

CONSENSUS

Expert consensus on quality control indicators of integrative medicine in primary Sjögren's syndrome (2023 version)

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Abstract

Treatment integrating traditional Chinese and Western medicine for primary Sjögren's syndrome (pSS) has yielded positive results and gained wide acceptance. However, the absence of standardized clinical management in certain regions has led to suboptimal outcomes in the diagnosis and treatment of pSS in China. In response, the Center for Traditional Chinese and Western Medicine at the China-Japan Friendship Hospital, in collaboration with the Beijing Association of Traditional Chinese and Western Medicine Rheumatology Professional Committee, initiated a project led by the Traditional Chinese Medicine Department of Rheumatism. The project (Beijing Association of the Integrating of Traditional and Western Medicine standardization expert consensus record number: 2021Z031A3) aims to develop a set of quality control indicators for the integrated treatment of pSS using traditional Chinese and Western medicine. Based on the 2021 version, the consensus revision incorporates seven new items, focusing on essential assessment areas for pSS patients, treatment response, and healthcare cost management. The 2023 expert consensus update seeks to enhance pSS diagnosis and treatment practices in China, offering a benchmark for medical quality control.

INTRODUCTION

Primary Sjögren's syndrome (pSS) is a prevalent chronic systemic autoimmune disease that mainly affects the exocrine glands, especially observed in middle-aged and elderly women. The most common symptoms include dry mouth and dry eye, though the severity of the disease can vary widely. In severe cases, it may lead to pulmonary interstitial fibrosis, and in some instances, even respiratory failure [1, 2]. The incidence of pSS in the Chinese population is estimated to range from 0.33% to 0.77%, with rates as high as 2%–4.8% observed in the elderly population [3]. Given

the aging population, pSS significantly affects individuals' health and quality of life.

Within traditional Chinese medicine (TCM), pSS is recognized as “Zao Bi”. Specialists in Chinese medicine and integrated traditional Chinese and Western medicine rheumatology in China are applying these combined approaches to treat pSS. Accurate diagnosis and treatment, utilizing integrated traditional Chinese and Western medicine methods, have been effective in alleviating symptoms, improving quality of life, and delaying the progression of pSS in patients. It is imperative to establish standardized quality control indicators for integrated traditional Chinese and Western medicine treatment of

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pSS. The overarching goal is to enhance the management of clinical diagnosis and treatment of pSS.

Therefore, in November 2020, the Center for Integrated Traditional Chinese and Western Medicine at the China-Japan Friendship Hospital, headed by Traditional Chinese Medicine Department of Rheumatism and supported by the Rheumatology Professional Committee of the Beijing Association of Integrating Traditional and Western Medicine, employed the Delphi method to collate suggestions from integrated traditional Chinese and Western medicine rheumatology experts in Beijing and to draft an expert consensus (Beijing Association of Integrated Traditional Chinese and Western Medicine standardization expert consensus filing number: 2021Z031A3) [4]. However, as time progresses and new clinical evidence emerges, updating the expert consensus becomes inevitable. To align with the latest developments in clinical diagnosis and treatment of pSS and to advance medical care quality, the project team has initiated the revision of the consensus. This includes incorporating new items into the original version and drafting the “Expert consensus on quality control indicators of integrative medicine in primary Sjögren's syndrome (2023 Version)”. This consensus aims to guide rheumatologists in the standardized application of integrated traditional Chinese and Western medicine treatment of pSS and serve as a reference for medical management personnel in the quality control of these treatments.

METHODS

The Center for Integrative Medicine at the China-Japan Friendship Hospital has established a committee called Quality Control Guidance Committee for Integrative Medicine. This committee's main role is to coordinate all aspects of developing medical quality control indicators for integrated traditional Chinese and Western medicine. They prioritize diseases where both traditional Chinese and Western medical approaches offer beneficial treatments. To achieve this goal, they formed a Quality Standard (QS) group for integrative medicine for rheumatic diseases, which developed quality control indicators for pSS in adult patients. The indicators are clinically applicable and closely related to the disease's characteristics.

