IV　研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表（平成24年度）

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
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研究成果の刊行に関する一覧表（平成24年度）

書籍

著者氏名	論文タイトル名	書籍全体の編集者名 書籍名	出版社名 出版地	出版年 ページ
横田和浩, 三村俊英	リウマチ性疾患-再発性多発軟骨炎	門脇孝/永井良三	西村書店	2012
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鴨居瑞加，小川葉子， 坪田一男.	私はこう治療する　眼の違和感、ドライアイ	医学書出版	診断と治療社	2012
		眼科	東京	1403-1407

V　平成24年度班会議プログラム

プログラム

	9:00- 9:10	厚生労働省健康局疾病対策課課長挨拶	山本尚子 様
	9:10- 9:40	班全体およびSS分科会統括	住田孝之
	9:40-10:00	SLE/ AOSD分科会統括	山本一彦
	10:00-10:20	PM/DM分科会統括	上阪 等
	10:20-12:30	SLE/AOSD分科会研究報告	座長 山本一彦
1	10:20-10:30	JAK阻害薬Tofacitinibにより誘導されるEgr2陽性PD-L1陽性CD4陽性T細胞に関する研究 東京大学大学院医学系研究科内科学専攻アレルギー・リウマチ学 山本一彦	
2	10:30-10:40	SLE/ASODの遺伝因子解析に関する研究 京都大学大学院医学研究科 山田 亮	
3	10:40-10:50	FcγレセプターIIB欠損YaaマウスにおけるRAからSLEへの表現型の変化についての研究 順天堂大学膠原病内科 天野浩文	
4	10:50-11:00	ループス腎炎発症における抑制性IgG Fc受容体の役割 順天堂大学大学院医学研究科・分子病理病態学 広瀬幸子	
5	11:00-11:10	全身性エリテマトーデスにおけるMAIT細胞の解析 (独)国立精神・神経医療研究センター神経研究所免疫研究部 三宅幸子	
6	11:10-11:20	B 細胞を標的とした全身性エリテマトーデスの治療の開発に関する研究 産業医科大学医学部第一内科学講座 田中良哉	
7	11:20-11:30	抗リン脂質抗体陽性全身性エリテマトーデスの血栓形成機序解析に関する研究 北海道大学大学院医学研究科免疫・代謝内科学分野 渥美達也	
8	11:30-11:40	成人スティル病の全国疫学調査に関する研究 埼玉医科大学リウマチ膠原病科 三村俊英	
	11:40-12:20	昼 食	
9	12:20-12:30	全身性エリテマトーデス難治性病態の治療標的分子探索に関する研究 慶應義塾大学医学部リウマチ内科 竹内 勤	

