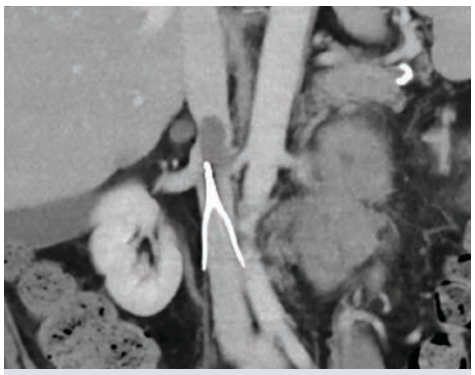
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Imaging and Technical Skills Applied to the Complex Management of a Thrombosed IVC Filter

Vinit Amin, MD

Inferior vena cava (IVC) filter placement is indicated for an expanding list of clinical situations to prevent pulmonary embolism (PE), including prophylactically for those with a high risk for venous thromboembolism (VTE) who have undergone a surgical procedure.[1] Once placed, optional or temporary IVC filters often become permanent[2] and are at the same time associated with myriad complications, both thrombotic and mechanical. Filter thrombosis has been shown to be the most common delayed complication from IVC filter placement.[3]

continued on page 16

In This Issue

CLINICAL TRIAL UPDATE

Discussing the Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischemia (BEST-CLI) Trial

CLD talks with trial co-principal investigators:

Alik Farber, MD, MBA, Chief of the Division of Vascular and Endovascular Surgery at Boston Medical Center and Professor of Surgery and Radiology at Boston University Chobanian & Avedisian School of Medicine;

Matthew Menard, MD, Co-Director of the Endovascular Surgery Program at Brigham and Women's Hospital; Associate Professor of Surgery, Harvard Medical School;

Kenneth Rosenfield, MD, Head of the Section of Vascular Medicine and Intervention in the Division of Cardiology at Massachusetts General Hospital.

continued on page 9

CATH LAB MANAGEMENT

A Retrospective Study Examining Pre-Pandemic Activity in Three UK Regional Cardiac Centers:

Is There Potential for Improvement in the Efficient Use of Operating Facilities for Cardiology Procedures?

W. R. Stables; B. Patel; A. Patwala; A. Hogarth; R. H. Stables

continued on page 12

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The Rundown: BEST-CLI

Both surgical bypass and endovascular revascularization are considered standard-of-care treatment for patients with chronic limb-threatening ischemia (CLTI), but it has remained largely unknown which treatment approach leads to better outcomes for patients. The randomized BEST-CLI trial enrolled more than 1800 CLTI patients from sites in the U.S. and abroad in order to compare clinical, patient experience, and cost outcomes for these two approaches.

Patients enrolled in the trial were randomized to receive bypass or endovascular therapy in two parallel trials. The first trial included a cohort of patients with an available, good quality single-segment great saphenous vein (SSGSV), which previous studies have shown to be the optimal conduit for surgical bypass. As not all patients have an ideal vein conduit available, a second cohort of patients compared bypass and endovascular treatment among those patients who only had alternative conduit options available. Patients in these groups were followed for an average of 2.8 and 1.9 years, respectively.

BEST-CLI found that patients who had a good quality SSGSV available and underwent bypass had a 32% reduction in major adverse limb events (MALE) or death compared to endovascular revascularization. SSGSV bypass patients experienced 65% fewer major reinterventions and 27% fewer amputations. For patients who had only an alternative bypass conduit available, there was no difference between bypass and endovascular revascularization in the primary outcome, although the endovascular arm had more major re-interventions.

Tell us about BEST-CLI's parallel trial design.

Alik Farber, MD, MBA, Chief of the Division of Vascular and Endovascular Surgery at Boston Medical Center and Professor of Surgery and Radiology at Boston University Chobanian & Avedisian School of Medicine: In order to design this trial, we brought together a multidisciplinary team of experts from the fields of vascular surgery, interventional cardiology, interventional radiology, and vascular medicine. We thought about the trial design from multiple perspectives. We believed that we needed to have two separate trials because it is a well-known fact that a SSGSV is a superior conduit to any other grafts. Rather than including all graft possibilities and then relying on multivariable analysis to sort out the data, we felt that it would be more valuable to separate this cohort out completely. The design thus had a separate parallel trial for patients with a good SSGSV, the cohort with the best possible option for bypass, and we compared it to endovascular revascularization. The second cohort is comprised of people who did not have a good SSGSV, but had other possible grafts available. Even though in the surgical world, it is clear that vein is better, in the endovascular world, there is a lot of disagreement about what constitutes an easy or a difficult endovascular revascularization. We stratified patients on anatomy and presentation to ensure that randomization was balanced across these important variables. Our group decided on a pragmatic trial design, allowing physicians to choose any set of procedures within a revascularization strategy that they used in clinical practice. We wanted to avoid limiting ourselves to 1 or 2 techniques that could change and so allowed all techniques and devices that were available on the U.S. market. Led by Dr. John Kaufman, the trial had an Evolving Technologies Committee that evaluated all new technologies. When new technologies, such as drug-coated balloons, became accepted for use, they were incorporated into the trial.

