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# Special Report: New Treatment for Refractory Angina: Robotic-Assisted TMR

This working group of cardiothoracic surgeons experienced in transmyocardial revascularization (TMR) reviewed recent developments in robotic-assisted TMR, a minimally invasive port-based technique using the da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, CA). The meeting was assembled to share best practices for stand-alone robotic-assisted TMR procedures, as well as strategies to build awareness of this option in the cardiology community for refractory angina patients.

## MODERATORS

Geoffrey Answini, MD (Ohio Heart and Vascular Center, Cincinnati, OH), cardiothoracic surgeon, has a special interest in minimally invasive surgery and endovascular surgery. He has been performing minimally invasive surgical TMR procedures since 2005, either through a small thoracotomy or via ports with robotic assistance. He has completed 50 stand-alone TMR cases to date, and has had no perioperative mortality. His cardiac robotic experience also includes mitral valve and coronary artery bypass grafting (CABG) procedures.

Averel Snyder, MD (Peachtree Cardiovascular and Thoracic, Atlanta, GA), cardiothoracic surgeon, focuses on adult cardiac surgery and minimally invasive robotic surgery. Dr. Snyder has completed more than 50 stand-alone minimally invasive TMR procedures, most of which were robotic-assisted, with no perioperative mortality. Dr. Snyder and his partners have established St. Joseph's Center for Robotic Surgery, one of the five training centers worldwide for minimally invasive robotic surgery training.

## TMR USERS GROUP

- John Entwistle, MD (Hahnemann University Hospital, Philadelphia, PA)
- Andrew Hansen, MD (College Station Medical Center, College Station, TX)
- Saqib Masroor, MD (Medical College of Wisconsin, Milwaukee, WI)
- George Palmer, MD (University of Florida Medical Center, Orlando, FL)
- Nilesh Patel, MD (St. Michael's Medical Center, Newark, NJ)
- Thomas Pollard, MD (East Tennessee Surgery Group, Knoxville, TN)
- Robert Poston, MD (Boston Medical Center, Boston, MA)

*The following are the highlights of the clinical and technical questions/comments generated and addressed during the TMR Users Group meeting.*

## CLINICAL NEED

### How many patients suffer from refractory angina?

**Dr. Answini:** Angina is an enormous problem today, with an estimated 9.8 million Americans suffering from chest pain and 1.76 million PCI/CABG procedures performed annually. Patients with end-stage coronary artery disease (CAD) and angina, who are not candidates for CABG or percutaneous coronary intervention (PCI), have a poor prognosis. Even with best medical therapy, these patients have high rates of myocardial infarction and mortality, and suffer from profound physical limitations and diminished quality of life.

With an aging population and longer life expectancies, the number of people with previous CABG and/or multiple interventions will dramatically increase the number of patients needing some form of alternative treatment.

### Why is TMR a reasonable option for patients with severe, refractory angina?

**Dr. Answini:** Because it is effective. I am absolutely convinced that TMR works. The success rate in our patients is 75% to 80%. Multiple prospective, randomized trials confirm this. The TMR procedure is safe, minimally invasive, with low morbidity and mortality, and our patients are doing well. Fundamentally, it is a great addition to our armamentarium as robotic stand-alone therapy or as an adjunct to coronary bypass.

## PATIENT PRESENTATION FOR ROBOTIC-ASSISTED TMR
## GEOFFREY ANSWINI, MD (CHRIST HOSPITAL, CINCINNATI, OH)

- 65-year-old man
- History of hypertension, hyperlipidemia, stroke, CAD
- Previous procedures: CABG X5 in 1989 and CABG X6 in 1996, multiple angioplasties and stents
- Symptoms of severe chest pain refractory to medical management
- Unable to walk to kitchen, mailbox, or up a flight of stairs without getting chest pain
- Takes 6 to 10 nitroglycerin tabs a day on average
- Stress test notes ischemia in inferior and lateral walls with an ejection fraction of 60%

**Preoperative angiogram depicts end-stage critical three-vessel CAD with no interventional option (CABG or PCI).**

### PATIENT SELECTION

#### How do you identify patients for stand-alone TMR?

**Dr. Answini:** I use the following criteria: class III or IV angina, stable, with no decompensated congestive heart failure (CHF). The ejection fraction should be "reasonable" (> 25%). For initial cases, I recommend keeping to an ejection fraction of at least 35%. Most of my patients have failed enhanced external counterpulsation (EECP) or ranolazine (Ranexa,® Gilead, Foster City, CA), or some other therapy, and typically have no other revascularization options.

