

Japanese guideline for clinical research of antimicrobial agents on urogenital infections: the first edition

Mitsuru Yasuda · Satoshi Takahashi · Hiroshi Kiyota · Kiyohito Ishikawa · Akira Takahashi · Shingo Yamamoto · Soichi Arakawa · Koichi Monden · Tetsuro Muratani · Ryoichi Hamasuna · Hiroshi Hayami · Tetsuro Matsumoto

Published online: 9 February 2011

© Japanese Society of Chemotherapy and The Japanese Association for Infectious Diseases 2011

Keywords Guideline · Urogenital infections · Antimicrobial agents · Clinical research · Clinical evaluation

Revision of criteria for evaluation of clinical efficacy of antimicrobial agents on UTI (including the title in the revised edition)

In the 1970s, clinicians and researchers specializing in urinary tract infections (UTIs) established and published the first-ever Criteria for Clinical Evaluation of Drug Efficacy on UTI. There had so far been no uniform criteria for the evaluation of drug efficacy, and different criteria for determining drug efficacy had been used in the development of drugs, which had caused problems in determining drug efficacy and had made it impossible to compare efficacy between drugs. To resolve these challenges, the Criteria for Clinical Evaluation of Drug Efficacy on UTI were established on the basis of the results of a large number of studies. The late Dr. Masaaki Ohkoshi, the late Dr. Joji Ishigami, the late Dr. Tsuneo Nishiura, Dr. Toyohei Machida, Dr. Yoshiaki Kumamoto, Dr. Joichi

Kumazawa, Dr. Yukimichi Kawada, Dr. Sadao Kamidono, and other senior physicians made efforts to create the world's first Criteria for Clinical Evaluation of Drug Efficacy on UTI, which had contributed enormously to the development of antimicrobial agents for UTIs. In 1989, an International Symposium entitled "Clinical Evaluation of Drug Efficacy on UTI" was held in Tokyo and offered opportunities to get international recognition of the Criteria for Clinical Evaluation of Drug Efficacy on UTI. Thereafter, the International UTI Symposium was established and came to be held biennially in conjunction with the International Congress on Chemotherapy. The joint symposium has been held ten times to date.

In Japan, the Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI were created by the UTI study group. The Criteria, which were those of the revised 3rd edition, involved various urological infections, including prostatitis, epididymitis, and urethritis, in addition to UTIs. Meanwhile, Infectious Diseases Society of America (IDSA)/ Food and Drug Administration (FDA) guidelines and the Criteria for Clinical Evaluation of Drug Efficacy were established in the United States and Europe, respectively, which led to an increased need for international harmonization as well as globalization of the development of antimicrobial agents. To move with the times and to allow compatibility between data accumulated in Japan and data from other countries, the Study Group on Urology, the Committee of Clinical Evaluation Methods, and the Japanese Society of Chemotherapy discussed and created the 4th edition of Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI (tentative) and its supplement in 1996.

However, further international harmonization was needed, as international drug development, extrapolation of clinical data from other countries, and bridging studies had been increasing. In bringing about international

M. Yasuda · S. Takahashi · H. Kiyota · K. Ishikawa · A. Takahashi · S. Yamamoto · S. Arakawa · K. Monden · T. Muratani · R. Hamasuna · H. Hayami · T. Matsumoto
UTI Subcommittee of the Clinical Evaluation Guidelines Committee, Japan Society of Chemotherapy, Tokyo, Japan

M. Yasuda (✉)
Department of Urology, Division of Disease Control,
Research Field of Medical Sciences, Graduate School of
Medicine, Gifu University, 1-1 Yanagido, Gifu 501-1194, Japan
e-mail: super7@gifu-u.ac.jp

harmonization, there were many challenges due to differences between Japan and Western countries in the classification and diagnosis of UTIs and in the criteria for the clinical evaluation of drug efficacy and for clinical response. Moreover, the 4th edition of the Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI (tentative) was not user-friendly, such that some clinicians suggested that the clinical evaluation of drug efficacy should be simplified for clinical practice. Based on these suggestions, we decided to review the Criteria for Clinical Evaluation of Drug Efficacy on UTI for revision.