How common is it in real-world practice to evaluate the suitability of great saphenous veins of CLTI patients for bypass?

Kenneth Rosenfield, MD, Head of the Section of Vascular Medicine and Intervention in the Division of Cardiology at Massachusetts General Hospital: It is highly variable and dependent upon the opinion and the specific practice of the treating clinician. In my practice, for example, it would depend on whether I thought the patient was a particularly suitable candidate for surgery or would potentially be better off with surgery, much like in the trial. Then I would scan the saphenous vein to see what their eligibility would be for bypass. There are probably many surgeons who automatically will scan the vein, though there are many surgeons who wouldn't, and many interventionalists or nonsurgeons who would just move right into an endovascular procedure.

"BEST-CLI found that among people who were judged to be good candidates for either treatment option, if they had a good saphenous vein, they did better with surgery. Therefore, patients who are candidates for both surgery and endovascular revascularization should have a venous duplex to see if they have a good vein before proceeding to an endovascular intervention."

— Alik Farber, MD, MBA

“One important message of the trial is that the patient benefits when all relevant opinions at a given institution are processed and heard. This is also a message that we very much want to propagate. The concept of a CLTI team is not new. It currently exists in the cancer world and in heart care. To the extent it can be propagated in this space as well, we all collectively think that is a very good thing.”

— Matthew Menard, MD

I will say that a significant number of patients over time have gone into the cath lab or the OR suite without an evaluation of the saphenous vein for bypass. They get an angiogram and then there is an ad hoc intervention performed right then and there. In some instances, I think BEST-CLI will change that practice and sway it more towards getting a venous duplex before doing an intervention.

Matthew Menard, MD, Co-Director of the Endovascular Surgery Program at Brigham and Women’s Hospital; Associate Professor of Surgery, Harvard Medical School: Venous duplex is a relatively inexpensive test. Most interventionalists would not get a duplex of the saphenous veins and many surgeons do not get one before doing an angiogram. Certainly, if bypass is planned, then the surgeon will absolutely get that test. Implicit here is also a question about what percentage of people have a good quality SSGSV. We haven’t done studies among all-comers to tell us what percentage are going to have a good vein. We do know from surgical studies evaluating people who needed bypass, that between 60% and 80% had an adequate SSGSV.

If a CLTI patient does have an adequate single-segment great saphenous vein, is there now the implication that surgery could be a better option for that patient?

Alik Farber, MD, MBA: We are not implying that everyone with CLTI is better served with a bypass. It is important to note that BEST-CLI studied a group of people who were deemed to be an adequate candidate for either surgical or endovascular revascularization. Additionally, it is not just about the saphenous vein. Patients also need to be at an acceptable risk for a surgical procedure. Next, for a bypass to be successful there has to be an adequate target artery to anastomose the bypass to. BEST-CLI found that among people who were judged to be good candidates for either treatment option, if they had a good saphenous vein, they did better with surgery. Therefore, patients who are candidates for both surgery and endovascular revascularization should have a venous duplex to see if they have a good vein before proceeding to an endovascular intervention. If they have a good SSGSV rather than proceeding directly with an endovascular procedure, the physician needs to stop and have a conversation with the patient about bypass.

Kenneth Rosenfield, MD: The patients enrolled in this trial were patients in whom the team or the investigators decided that there was equipoise between the two treatments. As with any randomized trial, there was a very small proportion of patients at each of our sites that was enrolled. I think we need to unpack the trial further to find out exactly the influence of selection bias in enrollment. It is a limitation of the trial. Implicit in any randomized trial, there is selection bias. We all acknowledge that in the limitations section of the manuscript. So the answer to this question is that we don’t know exactly. If you have a good SSGSV, it does not mean that you have to take every single patient off the table. If you haven’t done a duplex ultrasound, I do not believe that you have to take every patient off the table in the middle of or after an angiogram to assess the vein. I do think for a patient in whom it is going to be a challenging endovascular case, where it might be better to do surgery — or it might be equal, let’s say — then that patient probably should be taken off the table or have a duplex ultrasound done on the table.

