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Přehledový článek | Review article

Use of OPCAB in Czechia 2010–2015: Have we learned any lessons?

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ARTICLE INFO

Article history:
Received: 14. 10. 2017
Received in revised form: 9. 1. 2018
Accepted: 13. 1. 2018
Available online: 13. 2. 2018

Klíčová slova:
Kardiopulmonální bypass
Off-pump
Revaskularizace

SOUHRN

Úvod: Aortokoronární bypass na bijícím srdci (OPCAB) je zavedená technika revaskularizace myokardu, která se používá po celém světě. Nicméně počet pacientů, kteří podstupují tento druh operace, se liší podle pracoviště. Chtěli jsme zjistit, zda nejnovější publikace týkající se koronární revaskularizace bez mimotělního oběhu (MO) změnily vnímání OPCAB v očích českých kardiochirurgů.
Metody: Údaje z Národního kardiochirurgického registru ČR byly využity k vyhodnocení trendů v počtu revaskularizací bez MO u pacientů s ischemickou chorobou srdeční a k analýze faktorů, které jsou pro chirurgy určující při volbě strategie OPCAB. Zkoumané období bylo mezi lety 2010–2015.
Výsledky: Aortokoronární bypass bez MO se provádí na všech 12 kardiochirurgických pracovištích v ČR. Celkově jsme zaznamenali mírný pokles izolovaných revaskularizací mezi rokem 2010 a 2015 (z 3 884 na 3 569), přičemž procento případů OPCAB také klesalo (z 26,7 % na 24,9 %). Během studie se průměrný věk pacientů, operovaných na bijícím srdci zvýšil (66,2 vs. 68,1 roku) a zahrnoval pacienty se stále větším počtem komorbidit. Průměrná celková doba operace OPCAB klesla (3,3 vs. 3,1 hodiny) a ve srovnání se standardní revaskularizací trvá OPCAB podstatně méně času (3,1 vs. 3,3 hodiny, $p < 0001$). Počet periferních anastomóz prováděných bez MO byl signifikantně nižší než u operací na MO a obecně se snížil (2,1 vs. 3,0, $p < 0,001$ v roce 2010 a 1,9 vs. 2,9, $p < 0,001$ v roce 2015).
Závěry: Počet revaskularizací bez MO měl v ČR mezi lety 2010 a 2015 klesající tendenci. Nicméně není jasné, zda k tomu došlo vlivem nedávno publikovaných, široce uznávaných prospektivních randomizovaných studií. Přestože tyto práce neprokázaly nadřazenost OPCAB u vysoce rizikových pacientů, čeští kardiochirurgové upřednostňují off-pump strategii právě u těchto nemocných, zejména s anamnézou renální insuficience. Zdá se, že komunita českých kardiochirurgů je v tomto případě značně konzervativní a má tendenci k neúplné revaskularizaci.

ABSTRACT

Introduction: Off-pump coronary artery bypass grafting (OPCAB) is a well-established technique for coronary revascularization, which is used worldwide as well as in the Czech Republic (CZ). However, the number of patients undergoing this procedure varies from department to department. We wanted to see if the very latest publications regarding off-pump coronary revascularization had changed the way the procedure was viewed by Czech heart surgeons.

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DOI: 10.1016/j.crvasa.2018.01.005

Please cite this article as: J. Hlavička, et al., Use of OPCAB in Czechia 2010–2015: Have we learned any lessons?, Cor et Vasa 60 (2018) e393–e399 as published in the online version of *Cor et Vasa* available at https://www.sciencedirect.com/science/article/pii/S0010865017301741

