Reduction of unnecessary right ventricular pacing by managed ventricular pacing and search AV+ algorithms in pacemaker patients: 12-month follow-up results of a randomized study

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Aims
The present study was to assess the reduction of right ventricular pacing (RVP) by pacemaker algorithms of Managed Ventricular Pacing (MVP) and Search AV+ (SAV+) interval over a period of 12 months.

Methods and results
A total of 385 patients indicated for a dual-chamber pacemaker (DC-PM) were enrolled in the prospective, randomized COMPARE study at 29 centres in China between June 2009 and April 2011. Patients implanted with DC-PMs were randomized in a 1:1 ratio to the MVP group or the SAV+ group. The percentage of VP (%VP) was obtained from the device diagnostic data at 1-, 6-, and 12-month follow-ups and was expressed as the median %VP over all beats in patients with sinus node dysfunction (SND) and atrioventricular block (AVB) excluding persistent third-degree AVB.

Of 385 enrolled patients, 253 had SND and 72 had AVB. The %VP in the MVP group was significantly lower than that in the SAV+ group at 1-, 6-, and 12-month follow-ups, respectively. At 12-month follow-up, the median %VP in SND patients was 0.20% in the MVP group and 1.4% in the SAV+ group (P < 0.0001) and the median %VP in AVB patients was 11.8% in the MVP group and 98.1% in the SAV+ group (P < 0.001). There was no statistical difference in %VP from 1- to 12-month follow-up. A trend in the correlation between %VP and AT/AF burden was observed.

Conclusion
Over 12-month follow-up, the %VP was lower for MVP than SAV+ in patients with either SND or AVB. The sustainable %VP reduction has potential implications in reducing the development of heart failure and/or atrial arrhythmia morbidity.

Keywords
Right ventricular pacing • Managed ventricular pacing • Dual-chamber pacemaker • Sinus node dysfunction • Atrioventricular block

Introduction
Right ventricular (RV) apical pacing has long been practised in patients who need a pacemaker. However, several clinical investigations performed in the last decade have demonstrated that the conventional RV apical pacing increases the risk of atrial fibrillation (AF) and heart failure hospitalization.¹⁻⁴ On the other hand, the incidence of AF and tachycardia decreased in the studies using a single-chamber atrial pacing (AAI) mode when compared with dual-chamber RVP.⁵,⁶ Therefore, clinical practice has since promoted more physiological pacing and less VP and strategies for reducing unnecessary RVP have been implemented in modern pacemakers.⁷⁻¹² For example, of several
pacing modes for reducing the percentage of VP, Managed Ventricular Pacing (MVP) operates in the AAI/R mode with backup VP during atrioventricular block (AVB) and Search AV+ (SAV+) operates in the DDD/R mode with automatic extension of AV interval. Short-term cross-over studies demonstrated reduced VP using MVP and SAV+ algorithms in dual-chamber pacemaker (DC-PM) patients.

Patients with sinus-node dysfunction (SND) often receive a DC-PM in consideration of potential AVB though AAI(R) pacing has been considered as a physiological pacing mode. While MVP and SAV+ algorithms for reducing unnecessary RVP have been performed for last several years, clinical data related to long-term follow-up of these two algorithms in patients who have not only SND but also atrioventricular conduction abnormality are not available. Thus, the present prospective, randomized study was to primarily compare VP reduction achieved by pacemaker MVP and SAV+ algorithms in pacemaker-indicated patients over 12 months.

### Methods

The COMPARE trial was a multi-centre, prospective, randomized study with follow-up visits at 1, 6, and 12 months post-implant to compare the reduction of VP by two algorithms, the MVP and SAV+, in pacemaker-indicated patients. The study protocol was approved by the medical ethics committee of each participating hospital and in compliance with the Declaration of Helsinki and with the laws and regulations of China.

