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2023 Korean sexually transmitted infections treatment guidelines for *Mycoplasma genitalium* by KAUTII

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The Korean Association of Urogenital Tract Infection and Inflammation and the Korea Disease Control and Prevention Agency updated the Korean sexually transmitted infections (STIs) guidelines to respond to the changing epidemiologic trends, evolving scientific evidence, and advances in laboratory diagnostics and research. The main recommendations in the *Mycoplasma genitalium* infection parts of the Korean STIs guidelines 2023 revision are as follows: 1) For initial treatment: azithromycin 500 mg orally in a single dose, then 250 mg once daily for 4 days. 2) In case of treatment failure or recurrence, a macrolide susceptibility/resistance test is required, when susceptibility/resistance test is not feasible, doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally on the first day, then azithromycin 500 mg orally once daily for 3 days and then a test-of-cure should be considered 3 weeks after completion of therapy. 3) In case of macrolide sensitivity, doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally initial dose, then azithromycin 500 mg orally once daily for 3 days. 4) In case of macrolide resistance, doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by moxifloxacin 400 mg orally once daily for 7 days. In the Korean STIs guideline 2023, macrolide resistance-guided antimicrobial therapy was emphasized due to the increased prevalence of macrolide resistance worldwide. Therefore, in case of treatment failure or recurrence, a macrolide susceptibility/resistance test is required.

Keywords: Guideline; Mycoplasma genitalium; Sexually transmitted infections

INTRODUCTION

Mycoplasma genitalium infection is an emerging sexually transmitted infection (STI) that has gained increasing recognition and importance in recent years [1]. It is a small, non-motile, and cell wall-less bacterium that primarily infects the genital tract, causing various clinical manifestations, including urethritis, cervicitis, pelvic inflammatory disease (PID), and infertility [2]. *M. genitalium* was first identified in the early 1980s and was initially thought to be

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a commensal organism without any significant pathogenic effects [3]. However, subsequent research has established its role as a significant etiological agent of STIs, warranting the development of guidelines for its diagnosis, management, and prevention.

The prevalence of *M. genitalium* infection varies across different populations, but recent studies suggest a rising global prevalence, particularly among individuals with high-risk sexual behaviors [4-7]. The infection is often asymptomatic, making it challenging to identify and control its transmission [8,9]. Furthermore, the recent years, there has been a significant increase in the number of *M. genitalium* strains that are resistant to antibiotics [10-16]. This is a major concern, as it makes it more difficult to treat *M. genitalium* infections.

The consequences of untreated *M. genitalium* infection can be severe, with potential complications such as chronic pelvic pain, ectopic pregnancy, and adverse pregnancy outcomes [2,17,18]. Moreover, *M. genitalium* has been associated with an increased risk of human immunodeficiency virus (HIV) acquisition and transmission, highlighting the need for comprehensive management strategies to control its spread [19-21].

In response to the growing impact of *M. genitalium* infection, various international guidelines have been developed to assist healthcare professionals in effectively diagnosing and managing this STI [22-24]. Among these guidelines are the Korean STIs guidelines, which play a crucial role in the Korean healthcare system, providing evidence-based recommendations tailored to the local epidemiology and clinical practices.

This review article aims to critically evaluate the Korean STI Guidelines for *M. genitalium* infection, summarizing the key recommendations, their rationale, and the current evidence supporting their implementation. Ultimately, this review aims to enhance clinical decision-making and promote optimal patient care for individuals affected by *M. genitalium* infection in Korea.

MATERIALS AND METHODS

The Korea Centers for Disease Control and Prevention (currently the Korea Disease Control and Prevention Agency, KDCA) and the Korean Association of Urogenital Tract Infection and Inflammation (KAUTII) developed the first Korean STI guidelines in 2011, and later in 2016. The Korean STI guidelines 2016 was the first revision to be published. Six years after that, in 2022, the KDCA and KAUTII carried out the second revision of the guidelines from July 2022 to April 2023.

The development committee consisted of a steering committee, a development committee, a writing committee, an internal review committee, and an external review committee. The writing committee included the insurance team for insurance-related review, just like the first revision of the guideline. The external review committee consisted of the Korean Urological Association, the Association of Korean Urologists, the Korean Society of Obstetrics and Gynecology, the Korean Association of Obstetricians and Gynecologists, the Korean College of Obstetrics and Gynecology, the Korean Society for Laboratory Medicine, the Korean Society of Clinical Microbiology, the Korean Society of Infectious Diseases, and Division of HIV/AIDS Prevention and Control of KDCA. There was no conflict of interest at the beginning of development, and none was reported until the end of the development.