The QS group selected a panel of rheumatology experts in integrated traditional Chinese and Western medicine from China-Japan Friendship Hospital to conduct a literature search and drafted the “Quality control indicators for integrated traditional Chinese and Western medicine for primary Sjögren's syndrome (Draft)”. They consulted the Rheumatology Professional Committee of the Beijing Society of Integrated Chinese and Western Medicine and sought input from integrated traditional Chinese and Western medicine

rheumatology experts in Beijing through a Delphi questionnaire survey system. The quality control indicators were revised based on this feedback, leading to the formation of the expert consensus “Quality control indicators for integrative medicine for primary Sjögren's syndrome (2021)”. The quality control indicators were then revised based on this expert feedback, culminating in the expert consensus titled “Quality control indicators for integrative medicine for primary Sjögren's syndrome (2021)”.

Each quality control indicator in this standard has a clear definition and measurement method. It can be quantified by the ratio of numerator and denominator. Additionally, each quality control indicator is accompanied by clinical significance and usage instructions. This makes it easier for users to adopt. The experts evaluated the indicators and categorized them as A, B, or C. A represents important indicators and is recommended for inclusion, B represents general indicators, and C represents unimportant indicators not recommended for inclusion.

A total of 101 rheumatologists participated in the consensus formation process and 101 valid questionnaires were returned. Given the 2021 version's proven reliability, updates have been specifically targeted to include newly added items.

RESULTS

The expert consensus includes 16 quality control indicators for integrative medicine in primary Sjögren's syndrome (pSS). These indicators were agreed upon by a high percentage of experts, ranging from 68.3% to 98.7% agreement (Table 1).

The percentage of individuals with pSS who received confirmatory testing

The percentage of individuals with pSS who received confirmatory testing is a crucial factor in formulating an effective treatment plan. One important indicator is the percentage of pSS patients who received confirmatory testing. It is crucial to establish an accurate diagnosis before initiating a treatment plan. This indicator reflects the normative diagnosis of pSS patients and includes at least one antinuclear antibody profile and lip biopsy, along with existing diagnostic criteria.

The percentage of individuals with pSS who undergo disease activity assessment during hospitalization is being examined

Another indicator is the percentage of pSS patients who undergo disease activity assessment during

TABLE 1 Quality control indicators of integrative medicine in primary Sjögren's syndrome (2023).

Subject Indicators	Definition	Clinical significance	Explanation	Strength of recommendation	Agreement	
1	The percentage of individuals with pSS who received confirmatory testing	The proportion of pSS patients who had undergone confirmatory tests since the onset of the disease accounted for the total number of patients diagnosed with pSS in the same period	Diagnosis examination is an indispensable condition for diagnosing pSS and reflects the standardization of pSS diagnosis.	Diagnosis examination should include either a spectrum of anti-nuclear antibodies or a labial gland biopsy.	A: 74 B: 1 C: 1	97.4%
2	The percentage of individuals with pSS who undergo disease activity assessment during hospitalization is being examined	The proportion of hospitalized pSS patients who underwent pSS disease activity assessment during a unit of time, compared to the total number of hospitalized pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	The evaluation of disease activity uses the ESSDAI scale.	A: 75 B: 1 C: 0	98.7%
3	The proportion of patients diagnosed with pSS who are screened for overall symptoms	The proportion of pSS patients who underwent a comprehensive symptom assessment during a unit of time compared to the total number of pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	The overall symptom assessment uses the ESSPRI scale.	A: 74 B: 2 C: 0	97.4%
4	The percentage of pSS patients evaluated for extraglandular system involvement during hospitalization	The proportion of hospitalized pSS patients who underwent assessment of extraglandular system involvement during a unit of time compared to the total number of hospitalized pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	Systemic involvement includes the skin, muscles and bones, kidneys, respiratory system, digestive system, blood system, nervous system, and cardiovascular system.	A: 73 B: 3 C: 0	96.1%
5	The percentage of pSS patients evaluated for dry eye during hospitalization	The proportion of hospitalized pSS patients who underwent assessment of dry eye during a unit of time compared to the total number of hospitalized pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	The dry eye assessment uses Schirmer's test, Van Bijsterveld, etc.	A: 99 B: 2 C: 0	98.0%
6	The percentage of pSS patients evaluated for dry mouth during hospitalization	The proportion of hospitalized pSS patients who underwent assessment of dry mouth during a unit of time compared to the total number of hospitalized pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	The dry mouth assessment uses salivary flow rate, salivary ultrasonography, parotid scintigraphy, sialography, etc.	A: 98 B: 3 C: 0	97.0%

