INPLASY

Efficacy and safety of Baloxavir Marboxil compared with Oseltamivir against influenza virus in children: A systematic review and meta-analysis

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Zhong, Li; Zhu, L; Huang, GD.

Corresponding author:
Li Zhong

hgd2014@163.com

Author Affiliation:
Guilin Medical University.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 July 2024 and was last updated on 12 July 2024.

INTRODUCTION

Review question / Objective Comparing the clinical efficacy and safety of baloxavir marboxil and oseltamivir against influenza viruses in children, to provide theoretical references for clinical practice.

Condition being studied Influenza seriously affects their health and quality of life, especially in young children and immunocompromised children, who are prone to develop severe cases after influenza due to the imperfect function of the immune system, these populations are also the most common to be resistant to neuraminidase inhibitors (NAIs). However, vaccination is not fully effective and the rate of vaccination needs to be increased. Therefore, early treatment with anti-influenza drugs is essential once children are infected with influenza. Baloxavir Marboxil (BXM) is a novel single-dose oral capsule-dependent nucleic acid endonuclease inhibitor antiviral drug with a mechanism significantly different from that of conventional NAIs, which is hydrolyzed in the gastrointestinal tract, intestinal epithelial cells, blood, and liver by arylacetamide deacetylase to the antiviral activity of marbofloxacavir. Baloxaviric acid targets the endonuclease activity of the acidic protein subunit within the influenza virus RNA polymerase. Thereby acting as a key link in viral replication. The metabolite baloxavir acid inhibits the endonuclease activity of the acidic protein subunit of influenza virus RNA polymerase, thereby directly inhibiting viral replication and exerting anti-influenza viral effects.Such a mechanism of action makes baloxavir marboxil a novel, highly effective and targeted drug for influenza treatment. In February 2018,baloxavir marboxil was the first to be approved for marketing in Japan. In October of the same year, Baloxavir marboxil was approved by the Food and Drug Administration (FDA) in the U.S. for the treatment of influenza A and B. In April 2021, China also approved the marketing of baloxavir marboxil for use in patients 12 years of age and older who have been suffering from acute, uncomplicated influenza with influenza symptoms for less than 48 hours.In March 2023, the use of baloxavir marboxil was further expanded when it

was licensed for broader clinical use. Today, the drug is now available for the treatment of simple influenza A and B in children aged 5 years and older, bringing a whole new treatment option for pediatric influenza patients. This important advancement undoubtedly offers new hope for pediatric influenza patients and heralds more effective treatments.for pediatric patients infected with influenza viruses, it is now unclear which treatment is better: oseltamivir or baloxavir marboxil.

METHODS

Search strategy Systematic searches were conducted in PubMed, Embase, Web of Science, Cochrane, Epistemonikos, China Knowledge Network (CNKI), Wipo.com, Wanfang Database, and China Biomedical Literature (CBL) databases by using a combination of free-word and subject-word searches. The search included articles published from the inception of each database through January 31, 2024. and collected literature that met the inclusion criteria. Search terms mainly include “influenza virus”; “children”; “baloxavir marboxil”; “baloxavir”; “Xofluza”; “BXM”; “S-033188”; "s-03344"; “Oseltamivir”; “Tamiflu”.

Participant or population (1) The included patients were diagnosed with influenza, including those presenting with clinical influenza-like symptoms or those diagnosed with influenza by laboratory testing; (2) Patients were ≤18 years of age; (3) No restrictions on gender, race or severity of illness.

Intervention Given antiviral treatment with baloxavir marboxil.

Comparator Given antiviral treatment with oseltamivir.

Study designs to be included The main types of literature included were randomized controlled studies, retrospective observational studies, or cohort studies.

Eligibility criteria Only articles published in Chinese or English were included.
Exclusion criteria
(1) Missing data from thesis (2) No available outcome indicators (3) Data duplication (4) Full text not available (5) Low quality of literature (6) Non-Chinese and English literature (7) Reviews, case reports, animal experiment type studies.

Information sources PubMed, Embase, Web of Science, Cochrane, Epistemonikos, China Knowledge Network (CNKI), Wipo.com, Wanfang Database, and China Biomedical Literature (CBL) databases.

Main outcome(s) The outcome indicators for this study include: (1) Clinical efficacy:①Time to remission of symptoms (TTAS) in patients with influenza was defined as the duration from the start of treatment to the assessed disappearance or remission of all influenza-related symptoms;②Time to regression of fever (TTRF) was defined as the time to return to a fever-free state (37.5°C);③ Change from baseline in 48-hour viral titer;④Change from baseline in viral RNA load at 48 hours (2) Security Indicators: Incidence of adverse events; incidence of serious adverse events.

Data management Endnote.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias Assessment Tool was utilized to assess the risk of bias in the randomized controlled trials that were included.
The Newcastle-Ottawa scale was employed to evaluate the three components of quality assessment—selection, comparability, and outcomes—in retrospective observational studies for cross-sectional research.

Strategy of data synthesis Using RevMan 5.4 software from the Cochrane Collaboration.

Subgroup analysis Subgroup analyses were performed when there was heterogeneity in the included literature for an outcome indicator.

Sensitivity analysis For assessing the robustness and reliability of meta.

Country(ies) involved China.

Keywords Baloxavir Marboxil; oseltamivir; safety; Clinical efficacy; Childhood Influenza.

Contributions of each author

Author 1 - Li Zhong.
Email: zl312336@outlook.com
Author 2 - Ling Zhu.
Email: 592054762@qq.com
Author 3 - Guidong Huang.
Email: hgd2014@163.com