eCMTA | Evidence-Based Chinese Medicine and Technology Assessment

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Review

Current status of health technology assessment in Korean medicine

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Received: November 25, 2024; **Revised:** February 24, 2025; **Accepted:** March 20, 2025

ABSTRACT

"The New Health Technology Assessment (nHTA) system" assesses the safety and effectiveness of new medical procedures using scientific evidence and supports research for technologies requiring additional validation. In this review, we summarize and discuss the current status and challenges related to the application and evaluation of Korean medicine within the HTA framework. Successful examples of implementation, such as Chuna Manual Therapy and customized herbal decoctions, are presented as cases of inclusion in national health insurance coverage. Additionally, this review examines the evaluation status of Korean medicine and explores strategies for its broader adoption and expansion in Korea.

KEYWORDS

health technology assessment, Korean medicine, scientific evidence

CITE THIS ARTICLE

Lee MS, Lee HW. Current status of health technology assessment in Korean medicine. Evidence-Based Chinese Medicine and Technology Assessment, 2025, 1: 9570003. https://doi.org/10.26599/eCMTA.2025.9570003

1. Introduction

Health technology assessment (HTA) is a vital method used in healthcare decision-making, providing multi-dimensional evidence that includes effectiveness, safety, economic implications, and ethical, social, cultural, and legal considerations.[1,2] This approach can be applied to both conventional medicine and traditional, complementary, and integrative medicine (TCIM).[1] The utilization and demand for TCIMs are increasing globally, along with efforts to assess its validity and supporting evidence.[3] However, most national health agencies and health-related organizations do not evaluate the efficacy of TCIM interventions, resulting in their exclusion from clinical practice guidelines.[4-6] There are few publications which discuss HTA and TCIM.[1,2,7,8] A review investigating the economic evaluation of Korean medicine technologies identified 27 conditions which had been evaluated in Korean medicine.[9] The study concluded that priority should be given to establishing robust clinical evidence for Korean medicine, enhancing its satisfaction and reliability within the healthcare system.[9] In Korea, the New HTA (nHTA) system assesses the safety and effectiveness of new medical procedures using scientific evidence and facilitates research for technologies requiring additional validation. We will discuss the current status and challenges in applying nHTA to Korean medicine.

2. Korean nHTA system

The primary goal of the nHTA in Korea is to safeguard public health and foster the advancement of medical technology by evaluating the safety and efficacy of new medical procedures that are not yet classified as covered or non-covered services under the national health insurance system.[10,11] As a result, all medical procedures, except those already classified as covered or non-covered, must undergo the nHTA to ensure their safety and efficacy before being implemented in clinical practice.[10] Consequently, the nHTA has attracted considerable interest from both the medical community and the broader healthcare industry in Korea.[10-12] Applicants for new medical technologies are required to first obtain a device license from the Ministry of Food and Drug Safety (MFDS) before submitting an online application for nHTA services.[11,12] To expedite market entry, the nHTA and insurance registration processes have been integrated, allowing them to be conducted simultaneously.[11,12] This integration has reduced approval times by up to 100 days and resolved delays previously caused by separate review processes for insurance inclusion.[10-12]

3. Application of nHTA to Koran medicine technologies

In the initial stages, Korean medical doctors showed limited interest in applying new Korean medicine technologies to the nHTA system. The demand for registration has been steadily increasing, and several studies have analyzed the trends in applying Korean medicine to the nHTA system.[9,13-18] In the field of Korean traditional medicine (KTM), a total of 44 applications for the nHTA were submitted between 2007 and 2019, including duplicate submissions and resubmissions.[10,18] Excluding duplicates and resubmissions, 35 unique applications were submitted. The number of applications is very low (2%) compared to conventional medicine (2040, 96%).[10,18] When categorizing the technologies into diagnostics and procedures, diagnostics accounted for 18 cases, while procedures made up 26 cases.[2,10] This distribution contrasts with the overall nHTA applications across all fields, where diagnostics represent 65.9% and procedures 32.6%.[2,10] The most of application have been failed to be approved by nHTA except emotional freedom techniques (EFT) in 2018. EFT applied for the evaluation of new medical technology in 2014 but was determined to be a developmental stage technology and was not recognized as a new medical technology. After supplementing its data over several years, it reapplied for evaluation in 2018 and was ultimately registered as a new medical technology after its safety and efficacy were recognized.

4. Examples of inclusion of Chuna manual therapy and herbal decoction in National health insurance coverage

One example of Korean medical techniques entering the National Health

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Insurance (NHI) system is Chuna Manual Therapy (CMT), which has been widely practiced in Korea. CMT coverage was the result of collaborative efforts by various stakeholders, beginning with a pilot coverage project in 2017, which eventually expanded nationwide in 2019.[19] The Multiple Streams Framework (MSF) revealed that this success was primarily driven by three key streams: a governmental change that supported the policy (political stream), growing demand from the general public and Korean medicine doctors (problem stream), and the strengthening of the policy's feasibility and acceptability (policy stream).[19] Furthermore, the roles played by policy entrepreneurs and the resulting systemic changes were significant in facilitating the overall process.[19]

Another project is the health insurance coverage of customized herbal decoctions, which addresses the highest demand for insurance coverage among Korean medical treatments.[20,21] This initiative was launched on November 20th, 2020, introducing a pilot health insurance fee schedule for herbal medicine to alleviate patients' financial burden and evaluate the appropriateness of providing health insurance benefits.[20] During the first pilot phase (November 2020 to April 2024), the clinical applicability of a health insurance coverage model for herbal medicine was successfully confirmed for three conditions: dysmenorrhea, facial palsy, and stroke sequelae.[20] In the second phase (from April 2024), the scope of coverage expanded to include three additional conditions with proven therapeutic benefits of herbal medicine: allergic rhinitis, functional dyspepsia, and herniated nucleus pulposus of the lumbar spine, increasing the total to six conditions.[21] Furthermore, the second phase introduced significant expansions in the scope and duration of health insurance coverage, as well as an increase in the number of participating medical institutions compared to the first phase.[21]

5. Summary

This paper provides an overview of the nHTA system in Korea and the current status of including Korean medicine in the nHTA framework. It highlights two successful examples of implementing Korean medicine techniques—CMT and customized herbal decoctions—into the NHI system in Korea.

To further promote Korean medicine technologies, a dual approach is recommended: enhancing the institutional aspects of the nHTA process and expanding policy and internal support mechanisms. Long-term success will depend on fostering collaboration between Korean medicine and conventional medicine. These strategies are crucial for integrating Korean medicine technologies into the broader healthcare system and ensuring their sustainable development.

Funding

This work was supported by Korea Institute of Oriental Medicine (grant no.:KSN2122211).

Author Contribution Statement

Myeong Soo Lee: Conceptualization, investigation, funding acquisition, supervision, writing – original draft, and writing – review and editing. **Hye Won Lee:** Conceptualization, project administration, and writing – original draft.

Declaration of Competing Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. Prof. Myeong Soo Lee is the Associate Editor-in-Chief of *Evidence-Based Chinese Medicine and Technology Assessment*, but he is not involved in the peer review or decision of this article.

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