Methods: Data from the Czech National Register of Cardiac Surgery were used to evaluate trends in the number OPCAB cases, in patients with ischemic heart disease, and to analyze the factors that surgeons routinely used when opting for the OPCAB strategy. The study period was 2010–2015.
Results: OPCAB was performed at all 12 cardiac surgery departments in the CZ. Overall, we found a slight decrease of the total number of isolated revascularizations in the CZ per annum between 2010 and 2015 (from 3884 to 3569), the percentage of OPCAB cases also declined over the study period (from 26.7% to 24.9%). Over the study, the average age of OPCAB patients increased (66.2 vs. 68.1 years) and included patients with increasingly greater numbers of comorbidities. The average total OPCAB surgery time decreased (3.3 vs. 3.1 hours) and compared to standard revascularization, OPCAB took significantly less time (3.1 vs. 3.3 hours, $p < 0001$). The number of peripheral anastomosis performed off-pump was significantly lower than on cardiopulmonary bypass (CPB) and, in general, has decreased (2.1 vs. 3.0, $p < 0.001$ in 2010 and 1.9 vs. 2.9, $p < 0.001$ in 2015 resp.).
Conclusions: The prevalence of OPCAB in the Czech Republic has decreased. However, it is unclear whether this is due to the recent widely respected prospective randomized clinical trials. Published papers have not shown the superiority of OPCAB in high-risk patients, yet Czech cardiac surgeons prefer this strategy, especially in patients with a history of renal insufficiency. In that point, the community of Czech cardiac surgeons seems to have become more conservative with a trend toward incomplete revascularization.

Keywords:
Cardiopulmonary bypass
Off-pump
Revascularization

Introduction

Surgical revascularization plays a crucial role in the treatment of coronary artery disease (CAD). With considerable progress in interventional cardiology, it has become an integral part of patient care by (1) reducing the need for oral medication, (2) improving quality of life, and (3) improving overall long-term prognosis. Randomized studies in the 1990s showed the superiority of aortocoronary bypass (ACB) relative to medication. A total of 41% of conservatively treated patients required revascularization surgery within ten years. In addition, ACB patients had a significantly lower five-, seven-, and ten-year mortality compared to conservatively treated patients. Benefits of ACB surgery were particularly evident in cases of left main disease (LMD), triple vessel disease (3VD), and in high risk patients [1,2]. Comparable results were obtained in randomized trials comparing the results of revascularization and percutaneous coronary intervention. They reaffirmed that the beneficial long-term effects of aortocoronary bypass, especially in patients with diffusion sclerosis of the coronary arteries [3,4].

Today beating-heart myocardial revascularization is considered to be the next developmental stage of the same procedure performed using extracorporeal circulation with cardiac arrest. It is paradoxical that it was this technique, i.e., without circulatory support, that Vineberg used in 1950 [5] when he first tried to revascularize the myocardium by grafting the internal thoracic artery to the heart. Also, the first successful endarterectomy of coronary arteries, by Bailey (1957) [6] and Longmire (1958) [7], was also performed on a beating heart, as well as the first successful aortocoronary bypass in 1961, by Robert Goetz.

Extracorporeal circulation with cardiac arrest, using a cardioplegic solution, was introduced into practice by Favaloro in 1967, and the beating-heart method was abandoned for almost 20 years. Since then, myocardial revascularization using cardiopulmonary bypass has been referred to as "standard revascularization". In the 1990s Benetti and Buffalo published a retrospective analysis favoring off-pump techniques because of a reduction in serious post-operative complications (renal failure, stroke, respiratory failure, SIRS) [8,9]. They started a wave of comparisons with "standard techniques" that has continued for over 20 years. The discussion initially focused on the negative impact of extracorporeal circulation devices. It was also assumed that cannulation of large arteries and veins increased operational risks. In addition, it has been confirmed that blood contact with the artificial surfaces of extracorporeal tubular systems triggers a systemic inflammatory response in the organism (SIRS), which was formerly known as post-perfusion syndrome. Despite the mild, often subclinical course of inflammation, the brain, intestine, kidneys, heart, and coagulation disorders were subsequently affected [10]. In rare cases, there can be a serious clinical manifestation, known as multiorgan failure (MOF). The humoral component of the non-specific inflammatory response activates complement, kallikrein--kinin, hemocoagulation, and the fibrinolytic system. The result is increased levels of oxygen radicals, increased capillary permeability, and pain. All cellular components of the blood are involved in the cellular response of the body, resulting in leukocytosis, thrombocytopenia (by an average of 17% [11]) with subsequent bleeding, and physical damage to erythrocytes. The non-pulsatile flow of blood during extracorporeal circulation is also currently considered to be the cause of post-operative renal failure [12]. For these reasons, CPB-surgery was considered to be extremely non-physiological and risky. Newly developed miniECC with reduced surface of the tubing system avoiding or minimizing above mentioned pathophysiological mechanisms is used exclusively in specialized centers. In the Czech Republic there is only one department, using miniECC routinely, in ca. 40% of all isolated ACBs (personal communication). Therefore this technique represents marginal method in our conditions, especially from the financial reasons. The first on-pump/off-pump comparison demonstrated that non-use of CPB in direct myocardial revascularization significantly reduced the release of the pathological process mediators described above [13,14] and subsequent clinical outcomes were promising [15,16]. The literary sources for OPCAB can be divided into three groups: 1) the first are observational data from large groups that repeatedly show the benefit of revascularization on the beating heart, especially in high-risk patients; 2) large-format, randomized trials in

