Original article

Characterization of Tako-tsubo Cardiomyopathy in Spain: Results from the RETAKO National Registry

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ABSTRACT

Introduction and aims: The etiology and epidemiology of tako-tsubo cardiomyopathy remain uncertain. The symptoms of this condition are often similar to those of myocardial infarction and, although it usually has a good prognosis, it is not without complications. Our aim was to characterize this disease in our setting using a dedicated registry (Spanish REGistry for TAKOtsubo cardiomyopathy).

Methods: The prospective registry included 202 incident patients in 23 hospitals from 2012 to 2013. The patients’ clinical characteristics and analytical, echocardiographic, and imaging results were recorded, as were the events during follow-up. Patients were included when the attending physician considered the case proven, and incidence was calculated relative to the catheterizations requested for a presumptive diagnosis of acute coronary syndrome.

Results: The patients were predominantly women (90%), with a mean age of 70 years, and many had cardiovascular risk factors, such as hypertension (67%), dyslipidemia (41%), diabetes mellitus (15%), and smoking (15%). The incidence of tako-tsubo cardiomyopathy was 1.2%, and there was no clear weekly or seasonal distribution pattern. Chest pain was the predominant symptom, a triggering factor (emotional, physical, or both) was present in 72%, and most patients consulted within the first 6 h after symptom onset. The median duration of hospitalization was 7 days. There were heart failure symptoms in 34.0%, arrhythmia in 26.7%, and 2.4% of patients died.

Conclusions: The incidence of tako-tsubo cardiomyopathy is low. This disease primarily affects postmenopausal women, and occurs after a situation of emotional stress in more than half of affected individuals. It is characterized by anginal pain, shows no seasonal distribution, and has a good prognosis, although it is not without morbidity and mortality.

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Caracterización del síndrome de tako-tsubo en España: resultados del registro nacional RETAKO

RESUMEN

Introducción y objetivos: El síndrome de tako-tsubo es una entidad de etiología y epidemiología inciertas, capaz de semearse a un infarto y que, aunque suele tener buen pronóstico, no está exenta de complicaciones. El objetivo es caracterizar esta enfermedad en nuestro medio a través de un registro (Registro nacional multicéntrico sobre síndrome de TAKOtsubo).

Métodos: El registro prospectivo incluyó a 202 pacientes incidentes en 23 hospitales entre 2012-2013. Se recogieron las características clínicas, analíticas, electrocardiográficas y de imagen, así como los eventos durante el seguimiento. Se incluyó a los pacientes cuando sus médicos consideraron probable el caso, y la incidencia de la enfermedad se calculó en función de los catáteres realizados con el diagnóstico presunto de síndrome coronario agudo.

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**Resultados:** Los casos fueron predominantemente mujeres (90%), con una media de edad de 70 años y frecuentes factores de riesgo cardiovascular, hipertensión arterial (67%), dislipemia (41%), diabetes mellitus (15%) y tabaquismo (15%). Sin clara distribución semanal o estacional, se calculó una incidencia del 1.2%. El dolor torácico fue el síntoma predominante, con algún desencadenante (psíquico, físico o ambos) en el 72%, y la mayoría consultó en las primeras 6 h. La estancia mediana fue de 7 días; apareció algún síntoma de insuficiencia cardíaca en el 34.0% y arritmias en el 26.7% y murio el 2.4%.

**Conclusiones:** El síndrome de tako-tsubo es una enfermedad poco incidente, que afecta predominantemente a mujeres posmenopáusicas, en más de la mitad de los casos una situación psicológicamente estresante. Se caracteriza por dolor anginoso, sin distribución estacional; aunque no está exenta de morbimortalidad, conlleva buen pronóstico.