### Selection of patients

Subject enrolment was done between June 2009 and April 2011. Subjects were enrolled if they had indications for a Class I or II DC-PM (ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities) and received a Medtronic DR Adapta pacemaker. The Adapta DR pacemaker is equipped with MVP and SAV+ algorithms to assist with the minimization of VP. Settings for both MVP and SAV+ are detailed in Table 1.

All subjects completed written informed consent and were over the age of 18. They were excluded if they were scheduled for a pacemaker replacement, had a life expectancy of <1 year, an artificial tricuspid valve, persistent third-degree AVB or persistent and chronic AF. In addition, patients were not included if they were indicated for a pacemaker due to neurological syncpe or hypertrophic cardiomyopathy. Study physicians also excluded any subject with a medical condition thought to make them unsuitable, including pregnancy.

Subjects were indicated due to (i) abnormal AV conduction: symptomatic first-degree, second-degree Mobitz I, Mobitz II, and paroxysmal third-degree AVB, and/or (ii) tachycardia–bradycardia syndrome, sinus node-atrial block, sinus asystole, sinus bradycardia, atrial arrhythmias (atrial flutter, paroxysmal AF), and/or chronotrophic dysfunction. Subjects received an Adapta pacemaker (Model ADD01 or ADDR01), as well as the following leads: the Medtronic 4574 or 5076 leads for AAI and the Medtronic 4074 or 5076 leads for RVP. Pacing leads were placed in the RV apex in 304 (79%) of 385 enrolled patients, in mid/high septum in 63 patients (16.4%), and other locations in 18 patients (4.6%).

### Device characteristics

This study assessed the change in VP over a 12-month period in two interventional groups (Table 1). The MVP group utilized the AAI(R) ↔ DDD(R) pacing mode, whereas the SAV+ group utilized DDD(R) only, with SAV+ turned on. The MVP and SAV+ algorithms have been previously detailed. Briefly, the MVP utilizes atrial-based pacing (AAI/R), with VP as a backup during AVB. If two of four cycles occur without a ventricular event, the pacing mode is switched to DDD(R) for a period of 1 min. A single cycle conduction check is then performed 1 min following the mode switch to DDD. If the subsequent conduction checks occur without AV conduction, the time interval will be doubled up to 16 h. The SAV+ algorithm utilizes DDD/R, as well as DDI/R, DVI/R, or VDD modes with an automatic extension of paced and sensed AV intervals (PAV and SAV) as needed to promote intrinsic ventricular activation. Briefly, the nominal SAV (120 ms) and PAV intervals (150 ms) were programmed. When SAV+ is turned ‘ON’ a conduction check is automatically started. If AV conduction is not found, within the preset range, the adaptation of operational AV interval fails, the AV intervals revert to the programmed values and SAV+ suspends operation for progressively longer periods. The maximum SAV and PAV intervals are 290 and 320 ms, respectively. On the Adapta DR pacemaker, MVP and SAV+ cannot run simultaneously.

Full device interrogation was completed after the implant procedure and at 1-, 6- and 12-month post-implant and the data were recorded.

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### Table 1 Pacemaker settings

<table>
<thead>
<tr>
<th>Parameters</th>
<th>MVP group (n = 196)</th>
<th>SAV+ group (n = 189)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacing mode</td>
<td>AAI(R) ↔ DDD(R)</td>
<td>DDD(R)</td>
</tr>
<tr>
<td>Low rate</td>
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<td>60 ppm</td>
</tr>
<tr>
<td>Mode switch</td>
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<td>On</td>
</tr>
<tr>
<td>Detection rate</td>
<td>175 b.p.m.</td>
<td>175 b.p.m.</td>
</tr>
<tr>
<td>Detect duration</td>
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<td>No delay</td>
</tr>
<tr>
<td>Blanked flutter Search</td>
<td>On</td>
<td>On</td>
</tr>
<tr>
<td>Intrinsic activation and AV intervals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAV</td>
<td>150 ms</td>
<td>150 ms</td>
</tr>
<tr>
<td>SAV</td>
<td>120 ms</td>
<td>120 ms</td>
</tr>
<tr>
<td>SAV+</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Max increase to AV</td>
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<td>170 ms</td>
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<td>Data collection setup</td>
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<td>High rate detail</td>
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<td>High rate type</td>
<td>AHR and VHR</td>
<td>AHR and VHR</td>
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<td>EGM type</td>
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<td>Allocation</td>
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<td>4 for 4/4</td>
</tr>
</tbody>
</table>

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What’s new?