12:30–14:10　PM/DM分科会研究報告　座長　上阪　等

1　12:30–12:40　多発性筋炎・皮膚筋炎の筋力低下の治療法に関する非臨床研究

東京医科歯科大学大学院医歯学総合研究科 膠原病・リウマチ内科学　上阪　等

2　12:40–12:50　皮膚筋炎におけるmicroRNA解析

熊本大学大学院生命科学研究部皮膚病態治療再建学分野　神人正寿

3　12:50–13:00　皮膚筋炎患者における疾患マーカー自己抗体は必ずしも相互に排他的ではない

名古屋大学大学院医学系研究科皮膚結合組織病態学　室　慶直

4　13:00–13:10　抗SRP抗体陽性ミオパチー患者由来IgGは筋内小血管ペリサイトの細胞死を誘導する

山口大学大学院医学系研究科神経内科学　神田　隆

5　13:10–13:20　悪性腫瘍合併筋炎における臨床的・血清学的特徴に関する研究

京都大学大学院医学研究科内科学講座臨床免疫学　三森経世

6　13:20–13:30　皮膚筋炎における自己抗体の臨床的意義に関する研究

金沢大学医薬保健研究域医学系皮膚科学　藤本　学

7　13:30–13:40　抗ミトコンドリア抗体陽性筋炎の臨床病理学的特徴に関する研究

東京大学医学系研究科神経内科　清水　潤

8　13:40–13:50　Myositis Disease Activity Core Setを用いた多発性筋炎/皮膚筋炎の疾患活動性の評価に関する研究

東京女子医科大学膠原病リウマチ痛風センター/リウマチ科　川口鎮司

9　13:50–14:00　多発性筋炎/皮膚筋炎の記述疫学－臨床調査個人票の解析－

埼玉医科大学医学部公衆衛生学　太田晶子

10　14:00–14:10　「IMCCPが提示したPM/DMの診断基準の妥当性に関する疫学調査」研究計画

東京医科歯科大学大学院脳神経病態学　石原正一郎

14:10–14:30　コーヒーブレイク

14:30-14:40 国立保健医療科学院研究事業推進官挨拶 武村真治 様

14:40-16:10 SS分科会研究報告 座長 住田孝之

1 14:40-14:50 M3Rを分子標的とした自己免疫性唾液腺炎に関する研究2

筑波大学医学医療系(膠原病・リウマチ・アレルギー) 住田孝之

2 14:50-15:00 シェーグレン症候群の病態進展における IL-33 の関与

九州大学大学院歯学研究院 口腔顎顔面病態学講座 顎顔面腫瘍制御学分野 中村誠司

3 15:00-15:10 シェーグレン症候群唾液腺上皮細胞におけるToll-like receptor3による細胞死調節シグナルに関する研究

長崎大学大学院医歯薬学総合研究科医療科学専攻展開医療科学講座(第一内科) 川上 純

4 15:10-15:20 シェーグレン症候群におけるダイオキシンを介したEBV再活性化の関与

鶴見大学歯学部 斎藤一郎

5 15:20-15:30 シェーグレン症候群における口腔内病変と唾液中EGFの関係に関する研究

兵庫医科大学リウマチ・膠原病科 佐野 統

6 15:30-15:40 アクアポリン発現誘導によるシェーグレン症候群治療戦略の萌芽的研究

金沢医科大学血液免疫内科学 梅原久範

7 15:40-15:50 「シェーグレン症候群様病態を示すマウスモデルの加齢的解析」に関する研究

慶應義塾大学医学部 眼科 坪田一男

8 15:50-16:00 シェーグレン症候群の診断精度の検討

東京女子医科大学医学部医学科眼科 高村悦子

9 16:00-16:10 日本人シェーグレン症候群患者の診断における3つの診断基準の比較

筑波大学医学医療系内科(膠原病・リウマチ・アレルギー) 坪井洋人

SLE/AOSD分科会研究報告

10 16:10-16:20 SLEとStill病の治療法の改良に関する研究

国立国際医療研究センター 三森明夫

16:20-16:30 閉会の辞(事務連絡)

VI　研究成果刊行物・別刷

Mod Rheumatol
DOI 10.1007/s10165-012-0812-9

ORIGINAL ARTICLE

Validation of different sets of criteria for the diagnosis of Sjögren's syndrome in Japanese patients

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Received: 8 November 2012 / Accepted: 5 December 2012

Abstract
Objective To validate the revised Japanese Ministry of Health criteria for the diagnosis of Sjögren's syndrome (SS) (JPN) (1999), The American-European Consensus Group classification criteria for SS (AECG) (2002), and American College of Rheumatology classification criteria for SS (ACR) (2012).
Methods The study subjects were 694 patients with SS or suspected SS who were followed-up in June 2012 at ten hospitals that form part of the Research Team for Autoimmune Diseases, The Research Program for Intractable Disease by the Ministry of Health, Labor and Welfare (MHLW). All patients had been checked for all four criteria of the JPN (pathology, oral, ocular, anti-SS-A/SS-B antibodies). We studied the clinical diagnosis made by the physician in charge and the satisfaction of the above criteria.
Results Of the 694 patients, 499 patients did not have other connective tissue diseases (CTDs). SS was diagnosed in 476 patients (primary SS in 302, secondary SS in 174), whereas non-SS was diagnosed in 218 patients (without other CTDs in 197, with other CTDs in 21) by the physician in charge. The sensitivities of JPN, AECG, and ACR in the diagnosis of all forms of SS (both primary and secondary SS) were 79.6, 78.6, and 77.5 %, respectively, with respective specificities of 90.4, 90.4, and 83.5 %. The sensitivities of the same systems in the diagnosis of primary SS were 82.1, 83.1, and 79.1 %, respectively, with specificities of 90.9, 90.9, and 84.8 %, respectively. The sensitivities of the same systems in the diagnosis of secondary SS were 75.3, 70.7, and 74.7 %, respectively, with specificities of 85.7, 85.7, and 71.4 %, respectively.
Conclusion The sensitivity of JPN to all forms of SS and secondary SS, the sensitivity of AECG to primary SS, and the specificities of JPN and AECG for all forms of SS, primary SS, and secondary SS were highest in the diagnosis of SS in Japanese patients. These results indicate that

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Published online: 28 December 2012

the JPN criteria for the diagnosis of SS in Japanese patients are superior to ACR and AECG.

