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Research Article

Early Diagnosis of Sjogren's Syndrome: An Introduction to the Newly Designed Iran Criteria for Early Diagnosis of Sjogren's Syndrome

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Abstract

Background: The most commonly used American-European classification group (AECG) classification criteria for Sjogren's syndrome and the newly developed American College of Rheumatology (ACR)-Sjogren's International Collaborative Clinical Alliance (SICCA) classification criteria for Sjogren's syndrome both lack a good sensitivity for diagnosis. The corresponding author (ISA) present a new set of criteria according to the experience of more than 15 years of clinical practice in rheumatology: Iran Criteria for Sjogren's syndrome.

Methods: Iran criteria consist of two domains considering clinical manifestations of the disease and paraclinical findings. A total of 4 out of 10 points with at least one point from the domain of clinical manifestations make the diagnosis. Medical records of 42 patients at the outpatient Rheumatology Clinic of the author were reviewed for the data on new Criteria for Sjogren's syndrome, AECG and ACR-SICCA classification criteria for Sjogren's syndrome. Sensitivity of the three classifications was calculated considering the clinical diagnosis by a single rheumatologist as the gold standard.

Results: 6 male and 36 female patients with a mean follow-up duration of 22.86 ± 35.23 months were included. Mean age at diagnosis and mean disease duration were 47.36 ± 13.33 years and 24.43 ± 29.28 months, respectively. The sensitivity for new Criteria for Sjogren's syndrome, AECG classification criteria for SS and ACR-SICCA classification criteria for Sjogren's syndrome were calculated as 100%, 54.8% and 47.6%, respectively.

Conclusions: Iran-criteria for SS are a highly sensitive instrument for detecting Sjogren's syndrome compared with AECG criteria and ACR-SICCA criteria.

ABBREVIATIONS

AECG: American-European Classification Group; ACR: American College of Rheumatology; SICCA: Sjogren's International Collaborative Clinical Alliance; SS: Sjogren's Syndrome

INTRODUCTION

Sjogren's syndrome (SS) is a chronic autoimmune disease presenting with clinical hallmark of dry eye, dry mouth and salivary gland swelling and histological hallmark of lymphocytic infiltration of exocrine glands [1]. Several causes are explained for dry eyes such as prolonged working at computer monitor, aging and postmenopausal state, chemical burns, hypovitaminosis A, chronic blepharitis or conjunctivitis, prior keratoplasty, contact lens use, impaired blinking disease, herpetic ocular lesions, ocular pemphigoid, Stevens-Johnson syndrome, Grave's disease, drugs with anti-cholinergic properties, sarcoidosis, amyloidosis, IgG4-related systemic disease and specially SS. The causes of dry mouth include aging and postmenopausal state, complete fasting and dehydration, anxious individuals, drugs with anticholinergic properties diabetes mellitus, diabetes insipidus, previous head/neck irradiation, sialadenitis due to chronic obstruction, chronic viral infections, sarcoidosis, amyloidosis, IgG4-related systemic disease and specially SS. Parotid gland swelling can present in different forms including (i) acute bilateral parotid swelling due to viral infections, (ii) acute unilateral parotid swelling due to bacterial sialadenitis or stones, (iii) chronic or recurrent bilateral parotid swelling due to SS, diabetes mellitus, cirrhosis,

alcoholism, tuberculosis, malnutrition, acromegaly, bulimia, hepatitis C virus, HIV, sarcoidosis, amyloidosis and IgG4-related systemic disease, (iv) chronic unilateral parotid swelling due to tumors, stones, chronic bacterial sialadenitis and actinomycosis; although, SS most commonly presents with chronic or recurrent bilateral parotid swelling, it can present in any above mentioned forms of salivary gland swelling. Just like most of rheumatologic disorders, SS is identified by the presence of a combination of clinical and para-clinical features. Hence, in order to provide homogenous samples in clinical trials, many classification criteria for SS have been introduced [2]. Among the most commonly used criteria are the Preliminary European classification criteria for SS [3] which were developed in 1993 and later revised by the American-European classification group (AECG) in 2002 [4]. However, the studies comparing the prevalence of SS by using both 1993 and 2002 criteria showed that using the AECG criteria resulted in a lower prevalence of SS [5,6]; this was mainly due to the stringency of AECG criteria requiring presence of either histological manifestations of SS or SS specific autoantibody. Nonetheless, lack of appropriate diagnostic criteria for SS has made AECG criteria the most commonly used tool in the clinical practice to distinguish SS patients. The most recent classification criteria are proposed by American College of Rheumatology (ACR)-Sjogren's International Collaborative Clinical Alliance (SICCA) [7] which strictly relies only on the objective findings.