(Continues)

TABLE 1 (Continued)

Subject Indicators	Definition	Clinical significance	Explanation	Strength of recommendation	Agreement	
7	Proportion of pSS patients who completed MDT during hospitalization	Proportion of hospitalized pSS patients who completed MDT during a unit of time compared to the total number of hospitalized pSS patients during the same period.	Reflecting whether the diagnosis and treatment of the disease are standardized	MDT is a medical diagnosis and treatment model, which is patient-centered, and formulates personalized diagnosis and treatment plans for patients through multidisciplinary expert consultation and joint discussion	A: 81 B: 19 C: 1	80.2%
8	Percentage of inpatient pSS patients whose medical costs exceed or are significantly below DRG payment criteria	Proportion of hospitalized pSS patients with all costs incurred in the course of medical treatment during a single hospitalization that exceeded or were significantly below the DRG payment criteria, as a proportion of the total number of pSS inpatients admitted during the same period of hospitalization	The level of standardized treatment of different cases and the level of medical cost control in the diagnosis and treatment of pSS	Medical expenses include examination fees, treatment fees, drug fees, etc., and the DRG payment criteria are based on the current year's criteria of the National Health Security Bureau.	A: 72 B: 26 C: 3	71.3%
9	The rate of oral TCM usage among patients with pSS	The proportion of pSS patients taking oral Chinese medicine within a unit of time to the total number of pSS patients during the same period.	Participation in TCM treatment among patients with pSS	Oral TCM should be the related medication for treating pSS.	A: 74 B: 2 C: 0	97.4%
10	The utilization rate of external medical treatment among patients diagnosed with pSS can be enhanced by incorporating TCM treatments	The proportion of pSS patients receiving TCM treatment during a unit of time, compared to the total number of pSS patients during the same period.	Reflecting the participation of TCM treatment in patients with pSS	External treatment should be the treatment for pSS	A: 66 B: 9 C: 1	86.8%
11	The assessment of the quality of life for hospitalized patients with pSS	The proportion of hospitalized pSS patients who use the SF-36 scale to evaluate their quality of life during a unit of time compared to the total number of hospitalized pSS patients during the same period.	Reflect on whether the diagnosis and treatment of hospitalized patients with pSS are comprehensive	The evaluation of the quality of life is conducted using the SF-36 scale.	A: 75 B: 1 C: 0	98.7%
12	The completion rate of follow-up for patients diagnosed with pSS	The proportion of pSS patients who completed follow-up within a unit of time compared to the total number of pSS patients during the same period.	Reflecting the follow-up management level of pSS	Follow-up content includes ①Complete blood routine, urine routine, liver and kidney function, ESR, CRP, immunoglobulin examination, ESSPRI score every 3 months; ②Complete systemic involvement review every 6 months; ③Complete ESSDAI score annually.	A: 71 B: 4 C: 1	93.4%

TABLE 1 (Continued)

