I. Introduction

Atrial fibrillation (AF) is one of the most frequent complications following cardiac surgery, with incidence ranging from 30% to 60%1-3. Postoperative AF is associated with complications including an increased risk of stroke and a need for additional treatment, as well as a prolonged intensive care unit or hospital stay and increased hospitalization costs3. The incidence of postoperative AF in off-pump coronary artery bypass grafting (CABG) is similar to conventional CABG with cardiopulmonary bypass4.

β-blockers are widely used during the perioperative periods in cardiac surgery. The ACCF/AHA guidelines recommend that β-blockers should be administered for at least 24 hours before CABG in all patients without contraindications, should be re-instituted as soon as possible after CABG, and should be prescribed to all CABG patients at the time of hospital discharge5.

Landiolol hydrochloride (Onoact®; Ono Pharmaceutical Co., Osaka, Japan), is an ultra-short acting β-blocker, with a half-life of 4 minutes and a higher β-selectivity than any currently available β-blocker. Recently, some meta-analyses have shown that landiolol administration significantly reduces the incidence of postoperative AF following cardiac surgery6-9. The effectiveness of landiolol was similar for both valvular surgery and CABG, even with off-pump CABG10.

High right atrial overdrive pacing for patients with paroxysmal AF reduces the recurrence of AF when compared with ventricular demand pacing in observational and controlled clinical trials11, 12. Several randomized controlled studies of either right, left, or biatrial pacing to prevent postoperative AF following CABG or valve surgery and to reduce the length of the hospital stay were performed13-20.

Although the role of postoperative β-blockers in combination with atrial pacing has been pointed out as beneficial19, the efficacy of this combination therapy is still a matter of debate. This
prospective observational study was designed to assess the efficacy of intravenous landiolol infusion with temporary right atrial pacing for the prevention of AF after off-pump CABG.

II. Patients and methods

The patients in the study group (landiolol plus temporary right atrial pacing: LAP) were 28 consecutive patients who underwent isolated off-pump CABG at our hospital from January 2008 to August 2009. The patients in the historical control group (landiolol without pacing: L) were 24 consecutive patients who underwent isolated off-pump CABG from October 2003 to July 2004. Following approval of the landiolol study protocol by the Institutional Review Board (No. 115042), subjects from both groups were enrolled with informed consent for participation in the study at their respective times. This study was registered with University Hospital Medical Information Network (study ID: UMIN000036637). Exclusion criteria included a known history of AF or supraventricular arrhythmias, sick sinus syndrome, II-degree, III-degree atrioventricular block; contraindications to β-blockers, such as bronchial asthma or severe bradycardia; or left ventricular ejection fraction < 40% on preoperative echocardiography.

Patients in both groups received landiolol intravenously, starting with 5 μg/kg/minute in the intensive care unit (ICU) immediately after surgery. The heart rate was maintained at a range of 60 to 80 beats per minute (bpm), and intravenous landiolol was continued at 0–10 μg/kg/minute until oral drug administration occurred. Atrial pacing in LAP group patients was discontinued postoperatively.

In LAP group patients, one pair of atrial wires was implanted in the standard location 1 cm apart along the high lateral right atrium near the sinus node at the end of surgery (ETHICON BW11, Johnson & Johnson, New Brunswick, NJ, USA). Atrial pacing was commenced at a rate of approximately 90 bpm and the dose of landiolol was reduced while ensuring that the intrinsic heart rate did not exceed the pacing rate. Atrial pacing was terminated at the same time as discontinuation of intravenous landiolol infusion. PACING threshold and sensitivity were checked during each nursing shift.

Anesthesia was induced with intravenous fentanyl, propofol, and a muscle relaxant (pancuronium or vecuronium) and maintained with additional doses of these drugs or with inhaled sevoflurane. Off-pump CABG procedures were performed through a median sternotomy with standard left internal thoracic artery preparation. The type of stabilization device used in off-pump CABG was determined by the preference of the individual surgeon. Revascularization using arterial and vein grafts was conducted as thoroughly as possible.

