Editorial

Big Data and Artificial Intelligence in Vascular Surgery: Time for Multidisciplinary Cross-Border Collaboration

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Access to reliable and meaningful evidence derived from high-quality randomized trials and observational research is essential in clinical decision making and represents evidence-based medicine.[1] Technical achievements over the past decades including the rapid adoption of digital technologies, development of electronic health records (EHRs), widespread high-speed internet access as well as mobile devices, and the rise of artificial intelligence (AI) have opened a new era for clinical research and quality improvement using big data methods. Data used for real-world evidence research are provided from various sources such as EHRs, registries, picture archiving and communication systems (PACS), or even self-monitoring devices.[2] Efforts to generate real-world evidence have rapidly pointed to the importance for collaboration between centers and countries to collect, analyze, and report reliable and representative data to build recommendations for clinical practice.[3] With that aim in mind, international registry collaborations across medical and surgical disciplines have been created.[3,4]

In the field of vascular surgery, VASCUNET is a collaboration of clinical and administrative vascular registries that was created in 1997 at the European Society for Vascular Surgery (ESVS) annual meeting, and which now counts >40 members from 28 different countries.[5] In the United States (US), the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) collected data from >900,000 vascular procedures performed in the US and in Canada.[6] In 2014, the International Consortium of Vascular Registries (ICVR) was founded and is an umbrella for quality improvement launched in collaboration with the SVS-VQI, ESVS-VASCUNET, and the Medical Device Epidemiology Network (MDEpiNet).[7] More recently, the European Vascular Research Collaborative (EVRC) was implemented as a multidisciplinary research collaborative that aims to facilitate European cross-specialty vascular research.[8] In parallel, the creation of a European Health Data Space has become one of the priorities of the European Commission to promote access and exchange of health data among European institutions not only to support healthcare delivery but also for research.[9] The system is expected to be built in accordance with the European Union (EU) general data protection regulation (GDPR) and may bring promising perspectives for international collaboration.

While international registries bring great perspectives to enhance knowledge on the management and the outcomes of patients with vascular diseases worldwide, they mainly focus on clinical and administrative data. Imaging takes a central role in the management of patients with vascular diseases and AI has brought new insights in medical imaging by offering new tools that could help to enhance automatic segmentation and analysis to improve detection, classification, or identification of predictive patterns.[10-13] Machine learning (ML) models often require a large quantity of data to be trained and validated and data representability is crucial to build accurate and efficient models.[14] Building large scale consortiums and platforms to allow to collect, analyze, and share imaging data

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across institutions remains a challenge and efforts are currently ongoing to achieve this goal in Europe in the field of vascular surgery. Meanwhile, some platforms like "Grand-Challenge.org" offer access to datasets for end-to-end development of ML solutions in biomedical imaging.[15] Nevertheless, only a very few projects are related to imaging for non-cardiac vascular diseases.[15]

The emergence of big data in healthcare and medical research brings many challenges regarding data protection and privacy, security, ownership, management, control, and sharing.[16] In 2018, the EU GDPR provided a new legal framework regarding data privacy and security.[2,17] Within EU law, the charter of fundamental rights defines key values on which the EU is founded especially emphasizing the right to informational self-determination. While the GDPR has provided a uniform set of rules, the heterogeneity among EU countries in terms of digital health funding, readiness, use as well as differences among legislation represents a challenge to overcome when building international studies.[18] In the US, the collection, storage, and disclosure of personal health information is mainly regulated by the 1996 Health Insurance Portability and Accountability Act (HIPAA) and presents substantial differences from the GDPR in terms of definitions of health data requiring protection and methods.[19,20] While administrative requirements may vary from one country to another, they all adhere to the ethical principle of data protection and security. Multi-institutional collaborations most often require that the collaborating institutions share patient data with a centralized location for model training.[21] Therefore, various privacy-preserving techniques have been developed and can be used during big data life cycle from data generation, storage, and processing.[22] Alternative approaches have also been developed for ML methods to allow the development of training models across institutions without sharing patient data.[21] Federated learning is a data-private collaborative learning method where each collaborator trains a ML model on their own data at the same time and then sends their model updates to a central server to be aggregated into a consensus model.[21] In any case, limitations related to registries include lack of detailed information which may only collect selected data and lack long-term follow-up, posing a challenge when results need to be merged. Besides, in case of rare events, class imbalance is also important to consider for ML methods.[23,24] Finally, data interoperability remains a critical component to build high-quality and high-capacity platform that allow processing of various data formats and communication across IT systems.[25]

In addition to administrative, ethical, and technical aspects, international multicenter collaboration raises the question of data ownership. The several uncertainties associated with these complex considerations led to a rigorous legal framework where personal health data must not be processed in countries outside EU jurisdiction with very few exceptions. As reviewed by Mirchev et al., the concept of data ownership in context of big data has been poorly investigated and even its definition is not standardized.[16,26] Ownership of patient information is a multidisciplinary issue involving ethical, legal, political, and managerial aspects of medical information and communication technologies.[16] GDPR has only scratched the surface of data ownership although multidisciplinary academic team work remains necessary to build consensus on adequate policies and legal frameworks.

AI has brought wide perspectives of applications in vascular surgery, from clinical practice with new tools for the diagnosis, the prognosis or the treatment of patients,[12,13,27-32] to education and training of vascular surgeons,[33,34] as well as new tools for research.[13,27,33]

The development of such applications necessitates cross-border collaborations to allow access and processing of health data while respecting a heterogeneous ethical and legal framework. In addition to the collaborative work within vascular surgery departments, it has become crucial that health professionals work hand to hand with AI professionals, including engineers in mathematics and computer science as well as researchers and data scientists to improve data management and contribute to the development of accurate, safe, and efficient applications. Thus, there is an urgent need to strengthen and enlarge multidisciplinary collaboration.

In addition to legal, administrative, institutional, managerial, and financial aspects, collaborative and partnership research creates challenges between partners to successfully complete research projects.[35,36] Main challenges include dedicated time for coordination, communication, distribution of tasks, and responsibilities as well as intercultural and interpersonal agreements and understanding on motivations, expectations, goals, and organization among teams.[35,36]

Nevertheless, international multidisciplinary collaborations have the potential to increase knowledge for clinical practice, develop innovative solutions, and bring new insights into clinical research to solve complex scientific questions. Bibliometric studies indicate an increased number of publications and international collaborations in the past decade regarding applications of AI in vascular surgery.[30,31,33] This suggests an encouraging move toward this direction with an evolution of mindsets regarding strategies and approaches to research, but with strong emphasis on ethical authorship.[37] Finally, natural language processing brings new tools for text analysis and classification, offering great perspectives to enhance medical information retrieval, provide annotations for training ML algorithms, and access scientific content by empowering literature search and bibliometric analysis.[38-40] Taken together, these applications could help to disseminate knowledge, create, and reinforce links between teams beyond national boundaries.

Patients with vascular diseases commonly have complex comorbidity and risk profile, while a paucity of high-quality evidence and strong guideline recommendations challenge everyday decision making. This new era of big data and AI may help support individually tailored care and help fill the gaps. We truly believe that the challenge is

worthwhile and that cooperation across borders and disciplines should be encouraged by academic and research institutions.

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Author Contribution

All authors confirm that they contributed to the intellectual content of this article including conception and design. They revised the manuscript and approved the final version.

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