Demonstrating quality through data

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IR clinical specialty
Special Session
Tuesday, September 16, 08:30-09:30
Auditorium 5

Let us start by asking a Sesame Street-style question: "Why should we demonstrate quality through data?" Well, turf battles with friends from several disciplines aside, interventional radiology has reached social media and is described as a medical sub-speciality of radiology that utilises minimally invasive, image-guided procedures to diagnose and treat diseases in nearly every organ system. The concept behind IR is "to diagnose and treat patients using the least invasive techniques currently available, in order to minimise the risk to the patient and improve health outcomes" [1]. Following this description, it is mentioned that, "[m]any conditions that once required surgery can now be treated non-surgically by interventional radiologists. By minimising the physical trauma to the patient, peripheral interventions can reduce infection rates and recovery time as well as shorten hospital stays" [2].

While patients may prefer such treatments, colleagues who could be replaced by such a shift in care may not be equally enthusiastic, may not be motivated to provide such treatments or may look for other options. Furthermore, the older approach has to be regarded as the gold standard until newer treatment options have proven to be superior, which brings us back to the topic of this article.

Does quality win?

Let us assume that quality will ultimately win and that structures within national medical systems will subsequently change. Specialities able to provide better services will be empowered to provide such services to patients. This would be the case if systems were to react on the basis of current knowledge supported by recent data. In the era of evidence-based medicine, guidelines are developed on the basis of consistent, reproducible, and solid data, with an emphasis on randomised controlled trials and meta-analyses.

IR is not a field known for many publicly-funded randomised controlled trials, and the CE-mark paradox is a part of that reality. In order to convince clinical colleagues, medical authorities or national institutes that decide on reimbursement of IR's value, it is crucial to carry out discussions on the basis of sound scientific data. Sometimes it may be difficult to convince colleagues to participate in a trial that might prove the established therapy (former gold standard) inferior. Radiologists are especially reliant on the co-operation of physicians in other disciplines who are direct caretakers of patients.

How may we demonstrate quality through data?

Let us hypothesise that IR would gain more acceptance if professional societies were to stimulate, foster or organise clinical trials/registries with the potential advantage of faster enrolment. The clinical results of IR procedures can be documented at a national or professional society level by providing a database on technical/clinical complications, success rates, or relevant results, such as survival or quality of life. Such databases, initiated and provided by a national or professional society, can also be used to monitor new devices that are drifting into the market on the basis of CE-labelling in Europe without the availability of clinical trials. The registry of the German Society for Interventional Radiology (DeGIR - Deutsche Gesellschaft für Interventionelle Radiologie und minimal-invasive Therapie), organised within the German Society of Radiology (DRG), represents such a potential tool. DeGIR was founded in 2008, substituting the previously existing working group for interventional radiology (AGIR) within the DRG. DeGIR represents radiologists dedicated to interventional and minimally invasive procedures, with a special focus on ensuring quality education and documentation within clinical practise.

The first AGIR president (Prof. Zeitler) initiated a strategic quality assurance programme back in 1987, in the form of an AGIR registry that documented procedures, including complications, based on a paper sheet per patient. Data were mailed to his hospital for further evaluation. The sheets were manually transferred to FoxbaseR in 1990. General results were presented at the national radiology meeting and published. In 1993, Prof. Zeitler handed the data management over to Prof. Heuser, who introduced standardised software for decentralised data collection in 1994. Institutions copied their data to floppy discs once a year, and mailed these to Prof. Heuser in Bochum for further analysis on a larger scale, with more than 18,000 patients documented in 1998. Based on this system, each participating hospital received its quality data and an external benchmark comparison. In 2005, a new system, featuring server-based central data management and online documentation of pseudonymous patient data, was established. That development was accompanied by numerous suggestions and demands to improve manageability, and a software group was formed to discuss possible upgrades, including expansion. Currently, software modifications and improvements are implemented during the year and are released at the beginning of each year. Each participating institution may extract its own data as compared to the pooled data of all other participating institutions.

The current structure covers a broad spectrum of 45 procedure groups organised into 14 categories and 131 anatomic regions. Specific data are required per case to completely document a patient, including patient selection criteria, procedural details, outcome, involved interventionalists, technical success, medical success, complications or radiation exposure (Fig. 1 and 2). The names of interventionalists involved are also forwarded for the quality step 1 / step 2 programmes.

The number of participating institutions is steadily increasing; they receive an annual certificate that can be used for strategic purposes within or outside of the hospital. The pool of data is a valuable resource for systematic reviews, such as quality reports, by DeGIR, proving the broad range of vascular and non-vascular interventions [3, 4]. The number of documented cases exceeded 100,000 in 2012 (Fig. 3).

