

Expert consensus on quality control indicators for integrative medicine in ankylosing spondylitis (2023 version)

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Abstract

The integrated treatment with Chinese and Western medicine plays an important role in the treatment of ankylosing spondylitis (AS), which can significantly relieve the patient's symptoms and improve quality of life. However, as a result of the lack of standardization of clinical management in some regions, the quality of AS treatment in China remains unoptimistic. In 2021, initiated by the Center for Integrative Medicine of China-Japan Friendship Hospital, led by the traditional Chinese medicine department of rheumatology of China-Japan Friendship Hospital, relying on the rheumatology branch of the Beijing Association of the integrating of traditional and Western medicine, and using the Delphi method, an expert consensus on "Quality Control Indicators for Integrative Medicine in Ankylosing Spondylitis" was established (Beijing Association of the Integrating of Traditional and Western Medicine Standardization Expert Consensus Filing Number: 2021Z031A2). The consensus revision updates the 2021 version by adding four items, which will provide a reference for the quality control of integrated traditional Chinese and Western medicine for AS in China and help improve the current diagnosis and treatment status of AS.

KEYWORDS

ankylosing spondylitis, indicators, integrated Chinese and Western medicine, medical quality

INTRODUCTION

Ankylosing spondylitis (AS) is a chronic inflammatory autoimmune disease characterized by systemic inflammation and osteogenesis that can lead to severe back pain and stiffness, and spinal and pelvic fusion [1, 2]. In addition to affecting patients' physiological function, it has a significant economic impact on families and the society as a whole [3]. The global prevalence of AS is estimated to be between 0.07% and 0.31% [4]. Current therapy for AS includes nonsteroidal anti-inflammatory

drugs (NSAIDs) and biologics, which significantly relieve clinical symptoms and improve quality of life. However, long-term NSAID therapy is associated with a number of potential risks, including cardiovascular, gastrointestinal, and renal risks [5]. Moreover, there has always been a concern about the high cost of biologics [6]. Therefore, there is an urgent need to develop better treatment.

AS belongs to the category of "da lv" in Chinese medicine and AS has long been treated with Chinese medicine, whose economics and efficacy have been

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proven in clinical practice. Increasing evidence shows that the integrated treatment of AS with Chinese and Western medicine may be a promising therapy. It was reported that Duhuo Jisheng decoction, a Chinese medicine formula, combined with Western medicine can effectively improve the effective rate, functional scores, and symptoms of AS patients, compared with the use of Western medicine alone [7]. Similarly, Fengshi Gutong capsule combined with NSAIDs can decrease the activity of disease in patients with active AS having good gastrointestinal tolerability after 4 weeks of treatment [8]. Although the integration of Chinese and Western medicine has been widely used for treating AS, there is currently no standard of clinical management for AS in some regions, which affects its clinical efficacy and inhibits the development of integrated Chinese and Western medicine in rheumatology. Therefore, it is urgently necessary to establish an expert consensus on quality control indicators for integrative medicine in AS.

In 2021, initiated by the Center for Integrative Medicine of China-Japan Friendship Hospital, led by the traditional Chinese medicine department of rheumatology of China-Japan Friendship Hospital, relying on the rheumatology branch of the Beijing Association of the integrating of traditional and Western medicine and using the Delphi method, an expert consensus on “Quality Control Indicators for Integrative Medicine in Ankylosing Spondylitis” was established (Beijing Association of the Integrating of Traditional and Western Medicine Standardization Expert Consensus Filing Number: 2021Z031A2). However, it was impossible for the outdated consensus to meet the changing clinical reality over time. Therefore, a new “Expert Consensus on Quality Control Indicators for Integrative Medicine in Ankylosing Spondylitis (2023 Version)” was re-launched by the rheumatology branch of Beijing Association of the integrating of traditional and Western medicine, which contributes to guide rheumatologists in the more standardized implementation of integrated traditional Chinese and Western medicine in the treatment of AS.