Keywords Sjögren's syndrome · Criteria

Introduction

Sjögren's syndrome (SS) is an autoimmune disease that affects exocrine glands, including the salivary and lacrimal glands. It is characterized by lymphocytic infiltration into the exocrine glands, leading to dry mouth and eyes. A number of autoantibodies, such as anti-SS-A and SS-B antibodies, are detected in patients with SS. SS is subcategorized into primary SS, which is not associated with other well-defined connective tissue diseases (CTDs), and secondary SS, which is associated with other well-defined CTDs [1]. Primary SS is further subcategorized into the glandular form and the extraglandular form.

The revised criteria for the diagnosis of SS issued by the Japanese Ministry of Health (JPN) (1999) (Table 1) [2], as well as the American-European Consensus Group classification criteria for SS (AECG) (2002) (Tables 2, 3) [1], are usually used in both daily clinical practice and clinical studies in Japan. Thus, two sets of diagnostic systems are being applied for the same disease. This could result in a heterogeneous pool of SS patients. This heterogeneity of SS patients makes it difficult to analyze the diagnosis, efficacy of treatment, and prognosis of SS patients. A better alternative would be to use a unified set of criteria for the diagnosis of SS in Japan. Recently, The American College of Rheumatology (ACR) published the ACR classification criteria for SS (2012) (Table 4), which were proposed by the Sjögren's International Collaborative Clinical Alliance (SICCA) [3]. The new set of criteria is designed to be used worldwide, not only in advanced countries but also in developing countries. The SICCA established a uniform classification for SS based on a combination of objective tests that have known specificity to SS [3].

Table 1 The revised Japanese Ministry of Health criteria for the diagnosis of SS (1999)

1. Histopathology
Definition: Positive for at least one of (A) or (B)
(A) Focus score ≥1 (periductal lymphoid cell infiltration ≥50) in a 4 mm^2 minor salivary gland biopsy
(B) Focus score ≥1 (periductal lymphoid cell infiltration ≥50) in a 4 mm^2 lacrimal gland biopsy
2. Oral examination
Definition: Positive for at least one of (A) or (B)
(A) Abnormal findings in sialography ≥stage 1 (diffuse punctate shadows of <1 mm)
(B) Decreased salivary secretion (flow rate ≤10 ml/10 min according to the chewing gum test or ≤2 g/2 min according to the Saxon test) and decreased salivary function according to salivary gland scintigraphy
3. Ocular examination
Definition: Positive for at least one of (A) or (B)
(A) Schirmer's test ≤5 mm/5 min and rose bengal test ≥3 according to the van Bijsterveld score
(B) Schirmer's test ≤5 mm/5 min and positive fluorescein staining test
4. Serological examination
Definition: Positive for at least one of (A) or (B)
(A) Anti-Ro/SS-A antibody
(B) Anti-La/SS-B antibody
Diagnostic criteria: diagnosis of SS can be made when the patient meets at least two of the above four criteria

Upon comparing these three classification sets, there are some differences among them in their purpose and the items adopted in the set (Table 5). The JPN criteria (1999) are intended as an aid for diagnosis, whereas the AECG criteria (2002) and the ACR criteria (2012) are intended for classification purposes in clinical studies and trials. Although the ACR criteria include only three objective items (Tables 4, 5) and are the simplest among the three sets, the ACR criteria may not identify SS patients with negative findings in labial salivary gland biopsy, because the ACR criteria do not include salivary secretion analysis and imaging studies. On the other hand, the JPN criteria combined oral examinations such as salivary secretion, sialography, and salivary gland scintigraphy with three objective items adopted in the ACR criteria (Table 5). Only the AECG criteria include ocular and oral symptoms, which may cause false positives in patients with non-SS conditions such as aging or visual display terminals (VDT) syndrome (Table 5).

