The double balloon cannula: a means to prevent backward flow of retrograde cardioplegia to the right atrium

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Abstract

Retrograde cardioplegia (RC) delivery may result in suboptimal myocardial protection, due to leakage of cardioplegia to the right atrium. This study was undertaken to assess the efficacy of a double balloon cannula (DBC) occluding the coronary sinus ostium during RC. Fifteen patients were randomly assigned to receive RC via a conventional cannula or via the DBC. Cardioplegia was started at 200 ml/min, and the flow rate (Q) was adjusted to obtain a perfusion pressure (P) of 25–40 mmHg. Blood samples were collected at 13 different time points. The CPK-MB and TnI levels were measured on each sample. The use of the DBC was associated with increased P (P<0.03) at a lower Q (P<0.02). The CK-MB levels were significantly increased in both groups (P<0.001). However, the use of the DBC was associated with lower levels of CK-MB (P<0.002). A similar trend was observed for the TnI levels (peak 5.1±1.8 ng/ml vs. 8.7±5 ng/ml, P<0.11).

Conclusion of the coronary sinus ostium improved the hemodynamic efficiency of the RC, and this resulted in reduced perioperative ischemic myocardial damage.

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Keywords: Retrograde cardioplegia; Myocardial damage; Cardiopulmonary bypass; Myocardial protection

1. Introduction

Retrograde cardioplegia delivery alone may result in suboptimal myocardial protection. Indeed, backward flow from the middle cardiac vein (PDV) and subsequent leakage of cardioplegia towards the right atrium, resulting in a less than adequate perfusion of the posterior wall of the left ventricle, the posterior part of the interventricular septum, and of the right ventricle, have been reported to occur during retrograde cardioplegia delivery with a non-occlusive coronary sinus cannula [1–3]. Several maneuvers, among which digital occlusion of the PDV during cardioplegia delivery [4], purse string occlusion of the coronary sinus ostium [2], and PDV orifice occlusion with custom designed cannulas [1], have been employed with good results to minimize the backflow of cardioplegia to the right atrium and to improve myocardial protection. However, to the best of our knowledge, there is currently no evidence that a similar approach may reduce perioperative myocardial damage. The present study was designed to test the efficacy, in terms of hemodynamics and myocardial protection, of a double balloon cannula (DBC) (Edwards Double-Balloon Retrograde Cannula, Edwards Lifesciences S.A., St-Prex, Switzerland) designed to occlude the coronary sinus ostium during retrograde cardioplegia delivery.

2. Materials and methods

2.1. Patients

Fifteen consecutive patients (mean age 75±6 years, 2 males and 13 females) undergoing isolated aortic valve replacement at our institution from 23 October 2004 to 20 January 2005 were enrolled (Table 1). The following factors were considered as exclusion criteria: associated coronary artery disease, history of myocardial infarction, associated mitral or tricuspid valve disease, left ventricular dysfunction (Ejection Fraction <40%), peri-operative myocardial infarction, severe systemic illness. This study was approved by the Ethical Committee of the ‘G. Pasquiniucci Hospital’ and of the ‘Institute of Clinical Physiology’ of the Italian National Research Council. Informed consent was obtained from all patients.

2.2. Anesthetic technique and surgical management

Total intravenous anesthesia with diazepam, fentanyl, pancuronium and propofol was used in all cases. Cardio-
pulmonary bypass (CPB) was conducted on moderate hypothermia (34 °C), with aortic and right atrial cannulation. After the aortic cross-clamping, high flow retrograde hyperkalemic warm blood cardioplegia was administered through the DBC (study group, 8 patients) or through a conventional, single auto-inflating balloon, retrograde cardioplegia cannula (Edwards Lifesciences S.A., St-Prex, Switzerland) (control group, 7 patients). In the DBC group, after aortic cross-clamping, the distal balloon was manually inflated with 2–3 ml of saline before starting cardioplegia, to fix the cannula distally and avoid slippage of the proximal balloon in the right atrium (Figs. 1 and 2). Cardioplegia was started at 200 ml/min, and the flow rate was then adjusted to obtain a perfusion pressure of 25–40 mmHg. The administered flow and the perfusion pressure at the steady state were used as indicators of hemodynamic efficiency. Cardioplegia was repeated every 20 min. Controlled retrograde reperfusion was started before suturing the aortotomy, and was employed in all cases.