In the present study we aimed to introduce a new set of criteria for diagnosis of SS, IranCriteria for Sjogren's Syndrome, which is a result of more than 15 years of experience in clinical rheumatology; besides, we compare its sensitivity with the commonly used AECG classification criteria for SS and the newly developed ACR-SICCA classification criteria for SS in a sample of Iranian patients.

METHODS

Iran criteria for diagnosis of Sjogren's syndrome

Iran criteria for diagnosis of SS [created by Iraj Salehi-Abari entitled (ISA)] and the necessary explanations are presented in (Table 1). A patient with at least one of the complaints of pathologic dry eyes, pathologic dry mouth and salivary gland swelling in history, not better explained by another condition including sarcoidosis, amyloidosis, diabetes mellitus, prior head/neck irradiation, hepatitis C virus infection, acquired immunodeficiency syndrome, lymphoma, graft versus host disease, or use of anticholinergic drugs by history and/or physical examination can be evaluated for the SS using Iran criteria. The criteria consist of two domains: Domain I represents the clinical manifestations of the disease and Domain II takes para-clinical findings into consideration. A total of 4 out of 10 points with at least one point from Domain I make the diagnosis. The appropriate definition for each criterion is also presented in the table.

Table 1: Iran criteria for diagnosis of Sjogren's syndrome.

Iran criteria for Sjogren's Syndrome[ab]	Points
Domain I	**Up to 6 points**
· **Dry eyes**	Up to 2 points
➢ History of pathologic dry eye[c]	1
➢ Positive Schirmer test[d] or corneal ulcer[e]	2
· **Dry mouth**	Up to 2 points
➢ History of pathologic dry mouth[f]	1
➢ Beefy red tongue[g] or buccal salivary pearls[h]	2
· **Salivary gland swelling**[i]	Up to 2 points
➢ The first episode of swelling	1
➢ Chronic bilateral or recurrent swelling	2
Domain II	**Up to 4 points**
· **Autoantibodies**	Up to 2 points
➢ Positive RF or ANA	1
➢ Positive anti-Ro or anti-La	2
· **Pathology**[j]	Up to 2 points
➢ Simple lymphocytic infiltration[k]	1
➢ Lymphocytic infiltration with at least one focus score[l]	2

RF: Rheumatoid Factor; ANA: Anti-Nuclear Antibody
[a]Entry criteria: the presence of at least one of the complaints of pathologic dry eyes, pathologic dry mouth and salivary gland swelling in history, not better explained by another condition including sarcoidosis, amyloidosis, diabetes mellitus, prior head/neck irradiation, hepatitis C virus infection, acquired immunodeficiency syndrome, lymphoma, graft versus host disease, or use of anti-cholinergic drugs by history and/or physical examination.
[b]A total of 4 out of 10 points with at least one point from Domain I make the diagnosis.
[c]Eyes are pathologically dry if there is at least one of the following features: duration of at least 3 months; or gritty or sandy sensation in the eyes; or use of a tear substitute more than 3 times daily.
[d]Schirmer test involves placing a sterile filter paper strip beneath the lower eyelid for five minutes; if the moistened area measures less than 5 mm, the test is positive
[e]Detecting with slit lamp examination using Fluoroscein, Rose Bengal or other staining by ophthalmologist.
[f] Mouth is pathologically dry if there is at least one of the following features: duration of at least 3 months; or waking up at night to drink water because the mouth is too dry; or frequent drinking of water during eating dry foods or speaking.
[g] Dry scrotal tongue like beef.
[h]Concentrated drops of saliva similar to pearls attached to buccal mucosa.
[i]Swelling of major (parotid, submandibular, sublingual) salivary glands clinically or by imaging, with more than 3 weeks of duration means chronic swelling and with frequency of three episodes or more per year means recurrent swelling.
[j]Labial gland biopsy must be taken deeply from minor salivary glands of lower lip mucosa at a paramidline site
[k]Lymphocytic infiltration without malignant changes and granuloma.
[l]One focus score means at least 50 lymphocytes in at least 4 mm^2 of tissue.

