ESVS Physician-Industry Panel Explores Trends in Vascular Care and Symposia

Highlights from a candid discussion held at the 2015 ESVS meeting in Porto, Portugal.

PANEL

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Prof. Arkadiusz Jawien, MD, PhD (ESVS, President)
Lieven Mariën (ESVS)
Scott L. Rush (Bolton Medical)
Megan Eckerman (Bolton Medical)
Sabina Betti (Gore & Associates)
Claudio Celani (Gore & Associates)
Maria Pedrosa (Gore & Associates)
Angelique Balguid, PhD (Philips)
Marjolein van Lieshout, PhD (Philips)
Craig McChesney (*Endovascular Today*)
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In a closed session held during September's annual meeting of the European Society for Vascular Surgery (ESVS) in Porto, Portugal, leadership from the society met with key industry members and engaged in a roundtable discussion on several topics of interest in the vascular field. Central in the conversation were radiation safety, innovation in aortic therapies, and the need to treat the patient, rather than just the disease. Also prominent were discussions on the current state of vascular congresses and what the organizers, physician attendees, and industry all believe to be most valuable in the experience.

The following is a summary of the ESVS panel discussion, highlighting points of consensus and divergence among the participants.

RETURN ON INVESTMENT: DEFENDING THE SPEND

Noting that continued support from industry is vital in keeping educational symposia running, the ESVS leadership asked the industry panel members to candidly share their goals in attending and supporting vascular meetings—specifically, what makes a program attractive from their standpoint. As more and more meetings emerge, often chaired by individual physicians or small groups, the panel seemed unanimous that there is increased pressure for companies to "defend the spend" across all of the meetings they support. However, industry is not simply looking to fund programs that showcase their products. Angelique Balguid from Philips said that with the multitude of conferences currently being held, if a program does not provide a high level of education, it will quickly be seen as not important enough by attendees and industry alike. And, often, the qualities that make a meeting interesting to its physician attendees are the same that draw industry, suggesting that it may be counterproductive to view the interests of industry and physicians separately.

Bolton Medical's Megan Eckerman noted that, overall, it is important to support content that scientifically sup-

ports the growth of a market, rather than hinging on a particular product or even device class. However, industry goals may vary across markets and business lines. For instance, content that focuses on the field as a whole may be better suited to newer fields of study, whereas more mature markets with established data and product lines may warrant increased focus on specific devices and their ideal applications. Paramount in all instances, however, is progressive content that helps to move the field forward.

Marjolein van Lieshout from Philips emphasized the importance of discussions going beyond the standard lectures and talking points, focusing portions of the meeting's content on the uncertainties in the field and what to do when things do not go according to plan. Sessions such as these are engaging for physician attendees, but they also help companies stay informed on key unanswered questions to be addressed.

Of course, to be of value for industry, the meeting must also be well-attended, said Maria Pedrosa from Gore & Associates, who believes the value of industry supporting meetings is in the ability to help foster learning environments for physicians, but noted that it can be harder to support meetings with lower attendance numbers. Claudio Celani, also from Gore, added that it is important for the meeting and its associated industry-supported events to be aligned with EUCOMED guidelines. The relationship between industry and professional medical societies is key in preserving platforms for idea exchange, but it is increasingly the focus of much scrutiny.

Other common key elements industry takes into consideration when deciding on its support for a meeting include the ability to build relationships and their visibility and level of presence at the meeting. Sabina Betti from Gore also suggested that the importance of ease of logistics—ranging from the geographic location of the entire congress to the precision in scheduling of talks and satellite events—cannot be underestimated. A substantial amount of work and expense across several divisions goes into supporting congresses, and what may seem to be a slight change in schedule or venue for the organizer can have significant, unfavorable effects for the industry supporter.

In summary, although there is internal pressure within industry to show return on investment in order to justify expenditure, there is no simple, singular way to do so. Moreover, the more easily quantifiable elements of meeting support such as lead generation in the exhibit hall or numbers of product mentions in the lecture hall, while important, are perhaps less of a factor than the overall quality—and attendance—of the supported event. Grateful for the candid feedback, Prof. Jawien reaffirmed the ESVS's goal of continuing to learn more about how various elements of the congress each affect the society and industry differently and incorporate this into future congresses.

WHAT'S NEXT IN AORTIC REPAIR?

Prof. Debus from the ESVS leadership also asked the industry panel about their thoughts on the future of aortic repair, specifically endovascular aortic repair (EVAR). Who will be the primary operators? Which centers will handle cases, from simple to complex? And what are the most needed key developments in technology?

Regarding which physicians would likely be treating the aorta going forward, the consensus seemed to be that this will remain largely the domain of vascular

specialists, with the primary concentration continuing to be the vascular surgeon who is trained in endovascular repair. However, other vascular specialties could be increasingly involved, and the introduction of percutaneous valvular intervention could see more interventional cardiologists and cardiothoracic surgeons performing aortic stent grafting cases.