patients with relatively low surgical risk that do not show a significant difference in the main cerebrovascular outcomes compared to standard on-pump revascularization (on the other hand, they confirm smaller post-operative blood loss, lower transfusion rates, and shorter length of stay after OPCAB, however, this is offset by a higher number of incomplete revascularizations and a lower long-term graft patency); and 3) small randomized trials from specialized departments demonstrating equivalent or superior outcomes of OPCAB and similar completeness of revascularization and graft patency. At the beginning of the 21st century, extensive randomized trials (mainly ROOBY, CORONARY, DOORS, and GOPCABE) became the basis for recommendations from the European Society of Cardiology (ESC). All of the trials focused primarily on the occurrence of serious complications in the early and mid-term postoperative course (i.e., after 30 and ± 365 days). The first trial, ROOBY (2009), surprisingly, did not endorse OPCAB, and in some aspects revascularization on the beating heart appeared to be worse in terms of the occurrence of major adverse cardiac events (MACE) one year postoperatively (9.9% vs. 7.4%, $p = 0.04$, relative risk [95% CI] 1.33 [1.01–1.76]). It should be said that this study suffered from several shortcomings, such as inclusion of low-risk patients only, overwhelmingly percentage of male patients (99.5%), and participation of surgeons in training [17].

The remaining three studies had much better designs, and although they focused on specific groups of patients with moderate and high risk (CORONARY 2012, 2013), over 70 (DOORS, 2012), and over 75 years (GOPCABE, 2013) they were unable to show any major OPCAB benefits after one month or one year; however, off-pump procedures were shown to greatly reduce the need for blood products, decrease the percentage of revisions for post-operative bleeding, and reduce the number of new cases of renal and respiratory failure [18–21]. At the same time that the CORONARY trial was being conducted at our department, we concluded the PRAGUE-6 study, which focused on patients with high operational risks (additive EuroSCORE ≥ 6). Despite a significantly lower incidence of severe post-operative complications after 30 days, the trend was not present after one year. We were not able to demonstrate a clear benefit for the method even for this narrow group of patients, despite a reduction in some signs of postoperative morbidity [22]. The last two extensive meta-analyses of randomized trials led to somewhat different conclusions. Deppe et al. analyzed 51 trials with 17,000 patients and found no significant difference in MACE between the two groups in the near term (30 days postoperative) (OR: 0.93; 95% CI: 0.82–1.04) or in the medium term (OR: 1, 01; 95% CI: 0.92–1.12) [23]. Kowalewski et al. looked at 100 randomized trials with 19,192 patients and found comparable mortality associated with both techniques, but noted that OPCAB was associated with a 28% lower risk of brain stroke (OR, 0.72, 95% CI, 0.56–0.92, $p = 0.009$). In addition, they found a significant correlation between high operational risk and the benefit of revascularization on the beating heart in terms of a reduction in mortality, myocardial infarction, and postoperative cerebral events [24]. Accordingly, the ESC Guidelines of 2014 cautiously recommend "to consider revascularization without the use of CPB in high risk patients" (Class IIa, level of evidence B). OPCAB procedures present several problems, in particular, performing peripheral anastomoses is technically more demanding, and blocking the blood stream in the anastomosis artery may lead to regional ischemia, arrhythmias, and circulatory collapse. Additionally, perforation of the artery at the site of anastomosis causes bleeding into the operating field, and elevation and rotation of the heart during positioning leads to decreased cardiac output due to temporary changes in anatomical proportions. All these obstacles can be effectively minimized as follows: pharmacologically (vasopressors, inotropes), surgically by using stabilizers, intracoronary shunts, patient positioning and gentle cardiac manipulation, and by careful monitoring of the patient's temperature and metabolism. Additionally, the learning curve for these techniques is longer than for revascularization on CPB.

