level 4 performed in Croatia (Table 3). Distribution of cases operated abroad by complexity information, mortality rate and occurrence of postoperative complications is given in Table 4.

The most frequent procedure done in Croatia was pulmonary artery banding, follow by ventricular septal defect repair, coarctation repair, persistent arterial duct closure, modified Blalock-Tausig shunt and atrial septal defect repair. The most frequent procedure done in foreign countries was arterial switch followed by Norwood procedure, bidirectional Glenn, repair of atrioventricular canal defects, tetralogy of Fallot and repair of double outlet of right ventricle (Table 5). Among 202 procedures in Croatia classified by ABC score, or 200 procedures by RACHS-1 methodology, death occurred after 10 procedures with mortality rate of 5 %, on the other hand, among 351 procedures done abroad and assigned by ABC score, death occurred after 14 procedures with calculated mortality rate of 4%. After 336 procedures done abroad and classified by RACHS-1 methodology, death occurred after 14 procedures with mortality rate of 4.2%. There is no significant difference between mortality in Croatia

and abroad without adjustment for complexity (p=0.667). Among 202 procedures done in Croatia and which could be classified by ABC score, or 200 procedures according to RACHS-1 methodology, postoperative complications were registered after 50 procedures with percentage of 24.8% or 25%. On the other hand, among 351 procedures done abroad, there were postoperative complications after 83 procedures with percentage of 23.6% or by RACHS-1 methodology, among 336 procedures, postoperative complications were registered after 80 procedures with percentage of 23.8%. There is no significant difference between registration of postoperative complications in Croatia and after operation done abroad, without adjustment for complexity (p=0.836).

Among procedures done in Croatia and procedures done abroad, considerable variation in mortality and postoperative complications was observed in ABC level 2 and 3 with significantly higher mortality of procedures done in Croatia in ABC level 2, with mortality rate of 4.8 in Croatia in relation to 1.9 abroad, and in level 3 with mortality rate 13% in relation to mortality among procedures done abroad of 1.7% (Table 3 and 4 and Figure 1). By using classification according to RACHS-1 methodology, significantly higher mortality rate was observed in group 2 with mortality rate among procedures done in Croatia being 7.4 % in relation to 1% done abroad (Table 3 and 4 and figure 1) When analysing the differences in occurrence of postoperative complications, there is significantly higher rate of postoperative complications in ABC level 3, with rate of 34.8% among procedures done in Croatia in relation to 15% among procedures done abroad, and in group 3 according to the RACHS-1 methodology, with percentage of 36.2 % of postoperative complications among procedures done in Croatia in relation to 22.4% among procedures done abroad (Table 3 and 4 and figure 2). When analysing all procedures assigned by ABC score, we determined no statistically significant connection between ABC score and mortality rate (χ^2 =5.982; df=3, p=0.113), but we evinced that there is statistically significant connection between ABC score and mortality

only after exclusion of procedures done in Croatia, (χ^2=8.317; df=2, p=0.016). When analysing all procedures assigned by ABC score, we revealed statistically significant connection between ABC score and postoperative complications (χ^2=9.853; df=3, p=0.020) (V=0.134, p=0.020) and connection is stronger when analysing only procedures done abroad (χ^2=7.537; df=2, p=0.023) (V=0.147, p=0.023). When studying all procedures which could be classified by RACHS-1 methodology, we determined no statistically significant connection between RACHS-1 groups and mortality rate (χ^2=8.881; df=5, p=0.114), or when studying procedures done only abroad (χ^2=10.507; df=5, p=0.062). This finding might be because small number of deaths occurred in the groups. Analysing relation between RACHS-1 groups and percentage of postoperative complications, when studying all procedures, we determined a statistically significant connection (χ^2=16.590; df=5, p=0.005) (V=0.176, p=0.005) and association is stronger when analysing only procedures done abroad (χ^2=11.428; df=5, p=0.044) (V=0.184, p=0.044).

Discussion:

There is huge variety of unadjusted mortality rates between centres performing operations of congenital heart disease, with mortality rate ranging from 2.5% to 11.4% [13]. Previous reports illustrated well that an unadjusted mortality rate is inadequate for evaluating institution quality and that simple statistics can be misleading. Both ABC and RACHS-1 were predictive of in-hospital mortality as well as of prolonged post-operative length of stay, but both tools for stratification of complexity are slightly different, each is only an approximation of stratification of complexity, not true risk-adjustment and both might have several weaknesses. The Aristotle methodology allows classification of more operations, while the Risk Adjustment in Congenital Heart Surgery-1 system discriminates better at the higher end