Subject Indicators	Definition	Clinical significance	Explanation	Strength of recommendation	Agreement	
13	Satisfaction assessment completion rate of pSS patients	The proportion of pSS patients who completed satisfaction evaluations within a unit of time to the total number of pSS patients during the same period.	Reflecting the comprehensive management level of pSS	Satisfaction evaluation adopts the hospital's satisfaction evaluation.	A: 68 B: 7 C: 1	89.5%
14	The percentage of pSS patients evaluated for sleep quality during hospitalization	The proportion of hospitalized pSS patients who underwent sleep quality assessment during a unit of time, compared to the total number of hospitalized pSS patients during the same period.	Reflect on whether the diagnosis and treatment of hospitalized patients with pSS are comprehensive	The evaluation of sleep quality is conducted using the PSQI scale.	A: 69 B: 28 C: 4	68.3%
15	The percentage of pSS patients evaluated for fatigue during hospitalization	The proportion of hospitalized pSS patients who underwent fatigue assessment during a unit of time, compared to the total number of hospitalized pSS patients during the same period.	Reflect on whether the diagnosis and treatment of hospitalized patients with pSS are comprehensive	The evaluation of fatigue is conducted using the MFI.	A: 75 B: 22 C: 4	74.3%
16	The percentage of pSS patients evaluated for anxiety and depression during hospitalization	The proportion of hospitalized pSS patients who underwent anxiety and depression assessment during a unit of time, compared to the total number of hospitalized pSS patients during the same period.	Reflect on whether the diagnosis and treatment of hospitalized patients with pSS are comprehensive	The evaluation of anxiety and depression is conducted using the HADS.	A: 80 B: 19 C: 2	79.2%

Note: A: important indicators that are recommended to be included. B: general indicators. C: unimportant indicators that are not recommended to be included. Agreement: The number of experts who recommended A was divided by the total number of experts to obtain the corresponding percentage.
Abbreviations: CRP, C-reactive protein; DRG, diagnosis related groups; ESR, erythrocyte sedimentation rate; ESSDAI, EULAR primary Sjögren's syndrome disease activity indexes; ESSPRI, EULAR primary Sjögren's syndrome patient-reported indexes; HADS, Hospital Anxiety and Depression Scale; MDT, Multidisciplinary Treatment; MFI, Multidimensional Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index; pSS, primary Sjögren's syndrome.

hospitalization. Following diagnosis, it is recommended to assess disease activity using the EULAR primary Sjögren's syndrome disease activity index (ESSDAI) scale [5]. This scale holds significant importance for determining the appropriate treatment regimen.

The proportion of patients diagnosed with pSS who are screened for overall symptoms

Patients diagnosed with pSS should also undergo an overall symptom assessment. This assessment is crucial as pSS often presents with symptoms such as dry mouth, dry eyes, fatigue, limb pain, severe thirst, polydipsia, polyuria, and frequent night awakenings, which greatly impact the patient's quality of life. TCM treatment has shown advantages for such patients, making overall symptom assessment important in guiding treatment choices. The EULAR primary Sjögren's Syndrome patient-reported indexes (ESSPRI) scale is widely accepted for evaluating overall symptoms [5].

The percentage of pSS patients evaluated for extraglandular system involvement during hospitalization

The degree of extraglandular system involvement in diagnosed patients should be assessed as a focal point, including the skin, musculoskeletal, renal, respiratory, digestive, hematogenous, nervous, and cardiovascular systems. Early diagnosis and treatment are essential as the involvement of critical organs, such as interstitial pneumonia and pulmonary hypertension, directly affects prognosis.

The percentage of pSS patients evaluated for dry eye during hospitalization

pSS mainly affects the exocrine glands, including lacrimal glands and salivary glands. The evaluation of lacrimal glands should be considered. Clinically, Schirmer's test and Van Bijsterveld are commonly used to assess lacrimal gland function.

The percentage of pSS patients evaluated for dry mouth during hospitalization

The evaluation of salivary glands should also be considered. Salivary flow rate, salivary ultrasonography, parotid scintigraphy, and sialography are commonly used to assess salivary gland function.

Proportion of pSS patients who completed MDT during hospitalization

A Multidisciplinary Team (MDT) brings together healthcare professionals from different fields to determine a patient's condition. Doctors discuss and evaluate the patient's condition from a multidisciplinary, multi-professional, and multi-angle perspective. They combine existing medical resources and technology to formulate personalized treatment plans for patients, provide optimized and feasible reference opinions, give full play to the advantages of team cooperation, and improve the patient's condition to the greatest extent possible.

