Comment on the Article by Novick WM, et al. International Pediatric Cardiac Assistance in Croatia: Results of the 10 Year Program

To the Editor: Thank you very much for publishing the article “International pediatric cardiac assistance in Croatia: results of the 10 year program” (1). I also thank you for giving me the opportunity to respond to it in the form of this letter. In doing so, you have provided the means through which the readers of your esteemed Journal can consider both the article and this letter in a single issue.

It has previously been published in the literature that there are many congenital heart diseases in children, some of which occur in only a small percentage and among which most are very difficult to treat (2). For this reason, Croatia, as a country with 4.5 million inhabitants, would have great difficulty training a pediatric cardiac surgeon in some specific areas, namely complete transposition of great arteries and the hypoplastic left heart syndrome. Such difficulty would occur since this surgeon would not be able to operate on a number of patients significant enough to maintain his or her surgical skills in certain areas of pediatric cardiac surgery (3,4). The learning curve for such a surgeon in Croatia would in this instance be too long, and a high skill level would never be achieved (3).

We draw your attention to the situation in Great Britain, where several pediatric cardiac surgeries were recently closed by the Government because it did not consider less than 170 open heart procedures a year per Department sufficient to maintain the highly-needed surgical skill of the surgeons. This resulted in an unacceptably high mortality rate (3).

It was therefore of the utmost importance for Croatia to develop cooperation with a highly skilled specialist from a pediatric cardiac surgery center, who would be available for those congenital heart diseases that occur in only a few cases in 1,000 newborns as well as some other, so-called “routine” cases. Cooperation between the corresponding author and the Republic of Croatia thus began in 1993.

Regarding the article in the Croatian Medical Journal, we congratulate the corresponding author for his efforts in stating the problems in pediatric cardiac surgery in Croatia. We believe, however, that this article contains inaccuracies which may misinform your readers. We also point out that not all coauthors of this article have read it prior to publication, so we direct our comments to the corresponding author alone.

Training of Surgical Staff

The article well states the intended purpose of the program and the critical issues which remained unresolved after a ten-year program in which the corresponding author had a leading role. As the article states, the purpose of the program was to provide staff training, clinical services, and the development of an organized pediatric cardiac service team in Croatia. We agree that, due to the efforts of the corresponding author, the staff was trained in some aspects of pediatric cardiac care, namely anesthesiology, nursing, and the work of perfusionists, which is very specific and differs from adult cardiac care. We are truly grateful for this achievement. We disagree, however, with the assertion that the failure of surgical staff to achieve the necessary level of training was due to a lack of coordination and continuity among surgeons participating in the program.

The article includes cardiac surgery log books as a data source, which indicate the participation of anesthesiologists, nurses, and perfusionists. The log books also indicate, however, that the corresponding author did not assist our surgeons for at least 50% of every visit, as was his obligation according to the contract he signed with the Croatian Ministry of Health. Indeed, many times he assisted in only one or even none of the procedures (Zagreb University Hospital Center, unpublished data). This raises the question as to why there wasn’t a similar effort to train surgeons to the appropriate skill level, as was the case with other medical staff.

Data Sources andAnalysis

According to the article, data were extracted from a variety of sources, as there was no single source for “recording information on children undergoing cardiac surgical procedures” (4). We note the omission of the official registry of deaths in Maksimir district, which lists the name and date of every person who died in the Maksimir district of Zagreb, where the Zagreb University Hospital Center is located (5). The data shown in this registry should precisely match the data entered into the cardiac surgery log books and cited in the article.

While we applaud efforts to undertake detailed statistical analysis, we question whether appropriate statistical tests were used. Excluded from the analysis is the Gauss distribution of the analyzed variables, which is a condition for using the Student’s t-test. Such an oversight casts doubt onto the results of the statistical analysis described in the article. Furthermore, the chi-square test was used to compare individual Risk Adjustment in Congenital Heart Surgery
(RACHS) categories, raising the issue of multiple testing, which may cause inaccuracies in the interpretation of the results due to a possible mistake increase in the conclusion of the results.

Mortality Rates

It is difficult to understand the purpose of the statistical analysis contained in the article when the issue of mortality rates remains unclear. Between April 1993 and March 2001, the corresponding author’s mortality rate in children where complete transposition of the great arteries was performed was 60%. Although we congratulate the corresponding author on an improvement to 42.9% during the government sponsored program, I must remind him that the mortality rate after the same procedure during the same time period in another institution in Bratislava, Slovakia, was 4.8%, while world standards were no more than 6.2% (6-13). I also raise the issue of the difference in survival rates during the humanitarian program and the government sponsored program. Finally, we note so-called “easier” procedures, for instance ventricular septal defect, where the corresponding author’s mortality rates were 9.8% between 1993-2001, while the world standards were 0-1% (7-11,14).