If you start in the cath lab, 4% to 6% of patients undergoing diagnostic catheterization are candidates for TMR. The Cleveland Clinic reviewed the angiograms of patients referred for revascularization, and found that 12% had no conventional revascularization option (CABG or PCI). Of those patients, approximately half met the criteria for TMR. Starting in the cath lab is an ideal strategy to build awareness.

#### What about the role for adjunctive TMR?

**Dr. Answini:** Studies have shown that 15% to 25% of CABG procedures result in incomplete revascularization. I have been making 25 to 30 TMR channels in the myocardium of patients with what I determine are poor target vessels. The published data seem to support this approach.

**Dr. Poston:** Geoff, not only do I utilize that strategy in selected patients, but I have begun an investigation of making laser channels distal to vein grafts. In a preliminary series, I selected vein grafts with flow below 40 mL/min and randomized them to TMR or no treatment. What I saw intraoperatively was that TMR had a significant impact on flow. I am now in the process of proposing a study to be conducted at several sites to evaluate this application. It is intriguing.

#### Are there pitfalls to avoid when evaluating patients for stand-alone TMR?

**Dr. Answini:** The following warnings and precautions should be considered when screening patients for TMR: (1) Q-wave myocardial infarction (MI) within the past 3 weeks; (2) non–Q-wave MI within the past 2 weeks; (3) severely unstable patients (unweanable from intravenous antianginal medication); (4) uncontrolled ventricular tachy-arrhythmia; and (5) decompensated CHF.

#### Are you getting a stress test on everyone?

**Dr. Answini:** We require some kind of preprocedure stress test or imaging on all patients to document the zone of ischemia. That information is critical to target the zone for treatment. Also, in our group, we have begun utilizing MRI in follow-up to evaluate the impact of the therapy.

#### Would you exclude a patient with convincing anatomy and symptoms but no documented ischemia on the stress test?

**Dr. Answini:** I would be skeptical about the role of TMR for that patient. I have been less aggressive about taking those patients to the operating room because I think there is a certain subpopulation of "drug seekers." You may be setting yourself up for a failure.

#### What about a diabetic patient with documented ischemia and shortness of breath?

**Dr. Answini:** These patients typically do well with TMR. There are published data that show improvement in exercise capacity. However, if they have bad CHF, I am less likely to operate.

### PATIENT POSITIONING AND PORT PLACEMENT

#### How do you position a patient on the table for robotic-assisted TMR?

**Dr. Answini:** I change the position of the patient according to the anatomy and the targeted area for treatment, in order to maximize access. I will put a break in the bed to spread out the rib spaces. Usually, ischemia is on the lateral and inferior wall. Placing the patient in the full lateral position gets the heart away from the chest wall as much as possible and provides the most access. Getting to the inferior wall to access the right coronary distribution is the greatest challenge when using the robotic TMR approach. I will

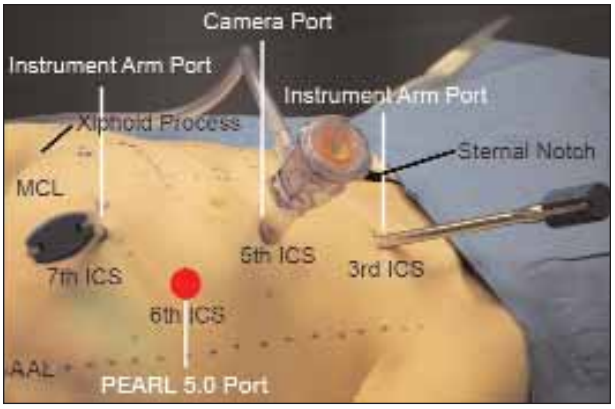


**Figure 1. Image represents the standard supine position to access the LAD and diagonal distribution. Robotic port placement is in the 3-5-7 intercostal spaces, as per Dr. Snyder's setup.**

move the bed to avoid manipulating the heart. If you have to move the table a lot, you need to disconnect the robot. If the targeted zone is the LAD region, I position the patient as I would for robotically assisted left internal mammary artery resection.