Electrocardiograms and hemodynamic variables, including arterial blood pressure, heart rate, and central venous pressure were monitored continuously during the perioperative period in the ICU. After discharge from the ICU, all patients were monitored with an alarm-triggered telemetry system and double-checked for unnoticed events every morning for at least 7 postoperative days. In addition, a 12-lead electrocardiogram was recorded and tachycardia or development of an arrhythmia was detected by clinical observation or telemetric monitoring. The endpoint of the study was the postoperative incidence of AF for a week, which was defined as an irregular narrow complex rhythm with an absence of a discrete P wave lasting for more than 30 minutes, or which required treatment because of intolerable symptoms and hemodynamic deterioration. If atrial fibrillation occurred, atrial pacing in LAP group patients was discontinued.

Statistical comparison of continuous variables between the LAP group and the L group was performed using a t-test or a Mann-Whitney’s U test as appropriate. Categorical variables were compared between the groups using a χ² test or Fisher exact test, and a t-test as appropriate. Logistic regression was used to assess the effectiveness of temporary right atrial pacing on the prevention of postoperative AF (expressed as odds ratio). Treatment selection bias was controlled for by constructing a propensity score matching analysis 1: 1 nearest neighbor matching using a logistic regression. The propensity score was the

| Table 1 Perioperative characteristics of the patients (Unadjusted) |
|------------------|-----|-----|----|
| Unadjusted       | LAP | L   | p value |
| Cases            | 28  | 24  |     |
| Age (years)      | 67.6 ± 7.9 | 67.4 ± 6.6 | 0.926 |
| Gender (Male)    | 0.79 ± 0.42 | 0.83 ± 0.38 | 0.671 |
| Body surface area (m²) | 1.62 ± 0.13 | 1.62 ± 0.16 | 0.949 |
| Body mass index  | 24.0 ± 2.14 | 23.13 ± 3.34 | 0.252 |
| Hypertension     | 0.82 ± 0.39 | 0.67 ± 0.48 | 0.206 |
| Diabetes mellitus| 0.57 ± 0.50 | 0.71 ± 0.46 | 0.316 |
| Dyslipidemia     | 0.54 ± 0.51 | 0.62 ± 0.49 | 0.525 |
| Preoperative use of β-blocker | 0.32 ± 0.48 | 0.54 ± 0.51 | 0.113 |
| Diameter of left atrium (mm) | 35.5 ± 3.9 | 39.1 ± 5.6 | 0.010 * |
| Left ventricular ejection fraction (%) | 62.9 ± 12.4 | 58.11 ± 11.9 | 0.228 |
| Intra-operative IABP support | 0.61 ± 0.50 | 0.25 ± 0.44 | 0.009 * |
| Number of anastomoses | 3.43 ± 1.07 | 3.46 ± 1.18 | 0.924 |
| Water Balance (mL/kg/hours) | 8.38 ± 2.69 | 9.68 ± 4.17 | 0.181 |
| Hemoglobin after operation (g/dL) | 11.0 ± 1.5 | 10.7 ± 1.2 | 0.308 |
| Peak CK-MB (IU/L) | 27.0 ± 21.6 | 16.77 ± 26.1 | 0.126 |
| Duration of landiolol infusion (hours) | 58.5 ± 17.1 | 51.2 ± 37.3 | 0.357 |
| ICU stay (days)   | 4.18 ± 1.31 | 4.62 ± 2.68 | 0.439 |

Group abbreviations defined as in Methods. IABP: Intra-aortic balloon pumping, CK-MB: creatinine kinase-MB, ICU: intensive care unit.