Settings and the patients

After the study protocol being approved by the Medical Ethics Committee of Tehran University of Medical Sciences, the medical records of the patients with a definite diagnosis of SS, made by a single expert rheumatologist (ISA, the correspondent author) at the outpatient Rheumatology Clinic of the author (private sector) or Rheumatology Clinic of Amir-Alam Hospital (a general hospital with a tertiary otolaryngology referral center in Tehran, Iran) between 1998 and 2012 were reviewed. Otolaryngology specialists and infectious disease specialists cooperated in ruling out other suspected diagnoses when necessary. The patients

with incomplete medical records, those with overlap disease or secondary SS, the patients under classic treatment of SS and those being followed up for less than 3 months were excluded. Demographic and clinical information including gender, age and follow-up durations were gathered. The cut-off points of the laboratory normal ranges were considered to interpret the results of the serologic tests. The data on the Iran criteria for SS, the 2002 revised version of the AECG classification criteria for SS andthe newly developed ACR-SICCA classification criteria for SSwere extracted and the patients with definite diagnosis of SSaccording to each set of criteria were recognized.

Statistical analysis was conducted using SPSS software version 16.00 (SPSS Inc., Chicago, IL). The diagnostic capacity of Iran Criteria for SSwas compared with that of the 2002 revised version of the American Consensus Groupclassification criteria for SSand the newly developed ACR-SICCA classification criteria for SSby calculating sensitivity of the two sets of criteria using the following formula: Sensitivity = (number of the patients classified as SSby the criteria)/(number of the patients diagnosed as SSby an expert rheumatologist); the clinical diagnosis by rheumatologists was considered as the gold standard. Continuous and categorical variables are expressed as mean ± standard deviation (SD) and number (%), respectively.

RESULTS

The medical records of 42 patients with a mean follow-up duration of 22.86 ± 35.23 months were reviewed. The mean age of the patients was 47.36 ± 13.33 years. Frequencies of the findings for each criterion of IranCriteria for SS are expressed in Table 2. Sensitivity of Iran Criteria was calculated as 100% while the sensitivity of the 2002 revised version of the AECG classification criteria for SS was 54.8% in our study population and that of ACR-SICCA classification criteria was 47.6%.

Table 2: The demographic information of the patients and the frequency of the findings for each criterion of IranCriteria for Sjogren's syndrome (N=42).

Characteristics	Mean ± SD / N (%)
Male/female	6 (14.3) / 36 (85.7)
Mean age, years (min-max)	47.36 ± 13.33 (13-77)
Mean disease duration, months (min-max)	24.43± 29.28 (3-180)
Mean follow-up duration, months (min-max)	22.86 ± 35.23 (3-158)
History of pathologic dry eye	33 (78.6)
Positive Schirmer test	11 (26.2)
Corneal ulcer	3 (7.1)
History of pathologic dry mouth	39 (92.9)
Beefy red tongue or buccal salivary pearls	3 (7.1)
The first episode of salivary gland swelling (*unilateral involvement of left parotid gland*)	1 (2.4)
Chronic bilateral or recurrent salivary gland swelling	35 (83.3)
Bilateral involvement of parotid glands	29 (69.0)
Bilateral involvement of submandibular gland	4 (9.5)
Simultaneous involvement of parotid and submandibular gland	2 (4.8)
Positive RF	18 (42.9)
Positive ANA	17 (40.5)
Positive anti-Ro	14 (33.3)
Positive anti-La	6 (14.3)
Simple lymphocytic infiltration	2 (4.8)
Lymphocytic infiltration with at least one focus score	28 (66.7)
Iran Criteria for Sjogren's syndrome Positive	42 (100)
Revised version of the AECG classification criteria for Sjogren's syndrome Positive	23 (54.8)
ACR-SICCA classification criteria for Sjogren's syndrome Positive	20 (47.6)

RF*:* Rheumatoid Factor; ANA: Anti-Nuclear Antibody; AECG: American-European classification group; ACR: American College of Rheumatology; SICCA: Sjogren's International Collaborative Clinical Alliance.