of complexity [10]. Neither the Risk Adjustment in Congenital Heart Surgery-1 system nor the Aristotle Basic Complexity Score incorporate detailed patient-specific risk factors into their algorithms [12]. On the other hand, the Risk Adjustment in Congenital Heart Surgery method has been demonstrated to be a useful tool in several studies in both Europe and North America and represents one of the first widely accepted tools for adjustment of complexity developed in field of paediatric cardiology [2,18]. The database of Society of Thoracic Surgeons and The European Association for Cardio-Thoracic surgery have been including the Aristotle Complexity score in their reports since 2002 [9]. The European Association for Cardio-Thoracic Surgery and the The Society of Thoracic Surgeons multi-institutional database indicate that the Aristotle Complexity Score correlates well to mortality prior to discharge from the hospital after congenital heart surgery, as well as to prolonged postoperative stay [21]. Although some papers favour one over other [1], in 2006, both databases, the databases of Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, unified two adjustment systems and incorporated ABC score and RACHS-1 methodology into their reports.

In the databases of both The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, mortality prior to discharge is now between 4% and 5% [6].

Here we reported that the mortality rate in Croatia was 5%, and, on the other hand, the mortality rate in procedures done in centres that helped treating our patients was 4%. As this report illustrated there are marked differences in mortality and occurrence of postoperative complications between Croatia and centres abroad only after adjustment for complexity. Using statistical analysis to test association between ABC score or RACHS-1 groups with mortality or morbidity rate, we determined association, or we find out stronger association after exclusion of procedures done in Croatia, by analysing only procedures done abroad. In our case, this strongly suggests relevance of institution where a procedure is performed and

indicates to a necessity of readjusting performance in our centres. In some risk categories there is significantly higher mortality and morbidity after procedures done in Croatia. When looking at mortality of those cases, having in mind that these cases are mostly classified in lower risk groups, mortality is higher than in reports from some other centres, suggesting clearly that there is a need to support and organize a retraining of our program. This differences may be explained by many reasons. Centres in Croatia could be classified as smaller centres performing less than 200 procedures per year, with the mortality of about 4-5 % only for selected cases, with more complex patients being sent away. Paediatric cardiac surgery is the only surgical procedure performed in children for which a volume-outcome relationship has been documented. Previous reports showed that unadjusted mortality rate in very small hospitals was no different than at large hospitals or might be even lower than in medium-volume hospital. After adjustment for complexity large hospitals performed significantly better than all other volume groups [5]. However, large-volume hospitals performed more complex operations and achieved superior results. Although a great proportion of published studies reported a statistically significant relationship between higher institutional case volume and better clinical outcomes, the most recent study suggested that this relationship might no longer exist and illustrated the inappropriateness of using volume alone as a marker of quality [22]. Since congenital heart defects in our country all still sometimes operated by surgeons who operate on adult patients, mortality rate, especially in some categories, could be higher as indicated by the report about procedures performed on GUCH patients [15].

Although outcome analysis is potentially dangerous with many implications, centres should not fear the potentially negative consequences of reporting less than stellar results. The point is to identify the problems and institute improvement initiatives, which can include inter-institutional team visits, mentoring schemes and educational programmes. These kinds of

inter-institutional visits have succeeded in improving outcomes in most countries [17]. As reported by Novick and all [20], Croatia was included in such a program from 1993 to 2003. After these years, the challenges to improve a standing programme in paediatric cardiac surgery in Croatia still exist. The results of this study might have important implications: a) the need for centralization in pediatric cardiac surgery to achieve best possible results is once again demonstrated, b) Europe still does not have a well established pathway for international cooperation in the field of healthcare and remains highly dependent on national structures, c) this study highlights how international cooperation is highly beneficial to provide best practice care for a particular patient population and in particular when it comes to rare diseases in small countries, d) the use of standardized risk scores allows selection of international partners according to evidence based outcomes for specific defects which may have very different outcomes in various centers, e) finally, the results demonstrate how risk adjusted outcomes may be used to develop initiatives to improve the services provided on a national level and also develop cooperation between neighboring small countries.

However, hospital discharge data and mortality rate may not be the only or the best way to evaluate congenital heart surgery program. Despite its importance, in-hospital mortality is only one of the clinically important end points that should be of interest to program directors. Relative performance with respect to postoperative complications, prolonged length of hospital stay in intensive care unit, late mortality and functional and neurological outcomes would also be of obvious interest for efforts at quality improvement. The databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery currently do not allow for long term follow up, and analysis of outcomes must reach beyond mortality, and encompass longer term follow-up, including cardiac and non cardiac morbidities and impacting health related quality of life and including functional state via the classification of the New York Heart Association [4,11,12].

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Table 1.

Age at operation	*N (%)*	
Less or 30 days	186	(33.6)
31 day to 1 year	279	(50.5)
1 – 3 year	82	(15.3)
>3 year	6	(1.1)
Extracardiac anomalies	*N*	
Down syndrome	62	
Other syndrome	22	
Other congenital defects	84	
Total	168	

Table 2.