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**Abbreviations**

RETAKO: Spanish REgistry for TAKOtsubo cardiomyopathy

TCM: tako-tsubo cardiomyopathy

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**INTRODUCTION**

In 1990 in Japan, a syndrome was described consisting of chest pain, electrocardiographic and biochemical changes similar to those seen in acute myocardial infarction, and abnormalities of left ventricular apical contractility.\(^1\) The peculiarity of this new disease, which was first attributed to multivessel spasm, was that the coronary arteries showed no lesions and the marked abnormalities of ventricular segments virtually resolved within a few days or weeks.\(^1,2\) The syndrome was named tako-tsubo cardiomyopathy (TCM), apical ballooning, or transient apical dyskinesia. Compared with classic coronary syndromes, TCM is notable for regional involvement of various coronary territories and its excellent ultimate prognosis.\(^2,3\) Nonetheless, although it is usually a benign condition, it is not without complications. The most common of these are heart failure, arrhythmia, intraventricular thrombi, and even death, mainly occurring in the acute phase.\(^4\)

Various groups from Spain and other countries have reported case series consistent with these features,\(^1,4\) including a description of the first series in Spain of the midventricular variant,\(^1\) which is also recognized outside our country.\(^5\) Other related articles from Spain have described patients with predominantly inferior ventricular involvement, and one has proposed the theory that the condition coincides with chronic ischemic heart disease.\(^6\) Some authors have focused on the relationship between the left ventricular hypertrophy and the mid- to long-term outcome of these patients,\(^4\) which may not be as benign as that of other patients with hypertrophic ventricles.\(^7\) In addition, Spanish researchers have intensively investigated the pathophysiology of the syndrome and have proposed some interesting theories in this line, such as a wraparound left anterior descending artery,\(^8\) or an effect of the intraventricular pressure gradient.\(^9\) Other studies have compared the electrocardiographic findings according to race.\(^10\)

Several hypotheses have been proposed to explain the etiopathogenesis of TCM.\(^11,13\) Although it remains to be clarified, there seems to be an important relationship between the development of this syndrome and an excess of circulating catecholamines resulting from a situation of emotional or physical stress.\(^1,4\) Nonetheless, the definitive cause of TCM is uncertain and precise epidemiologic data on this condition are not available in Spain, as most of the published articles report the experience of one or only a few centers.

The aim of this study was to create a collaborative, multicenter national registry of TCM cases with a view to describing this disease in more detail in our setting.

**METHODS**

The multicenter Spanish Registry for TAKOtsubo cardiomyopathy (RETAKO), created under the auspices of the Ischemic Heart Disease and Cardiovascular Acute Care Section of the Spanish Society of Cardiology, is a prospective, voluntary, national registry. It includes patients who meet the criteria for this disease (based on the modified Mayo criteria\(^15\)) in the opinion of the attending physicians, as reported previously.\(^7\) The present analysis included data on TCM patients consecutively hospitalized from (and including) 1 January 2012 to 31 December 2013, provided by 23 hospitals throughout the country (Table 1). The number of patients with this condition relative to the number of coronary angiographies requested in each hospital for the working diagnosis (subsequently confirmed or not) of acute coronary syndrome was calculated to determine the approximate incidence of this disease in our setting. The Registry collected information on the patients' clinical characteristics, complications during hospitalization, analytical results, and findings on electrocardiography, echocardiography, and other imaging techniques (magnetic resonance imaging was optional in the protocol). Initially, this information was recorded on a case report form and sent by e-mail to a data processing center, whereas later (after 2014), it was directly recorded on an on-line case report form. Some variables with aspects that were difficult to systematize were recorded on an open text field. To be included in the Registry, patients had to have undergone invasive coronary angiography that excluded significant obstructive lesions (> 50%) and any other potential cause of the clinical symptoms (eg, thrombus, dissection, ulcer). The treatment prescribed was always at the discretion of the attending physicians. At least 2 follow-up visits were recommended, one at 3 months and another at 1 year following the index event. Complete resolution of the regional wall motion abnormalities by any imaging technique was required, except in cases of death before the visit. The objectives investigated over follow-up were cardiovascular death, death due to any cause, and the need for readmission for any cause in a cardiology service. The study was approved by the Ethics Committee of Hospital Clínico San Carlos, and patients gave informed consent to participate in the Registry.