- A sustainable reduction in the percentage of ventricular pacing (%VP) by pacemaker algorithms of Managed Ventricular Pacing (MVP) and Search AV+ (SAV+) over a time period of 12 months with a larger %VP reduction by MVP than by SAV+.
- The %VP reduction by these two algorithms not only in patients with sinus-node dysfunction but also those with abnormal atrioventricular conduction.
- A trend in the correlation between %VP and AT/AF burden observed in this investigated population.
on case report forms and saved to disk files that provided diagnostic information.

Atrial fibrillation burden
The Adapta DR pacemaker can check the occurrence of atrial arrhythmias. The pacemaker monitors for any four of the last seven consecutive A–A intervals that are shorter than the set detection rate interval to detect duration that at nominal is set at 175 b.p.m. with no detect duration delay, followed by monitoring for eight consecutive A–A intervals less than twice the total atrial blanking period. The diagnostic data collected at the follow-up were retrieved to determine the frequency of atrial tachyarrhythmias (termed as AT/AF). AT/AF burden was classified as permanent (AT/AF ≥ 23 h/day over the entire follow-up), persistent (not permanent but ≥ 7 days with ≥ 23 h of AT/AF per day), paroxysmal (all others with ≥ 6 h AT/AF on at least 1 day), low burden (1 h < < 6 h), or insignificant/no AF (< 1 h AT/AF per day on all days). The AT/AF burden is expressed as the mean value of seconds per day over the follow-up period.

Outcomes
The primary objective of the COMPARE study was to assess the percentage of RVP (%VP) at 12-month (long-term) follow-up between the MVP and SAV+ groups. Secondary objectives included assessment of longitudinal changes over time of %VP, assessment of subjects with VP at incremental percentages, subgroup analysis of %VP over time, and AT/AF burden between groups. Finally, adverse events were collected and assessed as a secondary objective of the study.

Sample size
It was hypothesized that a 5% VP difference would be present between the MVP and SAV+ groups with an estimated standard deviation (SD) of 15% VP, which determined that the size of each group should achieve 165 cases. Due to the long follow-up period and projected attrition delay, followed by monitoring for eight consecutive A–A intervals that are shorter than the set detection rate interval to detect duration that at nominal is set at 175 b.p.m. with no detect duration delay, followed by monitoring for eight consecutive A–A intervals less than twice the total atrial blanking period. The diagnostic data collected at the follow-up were retrieved to determine the frequency of atrial tachyarrhythmias (termed as AT/AF). AT/AF burden was classified as permanent (AT/AF ≥ 23 h/day over the entire follow-up), persistent (not permanent but ≥ 7 days with ≥ 23 h of AT/AF per day), paroxysmal (all others with ≥ 6 h AT/AF on at least 1 day), low burden (1 h < < 6 h), or insignificant/no AF (< 1 h AT/AF per day on all days). The AT/AF burden is expressed as the mean value of seconds per day over the follow-up period.

Randomization
Subjects were randomized in a 1:1 ratio to the MVP and SAV+ (SAV+) groups utilizing a central electronic randomization system procedure. The study was performed with subjects blinded to the randomization. Subgroups for data analysis included (i) subjects with SND only, (ii) subjects with first-degree AVB (1AVB), (iii) subjects with second-degree AVB (2AVB) including Mobitz I (AVB2a) and Mobitz II (AVB2b), and (iv) subjects with episodic third-degree AVB (e3AVB).