DISCUSSION

The primary goal of this study was to introduce a new set of criteria for diagnosis of SS. In order to investigate the efficacy of our newly developed criteria for diagnosis of SS, we evaluated the medical records of an Iranian sample with clinical diagnosis of SS in a retrospective manner. A comparison was made between the sensitivity of Iran Criteria for SS and the commonly used 2002 AECG classification criteria and the newly developed ACR-SICCA classification criteria for SS. It was shown that the sensitivity of Iran Criteria for SS among our study population was 100% while AECG and ACR-SICCA classification criteria demonstrated lower sensitivities of 54.8% and 47.6%, respectively.

The emergence of biologic agents as the potential treatments of SS which are accompanied by serious adverse effects necessitates the need for establishment of reliable diagnostic criteria for early diagnosis of SS [8]. The items of such criteria need to be clear and easy to apply. Besides, although such criteria must respect the subjective complaints of SS such as dry eyes and dry mouth, they must take the importance of objective findings into consideration as well. The attempt to develop criteria able to diagnose SS has always been in prospect of researchers which resulted in emergence of more than 10 classification or diagnostic criteria since 1965 [3,4,7,9-12]. Among the most reliable criteria, the 1993 Preliminary European criteria was criticized for that one could be classified as SS in the absence of either autoantibodies or positive biopsy findings, which are considered as the systemic autoimmune pathological responses of the disease. This resulted in the development of 2002 AECG classification criteria which makes a diagnosis of SS in the obligatory presence of either salivary gland biopsy findings or positive serology for anti-Ro and anti-La [4]. The most recent classification criteria are proposed by American College of Rheumatology which strictly relies only on the objective findings of serology, pathology and ophthalmologic examination [7]. However, in the absence of appropriate diagnostic criteria, classification criteria are often missused in daily practice to facilitate the diagnosis process. Although highly specific, lack of an appropriate sensitivity leads the classification criteria to already miss a high proportion of patients. The experience of the author in clinical rheumatology during more than 15 years of practice revealed that the currently used criteria for diagnosing SS are poorly practical and the rheumatology society lacks a guideline for assessing the patients

suspicious for SS. Here, we propose a cost-effective diagnostic approach towards the patients suspicious for SS along with a set of diagnostic criteria, as well (Table 3).

As shown in (Table 1), the Domain I of New criteria consists of the clinical findings of SS. Considering more reliability of objective findings, for each subjective complaints of SS an equivalent objective assessment tool was defined which received a higher point of two. Since anti-Ro and anti-La are the most specific disease markers [13], they obtained a higher score compared with RF and ANA which only show the auto immune process of the disease [14]. Just like ACR-SICCA criteria, lymphocytic infiltration in salivary gland biopsy with at least one focus score was considered as a criterion but received 2 points when compared with a simple lymphocytic infiltration without granulomatous infiltration. There are several objective tests for quantifying xerostomia: Salivary gland scintigraphy is relatively insensitive being positive in approximately one-third of patients with SS [15]. Parotid gland sialography is limited by the risk of rupturing the duct and is forbidden during an episode of acute parotiditis [16,17]; besides, it is operator-dependent and needs experience [16]. Whole sialometry measures the rate of saliva production; a volume of saliva ≤1.5 mL after 15 minutes is considered to be a positive test. The lashly cup used in this test is not available in many countries and the collection process is difficult and is also affected by the variability of saliva secretion with the time of day [18]. In Saxon test the patient chews a gauze sponge for two minutes without swallowing; an increase in sponge weight of <2.75g over a two minute period suggests a positive test [19]. This test is also limited by the variation of saliva secretion during daytime, with meals and the stimulation by autonomic nervous system; besides, many patients do not tolerate the sponge in their mouth due to a sense of nausea and vomiting. All these tests are not included in our criteria due to low sensitivity or invasiveness.

Table 3: Amir Alam Hospital approach toward diagnosis of Sjogren's syndrome.