2.3. Blood samples collection and analysis

Central venous blood samples for the measurements of CPK-MB and TnI concentration were obtained from all patients at sternotomy, before aortic cross-clamping, after declamping, at the end of the operation, and then at 6, 12, 24 and 48 h postoperatively. Five additional samples of venous blood egressing from the coronary system were collected from the retrograde cardioplegia cannula before and after aortic cross-clamping, and from the aortic root during the administration of the first and second dose of cardioplegia and during reperfusion.

All samples were collected in serum separator tubes and immediately centrifuged and frozen at −20 °C. The CPK-MB isoenzyme and Troponin I were assayed with the AxSYM® microparticle enzyme immunoassay (Abbott Labo-
Control
P

heart arrest of coronary ostia, and timelyness and quality of the diastolic nary venous system, egress of desaturated blood from the protection as assessed by the usual clinical indicators operating surgeon.

during reperfusion cardioplegia flow during both doses of cardioplegia and with a significantly higher perfusion pressure at a lower patients are reported in Table 1.

eline and operative characteristics of the fifteen enrolled patients were discharged home or transferred for cardiac pacing wire removal on postoperative day 4, but having undergone emergency re-exploration for bleeding after stented prosthesis with a stentless one. A second patient root, and was treated by replacing the previously implanted artery orifice by a clot. This patient had a very small aortic ischemia, related to occlusion of the left main coronary from the analysis due to severe intraoperative myocardial protection.

4. Discussion

The results of our study support the concept that the protection of some regions of the heart may be hampered by backward flow in the PDV and subsequent steal of cardioplegia: in patients undergoing retrograde cardioplegia by a conventional cannula we observed significantly higher perioperative levels of CPK-MB, testifying increased myocardial damage despite a high perfusion flow. We also found that the perioperative ischemic myocardial damage may be prevented and consistently reduced by avoiding backward flow of cardioplegia to the right atrium, and that the use of the DBC may achieve this goal.

Table 2

<table>
<thead>
<tr>
<th>Perfusion parameters</th>
<th>DBC</th>
<th>Control</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPL 1 Flow (ml/min)</td>
<td>238.7 ± 29.0</td>
<td>285.7 ± 41.9</td>
<td>0.02</td>
</tr>
<tr>
<td>P (mmHg)</td>
<td>32.5 ± 7.2</td>
<td>23.0 ± 7.5</td>
<td>0.03</td>
</tr>
<tr>
<td>CPL 2 Flow (ml/min)</td>
<td>240.0 ± 35.8</td>
<td>300.0 ± 44.3</td>
<td>0.01</td>
</tr>
<tr>
<td>P (mmHg)</td>
<td>30.5 ± 7.7</td>
<td>21.0 ± 6.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Rep Flow (ml/min)</td>
<td>227.5 ± 55.7</td>
<td>295.7 ± 51.2</td>
<td>0.03</td>
</tr>
<tr>
<td>P (mmHg)</td>
<td>36.1 ± 5.5</td>
<td>24.4 ± 5.2</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Abbreviations are as follows: DBC: Edwards double balloon cannula; CPL1: cardioplegia 1; CPL2: cardioplegia 2; Rep: reperfusion.

Continuous variables are expressed as mean ± standard deviation. Dichotomous variables are expressed as percentages. Dichotomous patient characteristics were analyzed by the Fisher's exact test. Normally distributed continuous variables were analyzed by the unpaired Student's t-test. Longitudinal data, including the course of CPK-MB and TnI, were analyzed by the paired Student's t-test. The Bonferroni test was used for post-hoc multiple comparisons. All the analyses were performed using Statview 5.0 for Apple Mclntosh (SAS Institute Inc, Cary, NC). A P ≤ 0.05 was considered significant.

