INPLASY PROTOCOL

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Corresponding author:
Wenyu Hu

852885505@qq.com

Author Affiliation:
Department of Thyroid, Breast and Vascular Surgery, Xijing Hospital, Air Force Medical University.

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Conflicts of interest:
None declared.

Pyrotinib for HER2-positive metastatic breast cancer: a systematic review and meta-analysis

Hu, W[1]; Li, N[2].

Review question / Objective: **A systematic review and meta-analysis of the efficacy and safety (O) of clinical studies using a regimen containing pyrotinib (I) in patients with human epidermal growth factor receptor-2-positive metastatic breast cancer (P), Studies included single- or dual-arm clinical trials, including prospective and retrospective studies (S).**
Condition being studied: **According to the 2020 Global Cancer Statistics Report released by the World Health Organization (WHO), breast cancer increased by nearly 2.3 million cases (11.7%), surpassing lung cancer as the most common malignant tumor and the leading cause of cancer death in women.Pyrotinib is a small-molecule irreversible pan-ErbB receptor tyrosine kinase inhibitor independently developed in China. to function. A number of current clinical trials have shown that pyrotinib provides better and acceptable patient outcomes than lapatinib, a reversible HER2 tyrosine kinase inhibitor approved for the treatment of metastatic breast cancer security.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 March 2022 and was last updated on 16 March 2022 (registration number INPLASY202230076).

INTRODUCTION

Review question / Objective: **A systematic review and meta-analysis of the efficacy and safety (O) of clinical studies using a regimen containing pyrotinib (I) in patients with human epidermal growth factor receptor-2-positive metastatic breast cancer (P), Studies included single- or dual-arm clinical trials, including prospective and retrospective studies (S).**

Rationale: **PubMed, Embase, Web of Science and Cochrane Library databases**

were searched for all literatures in the last 5 years with "pyrrotinib", "metastatic or progressive" and "breast cancer" as the main search terms. Two search screeners independently screened the literature according to the inclusion criteria and extracted literature data. Corresponding methodological quality assessment tools were used to evaluate the included literature. Descriptive statistics (pooled means and proportions meta-analyses) were calculated using R.4.0.3, and for dichotomous variables, due to the heterogeneity of study size and the resulting large variability in proportions, we refer to a fix for heterogeneity Or a random-effects model to calculate weighted pooled event rates based on the number of clinically evaluable patients. Study heterogeneity was assessed by calculating the I2 statistic. I2 values of 25%, 50% and 75% were defined as low, moderate and high heterogeneity. When P50%, a random-effects model was used to summarize the heterogeneous effect sizes for each study, otherwise a fixed-effects model was chosen. Afterwards, the results were analyzed for publication bias using a funnel plot to control for published studies that may have reported different results from unpublished studies. We examined three tests of publication bias for the primary end point, and there was no publication bias by funnel plot analysis. Heterogeneity was tested by subgroup analysis.

Condition being studied: According to the 2020 Global Cancer Statistics Report released by the World Health Organization (WHO), breast cancer increased by nearly 2.3 million cases (11.7%), surpassing lung cancer as the most common malignant tumor and the leading cause of cancer death in women.Pyrotinib is a small-molecule irreversible pan-ErbB receptor tyrosine kinase inhibitor independently developed in China. to function. A number of current clinical trials have shown that pyrotinib provides better and acceptable patient outcomes than lapatinib, a reversible HER2 tyrosine kinase inhibitor approved for the treatment of metastatic breast cancer security.

METHODS

Search strategy: PubMed
#1 "Breast Neoplasms"[Mesh]
#2 breast cancer[Title/Abstract]
#3 #1 OR #2
#4 Pyrotinib[Title/Abstract]
#5 #3 AND #4
Embase
#1 pyrotinib:ab,ti
Web of science
#1 TOPIC: (pyrotinib)
Cochrane library
#1 (Pyrotinib):ti,ab,kw.

Participant or population: Patients with HER2-positive metastatic breast cancer.

Intervention: Pyrotinib.

Comparator: No or second-line medication for HER2-positive metastatic breast cancer.

Study designs to be included: Prospective or retrospective studies.

Eligibility criteria: A prospective or retrospective clinical trial of pyrotinib in the treatment of metastatic breast cancer, the primary outcome endpoints are objective response rate (ORR), progression-free survival (PFS), overall survival (OS), etc.

Information sources: PubMed, Embase, Web of Science and Cochrane Library databases.

Main outcome(s): Response rates of pyrotinib in metastatic breast cancer, such as objective response rate, complete response rate, partial response rate, etc. Survival outcomes, such as progression-free survival, in metastatic breast cancer treated with pyrotinib. In addition, the safety data for the clinical use of pyrotinib were pooled.

Data management: Using Endnote20 to manage documents.

Quality assessment / Risk of bias analysis: Corresponding methodological quality assessment tools were used to evaluate included studies, The Cochrane

collaboration's tool for assessing risk of bias was used to evaluate randomized controlled trial, the Newcastle-Ottawa Scale (NOS) was used to evaluate cohort studies and case-control studies, and Methodologival index for non-randommized studies (MINORS) tool was used to evaluate single-arm studies

Strategy of data synthesis: For meta-analyses of dichotomous variables, relative risk (RR) or odds ratio (OR) were selected as pooled statistics to describe the statistical results of multiple studies. Meta analysis of single rate data requires that the rate distribution should obey the normal distribution as much as possible. If the original rate does not obey the normal distribution, it can be transformed to conform to or close to the normal distribution, thereby improving the reliability of the combined results. The distribution determines which merging method to use. Single-group survival data (continuous variables) are summarized, the metamedian package is loaded through R, and the qe() function is used to perform meta-analysis (random effects model) through the quantile estimation method.

Subgroup analysis: Subgroup analysis for studies with greater heterogeneity.

Sensitivity analysis: Sensitivity analysis for studies with greater heterogeneity.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: breast cancer, Pyrotinib, metastatic tumor.

Contributions of each author:

Author 1 - Wenyu Hu.
Email: 852885505@qq.com
Author 2 - Nanlin Li.
Email: linanlingo@163.com