Statistical methods
Data are presented as mean ± SD, median, or frequency (percentage) where appropriate. Continuous variables were compared using the Wilcoxon rank-sum test or Wilcoxon signed-rank test. Fisher’s exact test and χ² tests were performed to distinguish differences between categorical variables. Statistical significance was defined as P < 0.05. All statistical analyses were performed using the SAS statistical software (SAS Institute, Inc.).

Results
Study population
There were 385 subjects (211 males, 174 females) enrolled between June 2009 and April 2011 from 29 hospitals. The mean age was 70 ± 10 years. Follow-up visits were completed for 335 subjects at 1 month, 297 subjects at 6 months, and 301 for the final 12-month follow-up. The demographics of these patients are detailed in Table 2. The primary indications for pacemaker implant were SND (n = 292, 76% of enrolments) and AVB (n = 87, 23% of enrolments). There were no significant differences in patient demographics (except the intrinsic PR interval) between the MVP and SAV+ groups at the baseline (Table 2).

Difference in the percentage of ventricular pacing between the algorithms
Managed Ventricular Pacing consistently had a lower %VP compared with SAV+ at all time points (Figure 1A), i.e., 1 month MVP 0.5% vs. SAV+ 4.2%; 6 months MVP 0.3% vs. SAV+ 2.5%; 12 months MVP 0.4% vs. SAV+ 2.98% (all P < 0.0001). Longitudinally, there was no significant change in %VP from 1 month to 6 months or 12 months post-implantation for either group (all P > 0.1). There were no differences in the percentage of AF (Figure 1B) between the two groups at 1 month (MVP 60.6% vs. SAV+ 59.2%; P = 0.75), 6 months (MVP 57.6% vs. SAV+ 55.8%; P = 0.55) or 12 months (MVP 57.0% vs. SAV60.1%; P = 0.92).

The results were also analysed in terms of the correlation between %VP and the accumulated patient numbers. Figure 2 only shows the results of the correlation at the 12-month follow-up. In the MVP group, the percentages of subjects with <10% VP cut-off were 79.0, 81.1, and 76.9% at 1, 6, and 12 months, respectively. In contrast, the percentages of subjects with SAV+ with VP <10% were 55.8, 60.8, and 60.7% at 1, 6, and 12 months, respectively. The MVP group had significantly more subjects with <10% VP at all follow-up visits compared with the SAV+ group (1 month P = 0.0001; 6 months P = 0.0001; 12 months P = 0.003 between the two groups). A similar trend between the two groups was observed for the accumulated patient numbers receiving 40% VP cut-off (Figure 2A and B). Moreover, when the subjects were divided into the SND only group (Figure 2C and D) and the AVB group (Figure 2E and F), the accumulated patient numbers receiving 10 or 40% VP cut-off were still significantly smaller in the MVP group than in the SAV+ group.

Subgroup variances
Two subgroups were assessed for %VP, the SND only and AVB groups, within the MVP and SAV+ groups (Table 3). Subjects in the MVP group with SND only (n = 99, VP = 0.2%) had significantly less %VP than those in the SAV+ group (n = 93, VP = 1.4%) at 12 months (P < 0.0001). Further, subjects in the MVP group with AVB (n = 27, VP = 11.8%) had significantly less %VP than those in the SAV+ group (n = 47, VP = 98.1%) at 12 months (P < 0.0001), especially for subjects identified as 1AVB and 2AVB (Table 3). However, in subjects with e3AVB, the %VP appeared to be higher in the MVP group (median 76.25%, n = 10) than in the SAV+ group (median 3.25%, n = 8, P = 0.11 vs. the MVP group).

