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Systematic review on the reporting quality of randomized controlled trials in patients with hepatitis B or C in China

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ABSTRACT

Background: The numbers of articles reporting randomized controlled trials (RCTs) on viral hepatitis in China have been increasing, but there have been few systematic studies evaluating the reporting quality of RCTs in this field. This study was performed to assess the reporting quality of RCTs on the treatment of hepatitis B and C in China from 1991 to 2015.

Methods: Articles published between January 1991 and December 2015 were identified via the PubMed, MEDLINE, and Embase databases using the key words "randomized clinical trials", "treatment", "therapy", "hepatitis B", "HBV", "hepatitis C", "HCV", "China", and "Chinese". The reporting quality was assessed against the Consolidated Standards of Reporting Trials (CONSORT) checklist.

Results: In total, 211 RCTs on the treatment of hepatitis B or C were included. The number of articles focusing on these RCTs increased rapidly over time, while the reporting quality improved steadily over time. Overall, compliance with the key components of the CONSORT checklist was low, with only 8.5%, 3.8%, and 11.4% of the articles fulfilling the reporting requirements of randomization, allocation concealment, and blinding, respectively.

Conclusions: Both the number and the quality of RCT articles were found to have increased steadily over the last two decades. However, compliance with the key components of the CONSORT checklist still needs improvement. It is hoped that the results of this study will lead to improvements in the reporting quality of clinical trials on hepatitis B and C in China.

Introduction

Hepatitis B and hepatitis C are among the most common infectious diseases with serious sequelae worldwide, especially in Asia (Schweitzer et al., 2015; Shepard et al., 2005; Messina et al., 2015; Zhang et al., 2015; Lu et al., 2013). The treatment of viral hepatitis has progressed greatly in the last two decades. Randomized controlled trials (RCTs) are generally regarded as the 'gold standard' design to assess the efficacy and safety of new therapies. Well-conducted and properly reported RCTs provide high-quality 'raw material' for the assessment of health technology and decision-making; however, they may provide misleading information (Xu et al., 2008; Jüni et al., 2001). The Consolidated Standards of Reporting Trials (CONSORT) statement was developed (first in 1998, and then revised in 2001 and 2010) to reduce the bias and improve the reporting quality of RCTs, and these guidelines are used widely to assess the reporting quality of RCTs (Schulz et al., 2010; Egger, 2001; Begg et al., 1996; Mills et al., 2005).

Numerous meta-analyses on RCTs have been conducted to assess the therapeutic efficacy and safety of hepatitis B and hepatitis C treatments (Lai et al., 2007). In these articles, allocation concealment and blinding have been addressed as key factors associated with the risk of bias (Simin et al., 2007; Zhao et al., 2011). However, few studies have specifically and systematically assessed the reporting quality of RCTs on the treatment of hepatitis B or hepatitis C according to the CONSORT guidelines. This study was performed to assess compliance with the CONSORT guidelines of RCT articles on the treatment of hepatitis B or C published from 1991 to 2015.

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Methods

Search strategy

The PubMed, MEDLINE, and Embase databases were searched systematically for all clinical trials published in English or Chinese using the following keywords: randomized clinical trials, hepatitis B or HBV, hepatitis C or HCV, China or Chinese, and therapy or treatment. The search was run on March 16, 2016 and included results between January 1, 1991 and December 31, 2015. Study protocols without results were not included in this systematic review.

The exact search string in PubMed was as follows:

#1. Hepatitis B or HBV (title/abstract)
#2. Hepatitis C or HCV (title/abstract)
#3. Treatment or therapy (title/abstract)
#4. China or Chinese
#5. #1 OR #2
#6. #5 AND #3 AND #4
#7. Limit #6 to humans, Chinese, and English

Inclusion and exclusion criteria

Trials were eligible if they had randomly assigned patients with hepatitis B or hepatitis C to at least two medical treatment groups and the corresponding author was from mainland China. The exclusion criteria were as follows: (1) not on patients with hepatitis B or hepatitis C; (2) not a randomized controlled trial; (3) not addressing clinical treatment or therapy (animal experiments, epidemiology, etiology, pathogenesis, pathology, diagnosis, and prognosis); (4) included patients with severe comorbidities such as diseases of the heart, brain, lung, or kidney, or infection with another virus such as HIV; and (5) corresponding author not from mainland China.

