HISTOSONICS®

HISTOSONICS CLINICAL EVIDENCE PORTFOLIO

Review of scientific and clinical research regarding histotripsy

The following is a representative sample of published literature regarding histotripsy of liver tumors and is intended for healthcare professionals seeking information about clinical evidence on histotripsy.

Histotripsy is a novel procedure for the non-invasive destruction of liver tumors. Prospective studies were used to demonstrate safety and effectiveness and obtain an FDA marketing authorization. Emerging literature continues to build upon those early studies to further inform the benefit/risk profile of hepatic histotripsy while documenting additional use cases from treating physicians.

HistoSonics provides the following scientific publications as representative but not exhaustive uses of histotripsy. All articles are subject to limitations in their ability to substantiate specific performance claims, particularly regarding long-term efficacy. Many articles are retrospective in nature with a small sample size. Patients in these articles also presented with liver tumors from a very heterogeneous origin (primary liver tumors and liver metastases from a large variety of primary organs). Many patients documented in these articles had multiple liver tumors, not all of which were targeted for treatment. Additionally, many patients received concomitant or adjunctive therapies. All these factors confound drawing specific conclusions about hepatic histotripsy beyond the general safety and effectiveness of destroying targeted liver tumors.

HistoSonics is providing this information as a free exchange of medical and scientific information. These articles represent a sample of clinical evidence and are available at the provided links. Some of the articles may involve discussions about specific disease cohorts or discuss possible uses of histotripsy that are futuristic and not yet approved by FDA. By including these articles, HistoSonics is not stating or implying the Edison System is effective at treating any specific disease. Nor is the company intending to make or imply any additional claims beyond those currently cleared within its device labeling.

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HISTOSONICS®

HISTOTRIPSY RESEARCH ARTICLES

SYSTEMATIC REVIEWS

Histotripsy for liver tumours: a systematic review and meta-analysis of current clinical evidence.
Wehrle CJ, et al. eClinicalMedicine. 2026;95:103926. https://pubmed.ncbi.nlm.nih.gov/42094235/

Clinical Outcomes of Histotripsy for Liver Malignancies: A Systematic Review of Early Clinical Evidence.
Kimura J, et al. HPB. 2026. doi: 10.1016/j.hpb.2026.06.015. https://pubmed.ncbi.nlm.nih.gov/42436069/

PROSPECTIVE CLINICAL TRIALS

The #HOPE4LIVER single-arm Pivotal Trial for Histotripsy of Primary and Metastatic Liver Tumors: 1-year Update of Clinical Outcomes.
Ziemlewicz TJ, et al. Ann Surg. 2025;282(6):908–16. https://pubmed.ncbi.nlm.nih.gov/40201962/

The #HOPE4LIVER Single-Arm Pivotal Trial for Histotripsy of Primary and Metastatic Liver Tumors.
Mendiratta-Lala M, et al. Radiology. 2024;312(3):e233051. https://pubmed.ncbi.nlm.nih.gov/39225612/

First-in-man histotripsy of hepatic tumors: the THERESA trial, a feasibility study.
Vidal-Jove J, et al. Int J Hyperthermia. 2022;39(1):1115-1123. https://pubmed.ncbi.nlm.nih.gov/36002243/

RETROSPECTIVE STUDIES

MULTICENTER

Early Outcomes of Histotripsy for Liver Tumors in US Clinical Practice.
Sears O, et al. JAMA Netw Open. 2026;9(8):e2627493. https://pubmed.ncbi.nlm.nih.gov/42555042/

Local Tumor Control of Liver Tumors After Histotripsy: A Preliminary National Multicenter Study.
Wehrle CJ, et al. JCO Oncol Pract. 2025. doi: 10.1200/OP-25-00550. https://pubmed.ncbi.nlm.nih.gov/41401400/

The first international experience with histotripsy: a safety analysis of 230 cases.
Wehrle CJ, et al. J Gastrointest Surg. 2025;29(4):102000. https://pubmed.ncbi.nlm.nih.gov/39978577/

SINGLE CENTER

Histotripsy for neuroendocrine liver metastases: Early single-institution outcomes and safety.
Liu E, et al. Surgery. 2026;194:110084. https://pubmed.ncbi.nlm.nih.gov/41950812/