OPCAB in Czechia 2010–2015

Introduction and methods

As mentioned above, OPCAB has gone through a period of great expectations (in the 1980s and 1990s), a period of sober judgment at the beginning of the 21st century, and now the slight skepticism we are experiencing today. According to some authors, the interest in OPCAB is typical for all new technologies, so called "Hype-cycle": Currently we are leaving "Trough of Disillusionment" [25] (see Fig. 1).

There are 12 cardiac surgery centers in the Czech Republic. All of them perform revascularization on the beating heart, although the percentage of these surgeries varies considerably from center to center. In cooperation with the National Register of Cardiac Surgery of the Institute of Health Information and Statistics of the Czech Republic, we decided to analyze the situation between 2010 and 2015, during which the above-mentioned papers were published. We wanted to see if these publications had changed the attitude of the cardiac surgery community relative to the use of OBCAB procedures. Standard descriptive statistics were applied in the analysis; absolute and relative frequencies for categorical variables and median supplemented by 5th–95th percentile and mean

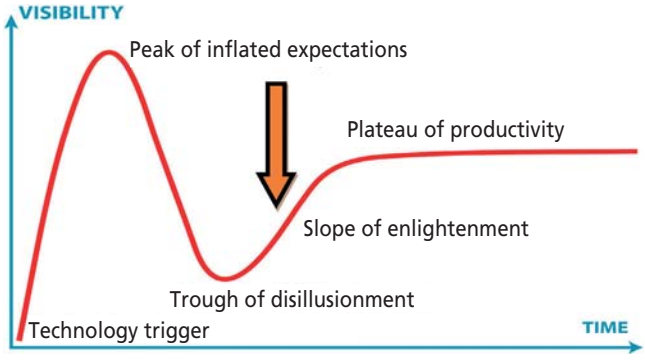

Fig. 1 – "Hype-cycle": The orange arrow shows where OPCAB is currently located.
Source: Wikipedia.

Table 1 – Number and percentage of OPCAB surgeries in patients undergoing isolated aortocoronary bypass.

	Year					
	2010	2011	2012	2013	2014	2015
Department 1	68 (14.3%)	45 (10.0%)	46 (10.7%)	36 (7.4%)	23 (4.5%)	27 (5.8%)
Department 2	27 (11.2%)	22 (9.2%)	66 (26.7%)	62 (22.6%)	56 (22.9%)	32 (15.5%)
Department 3	258 (73.9%)	201 (61.1%)	158 (54.7%)	163 (59.7%)	169 (66.3%)	206 (85.1%)
Department 4	46 (11.2%)	46 (13.0%)	62 (15.6%)	36 (8.8%)	35 (10.8%)	39 (11.3%)
Department 5	61 (43.3%)	63 (39.6%)	43 (38.4%)	24 (25.3%)	58 (37.7%)	85 (38.6%)
Department 6	181 (47.0%)	188 (55.6%)	238 (56.4%)	227 (62.0%)	235 (55.8%)	194 (45.5%)
Department 7	180 (52.6%)	187 (61.3%)	261 (76.8%)	238 (63.1%)	208 (54.2%)	144 (42.7%)
Department 8	5 (1.3%)	11 (3.1%)	12 (3.2%)	10 (2.6%)	14 (3.8%)	8 (2.1%)
Department 9	7 (3.5%)	8 (4.7%)	23 (11.5%)	16 (8.6%)	9 (4.8%)	2 (1.0%)
Department 10	75 (34.1%)	60 (35.7%)	39 (21.5%)	24 (15.7%)	52 (31.5%)	68 (41.7%)
Department 11	6 (1.8%)	9 (3.3%)	3 (1.0%)	18 (5.6%)	24 (9.5%)	17 (5.9%)
Department 12	123 (30.5%)	110 (31.3%)	94 (29.9%)	88 (25.0%)	104 (30.5%)	67 (22.9%)
Total in the Czech Republic	1 037 (26.7%)	950 (27.3%)	1 045 (29.0%)	942 (25.6%)	987 (27.3%)	889 (24.9%)

supplemented by standard deviation for continuous variables. Statistical significance of differences between groups of patients was tested using Chi-square test for categorical variables and Mann–Whitney U test for continuous variables. Statistical analysis was computed using SPSS 24.0.0.1 (IBM Corporation, 2016).