The following committee proceeded with the review of the 4th edition and agreed that a new revised version should be called the 5th edition of the Criteria for Clinical Evaluation of Drug Efficacy on UTI. However, when the committee introduced the outline of the 5th edition at the 19th symposium on UTI and discussed it among the members, the majority agreed that the new edition should be named “Japanese Guideline for Clinical Research of Antimicrobial Agents on Urogenital Infections”. In addition to creating this guideline, we would like to express gratitude for the cooperation of the members of the Japanese UTI Research Group, who will be listed later.

Introduction

This guideline aims to objectively evaluate the efficacy of antimicrobial agents for the treatment of UTIs.

We have made efforts to allow use of the guideline in both general clinical studies and comparative studies and objective comparisons of individual study results. We have established the minimum necessary criteria in the guideline so that there is allowance to change items when considering individual cases or according to the practice of each institution.

General considerations

Target infections

Urological infections are classified as urinary tract infections (cystitis, pyelonephritis) and genital infections (urethritis, prostatitis, epididymitis) according to the site of infection. These infections are non-specific inflammations caused by common bacteria and are not specific inflammations caused by fungi, *Mycobacterium* species, viruses, etc.

Urinary tract infections include acute uncomplicated cystitis, acute uncomplicated pyelonephritis, and complicated urinary tract infection.

Urinary tract infections are classified as acute or chronic according to the clinical course, as uncomplicated and complicated by the underlying disease, and further, as cystitis and pyelonephritis by infected site. Generally, the disease name is based on a combination of the clinical course, underlying disease, and site of infection. Whereas uncomplicated urinary tract infections are infections with no underlying disease that could affect urination. Complicated urinary tract infections of limited sense are defined as infections with underlying disease that could affect urination and complicated urinary tract infections of wider sense are infections with underlying disease (diabetes, immunosuppression, etc.) that could induce, exacerbate, and prolong urinary tract infections, in addition to infections in the limited sense and infections in men. Complicated urinary tract infections were defined in the conventional Criteria for Evaluation of Clinical Efficacy of Antimicrobial Agents on UTI as infections with underlying disease in the urinary tract; namely, complicated urinary tract infections in the limited sense. Considering the following facts, that: (1) complications such as diabetes can induce, exacerbate, and prolong urinary tract infections, as can underlying diseases in the urinary tract; (2) urinary tract infections are retrograde infections, so that men tend not to develop retrograde infection compared with women, in whom the urethra is 10 times shorter than in men; and (3) even if a male patient is diagnosed as having no underlying diseases in the urinary tract, further examination finds that most male patients with UTI have underlying diseases, including impaired urine excretion, we have decided to employ the definition of complicated urinary tract infections in the wider sense in this guideline. It is preferable to exclude from the guideline patients with urinary diversion using intestinal segments or those with a catheter, other than a permanent catheter, because it is difficult to determine the response of such patients to antimicrobial agents.

Genital infections include urethritis, acute bacterial prostatitis, and acute epididymitis.

Prostatitis is classified into four categories according to clinical condition by the NIH: category I, acute bacterial prostatitis; category II, chronic bacterial prostatitis; category III, chronic pelvic pain syndrome/chronic pain syndrome associated with prostatitis (A, inflammatory; B, noninflammatory); category IV, asymptomatic prostatitis. We include only category I; namely, acute bacterial prostatitis, in this guideline because the disease is clearly associated with bacteria, antimicrobial agents are used for the treatment of the disease, and it is possible to evaluate the efficacy of antimicrobial drugs over a relatively short period. Likewise, regarding epididymitis, we include only acute epididymitis in the guideline.

Download English Version:

<https://daneshyari.com/en/article/6124171>

Download Persian Version:

<https://daneshyari.com/article/6124171>

[Daneshyari.com](https://daneshyari.com)