Complexity level	Aristotle score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)	RACHS Score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)
1	1.5-5.9	29 (5.2)	0 (0)	2 (6.9)	1	53 (9.9)	0 (0)	5 (9.4)
2	6 – 7.9	254 (45.9)	10 (3.9)	69 (27.2)	2	164 (30.6)	7 (4.3)	35 (21.3)
3	8 – 9.9	143 (25.9)	4 (2.8)	26 (18.2)	3	223 (41.6)	9 (4.0)	61 (27.4)
4	10.0-15.0	127 (23)	10 (7.9)	36 (28.3)	4	73 (13.6)	5 (6.8)	19 (26)
Total		*553 (100)*	*24 (4.3)*	*133 (24.1)*	5	3 (0.6)	0 (0)	0 (0)
					6	20 (3.7)	3 (15.0)	10 (50)
					Total	*536*[b]	*24 (4.5)*	*130*[b] *(24.3)*

[a] procedures could not be classified and were excluded in subsequent analysis
[b] prolonged length of stay

Table 3.

Complexity level	Aristotle score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)	**RACHS** Score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)
1	1.5-5.9	29 (14.4)	0 (0)	2 (6.9)	1	47 (23.5)	0 (0)	5 (10.6)
2	6 – 7.9	146 (72.3)	7 (4.8)	40 (27.4)	2	68 (34)	5 (7.4)	15 (22.1)
3	8 – 9.9	23 (11.4)	3 (13)	8 (34.8)	3	80 (40)	5 (6.2)	29 (36.2)
4	10.0-15.0	4 (2)	0 (0)	0 (0)	4	5 (2.5)	0 (0)	1 (20)
Total		*202 (100)*	*10 (5)*	*50 (24.8)*	5	0 (0)	0 (0)	0 (0)
					6	0 (0)	0 (0)	0 (0)
					Total	*200*[b] *(100)*	*10 (5)*	*50*[b] *(25)*

[a] some procedures could not be classified
[b] prolonged length of stay

Table 4.

Complexity level	Aristotle score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)	RACHS Score	Cases N (%)	Mortality N (%)	PLOS[a] N (%)
1	1.5-5.9	0 (0)	0 (0)	0 (0)	1	6 (1.8)	0 (0)	0 (0)
2	6 – 7.9	108 (30.8)	2 (1.9)	29 (26.9)	2	96 (28.6)	1 (1)	20 (20.8)
3	8 – 9.9	120 (34.2)	2 (1.7)	18 (15)	3	143 (42.6)	5 (3.5)	32 (22.4)
4	10.0-15.0	123 (35)	10 (8.1)	36 (29.3)	4	68 (20.2)	5 (7.4)	18 (26.5)
Total		*351 (100)*	*14 (4.0)*	*83 (23.6)*	5	3 (0.9)	0 (0)	0 (0)
					6	20 (6.0)	3 (15.0)	10 (50)
					Total	*336*[b] *(100)*	*14 (4.16)*	*80*[b] *(23.8)*

[a] some procedures done abroad could not be classified in RACHS-1 categories but could be by ABC score
[b] prolonged length of stay

Table 5.

Croatia					**Abroad**				
Procedures	Incidence N/%of all	Discharge mortality %of operations	Mean ABC score	RACHS-1 category	Procedure	Incidence N/% of all	Discharge mortality %of operations	Mean ABC score	RACHS-1 category
Pulmonary artery banding	37/18%	5%	6.0	3	Arterial switch procedure	49/14%	0	10	4
Ventricular septal defect repair, patch	36/18%	0	6.0	2	Norwood procedure	34/10%	12%	14.5	6
Coarctation repair, end to end	18/9%	5%	6.0	1	Bidirectional Glenn	30/8.6%	0	7.5	2
Persistent arterial duct closure, surgical	18/9%	0	3.0	1	Complete atrioventricular canal defect	27/7.7%	4%	9.0	3
Modified Blalock- Tausig shunt	17/8%	18%	6.3	3	Tetralogy Fallot	25/7%	0	8.0	2
Atrial septal defect repair, patch	10/5%	0	3.0	1	Double outlet of right ventricle	15/4.3%	0	10.3	3

Table legends:

Table 1. Patient characteristics according to the age at time of operation and presence of other noncardiac anomalies.

Table 2. Distribution of *all cases* by complexity information, mortality rate and occurrence of postoperative complications (prolonged length of stay).

Table 3. Distribution of cases operated *in Croatia* by complexity information, mortality and occurrence of postoperative complications (prolonged length of stay).

Table 4. Distribution of cases operated *abroad* by complexity information, mortality rate and occurrence of postoperative complications (prolonged length of stay).

Table 5. The top 6 (by frequency) primary procedures, in Croatia and in foreign countries, with incidence, discharge mortality and complexity.