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Evidence-Based Integrative Medicine

Effects of Aidi Injection (艾迪注射液) with Western Medical Therapies on Quality of Life for Patients with Primary Liver Cancer: A Systematic Review and Meta-Analysis*

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ABSTRACT **Objective**: To evaluate the effects of Aidi Injection (艾迪注射液, AD) in combination with Western medical therapies (WMT) in patients with primary liver cancer (PLC). **Methods**: Randomized controlled trials (RCTs) comparing AD plus WMT with WMT alone were retrieved from inception to March 2013 by retrieving the literature database thoroughly and systematically. The extracted data from included studies were analyzed and synthesized by Review Manager 5.2 software. The Cochrane risk of bias tool was used to assess the quality of included studies, and Begg's and Egger's tests were used to evaluate the potential presence of publication bias. The studies were divided into 7 separate subgroups in terms of quality of life (QOL), recent chemotherapy and the incidence of leukocyte reduction. The subgroup analysis was applied to assess the heterogeneity between included researches, and the sensitivity analysis was used to weigh the stability of studies. **Results**: Twenty-four RCTs were included in this study. Compared with WMT used alone, AD as additional intervention was more effective on improving QOL ($P<0.01$), increasing short-term efficacy ($P<0.01$), prolonging life ($P<0.05$ or $P<0.01$), relieving clinical symptoms ($P<0.01$), and reducing adverse events (e.g. reduce white blood cell counts, $P=0.002$; reduce in platelet counts, $P<0.01$). Subgroup analysis showed that the hepatic artery interventions with AD was superior in improving QOL ($P<0.01$) and enhancing short-term response rates ($P=0.007$) and reducing white blood cell counts ($P=0.0004$) than hepatic artery interventions alone ($P<0.01$). The chemoembolization plus AD or the chemotherapy plus AD were both better than chemoembolization or the chemotherapy alone in improving the QOL and short-term response rate ($P<0.05$ or $P<0.01$). **Conclusions**: AD in combination with WMT improves QOL in patients with PLC. Considering the inherent limitations of the included studies, further well-designed, rigorously performed, high-quality, and double-blinded RCTs with large sample sizes are needed.

KEYWORDS Aidi Injection, primary liver cancer, quality of life, systematic reviews, Meta-analysis

Primary liver cancer (PLC), the most common gastrointestinal cancer, is a malignant tumor arising from hepatic cells or intrahepatic biliary epithelia that severely threatens patient health.[1] The incidence of PLC is ranked sixth among all malignant tumors worldwide, and it is emerging as the third leading cause of cancer-related mortality in the world. Approximately 748,300 cancer cases and 695,900 cancer deaths were recorded in 2008, and approximately 50% of these cases occurred in China.[2] The mechanisms of PLC have yet to be fully elucidated. Modern medical research has indicated that PLC is mainly related to hepatitis virus infection, liver cirrhosis, infections of aflatoxin and parasites, alcohol consumption, and drinking water.[3] The natural duration of PLC ranges from 3 to 6 months.[4] Patients diagnosed at the early stage of PLC achieve a better prognosis following radical surgery. Nevertheless, because the onset of PLC is subtle, most patients with PLC are diagnosed at intermediate or advanced stages; therefore, surgery is an option for less than 20% of patients. Most PLC patients are still treated with non-surgical approaches. Among these approaches, Chinese medicine (CM) offers an effective treatment for PLC.[5]

CM treatment of PLC improves quality of life

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(QOL) and cancer-related symptoms, prolonging survival and relieving side effects. Moreover, due to its relatively low costs, CM is suitable for long-term treatment in patients with PLC.[6]