Following the recommendation of the Korea Medical Guideline Information Center (KoMGi), we took the form of local adaptation to accommodate and develop foreign guidelines to suit the Korean situation. Therefore, various search data sources were searched for the existing treatment recommendations for acceptance development. PubMed (https://www.pubmed.gov), National Institute for Health and Care Excellence (NICE, https://www.nice.org.uk), KoreaMed (https://www.koreamed.org), Trials registers (https://www.clinicaltrials.gov), SciELO (https://www.scielo.org), Scopus (https://www.scopus.com), Embase (https://www.embase.com), Google Scholar (https://scholar.google.com), Cochrane Library (https://www.cochranelibrary.com), National Guideline Clearinghouse, and CMA Infobase: Clinical Practice Guidelines database were used. The search index words were STI index words ("sexually transmitted infection" or "sexually transmitted disease") and treatment guideline index words ("guideline", "national guideline", "practice guideline", "management guideline", "consensus", "recommendation"). The range of publication dates was limited from January 2017 to December 2022, and the latest edition was selected if there was a revision. Then the 10 foreign STI guidelines that were searched were as follows:

- Guidelines for the management of symptomatic sexually transmitted infections, World Health Organization (WHO), 2021
- Sexually Transmitted Infections Treatment Guidelines, Centers for Disease Control and Prevention (CDC), 2021
- Sexually Transmitted Infections - Summary of Guidelines, New Zealand, 2017
- British Association for Sexual Health and HIV (BASHH) National Guideline on the Management of

Sexually Transmitted Infections and Related Conditions in Children and Young People, BASHH, 2021
- STI Treatment Pocket European Guidelines, International Union Against Sexually Transmitted Infection (IUSTI), 2019
- Alberta Treatment Guidelines for Sexually Transmitted Infections (STI) in Adolescents and Adults, Canada, 2018
- Reducing sexually transmitted infections, NICE, 2022
- Guidelines for the diagnosis and treatment of sexually transmitted diseases, Japanese Society for Sexually Transmitted Infections (JSSTI), 2020
- NT Guidelines for the Management of Sexually Transmitted Infections in the Primary Health Care setting, Northern Territory Government, 2019
- Australian STI Management Guidelines for Use in Primary Care, ASHM, 2021

After excluding guidelines that were not developed based on evidence or published without references, we evaluated five guidelines, including WHO, CDC, BASHH, IUSTI, and JSSTI. For quality evaluation, the K-AGREE 2.0 (Korean version of AGREE 2.0) evaluation development scale distributed by the KoMGi was used, and four members of the development committee evaluated six areas to obtain standardized scores for each area calculated. After comparing the scores of each area, two guidelines (WHO and CDC) were finally selected.

To adapt to the domestic situation, domestic data were searched and analyzed in all fields. Key questions were derived using the population or patient problem, intervention, comparison, outcome (PICO) technique. For the search of evidence for the literature review, PubMed and KoreaMed were used. For a recently published systematic review or meta-analysis, previously published literature with low level of evidence was excluded, and case reports were also excluded. The Delphi technique was applied to derive and adopt recommendations for the draft. A total of 17 panels were formed to ensure the representativeness and expertise of the recommendation development group.

The guideline development committee and the review committee for verification of the recommendations adopted by consensus operated independently. Finally, it was certified by the professional bodies that participated in the development: the Korean Urological Association, the Association of Korean Urologists, the Korean Society of Obstetrics and Gynecology, the Korean Association of Obstetricians and Gynecologists, the Korean College of Obstetrics and Gynecology, the Korean Society for Laboratory Medicine, the Korean Society of Clinical Microbiology, the Korean Society of Infectious Diseases, and Division of HIV/AIDS Prevention and Control of KDCA.

RESULTS

The main differences from previous guidelines are shown in Table 1. And the summaries of diagnosis, treatments, and follow-up monitoring in *M. genitalium* infection are shown in Fig. 1.

1. Diagnosis

M. genitalium can cause a variety of symptoms in both man and woman. However, many people with *M. genitalium* are asymptomatic [8,9]. The incubation period is usually 2 to 35 days (can be up to 60 days or more), and if left untreated, in woman, it can cause PID [17,18].