**Statistical Analysis**

Statistical processing was done with SPSS version 20.0 (IBM SPSS; United States) and the multimedia software package, Office 2010 (Microsoft; United States). Data are expressed as the
mean ± standard deviation or the median (range), depending on their distribution and dispersal. This is mainly a descriptive study, and between-group differences were analyzed using the appropriate statistical method according to whether quantitative or qualitative variables were included, as specified in the text. In the statistical analysis, significance was set at a bilateral P value < .05.

**RESULTS**

**Patient Profile and Epidemiology**

A total of 202 patients were included, with a mean (SD) age of 70.0 (12.5) years. The sample was predominantly comprised of women (90.1%), and 98% of participants were white. The epidemiologic profile of the patients studied is shown in Table 2. The incidence calculation was performed using the number of patients undergoing coronary angiography with a presumptive diagnosis of acute coronary syndrome (of any type, with or without biomarker elevation) in the hospitals providing data (Table 1) with respect to those patients with a final diagnosis of TCM in these same centers (108 of 8950) during the study period. This yielded an estimated incidence of TCM of 1.2%. No significant differences were found between the seasonal, monthly (Figure 1), or daily incidences.

**Clinical Data and Hospital Stay**

The main reason for consulting was chest pain, present in 162 (80.1%) patients, most of whom had good previous functional status (81.2% in class I). In general, the symptoms led to a prompt consultation: 138 (68.3%) patients came to the hospital within 6 h after onset and only 10% consulted after 24 h. Among the total, 72.8% reported a situation that might trigger or favor the syndrome, such as intense emotional stress, which occurred in 101 patients (50%). The mean duration of hospitalization was 8.2 (median, 7) days. Details of these aspects are summarized in Table 3. The patients’ treatment before and during hospitalization, and at hospital discharge are presented in Table 4.
Table 3 (Continued)

Clinical Parameters and Hospital Stay (n=202)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>9 (4.5)</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Clinically relevant bleeding</td>
<td>9 (4.5)</td>
</tr>
<tr>
<td>New episode/symptoms during hospitalization</td>
<td>15 (7.4)</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>19 (9.4)</td>
</tr>
</tbody>
</table>

Infection during hospitalization

<table>
<thead>
<tr>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>162 (80.2)</td>
</tr>
<tr>
<td>Urinary</td>
<td>13 (6.4)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>20 (9.9)</td>
</tr>
<tr>
<td>Others</td>
<td>3 (1.5)</td>
</tr>
<tr>
<td>Unknown</td>
<td>4 (2.0)</td>
</tr>
</tbody>
</table>

Catheterization complications²

<table>
<thead>
<tr>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 (5.0)</td>
</tr>
</tbody>
</table>

DBP, diastolic blood pressure; HR, heart rate; HT, hypertension; NYHA, New York Heart Association; SBP, systolic blood pressure; SD, standard deviation

* As some patients had more than one, the percentage of cases does not add up to 100%.

² Nine of 10 vascular complications at the access site; the tenth, a systemic embolism of uncertain origin.

Values are expressed as No. (%), mean (standard deviation) or median (interquartile range).