Step 1 · History and physical examination by rheumatologist · Schirmertest and slit lamp examination using Fluoroscein, Rose Bengal or other staining by ophthalmologist · CBC, ESR, CRP, FBS, SGOT, SGPT, BUN, Creatinine, Urinary analysis · RF, ANA, Anti-Ro, Anti-La · Chest X-Ray (posteroanterior) · Sonography of major salivary glands if needed
Step 2 · CT scanning or MRI of major salivary glands if needed. · Labial gland biopsy of minor salivary gland by otolaryngologist (or general surgeon) which must be taken deeply from lower lip mucosa at a paramidline site
Step 3 · Plasma IgG4 level and ACE in suspected status · HIV, HBsAg and Anti HCV checking in suspected status · Biopsy of involved major salivary gland by otolaryngologist
CBC: Complete blood cell; ESR: Erythrocyte Sedimentation Rate; CRP: C-reactive Protein; FBS: Fasting Blood Sugar; SGPT: Serum Glutamic-Pyruvic Transaminase; SGOT: Serum Glutamic Oxaloacetic Transaminase; BUN: Blood Urea Nitrogen; RF: Rheumatoid Factor; ANA: Anti-Nuclear Antibody; CT: Computerised Tomography; MRI: Magnetic Resonance Imaging; ACE: Angiotensin-Converting Enzyme, HIV: Human Immuno Deficiency Virus; HBsAg: Hepatitis B Surface Antigen; HCV: Hepatitis C Virus.

Diagnostic criteria are different from classification criteria in that they should have a high sensitivity in order to detect as many patients with the disease as possible while the classification criteria need higher specificity to provide a homogenous sample. Here we showed thatIran criteria for SS is a highly sensitive set of criteria in detecting SS patients. Besides, in order to prevent over-diagnosis, the presence of at least one of the complaints of pathologic dry eyes, pathologic dry mouth and salivary gland swelling in history, not better explained by another condition including sarcoidosis, amyloidosis, diabetes mellitus, prior head/neck irradiation, hepatitis C virus infection, acquired immunodeficiency syndrome, lymphoma, graft versus host disease, or use of anticholinergic drugs by history and/or physical examination are considered as the entry criteria; this approach for diminishing over-diagnosis is acceptable in other diagnostic criteria in rheumatology [20-22]. Although the triad of xerophthalmia, xerostomia and salivary gland enlargement is associated with three other diseases of sarcoidosis, amyloidosis and IgG4 related systemic disease as non-dominant clinical features, this triad is the dominant clinical presentation in SS [1,8]; absent of skin rash, uveitis, pulmonary involvement and fever rules out sarcoidosis and failure to find any sign or symptom suggestive of amyloidosis or IgG4 related systemic disease makes these diagnoses less possible. Nevertheless, SS is highly associated with risk of developingnon-Hodgkin lymphoma with lifetime risk of 16 to 44 times higher than normal population [23,24], sialadenitis, and sialolithias is; hence, the first clinical presentation of SS might be these conditions andwe suggest a patient with the clinical features of lymphoma in salivary gland, sialadenitis or sialolithiasis must be referred for rheumatologic consultation for at least one session.

Here we also suggest a three step approach towards diagnosis of SS (Table 3). Step 1 must be thoroughly followed for all suspected patients and when Iran Criteria for Sjogren'sSyndrome is satisfied, the physician do not need to go through the next steps. Step 2 consists of using more costly para-clinical instruments and invasive procedure of labial gland biopsy. We believe that the second step is not necessary for the patients satisfying Iran Criteria in step 1, and labial gland biopsy in step 2 is only necessary for patients not diagnosed in step 1 or for research purposes. If the diagnosis of SS is not yet confirmed after the second step, the physician must follow step 3.

CONCLUSION

Newly designed Iran criteria for Sjogren's syndrome is a highly sensitive instrument to detect SS compared with AECG and ACR-SICCA criteria. The corresponding author (ISA) believes the Iran criteria for sjogren syndrome is a highly sensitive instrument to detect SS in earlier phase of the disease compared with AECG criteria and ACR/SICCA criteria. Upon the opinion of the authors, the specifity of these new criteria is high, but due to low financial facilities, we were not able to confirm it by research. However the authors would like to invite the ACR and/or EULAR members and all other rheumatologists in the world to evaluate this new

criteria and AECG and ACR/SICCA criteria separately in the initial presentations of cases of SS, diagnosed by clinical/ laboratory judgments, and publish their findings worldwide.

DISCLOSURE

All authors declare that there has been no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; any other relationships or activities that could appear to have influenced the submitted work. This article and its Contribution contains no violation of any existing copyright, other third party rights, or any libelous statements, and does not infringe any rights of others; therefore have nothing to declare.

AUTHORS' CONTRIBUTION

All the authors contributed significantly to the conception and design, acquisition of data, analysis and interpretation of data, drafting the article, critically revising the article and final approval of the version to be published. Anyone who participated substantially in the study has not been omitted from the article. All persons listed as authors qualify for authorship.

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