

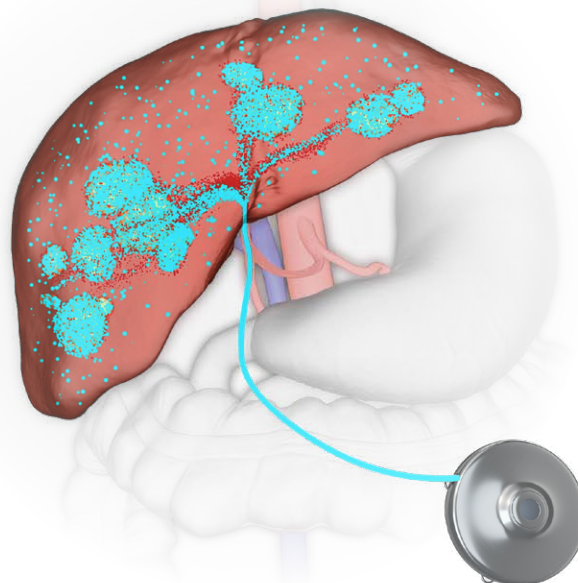


Hepatic Artery Infusion Therapy

What is HAI Therapy?

Hepatic Artery Infusion (HAI) therapy is a treatment in the NCCN guidelines¹ for patients with colorectal cancer liver metastases (CRLM) and intrahepatic cholangiocarcinoma (iCCA).

HAI therapy is delivered continuously and directly to tumors in the liver, without adding additional systemic side effects. It is used for patients with unresectable tumors or after resection. Clinical studies have demonstrated that adding HAI therapy to systemic chemotherapy increased conversion to resection,² improved disease control in the liver,^{2,3,4} and was associated with prolonged survival.^{5,6,7}



How HAI Therapy Works

- The Intera 3000 HAI Pump is surgically implanted under the skin in the abdominal wall.
- A catheter connects the pump to the hepatic artery, and body heat powers delivery of the therapy from the pump to the liver.
- HAI therapy treats the entire liver while achieving up to 400 times greater drug concentration in the liver compared to systemic infusion.⁸
- The drug typically used in HAI therapy, floxuridine, has 97% first pass liver metabolism, minimizing systemic exposure.⁸

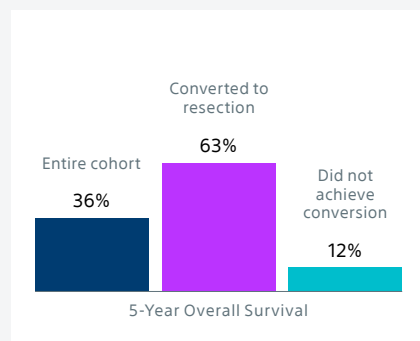
HAI Therapy Management

- HAI therapy is typically delivered in combination with systemic chemotherapy.
- HAI therapy is typically initiated 2-4 weeks after surgery to implant the pump.
- During active treatment, the HAI pump is refilled every two weeks, alternating floxuridine and heparinized saline.
- Liver function monitoring tests are performed at each refill to inform potential dose adjustments.
- While receiving HAI therapy, patients can travel and proceed with most of their daily activities.



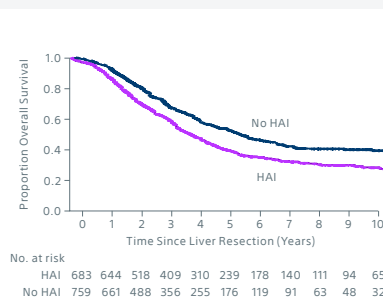
Clinical Data Supporting HAI Therapy

Unresectable CRLM²



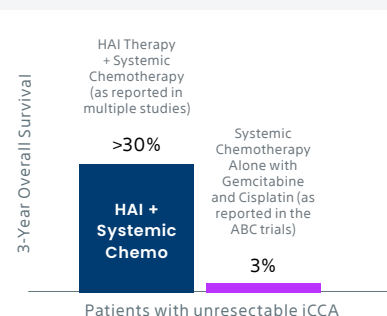
- High overall tumor response rate of 73% to HAI therapy plus systemic chemotherapy
- 52% of patients converted to resection using HAI plus systemic chemotherapy, despite high disease burden and previous chemotherapy; 5-year overall survival was 63% for these patients (comparable to 5-year survival seen in patients who are initially resectable)

After CRLM Resection⁶



- Use of adjuvant HAI therapy in combination with modern systemic chemotherapy was associated with a nearly 2-year longer median overall survival compared with a propensity matched cohort receiving modern systemic chemotherapy alone (67 vs. 44 months; $p < 0.001$).
- In the same analysis, patients who received HAI demonstrated a higher 10-year overall survival, reflecting a 60% increase in the probability of cure.

*Unresectable iCCA^{7,9,10}



- Multiple studies have consistently shown 3-year overall survival of >30% for unresectable iCCA patients treated with HAI therapy in addition to systemic chemotherapy
- Long-term follow-up in a study showed a 21% 5-year overall survival for patients treated with HAI + systemic chemotherapy⁶

** Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.*

Boston Scientific provides training and support for community cancer centers that continue managing patients after HAI pump implantation.

For physicians, learn more about HAI therapy or connect with your Boston Scientific representative:



Intera 3000 Hepatic Artery Infusion Pump Indications, safety and warnings

The Intera 3000 Hepatic Artery Infusion Pump is used to deliver medications such as chemotherapy to the blood vessels in the liver.

With all medical procedures, there are risks associated with the procedure to place the pump in your abdomen and with the use of the pump to deliver medications. The risks associated with placement and use of the pump include but are not limited to bleeding, blood clots, blockage within the device, damage to the blood vessels, fluid or blood build-up around the device under the skin, infection, movement or displacement of the pump or catheter, pump damage, and leakage or incorrect delivery of the medications.

Special care may be required after placement of the Intera 3000 Pump and includes but is not limited to avoiding rough physical activity, avoiding deep sea or scuba diving, avoiding saunas, avoiding long periods in hot tubs and avoiding direct sun exposure, heating pads or hot water bottles over the area of your abdomen where the pump is placed. Additional care may be needed for air travel, moving to or visiting a high-altitude place, or if you have a fever.

The Intera 3000 Pump is MRI Conditional, which means that certain conditions must be met to safely have an MRI after placement of the pump.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the use of the device. PI-2257307-AA