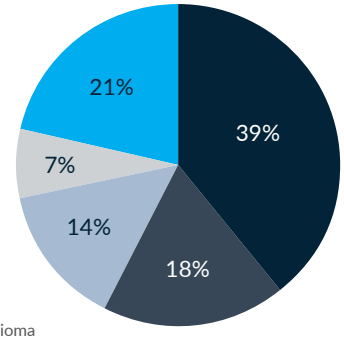
HISTOSONICS®

1-YEAR CLINICAL OUTCOMES FOR THE #HOPE4LIVER TRIAL, A SINGLE-ARM, NON-RANDOMIZED, PROSPECTIVE TRIAL[1]

STUDY POPULATION

- 8 US sites, 6 European Union and United Kingdom sites.
- 47 participants with 52 tumors treated:
  - 19 HCC participants
  - 28 participants with liver mets from:
    - Colorectal
    - Pancreas
    - Breast
    - Uveal Melanoma
    - Other Metastases*

*Other metastases were Liver Neuroendocrine, Lung Neuroendocrine, Brain Hemangiopericytoma, Ovarian, Bronchial Carcinoma, and Epithelioid Hemangioendothelioma



- Segments treated: II (n=10), III (n=27), IV (n=9), V (n=3), VI (n=3).
- 89.5% of HCC participants and 96.4% of metastatic participants had multifocal hepatic tumors at the time of treatment.
- Enrolled participants had failed previous locoregional therapies due to disease progression, were unable to physiologically tolerate or refused standard therapies making them not the typical participants in locoregional trials.

LOCAL TUMOR CONTROL

- Local tumor control of targeted tumor(s) at 1-year was 90% as assessed by the imaging core laboratory by Kaplan-Meier estimation.
- Presence of enhancement was initially evaluated using a definition consistent with assessing thermal ablation and required reassessment due to confounding enhancements unique to histotripsy such as vessel preservation which was observed in 20.8% of the treatment zones at 30 days.
- Immediate post-histotripsy abdominal CT or MR demonstrated 95.7% of the tumors were completely covered by the histotripsy treatment zone.
- The rate of local tumor control in #HOPE4LIVER participants at 1-year was similar to rates reported for other locoregional therapies.

ADVERSE DEVICE EFFECTS (ADE)

- The most frequently reported ADEs by participant were procedural pain, abdominal pain, and pyrexia.
- One ADE was reported after 30 days, a non-serious biloma at day 188 requiring no intervention.
- Six serious ADEs were reported, all within the first 30 days: hepatic failure, portal vein thrombosis, postoperative thrombosis, procedural pain, sepsis, and pleuritic pain.
- Histotripsy continues to demonstrate a low rate of adverse device effects with only a single event occurring more than 30 days after the procedure.

OVERALL SURVIVAL

- Overall survival at 1 year post histotripsy in participants with liver mets was 48.6% with a 3 month survival of 89.3% and 6 month survival of 71.4%.
- Overall survival at 1 year in participants with HCC was 73.3% with a 3 and 6 month survival of 100%.
- Although the trial was not designed for definitive treatment, participants demonstrated survival rates in-line with rates reported for similar HCC and metastatic populations treated with other locoregional therapies.

CONCLUSION

These outcomes support histotripsy as a safe and effective option for destroying and liquefying liver tumors noninvasively leveraging histotripsy's non-thermal, non-ionizing, mechanical mechanism of action.

ANNALS OF SURGERY

PUBLICATION OF 1-YEAR #HOPE4LIVER DATA

https://journals.lww.com/annalsofsurgery/abstract/9900

1. HistoSonics data on file

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