The purpose of this study was to investigate the incidence of both the first and subsequent inappropriate ICSD therapy, and to propose the appropriate duration for driving restrictions after inappropriate ICSD therapy in Japanese patients with an ICSD.

**Methods**

Briefly, patient registration was conducted from 48 Japanese ICSD centers (Appendix), using a web site registration (JCDTR: Japanese cardiac defibrillator therapy registration). The clinical background of the eligible patients was collected. All centers followed the consensus guidelines for implantation of an ICSD. We performed an interim analysis of the Nippon Storm Study regarding inappropriate ICSD therapy, which includes antitachycardia pacing and/or shocks. Follow-up data, including the incidence of a second implantable cardiac shock devices (ICSDs), including implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy devices with a defibrillator (CRT-Ds), have become an established therapeutic option for reducing the risk of sudden cardiac death.1-5 With the increase in both the implantation of an ICD and CRT-D, the number of patients with an ICD who drive a vehicle has grown. In 2003, a Joint Committee of the Japanese Circulation Society, Japanese Heart Rhythm Society and Japanese Association for Thoracic Surgery published a statement regarding the driving restrictions for patients suffering from syncope caused by a cardiac arrhythmia,6 and patients were advised not to drive for 12 months after inappropriate ICSD therapy. Because of recent advances in detection algorithms, the occurrence of inappropriate shock therapies has decreased. However, sufficient data concerning the incidence of inappropriate ICSD therapy is lacking for a large Japanese population.

**Background:** Little is known regarding the appropriate duration for driving restrictions after inappropriate implantable cardiac shock device (ICSD) therapy.

**Methods and Results:** We evaluated the Nippon Storm Study data, and found that inappropriate ICSD therapy occurred in 114 (7.6%) patients during a median follow-up of 464 days. Among those patients, 25 experienced further inappropriate ICSD therapy during a subsequent median follow-up of 380 days. Time-dependent recurrence of inappropriate ICSD therapy occurred in 19 (76%) patients within 180 days.

**Conclusions:** The interval for driving restrictions after inappropriate ICSD therapy can be reduced. (Circ J 2014; 78: 1989–1991)

**Key Words:** Cardiac resynchronization therapy; Driving restriction; Implantable cardioverter defibrillator

**Rapid Communication**

**Appropriate Duration of Driving Restrictions After Inappropriate Therapy From Implantable Cardiac Shock Devices – Interim Analysis of the Nippon Storm Study –**

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Visit and therefore were not part of this analysis. The interim analysis of the Nippon Storm Study revealed that inappropriate ICSD therapy occurred in 114 (7.6%) patients during a mean follow-up of 467 ± 169 days (Figure A). The median time to the first inappropriate ICSD therapy was 108 days (interquartile range, 43–234 days). The annual incidence of the first inappropriate ICSD therapy in this cohort of 1,504 patients was inappropriate ICSD therapy, were also collected.

**Statistical Analysis**

The results are expressed as frequencies and percentages for categorical variables and the median or mean±SD for numerical variables. Event-free survival curves were calculated according to the Kaplan-Meier method.

**Results**

**Patient Registry**

Data collection including the registration of new ICSD patients began in October 2010 and data accumulation for the Registry was terminated in July 2012. A total of 1,570 patients were enrolled.

**Baseline Characteristics of Registered Patients**

The baseline characteristics of the 1,570 ICSD patients are outlined in Table. At the time of the implantation, the mean age was 62±14 years. A total of 1,223 (78%) study subjects were male. As for the indications for an ICSD, 735 (47%) of the study subjects received an ICSD for primary prevention and 835 (53%) for secondary prevention. An ICD was implanted in 1,064 (68%) patients and CRT-D applied to 506 (32%). Regarding the underlying heart disease, 493 (31%) patients with ischemic heart disease and 357 (23%) with dilated cardiomyopathy were included. The mean left ventricular ejection fraction was 43±19%.

**Incidence of Inappropriate ICSD Therapy**

Of the 1,570 patients, follow-up data were available for 1,504; 66 enrolled patients were lost to follow-up before their first visit and therefore were not part of this analysis. The interim analysis of the Nippon Storm Study revealed that inappropriate ICSD therapy occurred in 114 (7.6%) patients during a mean follow-up of 467±169 days (Figure A). The median time to the first inappropriate ICSD therapy was 108 days (interquartile range, 43–234 days). The annual incidence of the first inappropriate ICSD therapy in this cohort of 1,504 patients was

![Table](image1)