Percentage of inpatient pSS patients whose medical costs exceed or are significantly below DRG payment criteria

Diagnosis-related group (DRG) is a case-mix complexity system implemented to categorize patients with similar clinical diagnoses in order to better control hospital costs and determine payor reimbursement rates. Similar clinical pathways should be adopted to reduce the number of unnecessary medical procedures. Compliance with the pathway should be strengthened, and quality control management for excessive and insufficient priority cases should also be improved.

The rate of oral TCM usage among patients with pSS

The rate of oral TCM usage among patients with pSS. Once the diagnosis of pSS is established and the patient's condition is evaluated, the treatment plan should be tailored to the patient's preferences. In the integrated treatment of pSS using both traditional Chinese and Western medicine, the rate of oral TCM usage among patients with pSS is an important indicator to assess patient involvement in TCM treatment.

The utilization rate of external medical treatment among patients diagnosed with pSS can be enhanced by incorporating TCM treatments

External TCM treatments have demonstrated effectiveness in improving local symptoms of pSS patients. For instance, gargling with TCM has been shown to alleviate dry mouth, and is a convenient and low-risk treatment option. Other external treatments, such as acupuncture application, can also improve systemic symptoms through

overall conditioning. The utilization rate of external TCM treatment in treating pSS, as part of an integrated traditional Chinese and Western medicine approach, can serve as an important indicator of patient participation.

The assessment of the quality of life for hospitalized patients with pSS

The assessment of the quality of life for hospitalized patients with pSS is a crucial component in determining the efficacy of integrated traditional Chinese and Western medicine treatments. An accurate evaluation rate serves as a measure of the comprehensiveness of both diagnosis and treatment. The SF-36 scale is currently the most widely utilized evaluation method.

The completion rate of follow-up for patients diagnosed with pSS

The completion rate of follow-up for patients diagnosed with pSS is a crucial aspect of managing rheumatism and chronic diseases. Regular follow-up of pSS patients aids in timely monitoring changes in their condition and guiding medication, thereby ensuring effective management. It is recommended that follow-up should include regular laboratory tests and assessments of disease activity. This indicator serves as a reflection of the level of follow-up management of pSS.

Satisfaction assessment completion rate of pSS patients

Patient satisfaction surveys are considered important. The satisfaction rate of patients reflects the comprehensive management level of pSS.

The percentage of pSS patients evaluated for sleep quality during hospitalization

Sleep disturbances are commonly reported in pSS patients [6]. Sleep quality assessment is recommended for pSS patients internationally. Pittsburgh Sleep Quality Index (PSQI) is widely used to measure sleep quality in rheumatologic diseases, including pSS [7].

The percentage of pSS patients evaluated for fatigue during hospitalization

Fatigue, as a common symptom in pSS, is an enduring, subjective sensation of generalized tiredness or exhaustion. Despite the fatigue VAS section in ESSPRI,

Multidimensional Fatigue Inventory (MFI) is also recommended for assessing fatigue symptoms in pSS [8].

The percentage of pSS patients evaluated for anxiety and depression during hospitalization

The mental health of pSS patients is increasingly being taken seriously. A significantly higher prevalence of anxiety and depression has been consistently demonstrated in pSS patients compared with the general population [9, 10]. Hospital Anxiety and Depression Scale (HADS) is a self-administered scale, which is commonly used to determine the levels of anxiety and depression for patients.

SUMMARY

PSS is a prevalent autoimmune connective tissue disease, however, its clinical diagnosis and treatment standards, as well as research numbers, have not kept pace with rheumatoid arthritis and systemic lupus erythematosus. This is partly due to the diversity of clinical manifestations of the disease, which lack specificity and labeling, and the presence of highly specific antibodies, leading to frequent misdiagnosis and missed diagnosis.