Additional Tests: Analyses, Electrocardiography, and Imaging

The analytical and electrocardiographic findings and the most relevant data from serial echocardiography and coronary angiography are shown in Table 5. One of the inclusion criteria was positive testing for biomarkers of myocardial necrosis (troponin T or I; a normal creatine kinase concentration was allowed). Nonetheless, the levels observed were notably low. On electrocardiogram, patients generally showed sinus rhythm (83.7%), and anomalies were common (89.1%) starting with the first tracing (Figure of supplementary material). The abnorrmalities seen were mainly in the precordial leads; 61.8% of patients showed ST-segment elevation in at least 1 lead. A negative T wave was seen in 39.5% on the initial test and in up to 94.4% at later testing. This finding explained the frequent development of a corrected (lengthened) QT interval (QTc), defined as > 450 ms duration, which was observed in 130 of 165 patients (78.8%) (maximum QTc was not determined in 37). The mean QTc interval was 501 (73) ms. There were 2 episodes of torsades de pointes ventricular tachycardia (1%), one with a long QTc (620 ms), which progressed to ventricular fibrillation, and another in a patient with a pacemaker that abated with an increase in the pacing rate to 80 bpm. Among patients in the Registry with a known maximum QTc value, comparison of those with some type of ventricular tachycardia (sustained or not) and the remainder showed no significant differences (Fisher test, P = .34). Nonetheless, although ventricular tachycardia was uncommon (4.8%), all cases occurred in the group of patients with a long QT interval. The left ventricular ejection fraction measured by transthoracic echocardiography was 44.01 (12.28)% at the initial evaluation and 63.17 (7.3)% during follow-up (determined a median of 56 days following admission). Coronary catheterization, carried out on an emergency basis (for primary or rescue coronary angioplasty) in 38.0% of cases, showed a right dominance in 90.1%. Invasive coronary angiography, performed in 100% of cases, ruled out coronary vasculature abnormalities that could be a potential cause of the symptoms (Figure 2). Mean left ventricular ejection fraction determined by ventriculography was 47.27 (12.48)%. As to other diagnostic tests, magnetic resonance imaging was performed at some point during follow-up (median, 9 days; interquartile range, 5–33 days) in 79 patients, 40% of the total. None of the patients underwent a coronary vasospasm provocation test.
Table 4
Treatment Before and During the Index Admission, and at Discharge

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Previous</th>
<th>Admission</th>
<th>At discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>34 (16.8)</td>
<td>185 (91.6)</td>
<td>126 (62.4)</td>
</tr>
<tr>
<td>Clopidogrel or similar</td>
<td>6 (3.0)</td>
<td>152 (75.2)</td>
<td>24 (11.9)</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>22 (10.9)</td>
<td>153 (75.7)</td>
<td>36 (17.8)</td>
</tr>
<tr>
<td>Nitrates</td>
<td>6 (3.0)</td>
<td>76 (37.6)</td>
<td>10 (5.0)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>55 (27.2)</td>
<td>82 (40.6)</td>
<td>56 (27.7)</td>
</tr>
<tr>
<td>Statins</td>
<td>59 (29.2)</td>
<td>149 (73.8)</td>
<td>120 (59.4)</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>18 (8.9)</td>
<td>160 (79.2)</td>
<td>147 (72.8)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>23 (11.4)</td>
<td>20 (9.9)</td>
<td>14 (6.9)</td>
</tr>
<tr>
<td>ACE inhibitors/ARB</td>
<td>102 (50.5)</td>
<td>153 (75.7)</td>
<td>143 (70.8)</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>10 (5.0)</td>
<td>16 (7.9)</td>
<td>12 (5.9)</td>
</tr>
<tr>
<td>Anxiolytics</td>
<td>58 (28.7)</td>
<td>121 (59.9)</td>
<td>69 (34.2)</td>
</tr>
<tr>
<td>Antidepressive agents</td>
<td>38 (11.4)</td>
<td>37 (18.3)</td>
<td>39 (19.3)</td>
</tr>
<tr>
<td>Oral antidiabetics</td>
<td>23 (11.4)</td>
<td>8 (4.0)</td>
<td>24 (11.8)</td>
</tr>
<tr>
<td>Insulin</td>
<td>5 (2.5)</td>
<td>21 (10.4)</td>
<td>9 (4.9)</td>
</tr>
<tr>
<td>Amiodarone/ dronedarone</td>
<td>3 (1.4)/(0.0)</td>
<td>7 (3.4)/(0.0)</td>
<td>4 (1.9)/2 (0.0)</td>
</tr>
<tr>
<td>Inotropes (catecholamines)</td>
<td>—</td>
<td>24 (11.9)</td>
<td>—</td>
</tr>
<tr>
<td>Levosimendan</td>
<td>—</td>
<td>1 (0.5)</td>
<td>—</td>
</tr>
<tr>
<td>Balloon pump</td>
<td>—</td>
<td>5 (2.5)</td>
<td>—</td>
</tr>
<tr>
<td>Noninvasive ventilation</td>
<td>—</td>
<td>17 (8.4)</td>
<td>—</td>
</tr>
<tr>
<td>Invasive ventilation (OTI)</td>
<td>—</td>
<td>17 (8.4)</td>
<td>—</td>
</tr>
<tr>
<td>GPIIb/IIIa inhibitors</td>
<td>—</td>
<td>1 (0.5)</td>
<td>—</td>
</tr>
<tr>
<td>Thrombolysis</td>
<td>—</td>
<td>6 (3)</td>
<td>—</td>
</tr>
</tbody>
</table>