On February 14, 2001, an official report signed by Professor Maščić, as the coordinator of the program, and me was submitted to the governing structures of Zagreb University Hospital Center and the Croatian Ministry of Health. This report showed an unacceptably high mortality rate (Zagreb University Hospital Center, unpublished data). The issue of the corresponding author’s unacceptable mortality rates was raised many times during the course of the program, especially during the tenure of the previous administration of Zagreb University Hospital Center. In 2003, an Independent Commission at Zagreb University Hospital Center, mostly composed of professors of surgery and cardiology, was officially named to investigate this matter. Their independent findings showed that the mortality rate of the author in the 30-day postoperative period was unacceptable (Zagreb University Hospital Center, unpublished data). As a result, the Commission recommended to the Zagreb University Hospital Center administration that cooperation with the corresponding author should cease, but this happened only after the new Director at the Zagreb University Hospital Center was named. The specific reason that cooperation between Zagreb University Hospital Center and the corresponding author ceased was due to his unacceptably high mortality rate of Croatian children during the 30-day postoperative period. This is the criterion for the postoperative period which has been defined by several world organizations, including the Institute of Public Health, Cambridge University, and published in the British Medical Journal in 2002 (4,15).

Summary and Conclusions

I agree with the article’s overall conclusion that more work needs to be done in pediatric cardiac surgery in Croatia, although I have reached the same conclusion via remarkably different data analyses. First, I agree that the educational component of the ten-year program is an area that requires additional work. We point out, however, that “inconsistent participation” (4) cannot be attributed to Croatian surgeons. Second, I do not share the article’s confidence that data sources were as comprehensive as possible since official Maksimir district records have been omitted. I also believe that some statistical methods have been misapplied, thus calling the results into question. Third, I wholeheartedly disagree with the article’s conclusion that the ten-year program provided “reasonable surgical outcomes” (1), as unacceptably high mortality rates indicate otherwise. Indeed, cooperation between the Zagreb University Hospital Center and the corresponding author ceased due to the findings of an Independent Commission, which showed his unacceptably high mortality rate. Finally, I question the validity of the article in general as it has not been read by all of its coauthors.

We reiterate our agreement with the article’s conclusion that more work needs to be done in pediatric cardiac surgery in Croatia, but with a pediatric cardiac surgeon who would not only have acceptable survival rate but would also educate young Croatian cardiac surgeons by assisting them in at least 50% of the procedures. These same surgeons are capable of performing most complicated adult cardiac surgery cases and would eagerly accept the transfer of knowledge to pediatric cardiac surgery.

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5 Registry of deaths in Maksimir district [in Croatian]. Archive of Maksimir district. Zagreb.
In Reply: We have read Dr Jelić’s letter to you and believe that a rebuttal to his letter is warranted. In 2001, a book “Pediatrijska kardiologija - odabrana poglavljia” (“Pediatric Cardiology – Selected Chapters”) was published, in which Dr Jelić was the lead author on a chapter concerning pediatric cardiac surgery at the Zagreb University Hospital Center (1). The article detailed the advances made in pediatric cardiac surgery during the time of our programs. Dr Jelić and his co-authors specifically cited their satisfaction in the education his team had received; their satisfaction with the mortality rates secondary to the complexity of cases performed when our team was in the country; the low costs of the surgery for children; and that the corresponding author was the answer to the problem for the children of Croatia with heart disease (1). Then in 2002, the administration of the Zagreb University Hospital Center asked the corresponding author to consider taking a 4-year sabbatical from international travel and concentrate his efforts in Croatia as the Chief of Cardiac Surgery. This request was made public in Croatian daily newspapers in December 2002 and January 2003 when the Minister of Health announced that the corresponding author was being considered for this position. The result was a complete change in the position of Dr Jelić towards the corresponding author, which resulted in several slanderous newspaper articles from “unknown” quoted sources and the creation of the Independent Commission at the Zagreb University Hospital Center. As a direct result of these activities Dr Jelić was removed as the Chief of Cardiac Surgery by the hospital administration and was not re-instated until a year later when the political climate of the country changed and a new hospital administration was installed. The article in this issue of the Croatian Medical Journal entitled “Academic cardiac surgery in Croatia: perspective of an international collaborator” (2) details many, but not all of the reasons why the previous administration removed Dr Jelić as the Chief of Cardiac Surgery at Zagreb University Hospital Center.