### How do you position the ports for this procedure?

**Dr. Snyder:** We place the ports at the 3-5-7 intercostal spaces in our standard setup. The port for the PEARL handpiece is positioned in the 6th intercostal space, approximately one fingerbreadth below the camera port (Figure 1).

**Dr. Answini:** I place the ports in the 5-7-9 intercostal spaces, a rib level lower than a mammary case to provide better access to the heart, especially for the right coronary distribution. If the targeted treatment zone is the LAD, I place the ports more anteriorly. The assistant at the table places a separate port for the robotic handpiece, between the camera port and the right arm of the robot. The port for the robotic PEARL handpiece is positioned a little posterior to and directly between the two other ports. Using one of the robotic instruments inside the chest, I then grasp the distal end of the PEARL handpiece on one of the blue grasping bands.

## PROCEDURAL RECOMMENDATIONS

**Number of Channels, Transesophageal Echo (TEE), Bleeding, Adhesions**

### How many channels are you making?

**Dr. Answini:** These patients are suffering from complex diffuse disease. I first target the documented area of ischemia. If the patient is tolerating the procedure well, I will then treat all viable areas of the left ventricle (LV), from the PDA to the LAD. I make up to 50 transmural channels.

**Dr. Snyder:** I make 30 to 40 channels on average, concentrating first in the ischemic area.

### Do you use TEE?

**Dr. Answini:** I do not use TEE routinely. I started with TEE to show transmurality, but after several cases one can hear a clear change in pitch when transmural. After correlating the pitch change with TEE in several cases, I felt comfortable with that confirmation.

**Dr. Snyder:** I use TEE routinely to confirm transmurality.

### What about bleeding?

**Dr. Answini:** I make three channels at a time, and then wait 1 to 2 minutes to avoid arrhythmias. If there is bleeding, I sometimes use a ray-tech cut in half and hold it up against the channel.

**Dr. Snyder:** I complete five channels, and then hold the pericardium over the channels for approximately 1 minute, which acts as a good hemostatic device.

### What about re-do patients with difficult adhesions?

**Dr. Snyder:** The vast majority of my patients are re-dos. The anterior/lateral wall is rarely stuck up; the pericardium comes off with some loose adhesions.

**Dr. Answini:** I too prefer to identify all structures and take the adhesions down.

### Do you get concerned about intramyocardial vessels?

**Dr. Answini:** No. I have never had to put a stitch in.

**Dr. Snyder:** I have never put a stitch in myself.

## INTRAOPERATIVE MANAGEMENT

### What are the periprocedure concerns?

**Dr. Answini:** Here is my approach for managing patients during robotic-assisted TMR: As this is a beating heart procedure, I use a lidocaine bolus (100 mg) and drip to limit arrhythmias. Initially, I kept the drip going for 6 hours, but learned that there was really no benefit. I use a double-lumen endotracheal tube. One thing I want to highlight with this procedure is to not fluid overload the patient; limit the use of fluids to avoid diastolic dysfunction. We treat liberally with dopamine or dobutamine as necessary.

**Dr. Snyder:** We do not use intravenous lidocaine routinely.

### What about patients with an automatic implantable cardioverter defibrillator (AICD) and low ejection fraction?

**Dr. Answini:** I do not turn off the AICD during a case. I use short bursts of electrocautery when needed, and I have not had any issues with a device discharging during a case.

**Dr. Snyder:** I turn off the AICD. Every patient has R2 pads placed before prepping.

### Do you administer heparin to patients?

**Dr. Answini:** No.

**Dr. Snyder:** No.

### What about patients on Plavix® (Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership, Bridgewater, NJ)?

**Dr. Snyder:** I do not stop Plavix administration because many patients are dependent on their stent. Plavix has

never been an intraoperative bleeding problem with this procedure.

