EXPERT OPINION: Afshin Gangi, MD, PhD
Award-winning abstract concludes cryoablation offers better visualization of ice ball and better protection of surrounding organs compared with RF ablation

Galil Medical recently talked with Afshin Gangi, MD, PhD, about the award-winning abstract* he presented at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) congress Oct. 2-6, 2010, in Valencia, Spain. Dr. Gangi used a Galil Medical Cryoablation System for his clinical studies.

GM: What are the benefits of percutaneous renal cryoablation (cryo) vs radiofrequency ablation (RFA)?
AG: First, a huge advantage of cryoablation is that you can see the ablation zone. You can see the ice ball so precisely on CT and especially on MR. This makes it very easy. You’re not driving in the fog – you’re driving on a very clear road on a sunny day.

With RFA, you do the best you can, but you have to wait one month to find out if it was enough. At the end of a cryo procedure, you know your operation is done, because you could see your ice balls, specifically on CT and MR. Visualization of the ice ball is a key point.

Second, you can treat more kinds of tumors with cryo. RFA is useful for treating small, easy tumors (2-3 cm). But with cryo, we can treat most renal tumors under 5 cm, in any location in the kidney: superior, inferior, central or peripheral.

U.S. PERSPECTIVES: Amit S. Sudan, MD
Cryotherapy vs RF ablation

Galil Medical also talked with two U.S.-based interventional radiologists about their experience with cryotherapy in their practices.

Amit S. Sudan, MD
Interventional Radiologist
Colorado Permanente Medical Group, Denver, CO

GM: What is one of the advantages of cryoablation over RF ablation?
AS: The Galil cryotherapy is simpler to set-up and has a greater ability to customize the ablation zone when compared to RFA or other cryotherapy systems. No ground pads are required, unlike RFA, and you don’t need to worry about interactions with the patient’s cardiac pacemaker or AICD.

GM: What would you say to other IRs considering cryoablation?
AS: The latest generation [17 G] cryoablation needle is fantastic. That’s been a limiting factor for quite some time -- previous probes were bulkier and more difficult to place properly. The Galil probes are much easier to place - just as easy as RF probes. I think it will convince many physicians to give cryo a try.
EXPERT OPINION: Gangi (continued from page 1)

For central tumors, near the excretory cavities, the ice ball can really cover the cavities. If you're not freezing the pyeloureteral junction and or the ureter itself, you have no risk of stenosis on retraction. This is not the case with RF. You have to continually cool the cavity with a stent to be able to do RF with central tumors. With cryo you have no problem.

Finally, cryo is less painful than RFA. If the lesion is small, you can treat it under light sedation or local anesthetic.

**GM:** What would you tell interventional radiologists (IR) currently using RFA about cryo?

**AG:** I like to say that cryo is “dummy proof.” Once the probes are in, your job is very easy. You’re doing your freezing; you’re making sure your ice ball is covering safely the tumor – that’s it. You’re not calculating anything. Doing the procedure, you’re a lot more comfortable. And the follow-up is very easy.

**GM:** What about this abstract do you think will generate the most interest among IRs?

**AG:** The key point is that with cryo, we are quite able to treat most renal tumors under 5 cm, in any location in the kidney.

The abstract describes how we guide the procedure under CT and MR, discusses new thermal protection techniques we’ve developed, and gives tips and tricks for treating tumors of the anterior part of the kidney, near the colon or the pancreas.

It has really opened the door for us to do a lot more than before.


**Dr. Gangi is a professor of radiology at University Hospital of Strasbourg, France. He can be reached at Afshin.Gangi@chru-strasbourg.fr**

To read the full abstract CLICK HERE
Cryotherapy Reimbursement Assistance Helps Provide Timely Care to Patients

The Galil Medical reimbursement team has a track record of working with payers on behalf of its customers throughout the U.S. Through its efforts, percutaneous renal cryotherapy is now covered by many regional BCBS plans, Aetna, Cigna, and Medicare in all 50 states.

Galil Medical offers comprehensive reimbursement assistance to help with payment and coverage for your cryotherapy patients through an exclusive partnership with North East Medical Solutions (NEMS).

Wes Lewis, MD, an interventional radiologist in Ashland, KY, has been using Galil’s reimbursement assistance for more than two years. “NEMS provides specialized support for our renal and liver cryoablation pre-certifications. NEMS’ specialized expertise in this area allows them to cut through the payer beaurocracy which allows our patients to be treated in a timely manner,” he says. “Our turnaround time -- our ability to get the patient approved and treated -- has been greatly improved.”

Working with NEMS has been easy for Dr Lewis and his staff. “My nurse collects all the data, and I dictate the office notes and the indications to present the patient’s full clinical picture to the payer. After ensuring the accuracy of the information being sent to the payer, she turns all that information in to NEMS for assistance. NEMS has been very good about getting the patient’s treatment approved,” he says. “The unique assistance offered by Galil has helped our patients receive the treatment that I feel is most appropriate.”