In man, *M. genitalium* can cause symptoms such as:
- Asymptomatic (70%)
- Urethral discharge
- Burning or itching sensation in the urethra
- Painful urination

In woman, *M. genitalium* can cause symptoms such as:
- Asymptomatic (40%–75%)
- Vaginal discharge
- Burning or itching sensation in the vagina
- Painful urination
- Dyspareunia
- Suprapubic or pelvic pain
- Vaginal bleeding between periods
- Vaginal bleeding after coitus

M. genitalium can cause PID in woman with symptoms such as:
- Fever
- Suprapubic or pelvic pain
- Dyspareunia
- Vaginal bleeding

M. genitalium is a small and fastidious bacterium that is difficult to culture in the laboratory. This is because *M. genitalium* requires a specific growth environment that is difficult to replicate in a laboratory setting. As a result, culture is not a reliable method for diagnosing *M. genitalium* infection. The most common method for diagnosing *M. genitalium* is a nucleic acid amplification test (NAAT). NAATs are highly sensitive and specific; therefore, they can detect even small amounts of bacteria and are unlikely to give false-positive results [25,26]. Multiplex polymerase chain reaction (PCR) is a type of NAAT that can be used to detect multiple pathogens in a single test. This makes it a more efficient and cost-effective way to screen for STIs.

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Table 1. Differences between the Korean sexually transmitted infection guidelines 2016 and 2023

	The Korean STI guidelines 2016	The Korean STI guidelines 2023
Diagnosis	Not described	In case of treatment failure or recurrence, a macrolide (azithromycin) susceptibility/resistance test is required.
Initial treatment	Azithromycin 500 mg orally in a single dose, then 250 mg once daily for 4 days (total 1.5 g). Alternative therapy: moxifloxacin 400 mg orally once daily for 7 days.	Azithromycin 500 mg orally in a single dose, then 250 mg once daily for 4 days (total 1.5 g).
When susceptibility/resistance test is not feasible	Not described	Doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally on the first day, then azithromycin 500 mg orally once daily for 3 days (total 2.5 g) and then a TOC should be considered 3 weeks after completion of therapy.
In case of macrolide sensitivity	Not described	Doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally initial dose, then azithromycin 500 mg orally once daily for 3 days (total 2.5 g).
In case of macrolide resistance	Not described	Doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by moxifloxacin 400 mg orally once daily for 7 days.

STI, sexually transmitted infection; TOC, test-of-cure.

In Korea, NAAT, especially multiplex PCR, is popular in diagnosing STIs and is also covered by the medical insurance system. This is because NAATs are considered to be the most accurate and reliable way to diagnose STIs in Korea. NAATs can be performed on a variety of samples, including self-obtained first-voided urine from man and vaginal or endocervical swabs by a physician from woman. Self-collected vaginal swabs by a woman are also available for NAAT and show equivalent sensitivity to physician-collected endocervical swab samples.

In Korea, the domestic prevalence of macrolide-resistant *M. genitalium* is still low compared to other countries, but fluoroquinolone resistance is high [27,28]. However, due to the increased prevalence of macrolide resistance worldwide, all *M. genitalium* positive specimens should be traced on an assay capable of detecting macrolide-resistant mutations. A variety of laboratory-developed test methods are available for this purpose [29-31]; however, macrolide or quinolone susceptibility/resistance tests for *M. genitalium* have not yet been activated in Korea.

2. Treatments

The initial therapy for the treatment of *M. genitalium*, recommended in the Korean STI guidelines 2016, is to administer 500 mg of azithromycin once a day orally, followed by 250 mg once a day for 4 days (total 1.5 g). However, azithromycin 1.5 g therapy may not be effective in cases of infections that have failed after a single dose of azithromycin 1 g or macrolide resistance has been confirmed.

The two-stage therapy involves using doxycycline as first-line therapy to reduce the bacterial load, followed by a high dose of azithromycin to treat macrolide-sensitive *M. genitalium*. This is a concept developed due to reports that the cure rate with azithromycin monotherapy was lower in high-load infections. Patients were treated with doxycycline, which lowers the load of *M. genitalium*, for 7 days while waiting for the result of macrolide resistance test. Then, azithromycin 1 g was administered orally, followed by azithromycin 500 mg orally once daily for 3 days (total 2.5 g) or moxifloxacin treatment for 7–10 days [32-34].

However, in Korea, the dose of azithromycin prescribed at one time is less than 1.5 g due to reimbursement issues. Therefore, the recommended initial treatment regimen in Korea is azithromycin 500 mg orally on the first day and then 250 mg once a day for 4 days (total 1.5 g).

