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Patient-Reported Outcomes Following Ablation for Primary Liver Cancer: A Systematic Review of Instruments, Clinical Evidence, and Conceptual Gaps

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2026 and was last updated on 26 April 2026.

INTRODUCTION

Review question / Objective We ask what patient-reported outcomes add to the care of patients with primary liver cancer undergoing local ablation. The review encompasses patients with primary liver cancer treated with radiofrequency ablation, microwave ablation, cryoablation, irreversible electroporation, or high-intensity focused ultrasound—alone or combined with transarterial chemoembolisation. Comparisons of interest include ablation versus resection, ablation versus TACE, head-to-head comparisons of ablative modalities, and pre- versus post-treatment trajectories within the same cohort. Outcomes span changes in validated PRO scores (EORTC QLQ-C30, QLQ-HCC18, FACT-Hep, SF-36, VAS), overall survival, and the prognostic discrimination of baseline PROs. Eligible study designs are randomised controlled trials and cohort studies.

Condition being studied Primary liver cancer is the sixth most commonly diagnosed malignancy worldwide and the third leading cause of cancer-related death. This dual ranking—high incidence combined with even higher mortality—reflects both biological aggressiveness and the challenge of detection at a curable stage. An estimated 905,000 new cases and 830,000 deaths occur annually, with over 90% of cases arising in low- and middle-income countries where viral hepatitis remains endemic. Geographically, the burden is concentrated in East Asia and sub-Saharan Africa, driven predominantly by chronic hepatitis B virus infection and, to a lesser extent, hepatitis C, aflatoxin exposure, and alcohol-related liver disease.

For patients diagnosed at Barcelona Clinic Liver Cancer stage 0–A, local ablation offers curative-intent treatment with minimal invasiveness. Thermal modalities (radiofrequency ablation, microwave ablation, cryoablation) and non-thermal techniques (irreversible electroporation, high-

intensity focused ultrasound) achieve complete tumour necrosis while preserving surrounding liver parenchyma. As indications broaden into combination strategies and as populations age, treatment selection increasingly requires information beyond tumour metrics and survival projections. Patient-reported outcomes capture symptom burden, functional capacity, and quality of life—dimensions that conventional radiological and biochemical endpoints do not address. The use of PRO instruments across the ablation care trajectory, from pre-treatment baseline assessment through perioperative recovery to long-term surveillance, remains incompletely mapped.

METHODS

Participant or population Patients with a confirmed diagnosis of primary liver cancer, at any Barcelona Clinic Liver Cancer stage. No restrictions on cirrhosis status, Child-Pugh grade, or prior treatment history.

Intervention Local ablative therapies for primary liver cancer: radiofrequency ablation, microwave ablation, cryoablation, irreversible electroporation, and high-intensity focused ultrasound. These interventions may be delivered as monotherapy or combined with transarterial chemoembolization, transarterial radioembolisation, or other interventional techniques.

Comparator Eligible comparators include: (1) surgical resection; (2) transarterial chemoembolisation alone; (3) an alternative ablative modality (e.g., RFA versus MWA); (4) ablation plus TACE versus ablation alone; and (5) pre-ablation versus post-ablation PRO scores within the same cohort. Studies without an external comparator arm that reported baseline and serial post-treatment PRO data were also included.

Study designs to be included Randomised controlled trials, prospective cohort studies, and retrospective cohort studies.

Eligibility criteria Inclusion Criteria: (1) Patients with pathologically or clinically confirmed: PLC; (2) Use of local ablative therapies, including radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, irreversible electroporation (IRE), or high-intensity focused ultrasound (HIFU); (3) Reported PROs, including health-related quality of life (HRQoL), symptoms, or functional status; (4) Randomized controlled trials (RCTs), prospective or retrospective cohort studies; (5) Peer-reviewed original research published in English.

Exclusion Criteria: (1) Non-PLC populations, including metastatic liver cancers; (2) No ablative treatment used; (3) No PRO-specific outcomes: studies using only clinician-reported measures (e.g., Karnofsky Performance Status, KPS) without patient-reported data; (4) Reviews, meta-analyses, case reports, case-control studies, conference abstracts, and preclinical animal models; (5) Non-English literature.

Prognostic Subgroup Analysis: Given the limited literature on the relationship between PROs and PLC ablation prognosis, we broadened the inclusion criteria for this subgroup. Studies primarily examining other locoregional therapies—such as transarterial chemoembolization (TACE) or surgical resection—were included if they used formal PRO assessments and included a certain proportion of ablation cases.

Information sources PubMed (MEDLINE), EMBASE and the Cochrane Library were searched from 1 January 2000 to 19 January 2026.

Main outcome(s) The primary outcome is patient-reported outcome data collected at any time point in the ablation care trajectory. This includes PRO scores obtained at baseline (pre-treatment), during the perioperative period, at early post-treatment follow-up (≤6 months), mid-term follow-up (6–12 months), or long-term follow-up (≥12 months).

Quality assessment / Risk of bias analysis For cohort studies, the Newcastle-Ottawa Scale (NOS) was used, with scores ranging from 0 to 9. We classified studies into three quality levels: high (≥7), moderate (5–6), and low (<5). For randomised controlled trials, the Cochrane Risk of Bias 2.0 (RoB 2.0) tool was applied across five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. An overall judgement of low risk, some concerns, or high risk was assigned. Certainty of evidence for each outcome was graded using GRADE (high, moderate, low, or very low), considering risk of bias, inconsistency, indirectness, imprecision, and publication bias.

Strategy of data synthesis A narrative synthesis was performed because clinical and methodological heterogeneity precluded meta-analysis. Studies were grouped by PRO instrument, comparator type, and timing of assessment, with findings summarised descriptively.

Subgroup analysis No formal subgroup analyses were performed. Studies were stratified narratively

by application domain (treatment comparison, combined therapy, prognosis prediction, different therapies, and baseline assessment) and by timing of PRO assessment.

Sensitivity analysis Sensitivity analyses were performed for the prognosis-prediction theme by excluding studies in which the majority of patients did not undergo ablation, to confirm the robustness of the association between baseline PROs and overall survival.

Country(ies) involved China.

Keywords primary liver cancer; ablation; patient-reported outcomes; quality of life; systematic review.

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