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EDITORIAL

The Key Role of the European Society for Vascular Surgery in Improving the Surveillance of High Risk Medical Devices

The history of vascular surgery is rich in success stories, many of which involve innovative medical devices. However, the increased use of implantable devices in cardiovascular disease has not always reflected a strong evidence base from independent randomised controlled trials (RCTs). A considerable proportion of what we have learnt about devices stems from direct adoption into clinical practice, published case series, and poorly designed trials. Many in the vascular community, and regulators of healthcare, have expressed concerns regarding a lack of good quality long term surveillance data on specific devices. This has led to comprehensive changes in terms of device regulation.

When we consider evidence regarding device safety and efficacy, it is important to reflect on the fact that, although variable in degree and dependent on study funding, design, and execution, virtually all clinical studies are affected by bias to some degree. Despite their indispensable advantages and ability to evaluate causative effects, even large scale RCTs have limitations. Numerous studies have demonstrated that patient selection, treatment, and outcomes in trials may be different from the population as a whole.[1] Furthermore, due to these design features, RCTs are not always suitable for quality assurance measures. Similarly, large multicentre national registries, which are the gold standard for quality improvement programs, may provide a valuable insight into good medical care, but are hindered by centres that do not participate. This can disguise those that may have worse outcomes and provide a false impression of overall quality improvement.

While different research design types may be influenced by bias and have specific flaws, they can provide complementary information to guide device safety and efficacy. In simplified terms, large registries have advantages for quality improvement due to sheer scale and broader outcome datasets. Randomisation of selected cohorts within trials are indispensable to determine causality between interventions and very specific outcomes. Good quality population based registries, that capture device identifiers, receive increasing attention from both the vascular community and industry. This has partially been spurred by comprehensive reformations of European Union (EU) Law.

In 2021, the EU Medical Device Regulation (MDR) came into force and introduced a novel framework for market access of high risk medical devices, such as aortic or peripheral stents.[2] Most attention has focused on conventional implantable devices, but another law specifically targets *in vivo* diagnostics; this may face an interesting future in the vascular field. Imagine aortic stent grafts that measure sac pressure, or a peripheral stent that can determine blood glucose levels and haemodynamic sheer stress in people with diabetes.

Meanwhile, an ever increasing volume of healthcare data are being generated in the biomedical field to meet the great need for information. Prior to the EU General Data Protection Regulation being introduced in 2018, the term Big Data was gaining attraction in vascular research.[2,3] An increasing number of projects have demonstrated the potential for artificial intelligence and machine learning to take advantage of these rich datasets.[4] Needless to say that regulators are currently working on further reformations of Union law to assure safe and secure data flow and data privacy compliant machine learning in the future.

We, as vascular surgeons, must accept that we have a responsibility to collect robust patient centred outcome data. Moreover, we have a responsibility by partaking in clinical trials and studies, to avoid research waste. If a patient is recruited into a trial or registry, their data should always be used to further clinical practice. We have an obligation to report all data, even if considered negative. We also need to adapt and harness routinely collected health data that may ultimately lead to an environment that works for us and patients.

All medical devices, especially those that are included in the high risk group III of the MDR, are critical to the care of vascular patients. Frameworks such as IDEAL (idea, development, exploration, assessment, long term follow up) can help to harmonise the process of market access and surveillance in a transparent way. There have been some high profile failures in vascular surgery, as well as in other medical specialties, that emphasise the urgent need for continuous long term device surveillance.[5] Some controversies in vascular surgery, such as the ongoing paclitaxel debate, illustrate the complementing value of data from RCTs *vs.* real world data to recognise and analyse potential safety signals.[6] Beyond monitoring lifelong device performance, we also need to harness opportunities to critically assess failed devices. European initiatives that specialise in vascular biomaterials may provide a collaborative solution.[7]

Almost all recent clinical vascular practice guidelines have highlighted the paucity of data and evidence to answer some of our most pressing clinical questions.[8,9] As a growing scientific society connecting more than 3,200 members in Europe and beyond, the European Society for

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Vascular Surgery (ESVS) has an obligation and opportunity to fill these gaps through supporting science, research, and education. Founded in 1997 at the ESVS annual meeting in Lisbon, Portugal, the VASCUNET committee effectively illustrates the value of shared knowledge. As of today, more than 40 vascular surgeons representing 28 national and regional quality improvement registry initiatives in Europe, Australasia, and South America meet bi-annually to combine their datasets and compare data, resulting in multiple publications.[10] Furthermore, the European Research Hub (ERH), which aims to support research activities within the ESVS network, was founded last year.

Embedded in a growing society network, these two ESVS committees may ultimately represent the perfect synergism for endorsing strong research proposals in the medical device evaluation field. We also wish to reinforce the 2019 ESVS Executive Committee Position Statement that long term evaluation should be an integral part of the clinical implementation of new vascular treatments.

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