Since there was a significant difference in the intrinsic PR intervals between the MVP group and the SAV+ group (Table 2), we performed additional comparisons of %VP at 12-month follow-up between the two groups in patients who had similar baseline PR intervals. For the baseline PR intervals <160 ms, the median %VP was 0.25% in the MVP group and 1.50% in the SAV+ group (P = 0.0001 between
The majority of subjects had insignificant AT/AF at 12-month follow-up. The AT/AF burden was compared between MVP and SAV + group. For the baseline PR intervals ≥ 160 ms but < 200 ms, the median %VP was 0.20% in the MVP group and 2.70% in the SAV + group (P = 0.0022 between the two groups). For the baseline PR intervals ≥ 200 ms, the median %VP was 1.40% in the MVP group and 9.80% in the SAV + group (P = 0.0042 between the two groups).

The AT/AF episodes were captured by the device during the study. The overall ATAF burden at 12-month follow-up visit was 20.0 ms per day per patient. The scatter plot correlation between AT/AF burden and %VP when all subjects were pooled together (Figure 3A). When %VP was divided into four quartiles based on the similar subject numbers, there was a trend in the correlation between %VP and AT/AF burden (Figure 3B). The AT/AF burden was compared between MVP and SAV + at the 12-month follow-up visit. The majority of subjects had insignificant AT/AF at 12-month follow-up [70.3% of subjects (n = 85) in the MAP group; 74.5% (n = 83) in the SAV + group]. The percentage of subjects who had low ATAF burden was 7.4% (n = 9) in the MVP group and 3.6% (n = 4) in the SAV + group. The MVP group had 16.5% subjects (n = 20) with paroxysmal AF, whereas the SAV + group had 16.4% (n = 18). Persistent/permanent AF was found in 5.8% of subjects in the MVP group and 4.6% of subjects in the SAV + group. No statistical difference was found in the AT/AF burden between the two groups.

### Adverse events

Each of the two groups reported one serious implant-related adverse event (pocket infection, repositioning of RV lead). Post-implant cardiac-related symptoms that did not require hospitalization...
NYHA Class II. There was no significant difference in NYHA classification between MVP and SAV+ groups at the baseline (Table 3).

Table 3.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>MVP Group</th>
<th>SAV+ Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average VP</td>
<td>10%</td>
<td>15%</td>
<td>0.05</td>
</tr>
<tr>
<td>Median VP</td>
<td>5%</td>
<td>10%</td>
<td>0.001</td>
</tr>
</tbody>
</table>

NYHA Classification was used to assess the cardiac function assessment of subjects. The results indicate that both MVP and SAV+ groups showed a significant reduction in VP over the 12-month study period. The results of the present study are consistent with previous studies, which have shown that VP reduction by MVP and SAV+ is sustainable over a period of 12 months and the differences in VP reduction by two algorithms are maintained.

Discussion

This is the first study that assessed both MVP and SAV+, algorithms for minimizing VP, longitudinally. The main results of the present study demonstrated that MVP and SAV+ significantly reduced unnecessary VP, which was longitudinally sustainable over the 12-month study period. Managed Ventricular Pacing reduced RV pacing, in terms of median VP and the percentage of patients having <10% and <40% VP, more than the SAV+ algorithm. Furthermore, the reduction of VP by both MVP and SAV+ was observed in not only patients with SND but also those with first-degree AVB and second-degree AVB. Moreover, the study observed a trend in the correlation between the VP pacing and the interval of atrial arrhythmias. Over the 12-month follow-up, there were no adverse events related to the use of MVP and SAV+ algorithms.

Since the conventional right VP is known to increase ventricular dyssynchrony and the risk of persistent AF in patients with AVB, strategies to reduce the VP, such as MVP and SAV+, have been developed. The efficacy of MVP and SAV+ for reducing the amount of VP has been investigated and compared in previous studies. Short-term cross-over studies by Purereffner et al. and Murakami et al. demonstrated a significant reduction in VP with more reduction by MVP than SAV+. The results of the present study further demonstrated that the VP reduction by MVP and SAV+ is sustainable over a period of 12 months and the differences in VP reduction by two algorithms are maintained.