METHODS

The Center of Integrative Medicine of China-Japan Friendship Hospital established a Steering Committee for Quality Control of Integrative Medicine (the committee), which was responsible for developing medical quality control indicators for advantageous diseases of integrative medicine. Based on clinical level and patient management experience, the committee established a quality standard (QS) group for integrated Chinese and Western medicine for rheumatic diseases. The QS group was responsible for organizing and developing literature retrieval strategies, listing AS quality control indicators for integrative medicine, and discussing with research team members to form the “Preparatory Quality Control

Indicator System for Integration of Traditional and Western Medicine for AS”. Then, “Expert Consensus on Quality Control Indicators for Integrative Medicine in Rheumatoid Arthritis (2023 Version)” was formed through anonymous voting among senior experts in the rheumatology branch of Beijing Association of the integrating of traditional and Western medicine. In the consensus, each quality control indicator has a clear definition and measurement method, and the quality of the indicator can be quantified by the ratio of numerator to denominator. At the same time, each quality control indicator is accompanied by clinical significance. In the expert evaluation, “A” represents important and recommended for inclusion; “B” represents average; and “C” represents unimportant and not recommended for inclusion. A total of 101 scoring tables and valid questionnaires of expert consultation were collected. Due to the reliability of the 2021 version, this update is only justified for newly added items (Table 1).

RESULTS

The expert consensus contains 13 quality control indicators, with an agreement rate of experts' recommendations of 71.29%–100.0%. Compared to the 2021 version, four new indicators have been added: the proportion of AS patients undergoing standardized syndrome differentiation and treatment based on expert consensus, the proportion of AS patients undergoing surveillance on adverse events during the integrated treatment of traditional Chinese and Western medicine, the proportion of AS with health education during hospitalization, and percentage of AS inpatients whose medical costs exceed or are significantly below the diagnosis-related groups (DRG) payment criteria.

The proportion of AS patients undergoing diagnostic tests during hospitalization

The earliest lesion site in AS is sacroiliac joint, and X-ray changes in the sacroiliac joints have definite diagnostic significance. For early clinical or suspected cases, CT or magnetic resonance imaging examination of the sacroiliac joint can be chosen [9]. This indicator can reflect the standardization of diagnosis for AS patients. A total of 75 experts believe that this indicator is important and suggest inclusion, with a consensus of 98.7% among experts.

The proportion of AS patients assessed for disease activity during hospitalization

Disease activity can be used to evaluate the degree of remission under treatment and can also be used to

TABLE 1 Quality control indicators for integrative medicine in ankylosing spondylitis (2023).

Number	Indicators	Definition	Clinical significance	Explain	Recommendation strength ^a	Agreement rate ^b
1	The proportion of AS patients undergoing diagnostic tests during hospitalization	Number of inpatients who completed sacroiliac joint X-ray, CT, or MRI as a proportion of total inpatients in the same period	Reflecting the standardization of diagnosis for AS patients	Diagnostic examination includes sacroiliac joint X-ray, CT, or MRI	A: 75 B: 1 C: 0	98.7%
2	The proportion of AS patients assessed for disease activity during hospitalization	Number of inpatients assessed by ASDAS and/or BASDAI for disease activity assessment as a proportion of total inpatients in the same period	Reflecting the standardized disease activity assessment of AS	Disease activity assessment using ASDAS and/or BASDAI	A: 76 B: 0 C: 0	100%
3	The proportion of AS patients in remission period without severe comorbidities during hospitalization	Number of inpatients in remission period without severe comorbidities as a proportion of total inpatients in the same period	Reflect the ability to grasp the hospitalization indications of AS patients and manage medical resources	-	A: 67 B: 8 C: 1	88.2%
4	The proportion of AS patients taking Chinese herb decoction (Chinese patent medicine) during hospitalization	Number of inpatients taking Chinese herb decoction and Chinese patent medicine as a proportion of total inpatients in the same period	The participation of TCM in treatment	-	A: 71 B: 4 C: 1	93.4%
5	The proportion of AS patients using TCM external therapeutic methods during hospitalization	Number of inpatients treated with TCM external therapeutic methods as a proportion of total inpatients in the same period	Reflecting the participation of TCM external therapeutic methods	External therapeutic methods of TCM include acupuncture, moxibustion, bone righting, and hot compress.	A: 71 B: 3 C: 2	93.4%
6	The proportion of AS inpatient quality-of-life evaluation	Number of inpatients using the ASQoL scale for quality-of-life assessment as a proportion of total inpatients in the same period	Reflecting the comprehensive evaluation and management level of AS patients	Using the ASQoL scale	A: 75 B: 1 C: 0	98.7%
7	The proportion of AS patients with joint imaging evaluation during hospitalization	Number of inpatients with joint imaging completed as a proportion of total inpatients in the same period	Reflecting the comprehensive evaluation level of AS disease progression	Suggestion: (1) use MRI annually to evaluate the affected spine and joints; (2) X-ray assessment of the affected spine is performed every 2 years	A: 75 B: 1 C: 0	98.7%
8	AS patient follow-up completion rate	Number of patients completing follow-up visits as a proportion of the total number of patients in the same period	Reflecting the management level of AS follow-up	Follow up includes rechecking blood routine, liver and kidney function, CRP, and ESR every 3 months; using ASDAS or BASDAI for disease activity assessment, and ASQoL for quality of life assessment	A: 69 B: 5 C: 2	90.8%