Based on experiences with the registry, and due to the ever-increasing importance of structured training, a second strategic tool for improving quality at a national level was developed. Focusing on the training and certification of specially trained interventional radiologists and interventional training centres, this system was incrementally introduced during the past five years. The broad field of interventional radiology was initially divided into four further fields:

Module A: vascular procedures – revascularisation
Module B: vascular procedures – embolisation
Module C: biopsy + drainage + pain treatment
Module D: oncology treatment

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Prof. Reimer was a member of the Local Host Committee for CIRSE 2011 in Munich. He is active in several professional societies, including as board member of the German Society for Interventional Radiology. Prof. Reimer's work has been recognised with multiple awards, including for exceptional reviews carried out for several journals, such as Radiology *and* The European Journal of Radiology.

Co-author Prof. Heuser formerly directed the Institute for Diagnostic and Interventional Radiology, Neuroradiology and Nuclear Medicine at the Ruhr-University Bochum.

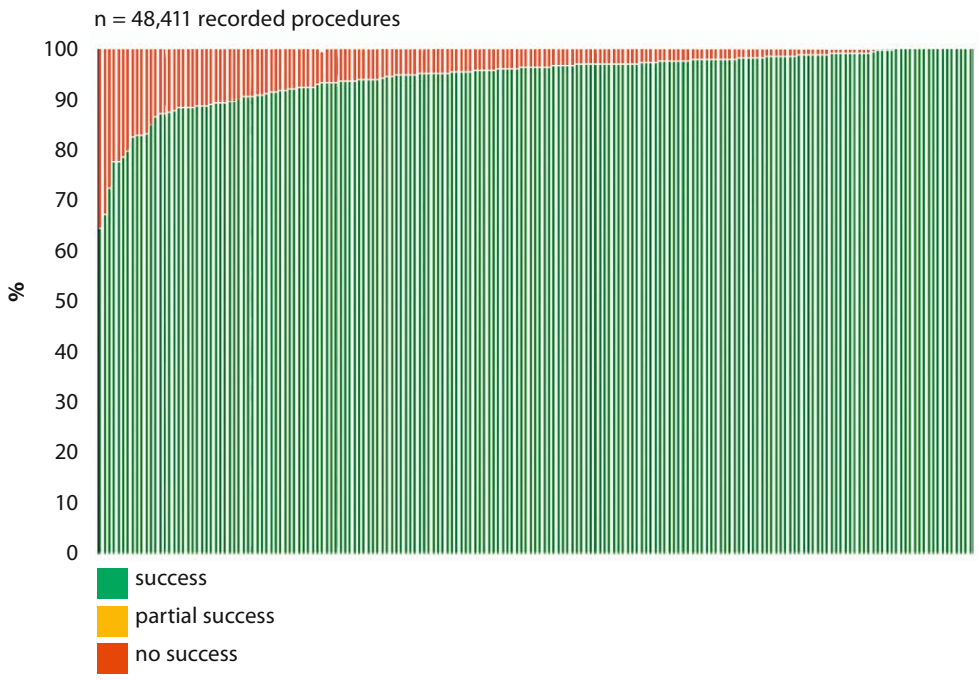

Fig. 2: Technical success rates in arterial recanalisation 2013

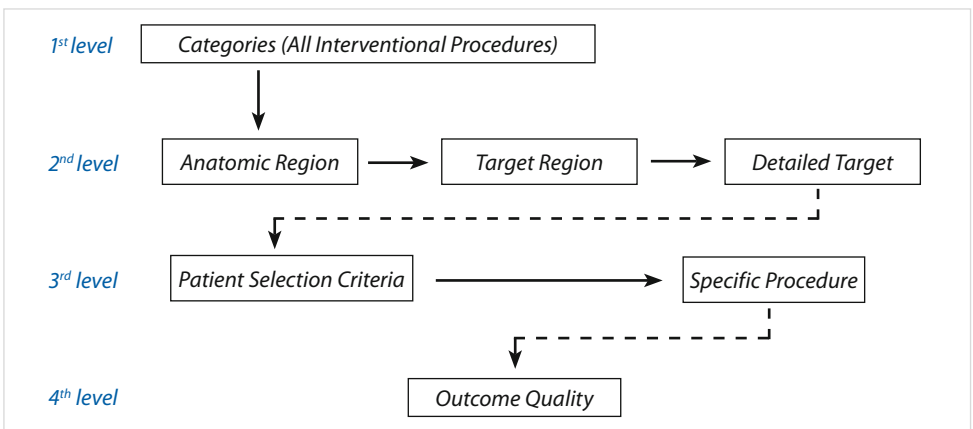

Fig. 1: Workflow of the QM Software

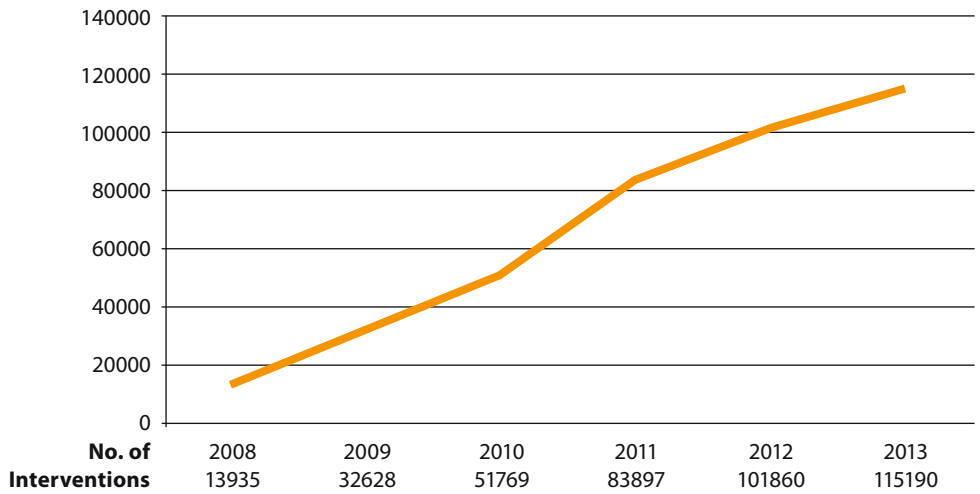

Fig. 3: Development of the reported number of interventions

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A two-step personal certificate is offered to colleagues who participate in a minimum number of CME activities and can prove a minimum number of cases per field. Level 1 is open to board-certified radiologists without an additional exam. Level 2 requires clinical practice of one year beyond board certification, and an additional oral and written test for each module. Furthermore, institutions can be certified as a centre of education for each module; this requires the presence of a colleague with a Level 2 certificate as well as several additional technical and structural requirements. The latter certificate is linked to the quality registry and a minimum number of annual cases per module. Fig. 4 displays a list of the top ten documented interventions, including the number of interventions performed in 2013 [5].

