TriNav® INFUSION SYSTEM

Precision and Accuracy of the TriNav® Infusion System in Y-90 Mapping and Therapeutic Delivery

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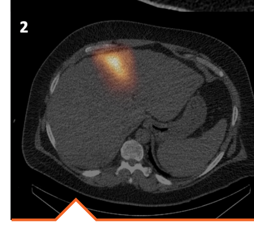
OVERVIEW

In two cases the TriNav Infusion System was used to precisely deliver technetium-labeled macroaggregated albumin (^{99m}Tc-MAA) in the mapping procedure, followed by Yttrium-90 (Y-90) therapeutic delivery. TriNav's SmartValve™ technology increases infusion pressure[1] which improves distribution and penetration of the therapy,[2] while reducing reflux.[3] These cases display the clinical utility of the TriNav Infusion System for precise Y-90 radioembolization treatment of patients with solid tumors of the liver.



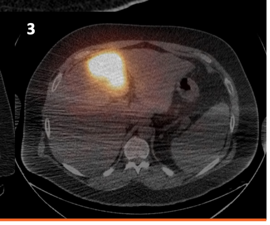


Figure 1: *Case 1 pre-therapeutic CT imaging shows multifocal metastatic hepatic lesions in segments 4 a & b.*

Figure 2: *Case 1 ^{99m}Tc-MAA mapping SPECT/CT demonstrates preferential MAA activity in the correlated target tumor location.*

Figure 3: *Case 1 post-therapeutic SPECT/CT demonstrates Y-90 activity within hepatic segments 4 a & b, correlating to the largest tumor area, and without evidence of reflux into adjacent subsegmental hepatic branches, the stomach, or adjacent solid organs.*

CASE 1:
PATIENT HISTORY

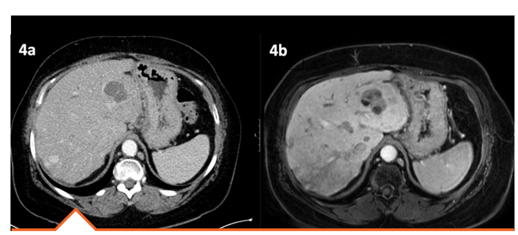
A 51-year-old man presented with an approximate 1-year history of multifocal poorly differentiated cholangiocarcinoma with unsuccessful response to chemotherapy which included 1^{st} line cisplatin/gemcitabine (combination therapy), followed by 2^{nd} line tibsovo, followed by FOLFIRI for salvage therapy. CT imaging showed hypovascular tumors within segment 4a and b (Figure 1). The patient was recommended for total hepatic palliative Y-90 radioembolization therapy for the enlarging liver lesions in a staged fashion, beginning with the left liver lobe.

TREATMENT

Arterial access was obtained through the right common femoral artery and a celiac axis angiogram was performed. The segment 4 hepatic artery was accessed using a 2.4 French TriNav Infusion System. A selective digital subtraction angiography was performed of the hepatic artery supplying segment 4 to confirm arterial localization. Delivery of ^{99m}Tc-MAA and Y-90 was performed in the same arterial distribution. Following the mapping procedure, SPECT/CT was performed and showed MAA activity within the correlated targeted tumor location (Figure 2). The total absorbed dose using SIR-Spheres® was 71.4 mCi of Y-90. Dilute contrast injection and intermittent fluoroscopy were used to confirm antegrade flow without reflux. Post-therapeutic SPECT/CT images demonstrate near-complete preferential involvement of the tumor without evidence of reflux into adjacent subsegmental hepatic branches or the adjacent solid organs (Figure 3).

CASE 2:
PATIENT HISTORY

A 62-year-old woman presented with a history of gastric neuroendocrine carcinoma with metastatic disease to the liver. She had previously undergone a partial gastrectomy to remove the gastric mass and has been on various chemotherapy agents for approximately 8 years to treat the metastatic disease, including: octreotide acetate, pazopanib, everolimus; temodir + capecitabine, avastin + capecitabine and 5-fluorouracil + streptozocin. The patient also underwent previous Y-90 treatments of the right hepatic lobe. Seven months prior, the patient began complaining of shortness of breath, weakness, and fatigue. Subsequently, the patient underwent a left hepatic lobe Y-90 radioembolization for palliative treatment to address the symptoms. Pre-therapeutic CT (Figure 4a) and MRI (Figure 4b) imaging showed multifocal disease within segments 2 and 3. She was recommended for an additional Y-90 radioembolization procedure to treat the remaining lesions in the left side of the liver given the association with endocrine manifestations.