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Table 2 The American-European Consensus Group classification criteria for SS (2002)

I. Ocular symptoms: a positive response to at least one of the following questions
1. Have you had daily, persistent, troublesome dry eyes for more than 3 months?
2. Do you have a recurrent sensation of sand or gravel in the eyes?
3. Do you use tear substitutes more than 3 times a day?
II. Oral symptoms: a positive response to at least one of the following questions
1. Have you had a daily feeling of dry mouth for than 3 months?
2. Have you had recurrently or persistently swollen salivary glands as an adult?
3. Do you frequently drink liquids to aid in swallowing dry food?
III. Ocular signs—that is, objective evidence of ocular involvement defined as a positive result for at least one of the following two tests
1. Schirmer's test, performed without anaesthesia ($\leq$5 mm in 5 min)
2. Rose bengal score or other ocular dry eye score ($\geq$4 according to van Bijsterveld's scoring system)
IV. Histopathology: in minor salivary glands (obtained through normal-appearing mucosa) focal lymphocytic sialoadenitis, evaluated by an expert histopathologist, with a focus score $\geq$1, defined as a number of lymphocytic foci (which are adjacent to normal-appearing mucous acuni and contain more than 50 lymphocytes) per 4 mm^2 of glandular tissue
V. Salivary gland involvement: objective evidence of salivary gland involvement defined by a positive result for at least one of the following diagnostic tests
1. Unstimulated whole salivary flow ($\leq$1.5 ml in 15 min)
2. Parotid sialography showing the presence of diffuse sialectasias (punctate, cavitary or destructive pattern), without evidence of obstruction in the major ducts
3. Salivary scintigraphy showing delayed uptake, reduced concentration and/or delayed excretion of tracer
VI. Autoantibodies: presence in the serum of the following autoantibodies
1. Antibodies to Ro (SS-A) or La (SS-B) antigens, or both

Table 3 The American-European Consensus Group classification criteria for SS (2002) rules for classification

For primary SS
In patients without any potentially associated disease, primary SS may be defined as follows:
(A) The presence of any 4 of the 6 items is indicative of primary SS, as long as either item IV (histopathology) or VI (serology) is positive
(B) The presence of any 3 of the 4 objective criteria items (that is, items III, IV, V, VI)
For secondary SS
In patients with a potentially associated disease (for instance, another well-defined connective tissue disease), the presence of item I or item II plus any 2 from among items III, IV, and V may be considered as indicative of secondary SS
Exclusion criteria:
Past head and neck radiation treatment
Hepatitis C infection
Acquired immunodeficiency disease (AIDS)
Pre-existing lymphoma
Sarcoidosis
Graft vs. host disease
Use of anticholinergic drugs (for a time shorter than 4-fold the half life of the drug)

The purpose of the present study was to validate the JPN criteria, AECG criteria, and ACR criteria for the diagnosis of SS in Japanese patients. The study identified the differences among these three classification sets.

Patients and methods

Study population

The study subjects were 694 patients (51 males and 643 females) with a diagnosis of SS or suspected SS who had been checked for all four criteria of the JPN (pathology, oral, ocular, anti-SS-A/SS-B antibody), and were followed up in June 2012 at ten hospitals across Japan (Kanazawa Medical University Hospital, Nagasaki University Hospital, Hyogo Medical University Hospital, Keio University Hospital, Tokyo Women's Medical University Hospital, Tsurumi University Hospital, Kyushu University Hospital, University of Occupational and Environmental Health Hospital, Kyoto University Hospital, and University of Tsukuba Hospital) that form part of the Research Team for Autoimmune Diseases, The Research Program for Intractable Disease of the Ministry of Health, Labor and Welfare (MHLW).

Data collection and analysis

We collected clinical data from the above ten hospitals using a questionnaire. We retrospectively examined the clinical diagnosis made by the physician in charge, as well as the satisfaction of the JPN, AECG, and ACR criteria. Because lissamine green ocular staining had not been adopted in Japan at the time of clinical examination, we regarded patients who had a positive rose bengal test or fluorescein staining test as having satisfied the ocular staining score in the ACR classification system.