(Continues)

TABLE 1 (Continued)

Number	Indicators	Definition	Clinical significance	Explain	Recommendation strength ^a	Agreement rate ^b
9	AS patient satisfaction assessment completion rate	Number of patients completing a satisfaction assessment as a proportion of the total number of patients in the same period	Reflecting the medical service level of AS	Using hospital satisfaction assessment	A: 65 B: 9 C: 2	85.5%
10	Compliance between TCM syndrome and recommended TCM syndrome by AS expert consensus	Number of patients undergoing standardized syndrome differentiation and treatment based on expert consensus as a proportion of the total number of patients in the same period	Reflecting the standardization of TCM treatment	Expert consensus: Adopting the "expert consensus on long term management of ankylosing spondylitis (2021)"	A: 91 B: 10 C: 0	90.1%
11	Surveillance on adverse event in the treatment of integrated traditional Chinese and Western medicine	Number of patients who undergo surveillance on adverse event during the integrated treatment of traditional Chinese and Western medicine as a proportion of the total number of patients in the same period	Reflecting the early warning ability for adverse events	Adverse reactions refer to events during the diagnosis and treatment process that may affect the diagnosis and treatment results, increase patient pain and burden, trigger medical disputes, and affect the normal operation of medical work	A: 90 B: 11 C: 0	89.11%
12	The proportion of AS with health education during hospitalization	Number of patients with health education in unit time as a proportion of the total number of patients in the same period	Reflecting the continuity of treatment and the degree of doctor-patient cooperation	Health education include diet, sleep, emotional regulation, exercise, etc.	A: 94 B: 7 C: 0	93.07%
13	Percentage of AS inpatients whose medical costs exceed or are significantly below the DRG payment criteria	Proportion of AS inpatients with all costs incurred in the course of medical treatment during a single hospitalization that exceed or are significantly below the DRG payment criteria, as a proportion of the total number of AS 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 AS	Medical expense include examination fees, treatment fees, drug fees, etc. and the DRG payment criteria is based on the current year's criteria of the National Health Security Bureau	A: 72 B: 26 C: 3	71.29%

Abbreviations: AS, ankylosing spondylitis; ASDAS, AS disease activity score; ASCoL, ankylosing spondylitis quality of life questionnaire; BASDAI, Bath AS disease activity index; CRP, C-reactive protein; DRG, diagnosis related groups; ESR, erythrocyte sedimentation rate; TCM, traditional Chinese Medicine.

^a"A" stands for important and recommended for inclusion, "B" stands for average, and "C" stands for unimportant and not recommended for inclusion.

^bAgreement rate = number of experts recommending A/total number of experts.

monitor changes in the patients' condition and treatment effectiveness, facilitating doctors to timely adjust treatment plans. It is recommended to use ASDAS (AS disease activity score) and/or BASDAI (Bath AS disease activity index) for disease activity assessment of AS patients [9]. A total of 76 experts believe that this indicator is important and suggest inclusion, with a consensus of 100.0% among experts.

The proportion of AS patients in remission period without severe comorbidities during hospitalization

Active AS patients and those with severe comorbidities need to be hospitalized to alleviate the disease and manage the comorbidities as soon as possible. Hospitalization of patients without obvious organ involvement or with worsening spinal lesions and in the state of disease remission will consume unnecessary medical resources. This indicator reflects the physician's ability to grasp the hospitalization indications of AS patients and manage medical resources. A total of 67 experts believe that this indicator is important and suggest inclusion, with an expert consensus of 88.2%.

The proportion of AS patients taking Chinese herb decoction (Chinese patent medicine) during hospitalization

Chinese herb decoction and Chinese patent medicine play an important role in the treatment scheme of integrated traditional and Western medicine for AS, and their usage rate reflects the participation of TCM in treating AS. In total, 71 experts believe that this indicator is important and suggest inclusion, with a consensus of 93.4% among experts.

The proportion of AS patients using TCM external therapeutic methods during hospitalization

TCM external therapeutic methods have unique advantages and potential in alleviating pain and stiffness in the lower back caused by AS, with flexible and diverse treatment methods, positive therapeutic effects, and few side effects. The commonly used external therapeutic methods of TCM include acupuncture, moxibustion, bone-setting therapy, application therapy, loutrotherapy, and ultrasonic atomization [10]. This indicator can reflect the participation of TCM external therapeutic methods in the treatment of AS. A total of

71 experts believe that this indicator is important and suggest inclusion, with a consensus of 93.4% among experts.