Data are presented as means ± standard deviation. *: p < 0.05 v the L group.
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Table 2  Perioperative characteristics of the patients (Adjusted for propensity score matching)

|                | LAP          | L            | p value | Std diff |
|----------------|--------------|--------------|---------|----------|
| Cases          | 23           | 23           |         |          |
| Age (years)    | 67.0 ± 7.5   | 67.7 ± 9.7   | 0.773   | 0.040    |
| Gender (Male)  | 0.83 ± 0.39  | 0.83 ± 0.39  | 0.999   | 0.000    |
| Body surface area (m²) | 1.64 ± 0.12  | 1.62 ± 0.16  | 0.774   | 0.071    |
| Body mass index | 23.88 ± 2.25 | 23.13 ± 3.34 | 0.360   | 0.132    |
| Hypertension   | 0.78 ± 0.42  | 0.65 ± 0.49  | 0.337   | 0.146    |
| Diabetes mellitus | 0.65 ± 0.49  | 0.70 ± 0.47  | 0.760   | 0.053    |
| Dyslipidemia   | 0.52 ± 0.51  | 0.61 ± 0.50  | 0.562   | 0.091    |
| Preoperative use of β-blocker | 0.39 ± 0.50  | 0.52 ± 0.51  | 0.386   | 0.132    |
| Diameter of left atrium (mm) | 35.5 ± 4.0  | 39.1 ± 5.6   | 0.015   | 0.370    |
| Left ventricular ejection fraction (%) | 61.1 ± 12.1 | 59.5 ± 11.6 | 0.650  | 0.067    |
| Intra-operative IABP support | 0.57 ± 0.51  | 0.26 ± 0.45  | 0.037   | 0.331    |
| Number of anastomoses | 3.54 ± 1.06  | 3.46 ± 1.18  | 0.798   | 0.036    |
| Water Balance (mL/kg/hours) | 8.1 ± 2.8 | 9.6 ± 4.2   | 0.160   | 0.211    |
| Hemoglobin after operation (g/dL) | 11.0 ± 1.5 | 10.7 ± 1.1  | 0.505   | 0.114    |
| Peak CK-MB (IU/L) | 28.8 ± 22.4 | 16.7 ± 26.1 | 0.091   | 0.249    |
| Duration of landiolol infusion (hours) | 58.8 ± 16.3 | 51.2 ± 37.3 | 0.372   | 0.132    |
| ICU stay (days) | 4.17 ± 1.40  | 4.70 ± 2.72  | 0.418   | 0.123    |

Group abbreviations defined as in Methods.
Std diff: Standardized Difference, IABP: Intra-aortic balloon pumping, CK-MB: creatinine kinase-MB, ICU: intensive care unit. Data are presented as means ± standard deviation.
*: p < 0.05 v the L group
A standardized difference (Std diff) of < 0.1 suggests adequate variable balance after propensity matching.

probability that a patient would receive temporary right atrial pacing. The defined matching criteria listed in Table 1. We found and compared 23 pairs. After propensity score matching, outcome variables were compared using Mann-Whitney U test for numerical variables and χ² test for categorical variables.

All statistical tests were 2-tailed, with P<0.05 regarded as statistically significant. All statistical analyses were performed using JMP, version 10.0 (SAS Inc., Cary, NC, USA).

III. Results

The perioperative characteristics and features of the patients are shown in Table 1. The two groups were similar except that the size of left atrium was statistically larger in the L group. In contrast, intra-aortic balloon pumping (IABP) use was significantly higher in the LAP group than the L group. After adjustment for the propensity score matching, there were significant differences in both the diameter of left atrium and IABP use (Table 2). There were no hospital deaths and major complications during the hospital stay in both groups.