Aidi Injection (艾迪注射液, AD, Guizhou Yibai Pharmaceutical Co., Ltd, Guizhou, China; lot number: Z52020236) is mainly composed of *Mylabris*, *Panax ginseng*, *Astragalus membranaceus* and *Acanthopanax senticosus*. As a new multi-target anti-cancer drug, AD could inhibit the proliferation of cancer cells and promote cell differentiation and apoptosis.[7-9] Norcantharidin and other various components, including ginsenoside Rg3 and Rh2, have varying roles in tumor occurrence, development, and metastasis. Therefore, they could be therapeutically effective as part of comprehensive treatment for PLC.[10] Compared with the majority of anti-cancer drugs that cause myelosuppression, AD can increase white blood cell (WBC) counts and enhance the body's immunity without myelosuppression.[11]

In the present study, we performed a systematic review and meta-analysis of randomized controlled trials (RCTs) completed or published before March 2013 on the treatment of PLC with AD. We aimed to examine the role of AD on QOL in patients with PLC.

METHODS

Inclusion and Exclusion Criteria

Inclusion criteria for this study were as follows: (1) studies of patients with PLC confirmed by pathology, cytology or imaging, according to National Comprehensive Cancer Network (NCCN) clinical guidelines for hepatobiliary cancers; (2) RCTs; (3) studies comparing the effects of AD plus Western medical therapy (WMT) with WMT alone in the treatment of PLC; and (4) studies including data on patient QOL and short-term response rates of chemotherapy. All studies that included patients with liver metastases or those with incomplete or inconsistent data were excluded.

Search Strategy

Electronic searches of the following databases (in English or Chinese) were conducted: Cochrane Library of Clinical Controlled Trials (Cochrane), Excerpt Medica Database (EMBASE, 1994 to March 2013), PubMed (1953 to March 2013), Wanfang Database (1998 to March 2013), China National Knowledge Infrastructure Database (CNKI, 1989 to March 2013) and China Science and Technology Journals Database (VIP, 1989 to March 2013). The search query was constructed using a combination of the following keywords: "Eddie injection", "ai di injection", "primary hepatic carcinoma", "primary liver cancer", "primary carcinoma of liver", "hepatocellular carcinoma" , "life quality or survival quality", "random".

Outcome Measures

The outcome measures of this study included the following: (1) primary outcomes: rate of short-term response to chemotherapy; QOL with karnofsky performance status (KPS) score ⩾ 10; (2) secondary outcomes: survival; improvement of clinical symptoms, such as abdominal pain and distension, fatigue, and loss of appetite; adverse events (AEs), including reduction in WBC and platelet counts.

Data Extraction and Quality Assessment

Before the systematic review, all investigators were trained and fully understood the concepts, methodologies, and techniques of evaluation systems, including study search, quality assessment, and data integration of randomized and non-randomized trials. Initially, two investigators independently screened the titles and abstracts of potentially eligible studies, then the article's full text was obtained for further evaluation. These studies were cross-checked, and any disagreements were discussed and resolved by consensus. Finally, data were extracted from each study using a standardized form. The following data were extracted: (1) sample sizes of the study population (treatment/control); (2) interventions; and (3) outcome measures.

The methodological quality of the included studies was assessed using the Cochrane Reviewers Handbook for RCT version 5.2, which consisted of 6 parameters of quality: (1) generation of allocation sequence; (2) allocation concealment; (3) blinding; (4) completeness of outcome data; (5) reporting bias; and (6) other bias.

All of the included studies were divided into 7 separate subgroups on the basis of treatment regimens: (1) those comparing AD plus chemoembolization versus chemoembolization alone (subgroup A); (2) those examining the effects of a combination therapy of AD and hepatic artery interventions compared with

hepatic artery interventions alone (subgroup B); (3) those comparing AD combined with chemotherapy and chemotherapy alone (subgroup C); (4) those assessing the effects of AD plus radiofrequency ablation versus radiofrequency ablation alone (subgroup D); (5) those comparing the combination of AD and WMT with WMT alone (subgroup E); (6) those examining AD combined with conventional treatment versus conventional treatment alone (subgroup F); and (7) those comparing AD plus proton radiation versus proton radiation alone (subgroup G).