Results and discussion

In addition to a slight decrease in all isolated revascularization operations in the given period (3884 in 2010 vs. 3569 in 2015), there was also a decrease in the percentage of revascularization OPCAB (26.7% vs. 24.9%). This change, to a certain extent, follows the global trend (e.g., USA by 19% in 2014), although, in many ways the practices of individual Czech departments appear independent of the global trend. Therefore, OPCAB procedures ranged from 1% to 85% in 2015. Some centers seem to have virtually given up on OPCAB over the years, while others have seen the percentage of OPCAB procedures increase (see Table 1).

The growing trend is obvious only in minimally invasive direct coronary artery bypass (MIDCAB) performed through left anterior small thoracotomy (LAST) on a beating heart. This approach seems to become more popular in the last years (see Table 2).

Therefore, an impact, relative to the latest findings, on the strategy within the whole Czech Republic cannot be clearly demonstrated, because the drop in the number of procedures on the beating heart has had a rather steady and long-term character (see Fig. 2). The characterization of surgical patients let us see how patients were selected. There was a marked increase in the mean age of patients in both groups and OPCAB patients were statistically significantly older (66.2 vs. 65.3, $p = 0.005$ in 2010 and 68.1 vs. 66.1, $p < 0.001$ in 2015). With regard to BMI, we saw a decline over the study period (28.7 vs 29.0, $p = 0.44$ in 2010 and 28.8 vs. 29.4, $p < 0.001$ in 2015). Surgeons therefore had a greater tendency to use OPCAB on older patients, with lower BMIs. Additionally, OPCAB was used

Table 2 – Number and percentage of the MIIDCAB/LAST among OPCABs in Czechia.

Year	N (%)
2010	58 (5.6%)
2011	80 (8.4%)
2012	84 (8.0%)
2013	144 (15.3%)
2014	175 (17.7%)
2015	142 (16.0%)
Total	683 (11.7%)

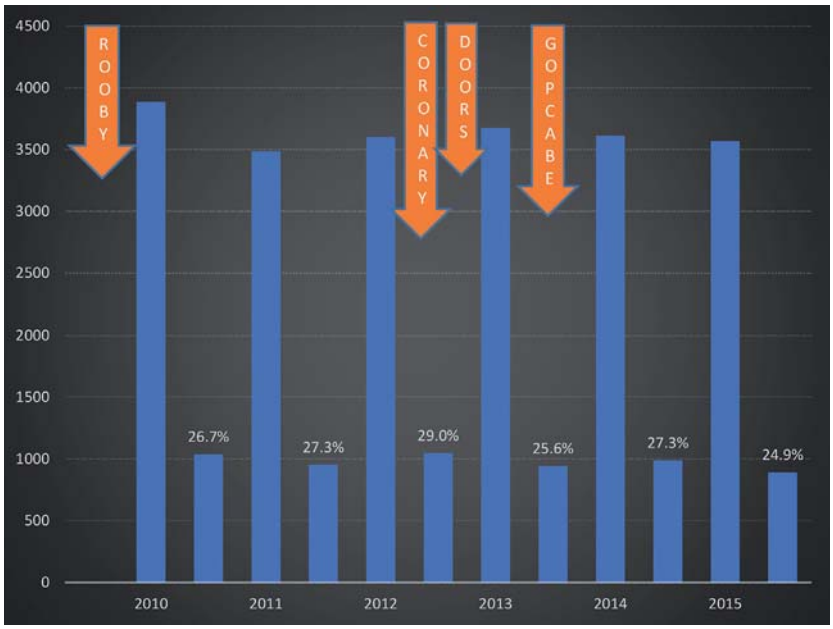

Fig. 2 – The number of isolated ACB surgeries and the proportion of OPCAB in Czechia between 2010 and 2015 in the context of the published large randomized trials.

