アミオダロンはアブレーション後の短期回復を改善する（Presentation #4947）

AMIO-CAT：心房細動に対するアブレーションの直後にアミオダロンを投与すると早期予後が改善する

AMIO-CAT: Better early outcomes seen when amiodarone is given immediately after ablation for atrial fibrillation

心房細動（AF）の治療として高周波アブレーションを施行される患者は、施術直後にアミオダロンを内服すると早期予後が改善するとの研究結果が2014年European Society of Cardiology Congressホットラインセッションで発表され、同時に*The European Heart Journal*に掲載された。AMIO-CATでは、発作性AFまたは持続性AFに対し高周波アブレーションを施行される患者212人を、アミオダロン（108人）またはプラセボ（104人）を施術直後から8週間投与される群にランダムに割り付けた。スタディの一次エンドポイントは、"ブランキング期間"ー治癒過程としてAF発作が起こり得る3か月間で通常最終的なスタディの結果にカウントしないーの後の30秒以上持続するAFであった。6か月後のAF再発は実薬群とプラセボ群とで有意差がなかった（39%対48%、p=0.18）が、ブランキング期間のAF再発数はアミオダロン群でプラセボ群よりも少なく（34%対53%、p=0.006）、不整脈による入院（p=0.006）および除細動率（p=0.0004）は半分以下であった。アブレーション後3か月間の早期再発性の不整脈はこの薬剤により効果的に減らすことができる、と筆者らは結論付けている。しかし、この有益性は3か月以上持続しなかった。

Full Text

Patients undergoing radiofrequency ablation to treat atrial fibrillation (AF) have better early outcomes if they take the drug amiodarone immediately after their procedure, according to results of a new study presented at ESC Congress 2014.

Early recurrences within the first few months after ablation for AF are common and often a discouraging experience for patients. The ablation itself is thought to cause some of these early recurrences, but the impact of preventing early recurrence on later success remains unclear.

AMIO-CAT, the first double-blind randomized clinical trial to evaluate a short-term course of amiodarone, an antiarrhythmic drug, after AF ablation showed that early recurrence of arrhythmia could be effectively reduced with this medication within the first three months after ablation. However the benefit did not persist beyond this.

"Although amiodarone did not affect recurrence at six months, our study shows that short-term use of this medication after ablation is still a relevant strategy because of its beneficial effects during the first three months," said investigator Stine Darkner M.D., from the Heart Centre at Rigshospitalet in Copenhagen, Denmark.

The study, presented as a Hot Line at the congress and published simultaneously in the *European Heart Journal*, also showed that amiodarone's beneficial impact on early rhythm control reduced hospitalizations among treated patients compared to those on placebo, and resulted in fewer cardioversions – a procedure by which normal heart rhythm is restored with electric shocks.

The study included 212 patients undergoing radiofrequency ablation for the treatment of either paroxysmal or persistent AF who were randomized to receive 8 weeks of either amiodarone (n=108) or placebo (n=104) starting immediately after their procedure.

The primary end point of the study was AF lasting more than 30 seconds after the "blanking period" - a three-month period in which AF episodes can occur as part of the healing process and are generally not counted in final study results.

At six months, the study showed no significant difference in AF recurrence between the treated and placebo groups (39% vs. 48%, p=0.18), however during the blanking period, amiodarone reduced the number of AF recurrences compared to placebo (34% vs. 53%, p=0.006), and more than halved arrhythmia-related hospitalization (p=0.006) and cardioversion rates (p=0.0004).

Looking separately at patients who entered the study with either paroxysmal (n=107) or persistent (n=105) AF, the analysis showed that, amiodarone prolonged the time to first AF recurrence compared to placebo in both subgroups (p=0.045 and p=0.005 respectively) during the blanking period. Hospitalization and cardioversion rates within the blanking period were only statistically significantly reduced by amiodarone in the subgroup of patients with persistent AF. "Thus, it seems that effect was largely driven by the group of patients with persistent AF," noted Dr. Darkner.

There was no statistically significant difference in the number of serious adverse events between the treated and placebo groups. Even though significantly more patients in the amiodarone group experienced transient adverse effects (sleep disturbances, gastrointestinal symptoms and asymptomatic changes in serum concentrations of thyroid hormones), these patients did not report reduced quality of life compared to those treated with placebo.

"The adverse effects of amiodarone therapy are well known and not unexpected," said Dr. Darkner. "The similarities in quality of life, despite the higher number of adverse events in the amiodarone group may be due to the reduced AF-related hospitalizations and cardioversions," she suggested.

"One might expect that the reduced hospitalization and cardioversion rates could also decrease the cost of post-ablation care," she added.

"Current guidelines for AF ablation do not give specific recommendations with respect to early antiarrhythmic drug therapy after ablation, but our data suggests that short term prophylactic treatment with amiodarone should be considered, particularly for patients with persistent AF."

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Dr. Darkner reported no conflicts of interest.

Conference News