**Dr. Answini:** I agree. We do not stop preoperative Plavix administration either.

## POSTOPERATIVE MANAGEMENT

### What recommendations do you have for managing the patient after TMR?

**Dr. Answini:** Postoperative management includes diuresis and limiting intravenous fluids. I resume nitrates immediately. I hold their beta-blockers/calcium channel blockers for at least 48 hours, mainly due to issues with potential diastolic dysfunction. In order to limit arrhythmias, I monitor the patient for 2 to 3 hours. We do not have a recovery area, so we move them from the OR to the ICU and let them wake up in the ICU and extubate them there. When they are stable, we move them to the floor. Patients are typically in the hospital for 48 hours.

**Dr. Snyder:** We normally have our patients in the ICU for 6 hours and then transfer to telemetry. We remove the chest tube the next morning and the patient is typically discharged on day 2 or 3.

## OUTCOMES

### When do you see improvement?

**Dr. Answini:** I see improvement in many of my patients immediately. It's probably acute denervation initially, and then angiogenesis develops. The studies show a survival/mortality benefit for TMR-treated patients at 5 years.

**Dr. Snyder:** When I see patients in the ICU after TMR, routinely patients say they feel better. On follow-up, they are doing well.

## OUTREACH TO CARDIOLOGY

### How have you built your referral base?

**Dr. Snyder:** My first priority was to approach my cardiologist friends and inform them I was doing TMR. These were folks I had a referral history with, and with whom I had built a level of trust based on results. It was easy to reach these physicians and inform them about the TMR solution for refractory angina patients. Secondly, I approached practices that do not normally send cases. I identified groups with potential for referrals, for a unique procedural option that their existing referrals were not offering. Within those groups, I targeted physicians with the most influence, who were the busiest, or who managed heart failure patients. It is important to meet them in person.

**Dr. Answini:** I am in a group with three cardiothoracic surgeons and 30 cardiologists. I initially presented at grand rounds for my group. We have an active EECP and medical management program, so we kicked off the TMR option by reviewing refractory angina patients who were not improving in the existing program. We also had a couple of news stories that ran locally, highlighting patients who benefited greatly from the robotic-assisted TMR procedure.

### How did you set up in-person meetings with cardiologists?

**Dr. Snyder:** I took a couple of days to meet with high-volume cardiology practices, in their offices. These cardiologists were referring to another hospital that was not doing TMR. Thus, I was offering them something the other center was not able to do. Also, I attended the state ACC meetings, and made some presentations at local cardiology group meetings and grand rounds.

### What are some typical questions raised by cardiologists about TMR?

**Dr. Snyder:** Almost every cardiologist I talk with thinks that TMR is not transmural and requires an open sternotomy. It is important to elucidate the current procedure: transmural channels (unlike DMR) in the targeted ischemic zone, based on preoperative perfusion studies, and the procedure is minimally invasive, either through a limited thoracotomy or via ports with robotic assistance. Also, cardiologists want to know how TMR patients are doing, and they need some comfort level with the safety and efficacy profile of the procedure. I have a large series of patients now, more than 50, with no mortality at 30 days. Furthermore, the 5-year randomized data demonstrated a survival benefit for TMR compared to maximal medical management.

**Dr. Answini:** I agree that the safety profile is important to share with cardiologists. This is a very, very safe procedure with relatively low morbidity. Also, the reimbursement is very good, which is important for hospital administration.

### What is a typical referral pattern?

**Dr. Snyder:** Following in-person meetings with cardiologists, I have typically seen patients referred within 2 weeks. Cardiologists have these patients now, and it is all about getting TMR on their radar screen. After you have demonstrated good results in one or two patients, the patients will continue to come.

**Dr. Answini:** Word of mouth spreads very quickly. We have generated patients up to 100 miles away. We saw a huge glut of patients initially, probably from EECP failures, and then more of a steady flow since. I make it a point to talk with my referring cardiologists every 6 to 12 months to remind them about TMR and share my clinical data. This keeps TMR in the forefront. ■

*Disclaimer: The participants in this Robotic TMR Users Group meeting were provided an honorarium from Cardiogenesis Corporation. The ideas discussed and presented in this meeting summary are not the recommendations of Cardiogenesis and may not be included in the approved product labeling. Please refer to the Cardiogenesis TMR system operators manual and instructions for use (IFU) for the device set-up, operation, utilization, precautions, warnings, approved indications, and labeling.*