The recommended treatments are as follows:

- Initial treatment: azithromycin 500 mg orally in a single dose, then 250 mg once daily for 4 days (total 1.5 g).
  In case of treatment failure or recurrence, a macrolide

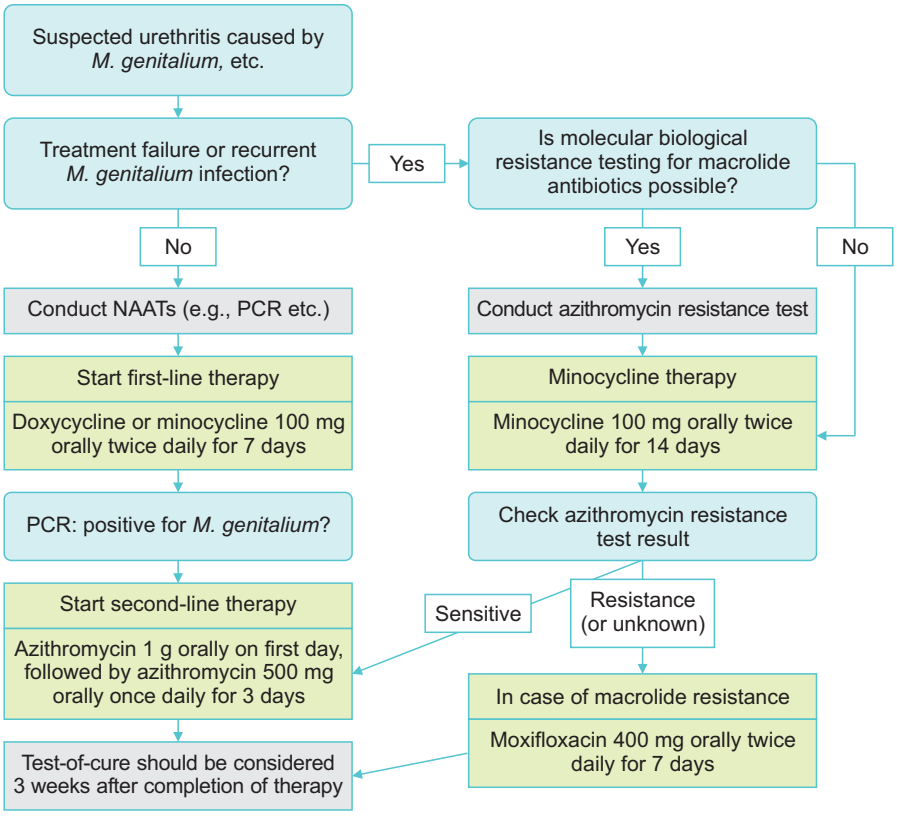

Fig. 1. Summary of *Mycoplasma genitalium* diagnosis, treatment, and follow-up monitoring. NAAT, nucleic acid amplification test; PCR, polymerase chain reaction.

(azithromycin) susceptibility/resistance test is required.

- When susceptibility/resistance test is not feasible: doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally on the first day, then azithromycin 500 mg orally once daily for 3 days (total 2.5 g) and then a test-of-cure (TOC) should be considered 3 weeks after completion of therapy.
- In case of macrolide sensitivity: doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by azithromycin 1 g orally initial dose, then azithromycin 500 mg orally once daily for 3 days (total 2.5 g).
- In case of macrolide resistance: doxycycline or minocycline 100 mg orally twice daily for 7 days, followed by moxifloxacin 400 mg orally once daily for 7 days.

3. Follow-up and monitoring

A TOC should be considered in all patients 3 weeks after completing treatment. NAAT is recommended for the TOC of *M. genitalium*. If the TOC is positive, it means that the infection has not been cured or reinfection, and therefore further treatment may be needed.

CONCLUSIONS

In the Korean *M. genitalium* guideline 2023, macrolide resistance-guided antimicrobial therapy was emphasized due to the increased prevalence of macrolide resistance worldwide. Therefore, in case of treatment failure or recurrence, macrolide (azithromycin) susceptibility/resistance test is required. This guideline will be updated when new facts about STIs are revealed and there is a reasonable need to improve the guideline. These guidelines provide guidance to physicians and other healthcare providers on the prevention and treatment of *M. genitalium*.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Seung-Ju Lee and Gilho Lee. Data acquisition: Sangrak Bae, Seong Woong Na, Hae Do Jung, and Hyun Jin Jung. Data analysis and interpretation: Seung-Ju Lee, Jin Bong Choi, and Gilho Lee. Drafting of the manuscript: Seung-Ju Lee and Jin Bong Choi. Critical revision of the manuscript: Seung-Ju Lee. Obtaining funding: Seung-Ju Lee. Administrative, technical, or material support: Seung Il Jung and Phil Hyun Song. Supervision: Gilho Lee. Approval of the final manuscript: all authors.

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