Follow-up and Mortality

The median follow-up was 3.20 [1.42-5.61] months. One patient, aged 51 years, was diagnosed with pheochromocytoma after inclusion in RETAKO, but was maintained in the analysis because of her typical pattern. She underwent surgery some months later, with no disease recurrence. All 5 deaths took place during hospitalization. There were no deaths during follow-up. Symptom recurrence (chest pain) was recorded in 2 patients, and the combined variable (cardiology readmission, recurrent symptoms, and/or death) was documented in 13 patients. Admissions for other reasons (eg, general surgery or respiratory infection) were not considered adverse events (Table 6).

DISCUSSION

The RETAKO is the largest TCM series compiled in Spain, containing first-hand information from the physicians treating these patients. Despite the limitations associated with a disease having a very low incidence and cases scattered across the country, the registry data provide a very close idea of the epidemiology of TCM in our setting. The characteristics of our patients are quite similar to those reported in series from other geographic areas.12,15–21 There is a predominance of hypertensive, postmenopausal women, and the common complications during admission include heart failure, arrhythmias (mainly supraventricular, but
also ventricular), renal failure, iatrogenic complications, and others derived from the comorbidities. Although an outcome analysis was not the aim of this study because of the short follow-up period, we observed a generally favorable outcome following hospital discharge, as described in other studies. The etiopathogenesis of TCM remains speculative. Despite some evidence from intracoronary imaging, angiographically-silent plaque rupture as a causal possibility is uncertain; hence, a number of etiologies have been suggested for the syndrome. One of the most widely accepted theories in the scientific community for the transient ventricular dysfunction is the influence of catecholamines and the distribution of myocardial beta-receptors. Other hypotheses have recently been proposed, such as microcirculation vasospasm, based on a detection of an endothelin-1 abnormality. The contribution of this factor is difficult to reliably define; further knowledge of the disease is needed to definitively confirm this possibility.

The information derived from this registry and previous series gives the impression that the syndrome known as TCM may be a catch-all encompassing quite varied origins from a situation of myocardial stunning. Cases have been described in almost every imaginable circumstance involving stress, including the classic grieving for the death of a loved one, a fall with inability to get up for some hours, an asthma attack, pulmonary embolism, surgery, dysthyroidism, cerebrovascular disease, and even catecholamine administration during stress testing. Other pertinent questions also require clarification: why is it that not all people who go through stressful situations experience the syndrome? Why is it that people who have had one episode of TCM do not have another in new situations of intense stress? (recurrence is uncommon).

