INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Transcatheter arterial chemoembolization with portal vein radioactive seeds insertion for hepatocellular carcinoma with portal vein tumor thrombus: a meta-analysis

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Review question / Objective: **To assess the safety and efficiency of transarterial chemoembolization (TACE) and portal vein radioactive seeds insertion (RSI) combination for hepatocellular carcinoma (HCC) with portal vein tumor thrombus (PVTT) and provide a novel choice for clinical practice.**
Condition being studied: **Transarterial chemoembolization (TACE) is an effective treatment, with improved survival rates, for advanced HCC patients. However, no standard treatment has been established for HCC with PVTT. Only about 10JC30% of HCC cases are amenable to radical surgical resection at diagnosis. Based on the Barcelona Clinic Liver Cancer staging system, patients with HCC and PVTT are classified as BCLC-C stage, which is recommended sorafenib as the first-line therapy. However, in developing countries, the current cost of sorafenib prevents it from being used as a standard therapy for advanced HCC. A recent treatment strategy for HCC with PVTT is TACE with portal vein radioactive seeds insertion (RSI). The primary HCC can be treated by TACE and the PVTT can be resolved by the radioactive seeds brachytherapy. Many researchers have already explored this field, but the results in different studies were controversial. Simultaneously, these studies lack of large samples to demonstrate the safety and efficiency of TACE with RSI for HCC with PVTT.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 February 2021 and was last updated on 10 February 2021 (registration number INPLASY202120036).

INTRODUCTION

Review question / Objective: **To assess the safety and efficiency of transarterial chemoembolization (TACE) and portal vein radioactive seeds insertion (RSI) combination for hepatocellular carcinoma (HCC) with portal vein tumor thrombus**

(PVTT) and provide a novel choice for clinical practice.

Rationale: The pooled treatment response of HCC and PVTT, overall survival (OS), and treatment-related side effects are compared.

Condition being studied: Transarterial chemoembolization (TACE) is an effective treatment, with improved survival rates, for advanced HCC patients. However, no standard treatment has been established for HCC with PVTT. Only about 10JC30% of HCC cases are amenable to radical surgical resection at diagnosis. Based on the Barcelona Clinic Liver Cancer staging system, patients with HCC and PVTT are classified as BCLC-C stage, which is recommended sorafenib as the first-line therapy. However, in developing countries, the current cost of sorafenib prevents it from being used as a standard therapy for advanced HCC. A recent treatment strategy for HCC with PVTT is TACE with portal vein radioactive seeds insertion (RSI). The primary HCC can be treated by TACE and the PVTT can be resolved by the radioactive seeds brachytherapy. Many researchers have already explored this field, but the results in different studies were controversial. Simultaneously, these studies lack of large samples to demonstrate the safety and efficiency of TACE with RSI for HCC with PVTT.

METHODS

Search strategy: ((((((I[Title/Abstract]) OR (iodine[Title/Abstract])) OR (seed[Title/Abstract])) OR (Brachytherapy[Title/Abstract])) AND ((((hepatocellular carcinoma[Title/Abstract]) OR (HCC[Title/Abstract])) OR (hepatic cancer[Title/Abstract])) OR (liver cancer[Title/Abstract]))) AND (portal vein tumor thrombus[Title/Abstract])) AND ((transcatheter arterial chemoembolization [Title/Abstract]) OR (TACE[Title/Abstract])).

Participant or population: HCC with PVTT.

Intervention: TACE with portal vein RSI.

Comparator: TACE without portal vein RSI.

Study designs to be included: The inclusion criteria were as follows: Studies: comparative studies regarding of TACE with and without portal vein RSI; Diseases: HCC with PVTT; Languages: Not limited. The exclusion criteria were as follows: (a) single-arm studies; (b) non-human studies; (c) case reports; or (d) reviews.

Eligibility criteria: The inclusion criteria were as follows: Studies: comparative studies regarding of TACE with and without portal vein RSI; Diseases: HCC with PVTT; Languages: Not limited. The exclusion criteria were as follows: (a) single-arm studies; (b) non-human studies; (c) case reports; or (d) reviews.

Information sources: Relevant publications were searched in the scientific databases Pubmed, Embase, and Cochrane Library.

Main outcome(s): overall survival (OS).

Additional outcome(s): Treatment response of HCC and PVTT, and treatment-related side effects.

Data management: Two independent researchers scanned through the selected publications and extracted relevant data, namely study baseline data, patient baseline data, and treatment-associated data. Any discrepancies in the collected data were resolved by discussion with a third researcher.

Quality assessment / Risk of bias analysis: Two researchers independently conducted potential biases assessments. Randomized controlled trials are evaluated using the Cochrane risk of bias tool, and evaluated bias in the selection, performance, detection, attrition, reporting, and other biases. The retrospective studies are evaluated using the 9-point Newcastle-Ottawa scale, with scores of Ён 7, 4-6, and < 4 corresponding to low, moderate, and high bias risk, respectively.

Strategy of data synthesis: RevMan v5.3 software is employed for all data analyses.

Dichotomous variables were analyzed based on the odds ratios (ORs) and 95% confidence intervals (CIs), whereas continuous variables were analyzed based on the mean difference (MD) and 95% CIs. Survival times were calculated using the hazard ratio (HR) with a 95% CI. X2 and I2 tests were used to evaluate heterogeneity among the studies. A random-effects model was used in case of significant heterogeneity (I2 > 50%), while a fixed-effects model was used for all other analyses. Sources of heterogeneity were further examined using sensitivity analysis, while the risk of publication bias was assessed using funnel plots.

Subgroup analysis: None.

Sensitivity analysis: None.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Hepatocellular carcinoma; Portal vein tumor thrombus; Radioactive seed; Transcatheter arterial chemoembolization; Meta-analysis.

Dissemination plans: Publish the meta-analysis in a Journal.

Contributions of each author:
Author 1 - Yu-Fei Fu.
Author 2 - Yuan-Shun Xu.
Author 3 - Fu-Kang Yuan.