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implantation. All these 15 patients experienced significant improvement in their NYHA classifications post pacemaker implantation, suggesting the presence of clinical benefits by pacemaker therapy. While the present study indicates a more reduced VP by MVP than SAV+, it is unclear whether the additional reduction in the amount of VP offered by MVP can translate into a more reduction in atrial arrhythmias and better clinical benefits than SAV+ algorithm. More studies with longer follow-up are needed to confirm the correlation between the reduction of VP and clinical benefits including the incidence of atrial arrhythmias.

**Limitations**

There was a 21.8% drop-off rate of follow-up visits in the present study. While the impact of the drop-off rate on the study outcome was unknown, the overall findings in the present study were consistent with previous investigations, suggesting that the impact might be minimal. During the study design phase, this drop-off rate had been estimated and the sample size had been increased for an appropriate power to detect a statistical difference.

There was a significant difference in the PR interval between the MVP group and the SAV+ group in this randomized study, raising a
potential bias for the comparisons between the two algorithms whose operation relies on the AV interval. We performed additional analysis on the VP reduction based on the similar PR intervals in the two groups. The findings are consistent with the general results, e.g., the VP reduction was still greater in the MVP group than in the SAV+ group in patients who had similar PR intervals.

While the present study only found an improvement in NYHA classifications in studied patients, no other direct evidence of clinical benefits in terms of quality of life and heart function assessment such as echocardiograph were investigated. In addition, the sample size of the present study might not have enough power and the follow-up interval was not long enough to detect changes in clinical outcomes. However, there were no adverse reports that were directly related to the use of the algorithms, suggesting the safe use of these two algorithms.

Another limitation is the absence of device electrograms for morphological confirmation of ATAF. In addition, there was no pacemaker control group without MVP or SAV+ algorithm for a comparison between ATAF burden and %VP.

Table 3 Subgroup analysis for %VP at 12-month follow-up

<table>
<thead>
<tr>
<th>Subgroup defined at baseline</th>
<th>MVP (n)</th>
<th>SAV+ (n)</th>
<th>MVP (median %VP)</th>
<th>SAV+ (median %VP)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SND only</td>
<td>99</td>
<td>93</td>
<td>0.20</td>
<td>1.40</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AVB</td>
<td>57</td>
<td>47</td>
<td>11.80</td>
<td>98.10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1AVB</td>
<td>18</td>
<td>8</td>
<td>0.70</td>
<td>73.00</td>
<td>0.01</td>
</tr>
<tr>
<td>2AVB</td>
<td>29</td>
<td>31</td>
<td>19.40</td>
<td>99.40</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>e3AVB</td>
<td>10</td>
<td>8</td>
<td>76.25</td>
<td>3.25</td>
<td>0.11</td>
</tr>
</tbody>
</table>

*Wilcoxon rank-sum test.

Figure 3 The correlation between AT/AF burden and %VP. (A) Scatter plot with the ordinate for AT/AF burden and the abscissa for the %VP for all subjects (n = 328) from whom retrieved diagnostic data were obtained at 1-, 6-, and 12-month follow-ups. (B) AT/AF burden based on the %VP that was divided into four quartiles with each quartile having a similar number of subjects. The median AT/AF burdens are 0.15, 1.00, 0.85, and 1.83 s per day for Quartiles 1–4 with a significant difference (P < 0.03) between Quartile 1 vs. each of other three quartiles based on permutation tests.
Clinical implications

The study by Sweeney et al. suggested that the risk of heart failure hospitalization could be reduced if %VP falls < 40% and the risk could be further minimized if %VP falls < 10% in patients who receive DC-PMs. Other studies indicated that the risk of AF is correlated with the percentage of RVP. Therefore, it is significantly important for patients with SND has clinical implications in potentially reducing pacemaker longevity.

Pacemaker algorithms of MVP and SAV+ reduce RVP over a time period of 12 months with more VP reduction by MVP than SAV+. The clinical implications of cumulative right ventricular pacing in the multicenter automatic defibrillator trial II. J Cardiovasc Electrophysiol 2005;16:359 – 65.


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