Data Synthesis and Statistical Analysis

The meta-analysis was performed using RevMan software version 5.2 (Cochrane Collaboration Review Manager Software, Oxford, UK). Subgroup analyses were conducted based on clinical and methodological heterogeneity, and the statistical heterogeneity among trials was measured using I^2 statistics. Studies with an I^2 statistic < 25% were considered to have low heterogeneity; those with an I^2 statistic of 25% to 50% were considered to have moderate heterogeneity; and those with an I^2 statistic of 50% to 75% were considered to have a high degree of heterogeneity. However, studies with I^2 > 75% were not recommended for the pooled estimate. A fixed-effect model was used for the pooled analysis of studies without statistical heterogeneity; otherwise, the random-effect model was used. The measurement data were assessed using relative risk (RR) with a 95% confidence interval (CI), and all data were expressed as mean ± standard deviation ($\bar{x} \pm s$). Patients lost to follow-up were considered to be failures, then a sensitivity analysis was conducted to describe the worst-case scenario. A possible publication bias was tested with funnel plots.

RESULTS

Study Selection

After initial screening, 307 potentially relevant clinical studies were identified. Of these, 30 duplicate publications and 253 studies that did not meet the criteria of patients, interventions, and outcomes or that contained incomplete or inconsistent data were excluded. Finally, a total of 24 studies[12-35] that met the inclusion criteria were analyzed, all of which were published in Chinese (Figure 1).

Of the included 24 studies, 10 studies[14-16,20,22,24,25,31,32,35] compared the effects of AD plus chemoembolization with chemoembolization alone. Five studies[13,19,26,27,34] compared the combination of AD plus chemotherapy with chemotherapy alone. In addition, 4 of the included studies[17,29,30,33] assessed the effects of a combination of AD and hepatic artery interventions in comparison with hepatic artery interventions alone; 2 studies[20,22] compared AD combined WMT with WMT alone; 1 study[18] compared the effects of AD plus radiofrequency ablation with radiofrequency ablation alone; 1 study[12] compared AD combined with proton radiation versus proton radiation alone; and 1 study[28] examined the effects of AD in combination with conventional treatment versus conventional treatment alone.

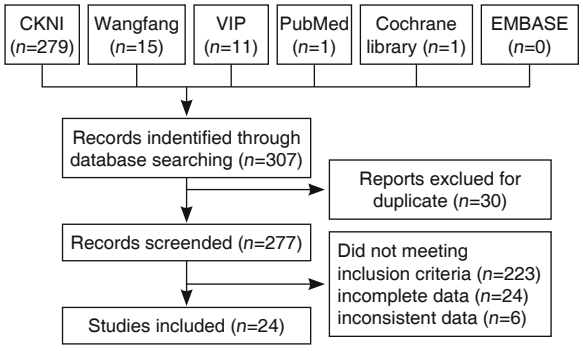

Figure 1. Flowchart of Studies Selection Progress

Characteristics of Included Studies

None of the included studies provided sample size calculations. Study sample sizes varied from 30 to 148 patients; 4 studies[15,17,33,34] included ⩾100 patients, accounting for 16.7% of all studies. Only 1 study mentioned the term "sortition randomization method", whereas the others used the term "random". Nevertheless, none reported the information on allocation concealment or blinding (Figure 2), and there were no patients lost to follow-up. The characteristics of included studies are shown in Appendix 1.

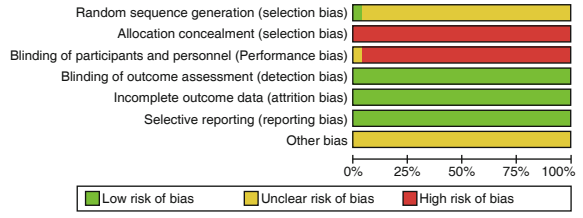

Figure 2. Risk of Bias Analysis

Publication Bias

Funnel plots of QOL data were created to assess publication bias. These funnel plots were asymmetrical, suggesting the possibility of bias (Figure 3).