In this article, we have systematically summarized consensus opinions on diagnosis, disease assessment, treatment, and management on pSS. Our consensus includes 16 distinct indicators, ranging from confirmatory testing rates and disease activity assessments to quality of life evaluations and the utilization of TCM treatments. Each indicator is defined by the proportion of pSS patients undergoing specific evaluations or treatments within a given timeframe, reflecting standardized practices in diagnosing and managing the disease.

Initially, ensuring a clear diagnosis of pSS is crucial, leading to our recommendation for antibody testing and labial gland biopsy. After diagnosis, both subjective and objective symptoms should be assessed, including disease activity, glandular involvement, and systemic involvement. Disease activity in pSS patients is rigorously assessed through the use of specific scales such as ESSDAI and ESSPRI. These indicators reflect the standardization in the diagnosis and treatment process, ensuring that disease progression and activity are closely monitored. Recently, the Sjögren's Tool for Assessing Response (STAR) [11] and the Composite of Relevant Endpoints for Sjögren's Syndrome (CRESS) [12] are also recommended to evaluate disease activity in pSS. Clinicians should choose the appropriate method and scale for assessment according to their needs.

The assessment of glandular involvement, specifically through evaluations for dry eye and dry mouth conditions, is critical. These assessments are standardized, employing specific tests that provide insights into the extent of glandular dysfunction in pSS patients.

The examination of extraglandular system involvement is pivotal, covering a broad spectrum of systems including skin, muscles, kidneys, and more. This indicator signifies the comprehensive approach needed to identify systemic manifestations of pSS and underscores the standardized nature of these assessments. It is also important to note that patients with pSS involving different systems should adopt individualized measures.

Furthermore, assessments for common symptoms associated with pSS, such as sleep quality, fatigue, and anxiety/depression, are essential for a holistic understanding of the patient's health status. These evaluations, using validated scales, reflect the comprehensive diagnosis and treatment approach, addressing the wide range of symptoms experienced by patients.

The treatment of pSS involves the utilization of oral TCM and external TCM treatments, highlighting the integration of TCM in managing the condition. These indicators demonstrate a significant consensus on the incorporation of TCM as a valuable component of the therapeutic strategy for pSS.

Finally, patient management encompasses MDT, the evaluation of medical costs in relation to DRG payment criteria, quality of life assessments, follow-up management, and satisfaction evaluations. These aspects emphasize the importance of personalized, patient-centered care plans and the comprehensive management of pSS, focusing on both clinical outcomes and patient satisfaction.

Overall, our consensus underscores the multifaceted approach required in managing pSS, emphasizing the role of standardized diagnostic and treatment protocols, the integration of TCM, and the assessment of patient quality of life and satisfaction with care.

In 2020, Chinese Sjögren's Syndrome Collaborative Research Group, Rheumatology and Immunology Physicians Committee of Chinese Medical Doctor Association formulated China's "Standardized Diagnosis and Treatment of Primary Sjögren's Syndrome" for the first time, taking a significant step toward promoting the development of pSS [13]. The formulation of this consensus will facilitate quality control of integrated traditional Chinese and Western medicine for pSS by medical and health managers, and improve the standard diagnosis and treatment of integrated traditional Chinese and Western medicine for pSS. This consensus is based on the expert opinions and clinical experience of experts in Beijing, and while it draws on a vast amount of literature both domestically and internationally, it will continue to be refined, supplemented,

and improved in practice. We invite feedback from our peers to refine and improve this consensus.

AUTHOR CONTRIBUTIONS

Qing-Wen Tao: Conceptualization; data curation; writing—original draft. **Jing Luo:** Conceptualization; data curation; methodology; writing—original draft; writing—review and editing. **Tzu-Hua Wu:** Data curation; formal analysis; writing—original draft; writing—review and editing. **Jian-Ming Wang:** Data curation; formal analysis. **Yuan Xu:** Data curation; formal analysis. **Di-Er Jin:** Data curation; formal analysis.

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CONFLICT OF INTEREST STATEMENT

All authors have no conflict of interest to disclose.

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