

# The EmboCoh Visceral Aneurysm Registry

A preview of this postmarket registry that aims to provide worldwide data on embolization.

**BY MARC SAPOVAL, MD, PhD, AND GERT ANDERSEN, BSE**

Peripheral embolization is one of the fastest-growing interventional and endovascular procedures worldwide. According to data from the Millennium Research Group,<sup>1</sup> there were more than 125,000 diverse embolization procedures performed globally in 2012. Embolization materials have also changed significantly, with improvements in coils and plug technology, the introduction of flow diverters and new stent grafts, and the development of sophisticated embolic particles that allow the extension of embolization as a means to deliver drugs and other therapeutic agents.

In spite of the relatively large overall number of procedures, there is still a significant gap in the level of evidence available in this field. There are many reasons explaining this lack of evidence that are beyond the scope of this article. One major explanation is that some procedures, such as embolization of visceral aneurysms, are not very frequent and are performed only in minimal numbers per center. This, in combination with the fact that most embolization materials are labeled for general embolization indications, means that there is a certain lack of consistent, indication-specific scientific data in the field. One of the consequences is that only a few indications, such as uterine fibroid embolization, can present an evidence-based consensus on treatment strategies.

Through providing evidence from around the world, it is our belief that more patients will benefit from minimally invasive treatments, and the field will achieve general acceptance by the medical community. Therefore, a group of interventional radiologists has conceived the idea of

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the EmboCoh study. We have focused on embolization procedures that are performed infrequently, such that a single team cannot record enough cases in a reasonable period of time for meaningful analysis. Providing an international tool for generating evidence will lead to publications, presentations, and ultimately, a better standard of care in these procedures. Marc Sapoval, MD, PhD, from Hôpital Européen Georges Pompidou in Paris, France; Jafar Golzarian, MD, from the University of Minnesota in Minneapolis, Minnesota; and John Kaufman, MD, from Dotter Interventional Institute in Portland, Oregon, with the assistance of Gert Andersen, BSE, a private consultant, have developed an infrastructure that can be applied to international registries and cohort studies.

The purpose of this cohort study is to collect data and create a global database on the use of embolization devices and embolization procedure outcomes. Focused outcome measures will contain overall immediate results according to the type of embolization material, trends in number of procedures according to the type of disease and intervention, and long-term outcome and subgroup

analysis. Additionally, this study will support innovation by creating a better overview of the products used and pathologies treated. It will also serve as an empowering tool to reach new operators and to develop new interventions in centers, regions, and countries where specific difficulties are encountered. The cohort study represents a novel approach as a way of allowing clinicians to generate reports based on an evolving, controlled, and well-organized database. The number of patients—and most of all, the quality of the data entered and the quality of the follow-up—will be key information that EmboCoh will allow physicians to assess: for instance, by comparing data from their own center against the global data.

Visceral aneurysm embolization has been selected as a first indication, and a steering committee that includes three interventional radiologists (Keigo Osuga, MD, PhD, of Osaka University in Osaka, Japan; Vincent Vidal, MD, PhD, of Hospital de la Timone in Marseille, France; and Michael Darcy, MD, of Washington University in Saint Louis, Missouri) has developed the electronic case report form for visceral aneurysms to capture the first datasets for this novel global database.

Patients will be enrolled from May 2014 in highly selected centers at the beginning. In the very near future, new centers will be invited to participate. The official launch of the project will be at GEST 2014 US, held May 1 through 4 in San Francisco, California (more details may be found at <http://www.gestweb.org>). ■

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1. Millennium Research Group, Inc. Medical Technology RPEU11TE10. July 2010.