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>62±14</td>
</tr>
<tr>
<td>Sex, male (%)</td>
<td>1,223 (78)</td>
</tr>
<tr>
<td>Indication for ICSD (%)</td>
<td></td>
</tr>
<tr>
<td>Primary prevention</td>
<td>735 (47)</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>835 (53)</td>
</tr>
<tr>
<td>Type of ICSD (%)</td>
<td></td>
</tr>
<tr>
<td>ICD</td>
<td>1,064 (68)</td>
</tr>
<tr>
<td>CRT-D</td>
<td>506 (32)</td>
</tr>
<tr>
<td>Etiology of underlying heart disease (%)</td>
<td></td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>493 (31)</td>
</tr>
<tr>
<td>Dilated cardiomyopathy</td>
<td>357 (23)</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>205 (13)</td>
</tr>
<tr>
<td>Brugada syndrome</td>
<td>142 (9)</td>
</tr>
<tr>
<td>Arrhythmogenic RV cardiomyopathy</td>
<td>28 (2)</td>
</tr>
<tr>
<td>Long QT syndrome</td>
<td>25 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>320 (20)</td>
</tr>
<tr>
<td>NYHA classification (%)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>648 (41)</td>
</tr>
<tr>
<td>II</td>
<td>498 (32)</td>
</tr>
<tr>
<td>III</td>
<td>371 (24)</td>
</tr>
<tr>
<td>IV</td>
<td>53 (3)</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>43±19</td>
</tr>
</tbody>
</table>

**CRT-D**, cardiac resynchronization therapy devices with defibrillator; ICD, implantable cardioverter defibrillator; ICSD, implantable cardiac shock device; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RV, right ventricular.

![Figure](image2)
Driving Restrictions After ICSD Therapy

6.7%. Shock deliveries induced neither fatal arrhythmia nor hemodynamic incapacitation. Atrial fibrillation or atrial tachycardia was the most common trigger for inappropriate therapy (Figure S1A); 62 (55%) patients received only antiarrhythmic pacing and inappropriate shocks occurred in 52 (45%) of them (Figure S1B).

Recurrence of Inappropriate ICSD Therapy
Among the 114 patients with a first inappropriate ICSD therapy, 25 (22%) received a second inappropriate ICSD therapy during a mean follow-up of 380±194 days (Figure B). The time-dependent recurrence of inappropriate ICSD therapy was within 90 days in 9 (36%) patients and within 180 days in 19 (76%) (Figure C).

Discussion
Several studies have investigated the risk associated with driving for patients with an ICSD, and based on those reports, guidelines for driving restrictions in patients with an ICSD have been published in some countries. The Consensus Statement published by the European Heart Rhythm Association recommends driving restrictions for 6 months after inappropriate ICSD therapy, whereas in the United States, the duration of driving restriction after inappropriate ICSD therapy is not mentioned specifically, but patients are recommended not to resume driving until the cause of the inappropriate therapy is corrected. The present study revealed that the time-dependent recurrence of inappropriate ICSD therapy was within 90 days in 9 (36%) patients and within 180 days in 19 (76%) patients. Based on that data, the annual risk of recurrent inappropriate ICSD therapy is calculated as 19.3% with a driving restriction of 90 days after inappropriate ICSD therapy and 13.6% with a driving restriction of 180 days after inappropriate ICSD therapy. According to several Western guidelines, private automobile drivers with a 22% or lower risk of “sustaining an annual risk of sudden cardiac incapacitation (SCI)” should be allowed to drive. Even if all the inappropriate ICSD therapies lead to an SCI, this level of yearly risk of inappropriate ICSD therapy is considered to be within a socially acceptable level. Moreover, on the assumption that ICSD patients drive for 1 h every day, the annual traffic accident rate because of inappropriate ICSD therapies is presumed to be 0.85% with driving restriction of 180 days and 1.21% with 90-day restriction after inappropriate ICSD therapy even if all the inappropriate ICSD therapies lead to an SCI. The former value is less than the Japanese annual traffic accident rate in 2010 of 0.90%."

Conclusions
The interim analysis of the Nippon Strom Study revealed that driving restrictions after an inappropriate ICSD therapy can be reduced.

Acknowledgments
We gratefully acknowledge all 48 Japanese ICSD centers and the office of the JHRS for data collection.

Disclosures
This manuscript represents original work that has not been published and is not being considered for publication elsewhere in whole or in part in any language except as an abstract. All co-authors have read and approved the submission of the manuscript.

Conflict of Interests and Statement
There was no financial support from a specific company for this study except from the Japan Arrhythmia Device Industry Association (JADIA) or any conflict of interest, and no specific unapproved usage of any compound or product occurred.

References

Supplementary Files
Supplementary File 1
Appendix
Figure S1. (A) Cause of inappropriate ICSD therapy.
Please find supplementary file(s): http://dx.doi.org/10.1253/circj.CJ-14-0589