Alik Farber, MD, MBA: I actually think what this issue will lead to is an increased use of cross-sectional imaging. You are not going to find yourself with a patient on the table doing a case and think, “The patient is already on the table, I’m just going to do this procedure.” You are going to know ahead of time: is this a bypass candidate? If the patient is a bypass candidate, then the patient deserves to know the data from our trial to make a decision about which way to proceed.

What are your plans for future analysis?

Matthew Menard, MD: Over the course of the trial, we have captured the cost associated with the inpatient care, outpatients, and reinterventions. One of our colleagues who is a specialist in this area is in the process of undertaking a very comprehensive analysis of this very important component of the trial. Combing the clinical results with the quality of life and cost outcomes will give us an unprecedented window into the full impact of our revascularization efforts on patients with CLTI. It is the third outcome being evaluated in this trial.

How might BEST-CLI encourage further interdisciplinary collaboration?

Matthew Menard, MD: The entire effort, from start to finish, was aimed at bringing together all the different specialties to treat CLTI. This was not always easy to do, but we made it crystal clear at every participating site that we wanted everyone who treated CLTI as part of their regular care to be invited and encouraged to participate in the trial. We mandated the creation of CLTI Teams at each institution. Also, an investigator credentialed in open surgery had to indicate that a patient was appropriate for open surgery and an investigator credentialed for endovascular therapy had to put forth their belief that the patient was an appropriate candidate for endovascular therapy. So at least two investigators at every site had to agree that any given patient was a candidate for the trial. This led to a significant amount of de facto collaboration that didn’t previously exist between specialties, so we did manage to move the needle on that front at numerous sites that had not previously bridged that gap. One important message of the trial is that the patient benefits when all relevant opinions at a given institution are processed and heard. This is also a message that we very much want to propagate. The concept of a CLTI team is not new. It currently exists in the cancer world and in heart care. To the extent it can be propagated in this space as well, we all collectively think that is a very good thing.

How do you feel about the balance in this trial in terms of measuring quality of life and more clinical measures? One criticism of clinical trial design in general has been that some trials have measured clinical outcomes only and patients may still experience reduced quality of life despite a positive clinical result.

Kenneth Rosenfield, MD: The quality of life, across the board, improved with patients in this trial, no matter which therapy they received. It also underscores the importance of and shines a light on CLTI, in general. How important it is to treat this disease, one way or the other. Hopefully patients will find their way, with the enlightened help of a CLTI team and docs who care about CLTI. The trial highlights the importance of focusing on this disorder and revascularizing these patients because it does improve their quality of life. Across the board, the quality of life measure showed equal improvement for both therapies. There were subtle differences between them, but essentially both therapies were associated with improvement in quality of life, quite dramatically, actually.

"The amount of data in this trial is enormous and we are only just beginning to unpack it. We have a plan to do so and look forward to digging much deeper to find out the more nuanced messages. The context in which it took place should be interpreted. There may be patients who are overwhelmingly better with bypass surgery and similarly there may be patients who are perfectly fine for endovascular procedures. The subset analysis is going to be important, as is the stratification analysis that we are doing, based on the pre-specified strata."

— Kenneth Rosenfield, MD

Matthew Menard, MD: It is interesting that the quality of life findings did not perfectly parallel the clinical findings. The exact reasons for this is not clear at present, and we are planning on digging deeper to try to further understand the quality of life component. What is notable is how poor the quality of life is in a typical CLTI patient, which was the case for patients coming into our trial as well. It means there is significant room to move with regard to improvement and it was great to see that both therapies had a significant impact. There may be some subtleties for why the results are what they are, but we don't know all the answers at the moment.

Kenneth Rosenfield, MD: BEST-CLI has a much longer follow-up than other trials. The amount of data in this trial is enormous and we are only just beginning to unpack it. We have a plan to do so and look forward to digging much deeper to find out the more nuanced messages. The context in which it took place should be interpreted. There may be patients who are overwhelmingly better with bypass surgery and similarly there may be patients who are perfectly fine for endovascular procedures. The subset analysis is going to be important, as is the stratification analysis that we are doing, based on the pre-specified strata. All of that is exciting to us to unpack and will inform the vascular community. As Alik always likes to say, "There's a treasure trove of data here that needs to be explored."

Alik Farber, MD, MBA: For Cohort 1, the median and maximum follow-up was 2.7 and 7 years, respectively. For Cohort 2, the median and maximum follow-up was 1.6 and 5 years, respectively. We are planning to spend the next three years really understanding the BEST-CLI trial data. We are excited to see what information we are going to learn. ■

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