Temporary right atrial pacing was technically successful in all patients in the LAP and no complications were associated with the placement or removal of the pacing wires. Low-dose intravenous administration of landiolol did not affect the changes in parameters such as blood pressure, central venous pressure, serum lactate level, and amount of catecholamine required shortly after off-pump CABG in both groups. No interruption of intravenous landiolol infusion was observed due to hypotension or bradycardia throughout the protocol. As a result of prioritizing IABP removal over tracheal extubation in postoperative management, the duration of intravenous landiolol infusion was 58.5 hours in the LAP group, slightly longer than 51.2 hours in the L group. Landiolol was administered intravenously at a mean rate of 4.0 µg/kg/minute in the LAP group, which was significantly lower than the rate of 6.4 µg/kg/minute in the L group (Fig. 1). After adjustment for propensity score matching, landiolol was administered intravenously at a mean rate of 4.3 µg/kg/minute in the LAP group, which was also significantly lower than the rate of 6.5 µg/kg/minute in the L group (Fig. 1). The overall incidence of postoperative AF was 15.4%, and the incidence of postoperative AF was not significantly different between the LAP group and the L group (17.9% vs. 12.4%, p=0.602). There was not a difference between two groups for the duration of AF. Most of them ranged from a few hours to half a day and there were no prolonged cases. Logistic regression analysis related to temporary right atrial pacing showed that the odds ratio was 1.52 (95% confidence interval, 0.32–7.16 ; P=0.595). After adjustment for propensity score matching, the incidence of postoperative AF was not significantly different between the LAP group and the L group (17.4% vs. 13.0%, p=0.689, standardized difference=0.056). Logistic regression analysis related
to temporary right atrial pacing showed that the odds ratio was 1.40 (95% confidence interval, 0.28 - 7.12; P=0.682) (Table 3). There was not a difference between two groups for the duration of AF. The mean length of time until development of initial AF was 2.0 postoperative days in the LAP group and 3.3 postoperative days in the L group, and almost all AF episodes occurred within the first 3 days after off-pump CABG.

Finally, we evaluated those two groups (10 cases each) with same doses of landiolol which was 5 μg/kg/minute during the study period as sub-analysis (Table 4). The incidence of postoperative AF was not significantly different between the LAP group and the L group (10% vs. 0%, p=0.9999).

IV. Discussion

The main finding of this prospective observational study was that temporary right atrial overdrive pacing did not have an additive effect to intravenous landiolol infusion accompanied by oral carvedilol intake for the prevention of AF after off-pump CABG. We believe that this is the first study to evaluate intravenous landiolol infusion accompanied by temporary atrial pacing to reduce the incidence of AF after cardiac surgery in a clinical setting.

Numerous randomized trials have demonstrated the efficacy of pharmacological interventions for prevention of postoperative AF in patients undergoing cardiac surgery. Crystal et al. reported that prophylactic treatments of amiodarone and sotalol respectively reduced the incidence of postoperative AF, with a meta-analysis showing a 22.5% incidence in the amiodarone treatment group compared to 37% in the control group, and 17% in the sotalol treatment group compared to 37% in the control group. Also several meta-analyses have shown that prophylactic administration of β-blockers prevented postoperative AF. Although the Guidelines recommend oral β-blockers to prevent postoperative AF, the bioavailability of oral β-blockers is
markedly impaired for a few postoperative days after cardiac surgery\textsuperscript{23}. Halonen et al. demonstrated that intravenous administration of metoprolol was more effective than oral metoprolol in the prevention of postoperative AF\textsuperscript{24}. On the other hand, the administration of intravenous esmolol has been found to induce serious adverse effects or interruptions of use\textsuperscript{25}.

Landiolol is an ultra-short acting, \(\beta\)-selective blocker, with a more potent negative chronotropic effect and less negative inotropic effect than other \(\beta\)-blockers\textsuperscript{26}. In four meta-analyses it has been demonstrated that landiolol administration in the perioperative period was able to reduce the occurrence of AF after cardiac surgery without increasing the risk of major complications\textsuperscript{6–9}. Intravenous administration of landiolol was well tolerated in the clinical settings. Li et al. suggested that landiolol seems more effective in patients undergoing CABG\textsuperscript{27}. It has been consistently demonstrated that intravenous landiolol administered immediately after CABG without cardiopulmonary bypass had a low incidence of the postoperative AF at percentage of 12.4%.