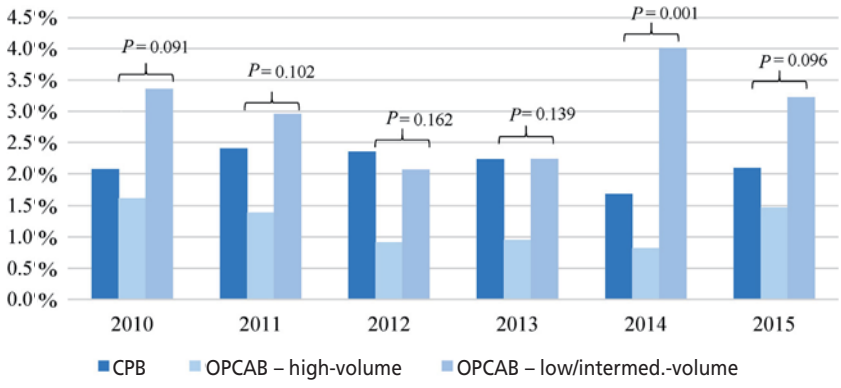

Fig. 3 – Development of 30-day mortality after isolated CABG from 2010 to 2015 (based on the number of hospitalized patients with an isolated aortocoronary bypass in a given year).

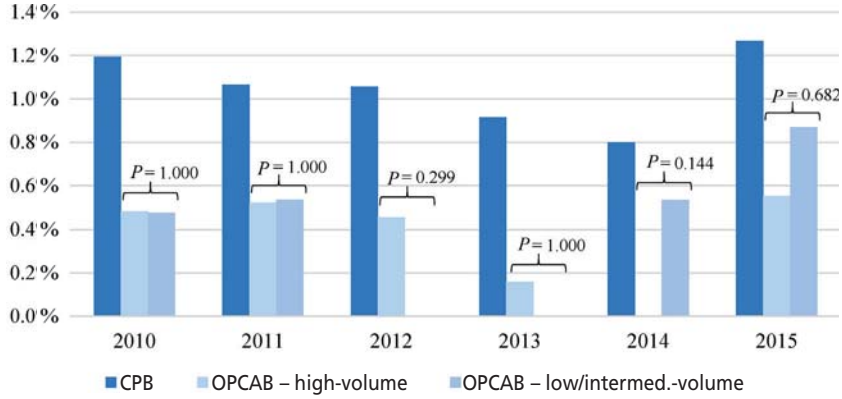

Fig. 4 – Postoperative complications after isolated CABG from 2010 to 2015: brain strokes.

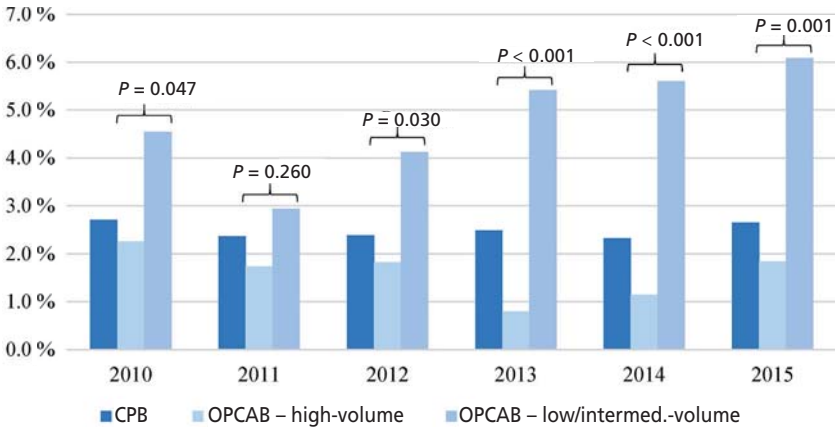

Fig. 5 – Postoperative complications following isolated CABG from 2010 to 2015: renal complications requiring dialysis.