2.4. Statistical analysis

Continuous variables are expressed as mean ± standard deviation. Dichotomous variables are expressed as percentages. Dichotomous patient characteristics were analyzed by the Fisher’s exact test. Normally distributed continuous variables were analyzed by the unpaired Student’s t-test. Longitudinal data, including the course of CPK-MB and TnI, were analyzed by the ANOVA for repeated measures. The Bonferroni test was used for post-hoc multiple comparisons. All the analyses were performed using Statview 5.0 for Apple Mclntosh (SAS Institute Inc, Cary, NC). A P ≤ 0.05 was considered significant.

3. Results

One of the sixteen initially enrolled patients was excluded from the analysis due to severe intraoperative myocardial ischemia, related to occlusion of the left main coronary artery orifice by a clot. This patient had a very small aortic root, and was treated by replacing the previously implanted stented prosthesis with a stentless one. A second patient underwent emergency re-exploration for bleeding after pacing wire removal on postoperative day 4, but having completed the study protocol, she was included in the analysis. There were no other major complications, and all patients were discharged home or transferred for cardiac and respiratory rehabilitation after 6.8 ± 3.2 days. The baseline and operative characteristics of the fifteen enrolled patients are reported in Table 1.

The use of the double balloon cannula was associated with a significantly higher perfusion pressure at a lower cardioplegia flow during both doses of cardioplegia and during reperfusion (Table 2). Of note, the myocardial protection as assessed by the usual clinical indicators (cardioplegia flow, perfusion pressure, filling of the coronary venous system, egress of desaturated blood from the coronary ostia, and timelyness and quality of the diastolic heart arrest), was judged adequate in all cases by the operating surgeon.

The CK-MB levels rose significantly in both groups (P < 0.0001). However, the use of the double balloon cannula was associated with significantly lower levels of CK-MB during the peri- and postoperative period (P = 0.002, Fig. 3). A similar trend was observed for troponine, although this result was not statistically significant (P = 0.11, Fig. 4).

4. Discussion

The results of our study support the concept that the protection of some regions of the heart may be hampered by backward flow in the PDV and subsequent steal of cardioplegia: in patients undergoing retrograde cardioplegia by a conventional cannula we observed significantly higher perioperative levels of CPK-MB, testifying increased myocardial damage despite a high perfusion flow. We also found that the perioperative ischemic myocardial damage may be prevented and consistently reduced by avoiding backward flow of cardioplegia to the right atrium, and that the use of the DBC may achieve this goal.

Fig. 3. Postoperative course of CK-MB. See text for explanations. Blood samples are labeled as follows: S: sternotomy; CV1: Central venous before cross-clamping; CS1: Coronary sinus cannula before cross-clamping; CP1: Aortic root during cardioplegia 1; CS2: Coronary sinus cannula after declamping; CV2: Central venous after declamping; T0: End of the operation; T6, T12, T24, T48: 6, 12, 24, 48 hours postoperatively.

Fig. 4. Postoperative course of TnI. See text for explanations. Time abbreviations are the same as in Fig. 1.
Retrograde cardioplegia delivery is a widely accepted method for myocardial protection, whose safety and efficacy have been repeatedly demonstrated [5–8]. However, doubts about the appropriateness of a strategy involving the use of retrograde cardioplegia alone have arisen by experimental data on animals [9,10], on the cadaveric human heart [2,3], and more recently by clinical studies [1,11]. Rudis and co-workers studied the distribution of retrograde cardioplegia in five explanted human hearts, and showed that coronary sinus ostial occlusion allowed for a significant decrease in total cardioplegia flow while maintaining an identical intracoronary sinus pressure [3], a finding similar to ours. They also showed that ostial occlusion resulted in an increase in the ratio of nutrient flow / total cardioplegia flow, and improved the capillary flow in the interventricular septum and posterolateral right ventricular free wall. In a very elegant study [2], Farge and associates were able to document at angiography that steal of cardioplegia through the PDV occurs, when a single balloon cannula is employed for retrograde cardioplegia delivery, and that this results in a poor opacification of the inferior part of the interventricular septum, and in reduced myocardial enhancement within the septum at electron beam computed tomography.