Training of Surgical Staff

Dr Jelić has made an accurate statement that the corresponding author was contractually bound to assist Zagreb University Hospital Center cardiac surgical staff in 50% of the cases. However when the corresponding author requested that Dr Jelić, his surgeons, and pediatric cardiologists generate a list of surgical candidates that reflected cases to be performed by his surgeons or by the corresponding author this request was only fulfilled on two trips. Additionally, on occasions, cases that had been designated for his surgeons were shifted to the corresponding author either by the designated surgeon before the case, or because they could not adequately or safely complete the case. Lastly, as one can see from the percentage of cases performed in RACHS-1 categories 3, 4, and 6 during the government sponsored program (3), it would have been irresponsible of the corresponding author to assign cases of this complexity to surgeons who were not assigned to them by their own Chief of Cardiac Surgery or the pediatric cardiologists.

Data Sources and Analysis

Dr. Jelić points out that the Maksimir official registry is omitted from the data sources and he is correct. Simply listing deaths from an official registry is an archaic method of statistical analysis and was discontinued as a usual method in the United Kingdom in the 19th century (4).

Mortality Rates

The “data” he says is unpublished Zagreb University Hospital Center’s data on ventricular septal defect (VSD) and is very interesting. The Ministry of Health requested a complete and verified report in June 2003, as a direct result of the report prepared by the Independent Commission of the Zagreb University Hospital Center. The report of the Independent Commission of the Zagreb University Hospital Center specifically states that the data provided by the corresponding author was not reviewed because it was in a
artery debanding and pulmonary artery reconstruction, 4 VSDs with pulmonary hypertension and one child with VSD and pulmonary artery debanding and reconstruction died 24 days postoperatively from pulmonary sepsis.

Regarding the claim made by Dr Jelić concerning children with the transposition of the great vessels (TGA) the following data was sent to the Ministry of Health as a part of the comprehensive report from the Department of Cardiac Surgery on pediatric cardiac surgery from June 1998 – July 2003. A total of 16 arterial switch operations (ASO) were performed. There were 3 children with TGA and intact ventricular septum, one of which underwent a 2-stage repair, and all survived; 1 child underwent a double switch and survived, and 13 children underwent ASO and VSD closure. A total of 3 children died while we were in the country, all in the ASO/VSD group. Another 3 children died later from pulmonary complications, one as late as 205 days after the team departed. The 30-day mortality for 2002 was 1/6 and in 2003 0/3, clearly not the mortality stated by Dr Jelić. One other point concerning patients operated on for TGA during the Government Sponsored Program that Dr Jelić failed to mention was that a number of children presented late with TGA/intraventricular septum (IVS) and received the Senning Procedure. There were 12 children from 6 months to 2 years of age who underwent the atrial switch procedure, without any deaths. So altogether there were 29 children who underwent one of these three operations, with 3 deaths (10.3%) while we were in the country.

Dr Jelić’s Summary and Conclusions

We disagree that the educational component in the broad sense implied needs more work; it is specifically in the domain of the cardiac surgeons that work needs to be done. We have outlined the discontinuous and diffuse participation of the surgeons in detail. The mortality rates are detailed in the manuscript and are the result of detailed search by multiple participants in the program of the databases available in the hospital and in the database maintained by the international collaborators. We would agree that the 15% 30-day mortality rate is high, however it was Dr Jelić’s team who cared for the children following the departure of the international team, and they certainly share in the responsibility of these late deaths. In the first article concerning the methodology and results of the RACHS-1 classification, the range in 30-day mortality rates was from 2.5% to 11.4% (6). Although we did not statistically analyze our 30-day mortality rate compared to those in this study, 11.4% is very similar to the 14.8% we obtained. The work of the international team was not stopped after the Independent Commission, as indicated by Dr Jelić. The team continued to work at the Zagreb University Hospital Center another 8 months. When the most recent elections resulted in a change in the politics of the country and another administration replaced the administration that removed Dr Jelić as Chief of Cardiac Surgery, we elected not to return when Dr Jelić was reinstated as the Chief of Cardiac Surgery. Lastly, we do not take issue with his statement that his surgeons who perform most complicated adult cardiac surgery cases would eagerly accept the transfer of knowledge to pediatric cardiac surgery. They perform adult cardiac surgery. However, we would note that the same Zagreb University Hospital Center’s “unpublished data” shows that the mortality rate for routine coronaries in his institution would be totally unacceptable in any country in Western Europe, and that a similar situation exists for pediatric mortality rates in the few cases his surgeons performed in the absence of our team.

We appreciate the opportunity the Editor-in-Chief of the Croatian Medical Journal provided us by allowing a rebuttal to the letter to the editor from Dr Jelić.

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