Dr Lewis recognizes the deep experience that NEMS brings to his practice, and appreciates that Galil offers reimbursement assistance to its customers. “I think it makes a huge difference in being able to provide timely care to patients, so I would highly recommend that any physician starting out with cryoablation talk to Galil about the NEMS reimbursement assistance.”

Galil/NEMS’ comprehensive reimbursement assistance includes:

• Coding explanations for cryotherapy procedures
• National regulations that may affect coverage for cryotherapy procedures
• Area-specific regulations that may affect coverage for cryotherapy procedures
• Precertification, certification, and predetermination of coverage and benefits for cryosurgical procedures
• Initiating the appeals process for denied precertification, lack of reimbursement or inappropriate reimbursement for cryosurgical procedures.

For more information, call the Galil Medical Reimbursement Line at 1-877-639-CRYO (2796) and select option 4 for reimbursement support.

An Overview of Galil Medical

Who is Galil Medical?
Galil Medical is a global leader in minimally invasive cryotherapy solutions. We’re developing cryoaulation technology to treat conditions affecting the bone, kidney, liver, lung and prostate, as well as targeted pain applications.

What is Galil Medical’s new focus?
Founded in 1996, Galil Medical has been providing cryotherapy solutions in the U.S. for 10 years, primarily in the urology market.

“In early 2009 we made a strategic decision to focus our clinical and R&D resources on new and exciting applications for our technology,” said Martin J. Emerson, president and chief executive officer of Galil Medical. “Our minimally invasive cryoablation technology has many potential uses that can benefit patients and physicians across many disease states and specialties.”

What is Galil’s technology?
Galil Medical is a global leader in cryotherapy, also referred to as cryoablation or cryosurgery.

Galil Medical cryotherapy systems precisely deliver sub-zero temperatures via a very light, patented 17-gauge cryoablation needle for the ablation of benign and cancerous tumors. High-resolution imaging with CT or MR enables a high level of control for needle placement and positioning and clear visibility of the ablation zone during minimally invasive surgery.

A strong commitment to technological innovation has enabled Galil Medical to develop and manufacture the smallest-diameter cryoaulation needles on the market.

What’s in your technology pipeline?
Next year, we expect to unveil new cryoablation needles, with larger zones of ablation, that facilitate greater procedural flexibility, with a re-designed handle that’s more user-friendly as well as the ability to cauterize the ablation zone post-operatively. We’re also working on a new, feature-rich and easier to use system platform.

What’s in your clinical research pipeline?
Currently we are actively pursuing clinical research projects around the globe. The focus of these clinical research projects includes lung tumors, kidney tumors, prostate cancer, bone tumors, Barrett’s disease and a handful of pain indications.

Where is Galil Medical located?
Galil is a transnational company. We are Israeli-incorporated. Our corporate headquarters are located in Arden Hills, MN. Our R&D and manufacturing teams are located in two locations - in our Arden Hills facility as well as in our Yokneam, Israel facility. We also have a European sales office London, UK.

For more information visit www.galil-medical.com.

REIMBURSEMENT / ABOUT GALIL MEDICAL
GM: What patients are good candidates for percutaneous cryoablation?

GG: Appropriate candidates for renal Cryoablation include:

1. Patients with surgically resectable disease, but high co-morbidities precluding surgery.

2. Tumors less than or equal to 5 cm in size. (Can treat larger tumors)

3. Patients with multiple renal masses [Von Whipple Lindau]

4. Patients with solitary kidneys

5. Patients with renal insufficiency, nephron sparing procedure

6. Patients who do not want surgery

Then the last group is patients who don’t want surgery. They’ve heard about this, they know that the success rates are very good with a lot less recovery, with a lot less pain, and something we can repeat easily.

GM: What are some downsides to cryo, and how do you compensate for them?

GG: First, there are some reports of higher rates of bleeding vs. thermal ablation techniques utilizing heat. Mayo reports a 4% vs. 2% difference in hemorrhage with cryoablation vs. RFA. From my experience, there may be 2 reasons why this occurred. One, physicians tend to be impatient with needle removal prior to a complete thaw. This can produce a tumor fracture and bleeding. Allowing an adequate thaw decreases the risk of bleeding. Second, the Cryoablation probes utilized in the quoted study were much larger than the Galil probes (11g vs. 17 g).

The second problem is the number of needles required to achieve a complete ablation zone. Cryoablation can be more technically challenging due to the potential need to place multiple needles in the tumor while simultaneously keeping the needles 2 cm away from each other at the skin surface to prevent dermal injury. With many RFA systems, one needle/probe is all that is required.

Overall, there are tradeoffs. While needle placement may take some extra time upfront, we gain the real time visualization of the zone of necrosis and should be able to modify treatment based on the images. This should allow higher complete ablations or sooner retreatment.