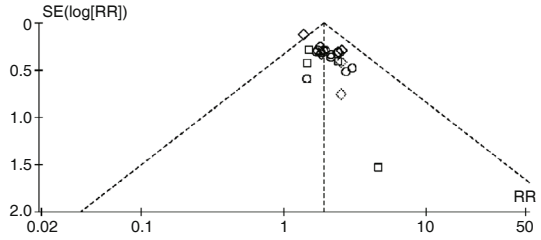

Figure 3. Funnel Plots of QOL Data

Notes: Subgroup analysis: ○Compared the effects of AD plus chemoembolization with chemoembolization; ◇Assessed the effects of a combination of AD and hepatic artery interventionsin; □Compared the combiation of AD plus chemotherapy with chemotherapy along; △Compared the effects of AD plus radiofrequency ablation with radiofrequency ablation; ×Compared AD combined with WMT with WMT alone; +Examined the effects of AD in combination with conventional treatment versus; ✱Compared AD combined with proton radiation versus proton radiation alone

QOL

QOL was assessed in all 24 studies,[12-35] which included a total of 1,811 patients. Findings from the meta-analysis revealed that QOL improved in the treatment groups compared with controls, with a pooled risk ratio (RR) >1 (pooled RR, 1.90; 95% CI, 1.66–2.16). The corresponding pooled RRs in each subgroup were as follows: group A: 2.03 (95% CI, 1.64–2.51); group B: 1.77 (95% CI, 1.49–2.19); group C: 1.72 (95% CI, 1.24–2.37); group D: 1.70 (95% CI, 0.91–3.16); group E: 2.50 (95% CI, 1.22–5.33); group F: 4.56 (95% CI, 0.23–91.30); and group G: 1.98 (95% CI, 1.11–3.52). In subgroups D and F, no differences in QOL were observed between treatment and control groups, with a pooled RR > 1. However, in the other subgroups, the improvement of QOL in the treatment groups was better than that in the control groups; the highest efficacy was exhibited in subgroup E, followed by subgroups A, G, B, and C (Appendix 2).

Short-Term Response Rates

In all 24 studies,[12-35] which included a total of 1,811 patients, the data were analyzed for short-term response rates. The meta-analysis showed that the response rates in the treatment groups were favorable compared with the control groups, with a pooled RR > 1 (pooled RR, 1.19, 95% CI, 1.19–1.42). In the subgroup analysis, the pooled RR in all subgroups were as follows: group A: 1.30 (95% CI, 1.12–1.51); group B: 1.29 (95% CI, 1.11–1.50); group C: 1.28 (95% CI, 1.02–1.60); group D: 1.26 (95% CI, 0.87–1.83); group E: 3.00 (95% CI, 0.86–10.43); group F: 6.36 (95% CI, 0.83–48.75); and group G: 1.04 (95% CI, 0.90–1.19). Patients in subgroups D, E, F, and G displayed similar response rates, which was reflected by the 95% CI including 1.0. Meanwhile, the other subgroups demonstrated higher response rates in the treatment groups when compared with the control groups, which were particularly higher in the subgroup A, followed by subgroups B and C (Appendix 3).

Survival

Five studies,[17,20,23,30,33] involving a total of 472 patients, were included in the meta-analysis of 6-month survival. No differences in 6-month survival were observed between treatment and control groups, indicated by 95% CI including 1.0 (pooled RR, 1.10; 95% CI, 1.00–1.22; Appendix 4A). In addition, 5 studies,[15,17,20,30,33] including a total of 580 patients, reported 1-year survival, and the statistical data were significantly favorable in the treatment groups compared with the control groups, with a pooled RR >1 (pooled RR, 1.34; 95% CI, 1.14–1.57; Appendix 4B). In addition, 2-year survival was reported by 5 studies,[15,17,20,30,33] comprising a total of 520 patients. The results of meta-analysis showed that the treatment groups had a higher 2-year survival than the control groups, with a pooled RR > 1 (pooled RR, 1.57; 95% CI, 1.21–2.04; Appendix 4C).