It has been argued that the results of experimental studies are contradicted by the clinical success of retrograde cardioplegia. Gundry and associates have provided several good explanations for this apparent discrepancy [6]. In particular, they advocated the use of a manually inflated, totally occlusive, single-balloon cannula as a mean to prevent cardioplegia steal, and stressed the importance of a proper position of the balloon during cardioplegia administration [3]. They also indicated a low cardioplegia flow and the lack of prompt detection of myocardial regional acidosis as the possible causes of some previously reported failure [6]. We also experienced excellent clinical results with retrograde cardioplegia alone: no patient in our series showed right ventricular dysfunction, and none needed postoperative inotropic support. Indeed, high flow intermittent retrograde warm blood cardioplegia has been the preferred strategy for myocardial protection in AVR patients at our institution during the last ten years. However, the results of the present study demonstrate that some myocardial damage may occur, and that the double balloon cannula may prevent it.

4.1. Limitations

Some limitations of the present study need to be addressed. Even if this was a prospective and randomized study, we were able to enroll only 15 patients. This notwithstanding, we observed highly significant differences in perfusion pressure, cardioplegia flow, and CK-MB levels, and considered these results to be conclusive. A larger trial would probably be needed to detect any significant difference on the clinical ground, if any actually exists.

As observed above, the self-inflating balloon cannulas may be not occlusive, resulting in cardioplegia leakage around the balloon and backward flow towards the right atrium [3, discussion]. In the control group, we used a single, self-inflating balloon cannula. As a consequence, our data do not permit to discriminate between the effect of the manually inflated distal balloon and that of the proximal balloon on the cardioplegia distribution. In other words, we were not able to determine which of the two mechanisms leading to cardioplegia steal represented in the Fig. 2 was responsible for the suboptimal myocardial protection that we observed in the control group. However, in our opinion, this is not a major limit, for the following reasons: (a) Whatever, the mechanism of the cardioplegia steal, our data strongly suggest that it may occur in the clinical setting, that it may results in suboptimal myocardial protection, and that the double balloon cannula is effective in preventing it; (b) Previous research has shown that the internal occlusion of the coronary sinus (as can be obtained with a manually inflated balloon) results in backward flow in the PDV, leakage of cardioplegia to the right atrium, and poor perfusion of the septum [2,4], at least when the balloon is positioned distal to the PDV orifice; (c) As already observed (Fig. 2), a manually inflated, totally occlusive balloon, positioned at the orifice of the coronary sinus could completely avoid cardioplegia steal. However, this was probably not the mechanism of the protective effect of the double balloon cannula in our series. In fact, when the proximal balloon is correctly positioned across the coronary sinus ostium, the distal balloon should lie well beyond the PDV orifice, that is usually located 1.7 ± 0.6 mm away from the coronary sinus ostium itself [4]. Furthermore, a proximally positioned catheter may be easily dislodged, especially when the coronary sinus is short [4].

Finally, a third limitation of the present protocol relates to the device itself: the Edwards DBC is available in a single measure, and it is quite big. We found it really hard to position it correctly in some cases, especially in elderly women with aortic stenosis as the predominant lesion and a small BSA (who represent a significant fraction of our current AVR patients population). Furthermore, in this particular subgroup, the conventional single-balloon cannula, if correctly positioned, is usually occlusive. We therefore currently employ the Edwards DBC, especially in male patients with a large BSA and with aortic regurgitation as the predominant lesion.

5. Conclusion

Occlusion of the coronary sinus ostium by a commercially available device may improve the hemodynamic efficiency of the retrograde cardioplegia, resulting in reduced perioperative ischemic myocardial damage. Larger studies are needed to define the clinical relevance of this finding.

References