Figures 4: *Case 2 pre-therapeutic CT (a) and MRI (b) imaging shows hypovascular metastatic lesions from the primary gastric neuroendocrine tumor within segments 2 & 3.*

TREATMENT

Arterial access was obtained through the right common femoral artery via ultrasound guidance and a common hepatic arteriogram was performed. A 2.4 French TriNav Infusion System was then used to selectively catheterize the hepatic artery supplying segments 2 and 3. Delivery of ^{99m}TcMAA and Y-90 was completed from the same arterial distribution of the segment 2 and 3 hepatic artery. Following the mapping procedure, SPECT/CT was performed and showed MAA activity within the correlated targeted tumor location (Figure 5). The total absorbed dose using SIR-Spheres® was 24.18 mCi of Y-90. Post- therapeutic Bremsstrahlung Y-90 and SPECT/CT demonstrates Y-90 activity within the target location of treatment (hepatic segments 2 and 3), correlating to the largest tumor area, and without evidence of reflux into adjacent subsegmental hepatic branches, the stomach, or adjacent solid organs (Figure 6).

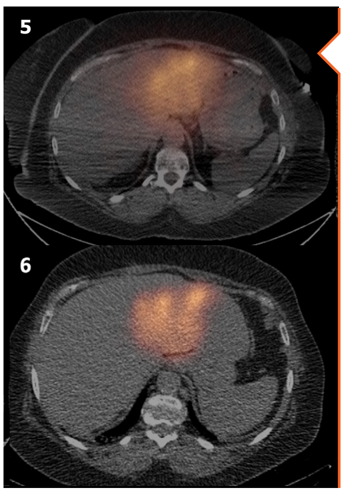


Figure 5: *Case 2 ^{99m}Tc-MAA mapping SPECT/CT shows MAA activity in the correlated target tumor location.*

Figure 6: *Case 2 post-therapeutic Bremsstrahlung Y-90 images and SPECT/CT demonstrate near-complete preferential involvement of the tumor without evidence of reflux into adjacent subsegmental hepatic branches or the adjacent solid organs.*

DISCUSSION

The majority of gastric neuroendocrine tumors arise from enterochromaffin-like cells (ECL cells) of the gastric mucosa with a wide variability in subtype metastatic propensity.[4] Cholangiocarcinomas are the most common biliary tract malignancy as well as the second most common primary hepatic malignancy.[5] Primary and secondary hepatic malignancies that do not respond to chemotherapy often require treatment via surgical resection or liver transplantation. In inoperable tumors or for patients awaiting liver transplantation, a Y-90 radioembolization procedure may help to reduce the size of the tumor in order to alleviate symptoms and prolong life.[6] This is achieved by placing microbeads coated with radioactive Y-90 into hepatic arteries located near the tumor through means of a minimally invasive catheter device. The proximity of the placed radiation allows for the selective radiation of cancerous tissue while minimizing radiation to surrounding healthy liver tissue.

Therapeutic Y-90 radioembolization is difficult due to exact localization of the tumoral arterial supply as well as establishing direct therapy without reflux into adjacent organs. The TriNav Infusion System was used in these two cases to deliver both ^{99m}Tc-MAA for mapping and targeted Y-90 radioembolization with precision and accuracy, without evidence of reflux, and with optimal targeted tumoral perfusion. TriNav's SmartValve™ technology increases infusion pressure,[1] which improves distribution and penetration of the therapy to the tumor,[2] while reducing reflux.[3] Reflux protection, as demonstrated in these cases, may reduce the risk of non-target delivery to help protect healthy tissue.[7]

My experience with TriNav is that the device is very easy to use, and it fits well within my workflow, particularly in Y-90 radioembolization procedures. At our institution the goal is to replicate the MAA as much as possible with the treatment Y-90 dose because much of the dosimetry is based on MAA perfusion. TriNav has allowed us to establish great consistency between the mapping and treatment procedures.

CONCLUSION

These two cases demonstrate the precision and accuracy achieved by TriNav in delivering both ^{99m}Tc-MAA for mapping as well as targeted Y-90 radioembolization. Both cases showed no evidence of reflux and optimal targeted tumoral perfusion. In addition, these cases illustrated a strong correlation between the perfusion patterns of MAA and Y-90 when TriNav is used in both procedures, which is particularly important for dosimetry.

ABOUT THE AUTHOR

Dr. Davidson serves as an Associate Professor at Case Western Reserve University School of Medicine and the Division Chief for the Department of Interventional Radiology at University Hospitals Cleveland Medical Center, where he has practiced for the past 12 years. Dr. Davidson also serves as the Vascular & Interventional Radiology Fellowship Director at University Hospitals Cleveland Medical Center. Dr. Davidson is active within the Society of Interventional Radiology, and an active member of the RSNA (Radiologic Society of North America), ACR (American College of Radiology), and AMA (American Medical Association).

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