The first full year of histotripsy for liver tumors: Local tumor control and preliminary oncologic efficacy.
Wehrle CJ, et al. Surgery. 2026;191:109898. https://pubmed.ncbi.nlm.nih.gov/41353073/

First FDA approved experience with histotripsy for liver cancer management.
Jimenez-Soto C, et al. Int J Surg. 2026;112(3):7227-7237. https://pubmed.ncbi.nlm.nih.gov/41255274/

Prospective analysis on the outcomes of histotripsy for primary and metastatic liver tumours.
Chan AC, et al. Int J Surg. 2026;112(2):3287-3296. https://pubmed.ncbi.nlm.nih.gov/41217432/

Histotripsy of Liver Metastases: Short-Term Safety and Imaging Findings.
Mabud TS, et al. Cardiovasc Intervent Radiol. 2025;48(11):1594-1603. https://pubmed.ncbi.nlm.nih.gov/41016946/

Histotripsy of Pancreatic Cancer Liver Metastases: Early Outcomes and Imaging Findings.
Mabud TS, et al. World J Surg. 2025;49(7):1899-1902. https://pubmed.ncbi.nlm.nih.gov/40445073/

CASE REPORTS

Observed Immune Response Following Histotripsy in Metastatic Hepatocellular Carcinoma.
Staley C, et al. Case Rep Oncol Med. 2026;2026:4245816. https://pubmed.ncbi.nlm.nih.gov/42004160/

Histotripsy for multifocal breast cancer liver metastases with early complete metabolic response: a case report.
Juarez TM, et al. Front Oncol. 2026;16:1782397. https://pubmed.ncbi.nlm.nih.gov/42022317/

Histotripsy for portal vein tumor thrombus in a patient with hepatocellular carcinoma: a case report.
Burns K, Juarez TM. Front Oncol. 2025;15:1721814. https://pubmed.ncbi.nlm.nih.gov/41409237/

Hyperprogression and Systemic Metastasis of Cholangiocarcinoma after Histotripsy Therapy.
Berman ZT, et al. J Vasc Interv Radiol. 2025;36(9):1465-1466. https://pubmed.ncbi.nlm.nih.gov/40846437/

Distant Tumor Response in the Pelvis After Histotripsy of a Metastatic Sarcoma of the Liver in a Patient With Differentiated Liposarcoma.
Ong ES, et al. Am Surg. 2026;92(2):452-456.https://pubmed.ncbi.nlm.nih.gov/40873348/

Use of Histotripsy to Rapidly Relieve Biliary Obstruction in a Patient with Recurrent Hilar Cholangiocarcinoma.
Ong ES, et al. Am Surg. 2026;92(1):282-285. https://pubmed.ncbi.nlm.nih.gov/40876872/

Bridging therapy with histotripsy prior to liver transplantation for hepatocellular carcinoma: a first case report.
Uysal M, et al. Exp Hematol Oncol. 2025;14(1):20. https://pubmed.ncbi.nlm.nih.gov/40001149/

PROCEDURAL AND SAFETY ANALYSIS PUBLICATIONS

Airway management and one-lung ventilation strategies during hepatic histotripsy: a retrospective service evaluation from a single institution in Hong Kong.
Chu MHM, et al. Anaesthesia Reports. 2026;14(2):e70092. https://pubmed.ncbi.nlm.nih.gov/42482981/

Acute Kidney Injury, Vascular Complications, and Deaths after Hepatic Malignancy Histotripsy: An Analysis of FDA MAUDE Database Reports.
Iqbal T, et al. Cardiovasc Intervent Radiol. 2026. doi:10.1007/s00270-026-04569-2.
https://pubmed.ncbi.nlm.nih.gov/42552284/

Management and Prevention of Histotripsy-Induced Acute Bland Portal Vein Thrombosis in Histotripsy-Treated Liver Tumors.
Worlikar T, et al. J Vasc Interv Radiol. 2026;37(9):108883. https://pubmed.ncbi.nlm.nih.gov/42235819/

Histotripsy-induced acute kidney injury following liver tumor treatment: A preliminary report of 9 cases.
Poe LL, et al. J Vasc Interv Radiol. 2026;37(9):108882. https://pubmed.ncbi.nlm.nih.gov/42218940/

Delayed Hepatic and Portal Venous Thrombosis Following Histotripsy: A Single-Institution Case Series.
Cook M, et al. J Vasc Interv Radiol. 2026;37(8):108864. https://pubmed.ncbi.nlm.nih.gov/42184902/

PROCEDURAL AND SAFETY ANALYSIS PUBLICATIONS cont.