Moreover, in a considerable number of cases (40-50%) in our series and in the literature, no potential triggering factor could be identified even after careful questioning. Could these be a primary form? This might be relevant from the prognostic standpoint, since it seems that patients with more severe diseases or comorbidities (secondary forms?) may have a poorer outcome, with the underlying or concomitant disease being the determinant of the poorer prognosis. At this time, however, it is difficult to say whether the prognosis is marked by the comorbidities or the triggering factors, although it is likely that both play a part. It is important to interpose this consideration in the decision of where to hospitalize the patient. If there are no comorbid conditions (or “secondary” form), the clinical status is good, and the ventricular dysfunction and biomarker elevations are not severe, it may be a safe choice to admit the patient for a few days to a hospital ward. In our cohort, 4 of the 5 deaths were due to causes unrelated to TCM. Of course, this reflection should be confirmed in larger TCM series with rigorous data collection. In summary, TCM has gained sufficient importance in recent years to merit a place in several clinical guidelines; for example, the European guidelines for the diagnosis and treatment of acute and chronic heart failure of 2012, in which it still appears as an unclassified cardiomyopathy. In this line, RETAKO will continue its activity, attempting to respond with greater accuracy to the questions that arise about this enigmatic disease or group of diseases.

**Limitations**

The limitations of this study include the logistical constraints of the study design and a disease having a relatively low incidence. It is possible that some incident cases in the participating hospitals were not diagnosed, were hospitalized in other specialty departments, did not undergo catheterization, did not have elevated troponin levels, did not accept to participate, or were not notified to the Registry, which would imply underestimation of the true

**Table 6**

Follow-up and Mortality (n=202)

<table>
<thead>
<tr>
<th>Event</th>
<th>Value (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical follow-up, months</td>
<td>3.20 (1.42-5.61)</td>
</tr>
<tr>
<td>Deaths*</td>
<td>5 (2.4)</td>
</tr>
<tr>
<td>Tamponade, possible cardiac rupture</td>
<td>1</td>
</tr>
<tr>
<td>Combined variable*</td>
<td>13 (6.4)</td>
</tr>
<tr>
<td>Tako-tsubo recurrence requiring hospitalization</td>
<td>0</td>
</tr>
<tr>
<td>Recurrence of symptoms</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Re-admittance in cardiology department</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Follow-up NYHA functional class (assessable)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>162 (82.2)</td>
</tr>
<tr>
<td>II</td>
<td>30 (15.2)</td>
</tr>
<tr>
<td>III</td>
<td>5 (2.5)</td>
</tr>
</tbody>
</table>

GP IIb/IIIa, glycoprotein IIb/IIIa; NYHA, New York Heart Association.

* Mesenteric ischemia, hypoxic encephalopathy, hemoptysis and respiratory effort, acute abdomen.

* During hospitalization the patient received dual antiplatelet therapy, but not anti-glycoprotein IIb/IIIa or thrombolysis.

* Combination of death, re-admittance for any cause in cardiology, or recurrence of similar symptoms.
number of TCM cases that occurred over the study period. The incidence calculation was adjusted by the number of coronary angiographies requested for an acute coronary syndrome, and it was not possible to relate the number of TCM to the total number of acute coronary syndromes. This, however, does not depart greatly from daily clinical practice, where coronary angiography is performed increasingly more often in patients with a suspected acute coronary syndrome (updated information on this is available in the DIOCLES registry); hence, the analysis still provides a good idea of the size of the problem involving this condition. In addition, most of the participating centers are equipped with highly sensitive (or ultrasensitive) techniques for determining troponin I or T, but because the Registry includes patients from many different hospitals, the heterogeneity made comparisons impossible. The creatine kinase values are presented in Table 5 with the purpose of orienting the reader. Lastly, the coronary angiographies and remaining tests were interpreted by investigators from each of the centers; reading by a centralized laboratory was not carried out.

CONCLUSIONS

Tako-tsubo cardiomyopathy is an uncommon disease that predominantly affects postmenopausal women and occurs following an emotionally stressful situation in half the cases. It is generally characterized by anginal chest pain and shows no weekly or seasonal distribution pattern. The acute phase is not without complications or mortality, but once it has passed, the condition usually has a favorable outcome.

ACKNOWLEDGEMENTS

The authors thank all the RETAKO investigators and the institutions that have made this study possible.

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CONFLICTS OF INTEREST

None declared.

APPENDIX. RETAKO STUDY INVESTIGATORS

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SUPPLEMENTARY MATERIAL

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