We regarded the clinical diagnosis made by the physician in charge as the gold standard for the diagnosis of SS in this study. We compared the sensitivities and specificities of the JPN, AECG, and ACR diagnostic systems in the diagnosis of SS (both primary and secondary SS), primary

Table 4 The American College of Rheumatology classification criteria for SS (2012)

The classification of SS, which applies to individuals with signs/symptoms that may be suggestive of SS, will be met in patients who have at least 2 of the following 3 objective features:
1. Positive serum anti-SS-A/Ro and/or anti-SS-B/La or (positive rheumatoid factor and ANA titer ≥1:320)
2. Labial salivary gland biopsy exhibiting focal lymphocytic sialadenitis with a focus score ≥1 focus/4 mm^2
3. Keratoconjunctivitis sicca with ocular staining score ≥3 (assuming that individual is not currently using daily eye drops for glaucoma and has not had corneal surgery or cosmetic eyelid surgery in the last 5 years)
Prior diagnosis of any of the following conditions would exclude participation in SS studies or therapeutic trials because of overlapping clinical features or interference with criteria tests:
History of head and neck radiation treatment
Hepatitis C infection
Acquired immunodeficiency syndrome
Sarcoidosis
Amyloidosis
Graft vs. host disease
IgG4-related disease

SS, and secondary SS. Agreement between the three was assessed via the kappa coefficient.

Results

Diagnosis of SS (primary and secondary SS) and non-SS

Of the 694 patients, 499 patients did not have other well-defined CTDs, whereas 195 patients did. SS was diagnosed in 476 patients (302 primary SS, 174 secondary SS), whereas non-SS was diagnosed in 218 patients (197 without other CTDs, 21 with other CTDs) by the physician in charge (Table 6).

Sensitivities and specificities of the three diagnostic systems for SS

The sensitivities of JPN, AECG, and ACR in the diagnosis of all SS (302 primary SS and 174 secondary SS) were 79.6, 78.6, and 77.5 %, respectively, whereas the respective specificities in the diagnosis of all SS were 90.4, 90.4, and 83.5 %. The sensitivities of JPN, AECG, and ACR in the diagnosis of 302 primary SS were 82.1, 83.1, and 79.1 %, respectively, with specificities of 90.9, 90.9, and 84.8 %, respectively. The sensitivities of JPN, AECG, and ACR in the diagnosis of 174 secondary SS were 75.3, 70.7, and 74.7 %, respectively, with specificities of 85.7, 85.7, and 71.4 % (Table 7).

Table 5 Comparison of the items adopted in the JPN and AECG and ACR criteria

	JPN	AECG	ACR
Ocular symptoms	×	○	×
Oral symptoms	×	○	×
Ocular signs			
Schirmer's test	○	○	×
Ocular staining	○	○	○
Labial salivary gland biopsy	○	○	○
Salivary gland involvements			
Salivary secretion	○	○	×
Sialography	○	○	×
Scintigraphy	○	○	×
Autoantibodies			
SS-A	○	○	○
SS-B	○	○	○
ANA	×	×	○
RF	×	×	○

SS-A anti-SS-A antibody, *SS-B* anti-SS-B antibody, *ANA* anti-nuclear antibody, *RF* rheumatoid factor, ○ adopted, × not adopted, *JPN* the revised Japanese Ministry of Health criteria for the diagnosis of Sjögren's syndrome (1999), *AECG* The American-European Consensus Group classification criteria for Sjögren's syndrome (2002), *ACR* American College of Rheumatology classification criteria for Sjögren's syndrome (2012)

Table 6 Diagnosis of SS and non-SS

	Associated with other CTDs		Total
	No	Yes	
Clinical diagnosis			
SS	302 (primary SS)	174 (secondary SS)	476
Non-SS	197	21	218
Total	499	195	694

Clinical diagnosis diagnosis of SS by the physician in charge
CTDs connective tissue diseases

Comparisons of the satisfaction of the three diagnostic systems

Figure 1 displays Venn diagrams showing comparisons of the satisfaction of the three diagnostic systems. Among all SS patients ($n = 476$), more patients satisfied only the AECG criteria ($n = 42$) rather than only the JPN criteria ($n = 8$) or the ACR criteria ($n = 6$). The same tendency was also observed in patients with primary SS only and in those with secondary SS only. The diagrams indicate that the JPN and ACR diagnostic systems are similar, whereas the AECG diagnostic system is different from the other two. Table 8 shows the agreement among the three