AKI After Hepatic Histotripsy.
Bhutta S, et al. Kidney Int Rep. 2026;11(7):106603.
https://www.sciencedirect.com/science/article/pii/S2468024926028354

Vascular Injury after Histotripsy: A Case Series of Hemorrhage and Pseudoaneurysm Complications in Human Patients.
Breuer JA, et al. J Vasc Interv Radiol. 2026;37(6):108576. https://pubmed.ncbi.nlm.nih.gov/41655899/

Vascular complications following histotripsy of hepatocellular carcinoma.
Wong BO, et al. Int J Hyperthermia. 2025;42(1):2603108. https://pubmed.ncbi.nlm.nih.gov/41403239/

Histotripsy of Liver Tumors: Patient Selection, Ethical Discussions, and How We Do It.
Uysal M, et al. Cancers (Basel). 2025;17(7):1100. https://pubmed.ncbi.nlm.nih.gov/40227626/

REVIEWS & EDITORIAL PERSPECTIVES

Where does histotripsy fit into hepatocellular carcinoma care?
Lau-Min KS, Wang J. Cancer. 2026;132(15):e70547. https://pubmed.ncbi.nlm.nih.gov/42504148/

Noninvasive Is Not Risk-Free: Confronting the Real-World Safety Profile of Liver Histotripsy.
Sotirchos VS, et al. J Vasc Interv Radiol. 2026;37(9):108884. https://pubmed.ncbi.nlm.nih.gov/42218941/

Histotripsy and the IDEAL Framework: A Clarion Call for the Responsible and Evidence-Based Application of New Technology.
Levi ST, et al. J Clin Oncol. 2026;44(22):2075-2078. https://pubmed.ncbi.nlm.nih.gov/42018971/

Thermal and Nonthermal Liver Ablation: Mechanistic Foundations, Clinical Implementation, Immunologic Trial Design, and Artificial Intelligence.
Centner CS, et al. Radiology. 2026;318(3):e250263. https://pubmed.ncbi.nlm.nih.gov/41874295/

Surgery Without Scalpel: Histotripsy as a Non-Invasive and Non-Thermal Modality for Liver Tumor Ablation.
Paramythiotis D, et al. J Clin Med. 2025;14(18):6391. https://pubmed.ncbi.nlm.nih.gov/41010594/

Breaking Barriers with Sound: The Implementation of Histotripsy in Cancer.
Raman AP, et al. Cancers (Basel). 2025;17(15):2548. https://pubmed.ncbi.nlm.nih.gov/40805244/

Are We Advancing Local Control of Liver Tumors with Histotripsy?
Haddad A, Vauthey JN. Ann Surg. 2025;282(6):917-918. https://pubmed.ncbi.nlm.nih.gov/40560672/

PRECLINICAL STUDY SUBSET

These studies are a representative sample of preclinical evidence that are relevant to the current use of histotripsy in clinical practice.

Clinical translation of abdominal histotripsy: a review of preclinical studies in large animal models.
Falk KL, et al. Int J Hyperthermia. 2023;40(1):2272065. https://pubmed.ncbi.nlm.nih.gov/37875279/

A comparison study of microwave ablation vs. histotripsy for focal liver treatments in a swine model.
Knott EA, et al. Eur Radiol. 2023;33(2):1050-1062. https://pubmed.ncbi.nlm.nih.gov/36048208/

Histotripsy: the first noninvasive, non-ionizing, non-thermal ablation technique based on ultrasound.
Xu Z, et al. Int J Hyperthermia. 2021;38(1):561-575. https://pubmed.ncbi.nlm.nih.gov/33827375/

Effects of tissue mechanical properties on susceptibility to histotripsy-induced tissue damage.
Vlaisavljevich E, et al. Phys Med Biol. 2014;59(2):253-70. https://pubmed.ncbi.nlm.nih.gov/24351722/