As a non-pharmacological modality to reduce the incidence of AF, atrial overdrive pacing is one of the most effective methods in selected patients with an implanted pacemaker. Saksena and colleagues concluded that dual right atrial pacing was feasible, effective and safe for long-term application\textsuperscript{13}. They suggested that the principal outcome of overdrive atrial pacing which led to a marked decline in AF recurrence was its effect on the atrial substrate, rather than the prevention of the atrial or ventricular bradycardic pause that may precede bradycardia-dependent AF. It is possible that atrial overdrive pacing may inhibit atrial ectopy, particularly through suppression of automatic foci.

Temporary epicardial pacemaker wires are routinely implanted at the time of surgery in patients who undergo open-heart surgery as a precaution against postoperative arrhythmias. There were several trials and meta-analyses to investigate the efficacy of prophylactic atrial pacing, the optimal pacing site, or most effective type of pacing in patients undergoing cardiac surgery postoperatively\textsuperscript{13–20}. In three clinical trials comparing biatrial pacing with no pacing, the incidence of postoperative AF reduced from 38.5\% to 13.8\%, from 35\% to 19\%, from 45\% to 20\%, respectively\textsuperscript{14,16,17}. In two other trials comparing right atrial pacing to no pacing, the incidence of postoperative AF reduced from 27\% to 10\%, and from 31.1\% to 5.2\%, respectively\textsuperscript{13,18}. In a meta-analysis by Daoud et al., overdrive biatrial pacing, overdrive right atrial pacing, and fixed high-rate biatrial pacing demonstrated a significant antiarrhythmic effect for prevention of AF after open heart surgery\textsuperscript{19}. Goette et al. suggested that pacing thresholds were significantly better at Bachmann’s bundle compared to the lateral wall of the right atrium\textsuperscript{20}. However, conflicting results have been reported in the prevention of postoperative AF\textsuperscript{27–30}.

The combination therapy of \(\beta\)-blockers and atrial pacing is expected to enhance antiarrhythmic effects after cardiac surgery. A few clinical trials demonstrated that hybrid regimens combining temporary atrial pacing and postoperative oral \(\beta\)-blockers were effective in reducing the incidence of postoperative AF\textsuperscript{15,16,18}. In contrast the results of this study did not show that temporary right atrial pacing accompanied by intravenous landiolol infusion for approximately 60 hours was effective in the prevention of postoperative AF. The duration of atrial pacing should be extended to 72–120 hours to suppress the premature atrial beats during the transition from intravenous to oral of \(\beta\)-blocker administration.

V. Limitations

This was not a randomized trial and was conducted in a single center with a comparatively small sample size. In this study, target range of heart rate differed between two groups, which heart rate was higher in the LAP group than the L group. To validate the efficacy of combined therapy with postoperative temporary atrial overdrive pacing and landiolol, further investigation with same doses of landiolol should warrant. Also we did not include high risk patients (e.g. those with low left ventricular ejection fraction or complex heart disease). The optimal postoperative pacing site or duration of treatment was not elucidated in this study. To validate the efficacy of hybrid combined therapy with postoperative temporary atrial pacing and \(\beta\)-blockers, multicenter studies associated with larger populations are thus recommended for future investigations.

VI. Conclusions

Temporary right atrial overdrive pacing did not demonstrate an additive effect on landiolol in the prevention of the incidence of postoperative AF. However, setting the heart rate to 90 bpm by the overdrive pacing resulted in a reduction in landiolol dose, and might contribute to a reduction in the adverse effects of landiolol, or a lowering of medical cost.

Clinical registration URL and number

University Hospital Medical Information Network Clinical Trials Registry (https://www.umin.ac.jp/ctr/), registration number: UMIN000036637.

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Conflicts of interest

Nothing to declare that conflict of interest exists.

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