Improvement of Clinical Symptoms

Five studies[12,13,27,31,32] involving 326 patients were included in the meta-analysis of improvement of clinical symptoms. The improved clinical symptoms in the treatment groups were superior to the control groups, with a pooled RR > 1 (pooled RR, 1.78; 95% CI, 1.43 to 2.20; Appendix 5).

AEs

In this study, AEs were considered to include reduction in WBC and/or platelet counts. Nine studies,[15,19,20,27,29,30,31-33] involving a total of 726 patients, reported decreased WBC counts. The meta-analysis revealed significant differences between treatment and control groups in terms of reduction in WBC counts (pooled RR, 0.78; 95% CI, 0.66–0.91), and the treatment groups showed favorable results, with a pooled RR < 1. The pooled RRs in subgroups A, B, and C were as follows: group A: 0.83 (95% CI, 0.66–1.04); group B: 0.71 (95% CI, 0.59–0.86); and group C: 0.66 (95% CI, 0.23–1.85). In subgroups A and C, no differences between treatment and control groups were found, with 95% CI including 1.0, whereas in subgroup B, patients in the treatment

group showed significantly lower WBC counts than the control group (Appendix 6). In addition, 3 studies[15,19,27] involving 183 patients provided information on decreased platelet counts. In comparison with the control groups, the treatment regimens in the treatment groups could effectively prevent the reduction in platelet counts, with a pooled RR < 1 (pooled RR, 0.56; 95% CI, 0.44–0.72; Appendix 7).

Sensitivity Analysis

A high degree of heterogeneity was identified in the reduction of WBC counts. A sensitivity analysis showed that the fixed-effect and random-effect models yielded similar conclusions, with the pooled RRs of 0.78 (fixed-effect model, 95% CI, 0.71–0.86; random-effect model, 95% CI, 0.66–0.91). Therefore, the data in this meta-analysis were stable.

DISCUSSION

Based on our systematic review and meta-analysis, the results showed that AD as one adjuvant treatment of WMT for PLC was more effective. It could significantly improve QOL, enhance short-term response rates, prolong survival, improve clinical symptoms, and lower AEs in patients with PLC.

The results of the present study indicate a significant advantage of AD in combination with WMT compared with pure WMT. However, limitation of the current meta-analysis should be taken into account. First, the search did not include unpublished studies. Second, the included studies were poor in quality. The sample sizes in these studies ranged from 30 to 148, and only 4 studies (16.7%) included more than 100 patients. None of these studies provided sample size calculations, and the number of studies was very limited, which increases the risk of type Ⅱ errors. Third, only one study mentioned the term "sortition randomization method", and the others used the term "RCT". None of these studies described the random allocation, allocation concealment, or blinding in detail. Finally, data for analyzing survival, QOL, and AEs were limited and insufficient; thus, a publication bias might have existed for QOL.

In summary, in the current studies we demonstrated that AD combined with WMT shows potential for improving QOL, short-term response rates, survival, and clinical symptoms, as well as reducing the incidence of AEs. Nevertheless, at present, the available studies on the effects of AD combined with WMT on QOL in patients with PLC are poor in quality. Therefore, these studies do not provide a reliable basis for clinical trials. Further well-designed, rigorously performed, and double-blinded RCTs with multiple centers and large sample sizes are required. These future studies should use adequate random sequence generation, allocation concealment, and blinding methodologies, and the data regarding negative outcomes should be seriously considered. In addition, these studies should include long-term follow-up.

Conflict of Interest

None.

Authors' Contributions

Deng X designed the research project. Liang J was responsible for data analysis. Liu L prepared the manuscript and collected the documents. All authors read and approved the final manuscript.

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