This initiative received a lot of attention and triggered a steep increase in DeGIR's membership, with >1,300 individuals and >250 institutions currently involved, providing a service network across the nation and strengthening the position of radiologists providing interventional services. Several new IR courses are being offered, intensifying educational opportunities. This unexpected success prompted our colleagues from the German Society of Neuroradiology (DGNR) to join forces with us. Two new modules were introduced:

Module E: neurovascular procedures – revascularisation
Module F: neurovascular procedures – embolisation

Starting in 2016, we plan to offer combined Level 2 exams. The teamwork with neuroradiology will allow us to provide a complete vascular service in developing areas like acute stroke treatment, where offering a broad service at a national level will only be possible by way of joint efforts.

The most recent development targets the issue of new devices with CE marks. These devices sometimes lack the clinical data available for approved drugs. It is true that without the rapid technical progress made in the field of medical devices, it would not have been possible for interventional radiology to develop as quickly as it did during the last decade, and that no major complications have occurred so far. Nonetheless, new devices should be monitored separately and with more care to ensure patient safety and even greater technical and clinical success. The DRG and DGNR therefore joined a software development group that tailors online documentation to respective new devices.

In summary, the DeGIR quality management software is an important tool for quality assessment and quality assurance in interventional radiology. It is adaptive to modifications of interventional procedures and the introduction of new techniques and devices. Furthermore, it forms the basis for documenting expertise for the certification of qualified departments and radiologists.

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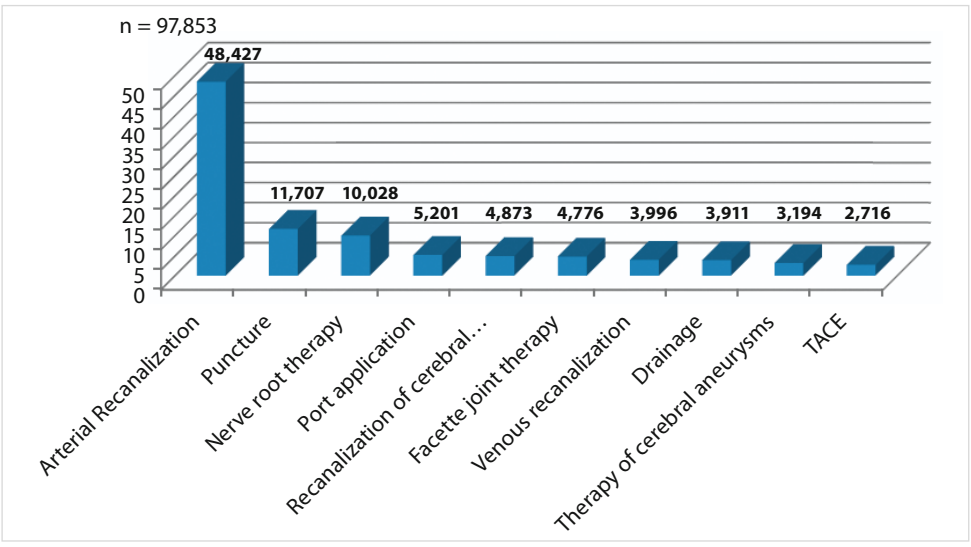

Fig. 4: Top Ten Interventions 2013

References:

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