Also of interest was where future aortic cases will be performed. Will the majority be done in specialized aortic centers of excellence, or will more cases be done outside of the larger centers, even into ambulatory care centers? The discussion centered on how the process has been in evolution since it began, and that it will continue. At the outset of EVAR, even basic cases were concentrated to the larger centers, but in many areas, the procedure has now moved to smaller hospitals with lower volumes. Today, complex (eg, ascending, arch, thoracoabdominal) EVAR is currently offered primarily only in high-volume centers, where the primary initial research as to which options will ultimately work well and be disseminated further will continue to take place. But, Scott Rush from Bolton Medical pointed out, as the definition of what is and is not complex changes, and technologies are developed to better meet more challenging anatomies, these procedures could have the potential to eventually be done in smaller hospitals as well. Of course, this will depend on the progress of technology, techniques, and continued improvement in the long-term understanding of this progressive disease, so there is some debate as to whether complex cases will remain the purview of the centers with the most experience.

Regional considerations, government regulations, and reimbursement/health care economics may, however, play an even bigger role than technological and skill development. For example, if a particular country's governing agency were to determine that the care in designated, specialized centers were to demonstrate better outcomes and more efficiency from a cost standpoint, it could restrict reimbursement to only those centers. In terms of the potential for evolution in this concept, it is also possible that with more cases being done endovascularly and more physicians being trained with improved skills and devices, more centers could achieve this status than would currently be the case. Prof. Jawien did note, however, that the evolution of the patient population could be just as big a factor. In populations that focus on eliminating risk factors that lead to aneurysmal disease, volumes in surrounding EVAR centers will ultimately decline, a force that could lead to procedures being done predominantly in specialized centers rather than locations that do only a handful of cases per year.

With published articles and presentations now showing increasing numbers of cases being treated outside of the approved instructions for use, Prof. Jawien asked the industry panel their thoughts on off-label use. Representatives from the device side answered that although the companies do not advocate off-label use, they understand the decision on whether and how to use the device is ultimately the treating physician's. Industry representatives described stent grafts as being designed for use within their labels, which are determined in the course of rigorous testing and trials, contrary to the notion that they are possibly engineered for expanded indications (ie, "foreseeable misuse"). With some of the aforementioned articles showing that long-term results are not as good when devices are used off-label, this can reflect negatively on the device, which can be frustrating from the industry standpoint. But, communication and structured study regarding these uses can inform industry of clinical needs, and ideally lead to further development and study so that there is no need to perform these procedures off-label in the future.

One area in which physicians and industry are collaborating to expand the population that is treatable via on-label EVAR is customization. Custom devices may involve tapering schemes and grafts of different lengths pieced together, as well as branch and fenestrated elements to maintain thoracoabdominal and arch vessel circulation in patients with aneurysms surrounding these vessels or with insufficient necks for adequate sealing. However, the goal of a custom program as discussed in the panel is to keep the evolution of devices and the treatable patient populations on-label regarding critical aspects of stent graft design such as seal length and oversizing, rather than to enable operators to work outside the intended uses..

When industry representatives in turn asked the physicians present for their opinions on off-label usage, the first point of discussion was that what might be an off-label case for endovascular repair may in fact be better suited for open repair, underscoring the need for continued training in the latter. They also discussed the thin line between making a device decision outside of the approved indication in order to meet unique patient needs and a decision that carries potential to cause complications.

FOCUS ON RADIATION SAFETY

Among this panel representing both the imaging and implantable device industries as well as surgeons trained in both open and endovascular repairs, one topic that came up often across several discussions was the need for more focus on radiation safety for operators and

patients alike. Prof. Debus and Prof. Jawien described a modern landscape in which, from training to practice, today's surgeons are increasingly performing endovascular procedures rather than open. This calls into focus both the need to ensure that the training pendulum also swings sufficiently to the open side so that the needed surgical skills do not decline, but also the importance of limiting the amount of time today's interventional specialists spend exposed to radiation. The recent increased awareness regarding the dangers of radiation exposure has even begun to result in a decline in some vascular surgeons' interest to go into the cath lab, commented Prof. Jawien.

However, with the overall trend toward significantly more endovascular versus surgical procedures across nearly all vascular anatomies still prevailing in most centers, physician safety initiatives must also increase. It was noted that this may be particularly challenging as aortic interventions trend toward treating more complex cases, which typically require more exposure time. The panel discussed the need for everything from agreed-upon standards to better lead solutions to reduce physical wear and tear on the operator, and representatives from Philips described efforts toward radiation reduction via improved software, navigation, and monitoring capabilities, but also an increased focus on education, which is part of their goal in having a presence at congresses such as ESVS. At live symposia, there are opportunities to showcase technological capabilities, but perhaps more importantly, to converse and collaborate with physicians who have experience using these imaging systems and ideas on how to improve them.

With each of the discussed topics still open-ended, it was determined that questions such as these might be something that societies such as ESVS could collaborate with industry to learn more about. ■