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The randomised study of epicardial application of hydrogel with amiodarone for prevention of postoperative atrial fibrillation in patients after coronary artery bypass grafting

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The purpose of our study was to evaluate safety and efficacy of local epicardial application of amiodarone-releasing hydrogel in the prevention of postoperative atrial fibrillation (AF) in patients undergoing coronary artery bypass grafting (CABG).

Material and methods.
We present an open prospective randomised study, in which 60 patients (47 male), mean age of 62 ± 8.5 were included. Baseline clinical, laboratory and instrumental characteristics were similar in all patients. Patients didn't have any arrhythmic complains or previously registered AF. All patients underwent elective CABG and were randomised into two groups: Group #1 (n=30) - had the amiodarone-releasing hydrogel application before chest closure, and Group #2 (n=30) regular CABG surgery, no local application. We used 60 mg of amiodarone in hydrogel. This dose was experimentally determined during previously performed animal study. Heart rhythm control was monitored continuously during first 5 postoperative days and occasionally (mornings and evenings) the remaining days before the discharge. The local ethics committee approved this study design.

Results.
The incidence of postoperative AF occurrence was significantly lower in Group #1: AF was registered in 3.3% cases versus 37% of patients from Group #2 (p <0.001). There was slight increase of PQ interval duration in Group #1 - 0.14 sec (0.12; 0.16), which however was significantly higher then in Group #2 - 0.12 (0.12; 0.14), (p < 0.01). QRS and QT intervals were similar in both groups without significant difference.

There were no complications associated with the application procedure neither during postoperative period, such as AV block, infection or life-threatening situations.

According to 5 days ECG monitoring, the average heart rate in the Group #1 was 59 (52; 60) beats per min versus 69 beats per min (65; 75) in Group #2 (p <0.001). Temporary atrial or atrio-ventricular pacing used for correction of the heart rate if required in both groups. By the time of discharge none of the patients required permanent cardiac pacing. The length of stay in Group #1 was significantly shorter: 6 (6; 7) days versus 8 (8; 9) days (?<0.001).

Among all studied parameters, amiodarone-releasing hydrogel application and older age were statistically significant in postoperative AF occurrence (p < 0.01). According to the Cox regression model amiodarone-releasing hydrogel application decreases the incidence of postoperative AF by 18.9 folds. The older age instead increases the incidence of postoperative AF by 1.2 folds.

Conclusions: The local epicardial amiodarone (60 mg) application in hydrogel before chest closure is a safe procedure. This approach showed it’s effectiveness in AF prevention in patient undergoing elective CABG.