more often for those more likely to experience strokes or transient ischemic attack (TIA) (10.0% vs 7.7% in 2010, $p = 0.018$ and 9.1% vs. 7.5% in 2015) and had signs of renal insufficiency to varying degrees (4.2% vs. 2.3% in 2010, $p = 0.002$ and 3.6% vs. 2.3% in 2015, $p = 0.029$). Other characteristics, such as left ventricular ejection fraction, previous myocardial infarction, gender, and the level of dyspnea or angina did not influence the decision process significantly. Substantially reduced OPCAB performance time from 3.3 (2010) to 3.1 hours (2015) and currently is statistically significantly shorter (3.1 vs. 3.3 hours, $p < 0.001$) compared to standard revascularization using CPB. However, the number of peripheral anastomoses performed using OPCAB decreased (2.1 vs. 3.0 [2010], $p < 0.001$ compared to 1.9 vs 2.9 [2015], $p < 0.001$), both in the lateral and lower walls. This may have been caused by the fact that the quality of the target vessels in older polymorbid patients does not allow for a higher numbers of bypasses, or it may be associated with the inconclusive benefit of complete revascularization in such patients. The total number of OPCAB to CPB conversions in the observed period was low (1.2%) and decreased over the study period (from 1.6% to 0.4%).

We expected the incidence of serious post-operative complications could be influenced by the experience of the off-pump team. That is why we analyzed the data according to the number of OPCAB procedures and divided the centers into two groups: "high-volume" vs. "intermediate-/low-volume". We defined the "high-volume" center as a department, performing at least 200 OPCAB surgeries a year or at least 50% of all ACB on beating heart. Finally there were only 3 departments meeting these conditions in all the Czech Republic.

Even though there is mostly no significant difference in the early postoperative mortality according to the off-pump experience, "high-volume" centers reached at least 50% of its reduction (see Fig. 3). Surprisingly, the volume of off-pump operated patients per year did not significantly influence the incidence of early cerebrovascular accidents. Nevertheless, OPCAB has generally decreased the occurrence of brain strokes compared to the on-pump group (see Fig. 4). This experience clearly corresponds to the tendency of surgeons to choose less invasive approaches, i.e., OPCAB, in patients with stroke/TIA in pre-treatment. We consider for an unexpected finding the significantly higher incidence of serious renal failure in off-pump patients, operated in the "intermediate-" and "low-volume" centers. Not only compared to the highly specialized centers, but also to the on-pump group (see Fig. 5).

All these findings indicate, that the early postoperative results are partly dependent on the method, but also on the experience of the entire team, surgeons and physicians of the ICU.

Conclusions

Surgery for coronary heart disease without the use of extracorporeal circulation is a surgically demanding discipline requiring considerable skill by the entire surgical team. A number of prospectively randomized trials in recent years have shown some benefits for this surgical procedure, particularly in high-risk patients, but the studies have not provided convincing and consistent evidence of critical benefits in terms of reducing the incidence of mid-term serious post-operative complications. Therefore, the views of these well-known cardiac surgeons should be carefully considered:

1. "There is currently no evidence to show that OPCAB procedures result in any superior outcomes compared to on-pump procedures." (Dr. Lazar)
2. "For patients at low risk for cardiopulmonary bypass, there is no survival benefit, with off-pump revascularization." (Dr. Puskas)
3. "There is a small minority of patients who really do benefit from off-pump surgery." (Dr. Taggart) [26]

The Society of Thoracic Surgeons states that "in highly specialized centers, postoperative results depend on other circumstances rather than on which method of revascularization was chosen". In the relatively conservative society of Czech cardiac surgeons, an overall decline in revascularization without extracorporeal circulation was recorded, however, the frequency of these procedures varies considerably from center to center. Czech cardiac surgeons tend to use OPCAB on older, sicker patients. These procedures are carried out even when it means incomplete revascularization. A very positive note is that

the very low number of conversions to extracorporeal circulation is evidence of OPCAB teams with considerable experience providing high-quality surgical care. On the other hand the best early postoperative results have been reached in highly specialized centers, operating off-pump more than 200 patients or at least 50% of all CABG per year. The saying "Take it or leave it" gains a new dimension.

Conflict of interest
None declared.

Funding
This work has been supported by Charles University Research Centre program No. UNCE/MED/002.

Ethical statement
Authors state that the research was conducted according to ethical standards.

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