Data extraction

After the removal of duplicates, the final inclusion of articles in this study was determined through a screening of titles and abstracts by two authors (ZN and ZCL). The full texts of the articles included were independently assessed by two of the authors. The CONSORT 2010 checklist was used as the structured data extraction form. In addition, information on the year of publication, sample size, journal, citation on Web of Science, ethics approval, funding support (by government or by a company), and single or multicenter design was collected.

Assessment of quality

The reporting quality of each RCT was evaluated using the CONSORT 2010 checklist. Each item on the checklist was weighted equally, and the following criteria were used: a score of 1 was given if the details required by a CONSORT item had been reported, and a score of 0 was given if the details required by a CONSORT item had not been reported or were only partially reported. Overall compliance with the CONSORT guidelines was defined as the percentage of the CONSORT checklist items fulfilled by a paper, which was calculated by dividing the sum of a paper's scores by the total number of items on the CONSORT checklist (37 items).

Compliance with randomization, allocation concealment, and blinding was defined as studies reporting both item 8a (randomization method) and item 8b (type of randomization and details of any restriction), reporting both item 9 (mechanism of random allocation sequence) and item 10 (who is involved in the random allocation process), and reporting both items 11a (blinding details) and 11b (description of the similarity of interventions), respectively. Considering that these three aspects are the key elements in the CONSORT checklist, compliance with them was regarded as high reporting quality.

To avoid different interpretations of the CONSORT checklist, the assessment process started with a discussion of the first 10 papers reviewed. Then, two authors (ZN and ZCL) assessed the reporting quality independently. Discrepancies in compliance were resolved by discussion between the two authors. Any unresolved discrepancies were decided by a third author (KYY).

Statistical analysis

The number of publications and overall compliance with the CONSORT checklist were calculated with stratification of the publication years: 1991–1995, 1996–2000, 2001–2005, 2006–2010, and 2011–2015. Trend graphs were used to depict the changes in quantity and reporting quality of the publications over these periods. Pearson's Chi-square test was used to analyze the correlation between the study characteristics and the key elements (randomization and blinding) of the CONSORT guidelines. The non-parametric test (Z-test) was used to analyze the differences in characteristics (sample size and citation) between groups. A p-value of <0.05 was considered statistically significant.

Results

Article identification and data extraction

A total of 5746 studies were identified with the keywords, and 211 RCTs on the treatment of hepatitis B or C were finally included after screening the titles and abstracts (Figure 1).

Characteristics of the literature

The characteristics of the literature are shown in Table 1. All of the publications were submitted from mainland China: 65.9% ($n = 139$) of them were from university hospitals, 22.7% ($n = 48$) of them were multiple center RCTs, and 28.0% ($n = 59$) of them had ethics approval. Among all of the studies included, 35.1% ($n = 74$) were published in English and 64.9% ($n = 137$) were published in Chinese.

Trends in publication numbers and reporting quality

The number of publications is shown in Figure 2. Of the 211 RCT studies, 126 were published during the period 1991–2010 and 85 were published during the period 2011–2015, with an average increase of 230% every 5 years. The number of articles published in English increased steadily from 1991 to 2015, whereas publications in Chinese rose rapidly from 1991 to 2010 and then decreased significantly from 2011 to 2015.

While the number of publications increased rapidly, the reporting quality (measured by overall CONSORT compliance) improved slowly and steadily (Figure 3). The average overall compliance with the CONSORT checklist was 39.4% for the years 1991–1995, 48.0% for 1996–2000, 46.3% for 2001–2005, 48.0% for 2006–2010, and 54.2% for 2011–2015, with an average 3.0% increase every 5 years. The reporting quality of articles published in English improved rapidly starting in 2010, whereas the reporting quality of articles published in Chinese improved rapidly between 1996 and 2000.

Compliance with the CONSORT checklist

For all 211 studies, the average overall compliance with the CONSORT checklist was 49.2%, with compliance of 46.8% for studies