ASK THE EXPERTS

What Is the Most Needed Key Trial in Peripheral Embolization?

With Robert Abraham, MD, FRCPC; Christoph A. Binkert, MD, MBA; Roberto Iezzi, MD; and Nikki Keefe, MD

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Yttrium-90 (Y-90) embolization is a valuable therapeutic option for patients with liver cancer, as it results in significant tumor response with the potential for cure. One aspect of Y-90 radioembolization that has not been studied enough is the effect of Y-90 microsphere quantity (best expressed as mass in milligrams) on tumor response, considering that both current Y-90 technologies provide the ability to significantly increase quantity of microspheres later in the decay curve. Use of a larger quantity of Y-90 microspheres may theoretically improve coverage and distribution throughout a tumor and optimize crossfire radiation effect, thereby maximizing tumor response. For glass Y-90, this is done through second-week postcalibration dose vial offerings, whereas with resin Y-90, this can be achieved by using more Y-90 microspheres later in the 3-day flex dose offering. In both instances, users can choose a quantity or mass of microspheres that can be correlated with the planned perfused volume while also choosing an overall activity that would result in tumor response using personalized dosimetric planning.

As a first step, I would welcome a prospective study comparing 10,000 microspheres (based on mass) per milliliter perfused volume versus 15,000 microspheres/mL perfused volume with a total activity that would provide a standardized absorbed dose to the tumor that results in significant tumor response (ie, > 210 Gy for glass Y-90). Depending on the results, future studies could also evaluate higher quantities (ie, 20,000 microspheres/mL perfused volume). I strongly believe the results of such studies will provide us with important information in our quest to improve outcomes for patients with liver cancer.

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Hemorrhoids are a common problem causing bleeding, discomfort, and pain. The most common treatment is rubber band ligation, which can be painful, and often hemorrhoids recur. Surgical treatments range from Doppler-guided hemorrhoidal artery ligation to stapled hemorrhoidopexy to standard surgical resection (Milligan-Morgan hemorrhoidectomy). All treatments are quite uncomfortable for the patient and can lead to local infection.

Especially in France, hemorrhoidal artery embolization (HAE) has been used to treat symptomatic hemorrhoids. The technical concept is to embolize all branches of the superior rectal artery feeding the hemorrhoids and, if needed, also the supply from the middle rectal artery. The results have been very encouraging, with decreased bleeding, reduced pain, improved quality of life, and no major complications. Despite these promising results, HAE has stayed a niche procedure.

Therefore, a randomized controlled trial comparing HAE versus ligation or surgical treatment for bleeding grade II/III hemorrhoids is needed. Besides the improvement of bleeding and pain, the trial should look specifically at patient comfort and quality of life during and after the therapy.

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Endovascular therapy has evolved dramatically over the last 2 decades, with a wide array of endovascular tools and new devices now available to perform peripheral embolization and treat complex lesions in advanced patients. These new technologies have allowed for wide clinical indications that offer new treatment options, not only for tumors but also for patients with benign diseases.

Recently, endovascular embolization of hemorrhoids has emerged as a promising minimally invasive alternative to surgical treatment; it avoids any anorectal manipulation and has the advantage to also treat patients with systemic comorbidities (eg, respiratory or cardiovascular compromise, anticoagulation or antiplatelet therapies) or local pathologies (eg, fecal incontinence, inflammatory bowel disease, proctitis, previous radiotherapy) who cannot be approached with classic or minimally invasive surgical interventions. However, there is no consensus on the best embolic agent to be used, and there is still limited clinical evidence on the medium- and long-term follow-up, particularly when compared with surgical options.

Based on this background, prospective studies with large case series comparing the different embolic agents and medium- and long-term follow-up to better define the efficacy and safety of the procedure are needed. The studies should also compare with established and scientifically validated techniques, such as circular stapled anopexy (Longo procedure) and elective Doppler-guided hemorrhoidal artery ligation.

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Pelvic venous disease (PeVD) remains a poorly understood entity due to limited diagnostic criteria, variable terminology, and lack of prospective randomized control trials. Recently, the SVP (symptoms, varices, pathophysiology) classification was approved to improve clinical decision-making and diagnosis. This provided a more precise, standardized way of reporting the disorders of pelvic veins, such as May-Thurner syndrome, nutcracker syndrome, and pelvic congestion syndrome. Adoption of the SVP system is in its infancy and requires clinical validation.

In addition to terminology, there is a lack of standardization of embolization due to the lack of prospective trials. It is uncertain whether embolization of the pelvic venous plexus is necessary, in addition to the gonadal veins. Also, the type of sclerosant and coils used vary greatly between providers. More data are needed to determine if concurrent left iliac vein stenosis and pelvic varicosities should be treated in a single session or staged sessions, or if treatment of the iliac stenosis alone is sufficient. To provide the best symptom improvement for our patients, we must have the data to help steer treatment. A prospective randomized controlled trial is needed not only to validate the new SVP classification of PeVD but also to understand the best way to treat. ■