The proportion of AS inpatient quality-of-life evaluation

AS can lead to the loss of physiological function in patients, affecting their socialization and causing a decrease in their quality of life. An effective treatment plan can improve the quality of life of patients. It is suggested to use the Ankylosing spondylitis quality of life questionnaire (ASQoL) to assess the impact of AS on the quality of life of patients. The higher the ASQoL score, the poorer the quality of life. This indicator can reflect the comprehensive evaluation and management level of AS patients. A total of 75 experts believe that this indicator is important and suggest inclusion, with a consensus of 98.7% among experts.

The proportion of AS patients with joint imaging evaluation during hospitalization

Imaging evaluation contributes to better reflect disease activity and progression, providing reference information for the treatment and prognosis of AS. This indicator reflects the comprehensive evaluation level of AS disease progression. In total, 75 experts believe that this indicator is important and suggest inclusion, with a consensus of 98.7% among experts.

AS patient follow-up completion rate

Regular follow-up, assessment of disease, and adjustment of treatment are crucial for the medium and long-term management of AS. Suggested follow-up indicators include rechecking blood routine, liver and kidney function, C-reactive protein, and erythrocyte sedimentation rate every 3 months, evaluating disease activity using ASDAS or BASDAI, and evaluating quality of life using ASQoL. In all, 69 experts believe that this indicator is important and suggest inclusion, with a consensus of 90.8% among experts.

AS patient satisfaction assessment completion rate

The completion rate of patient satisfaction assessment can reflect the level of comprehensive management of AS and help doctors to improve their diagnosis and treatment. 65 experts believe that this indicator is

important and suggest inclusion, with a consensus of 85.5% among experts.

The proportion of AS patients undergoing standardized syndrome differentiation and treatment based on expert consensus

Treatment based on pattern identification is the fundamental principle of TCM for treating AS, and correct and standardized syndrome differentiation and treatment are the guarantee of therapeutic effect. "Consensus on Long-term Management of Ankylosing Spondylitis (2021)" can be referred to identify the syndrome and administer treatment [11]. Ninety-one experts believe that this indicator is important and suggest inclusion, with a consensus of 90.1% among experts.

The proportion of AS patients undergoing surveillance on adverse event during the integrated treatment of traditional Chinese and Western medicine

Adverse event refers to the event during the diagnosis and treatment process that may affect the diagnosis and treatment results, increase patients' pain and burden, trigger medical disputes, and affect the normal operation of medical work. Surveillance on adverse events contributes to ensure patients' safety. Ninety experts believe that this indicator is important and suggest inclusion, with a consensus of 89.11% among experts.

The proportion of AS with health education during hospitalization

Health education includes diet, sleep, emotional regulation, exercise, etc. Physiotherapy has been shown to be effective in improving spinal flexibility and fitness as well as reducing pain. Health education is beneficial for the health outcomes of AS patients and reduces medical costs. Ninety-four experts believe that this indicator is important and suggest inclusion, with a consensus of 93.07% among experts.

Percentage of AS inpatients whose medical costs exceed or are significantly below the DRG payment criteria

Responding to rising healthcare costs, a reform that shifts the payment of out-of-pocket costs from fee-for-service to DRG has been implemented [12]. It is important to develop the clinical pathway according to the characteristics of the DRG payment. Seventy-two

experts believe that this indicator is important and suggest inclusion, with a consensus of 71.29% among experts.

CONCLUSION

AS is a common rheumatic and immunological disease, and integrative medicine has achieved better results in treating AS. The selection of quality control indicators for integrated traditional Chinese and Western medicine in AS should consider multiple aspects such as the importance, scientificity, feasibility, and comparability. The establishment of expert consensus on the quality control indicator system can help us further standardize the quality management of integrated traditional Chinese and Western medicine in AS, contributing to the continuous improvement of AS diagnosis, treatment, and service level. This consensus is based on expert opinions and clinical experience in the Beijing region, which inevitably has certain limitations and needs to be continuously improved in practice. Therefore, this consensus will be regularly revised, supplemented, and improved based on academic development, and we hope that colleagues can provide valuable advice.

AUTHOR CONTRIBUTIONS

Qingwen Tao: Project administration; supervision. **Liubo Zhang:** Writing – original draft. **Zeran Yan:** Writing – review and editing; **Weiping Kong:** Investigation. **Yuan Xu:** Conceptualization. **Nan Zhang:** Writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

All authors declare that there are no conflicts of interest.

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