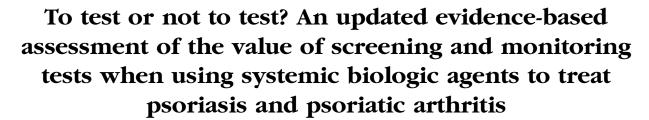
ORIGINAL ARTICLE



Christine S. Ahn, MD,^a Emily H. Dothard, BA,^a Michael L. Garner, BA,^d Steven R. Feldman, MD, PhD,^{a,b,c} and William W. Huang, MD, MPH^a

Winston-Salem and Chapel Hill, North Carolina

Background: Safety profiles of systemic biologic agents for the treatment of psoriasis and psoriatic arthritis (PsA) encompass a wide spectrum of adverse events. To date, no uniform evidence-based guidelines exist regarding screening and monitoring patients who are undergoing biologic therapy.

Objective: We sought to identify studies evaluating screening and monitoring tests in the treatment of psoriasis and PsA with systemic biologic agents, and to propose evidence-based practical guidelines.

Methods: The MEDLINE database was searched to identify data on risks associated with adalimumab, etanercept, infliximab, and ustekinumab. Articles were reviewed and graded according to methods developed by the US Preventative Services Task Force.

Results: Evidence was strongest (grade B) for tuberculosis screening. Interferon-gamma release assay was preferable to tuberculin skin testing. Among known hepatitis B virus carriers, the evidence grade was C for monitoring liver function tests and viral load.

Limitations: This study was limited by the lack of high-quality controlled trials evaluating screening and monitoring tests in patients treated with biologic agents.

Conclusions: Baseline tuberculosis testing remains the only screening test with strong evidence to support its practice. Other screening and monitoring tests commonly performed in patients who are taking biologic agents are supported only in certain clinical settings or lack evidence to support or recommend against their practice. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2015.06.004.)

Key words: adalimumab; biologics; etanercept; infliximab; monitoring; psoriasis; psoriatic arthritis; safety; screening; ustekinumab.

since the introduction of biologic agents in dermatology in 2002, they have become one of the most frequently used systemic

treatments for moderate to severe plaque psoriasis and psoriatic arthritis (PsA).¹ As clinicians have gained experience using biologics, the knowledge

From the Departments of Dermatology, Center for Dermatology Research, Pathology, and Public Health Sciences, Wake Forest School of Medicine, Winston-Salem, and the University of North Carolina School of Medicine, Chapel Hill.

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stock in Causa Research. Drs Huang and Ahn, Ms Dothard, and Mr Garner have no conflicts of interest to declare.

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Correspondence to: William W. Huang, MD, MPH, Department of Dermatology, Wake Forest School of Medicine, 4618 Country Club Rd, Winston-Salem, NC 27104. E-mail: whuang@wakehealth.edu.

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There are no evidence-based guidelines

for screening and monitoring patients

who are receiving biologic therapy for

• We found that evidence was strongest

support other routine testing; therefore,

(grade B) for tuberculosis screening

in patients treated with biologic

High-grade evidence is lacking to

judgement when screening and

physicians should use their clinical

monitoring patients who are taking

psoriasis and psoriatic arthritis.

CAPSULE SUMMARY

agents.

biologic agents.

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of potential adverse effects has expanded. Safety profiles of biologics include a wide spectrum of events, including opportunistic infections, the reactivation of infections, malignancy, hepatotoxicity, and the exacerbation of comorbidities.

Anti-tumor factor-alfa $(TNF-\alpha)$ necrosis agents that have been approved by the US Food

and Drug Administration (FDA) for the treatment of psoriasis and PsA include infliximab, etanercept, and adalimumab. Ustekinumab, an interleukin-12/23 monoclonal antibody, was approved by the FDA in 2009. Based on trials conducted for registration, the FDA recommends screening and monitoring in patients treated with systemic biologic agents.² As new adverse effects have emerged, professional dermatologic associations, like the American Academy Dermatology (AAD), the Japanese Dermatology Association (JDA), British Association of Der-

matologists (BAD), and the European Academy of Dermatology and Venereology (EADV) have attempted to provide guidance for screening and monitoring tests (Table I).3-10

In 2006, a previous systematic literature review sought to develop evidence-based guidelines for screening tests in the use of biologics. 11 Alefacept and efalizumab were discontinued in the United States and European Union in 2006, and ustekinumab has been introduced. The purpose of this study is to review the literature supporting the current recommendations for screening and monitoring with the use of currently available biologics. This study will highlight changes in screening and monitoring guidelines that have been recommended since our previous report and synthesize evidence-based guidelines for clinicians using biologics for the treatment of plaque psoriasis and PsA.

METHODS

The MEDLINE database was searched for studies pertaining to systemic biologic treatments and screening tests in the context of psoriasis and PsA. Additional articles not contained in the MEDLINE database were identified from citations within reviewed articles. 11 Search terms included: psoriasis or psoriatic arthritis, safety, screening tests, and biologic treatments (etanercept OR Enbrel OR adalimumab OR Humira OR infliximab OR Remicade OR ustekinumab OR Stelara). The search was limited to English articles published between July 1, 2006 and June 1, 2014. Case reports, data from animal studies, and studies involving

> multiple systemic agents used simultaneously or biologics used for indications other than psoriasis or PsA were excluded. Screening and monitoring tests in otherwise healthy patients without known comorbidities were distinguished from testing in patients with

> guidelines of the USPSTF and correlated to practice suggestions (Appendices A

preexisting comorbidities. Articles were reviewed and graded according to standardized methods developed by the US Preventative Services Task Force (USPSTF). Grades of evidence were determined using current

and B, available at http://www.jaad.org).

RESULTS

A total of 1039 articles were identified. Screening for relevant articles yielded 145 records. After articles were assessed for content and eligibility, 26 were included in the qualitative analysis (Fig 1). Among these, 16 studied screening tests in patients without comorbidities^{3,12-26} and 13 studied monitoring tests in patients with hepatitis C virus (HCV) infection, hepatitis B virus (HBV) infection, and congestive heart failure (CHF). 3,17,19,27-36

Screening and monitoring tests

Anti-TNF-α agents were studied in HBV and HCV, tuberculosis, and human immunodeficiency virus (HIV) screening, skin cancer screening, renal, hepatocellular, and biliary liver function, complete blood cell counts (CBCs), urine studies, pregnancy tests, antinuclear antibody (ANA) and doublestranded DNA (dsDNA), and C-reactive protein (CRP). Ustekinumab was studied with regard to tuberculosis and skin cancer screening (Table II).

The highest evidence grade for screening studies was B, seen in the use of tuberculin skin testing (TST) and interferon-gamma release assay (IGRA; Table II). Based on the USPSTF grading system, it is

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