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Quality Assurance (QA) and Quality Indicators (QI) in the Treatment of Varicose Veins

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Abstract

Quality Assurance (QA) is an element of Quality Management (QM). QA is an original duty of service providers in medicine. It begins with the systematic collection of data from the respective [health care] processes with the aim of converting the documented quality into measurable parameters. The goal is to generate indicators that quantify the documented quality. The preferred instruments of QA are quality registries. Examples of Quality Indicators from the German Society for Vascular Surgery and Vascular Medicine (DGG) Varicose Vein Quality Registry are presented.

Keywords: Quality management; Quality assurance; Quality indicators; Quality registries; Varicose veins

Quality Assurance

Quality Assurance (QA) is an element of Quality Management (QM). The assurance of the quality of the medical services provided in its area of responsibility is in Germany an original duty of every physician and derives directly from the rules of the code of professional conduct for physicians, from the civil law treatment contract, and from German tort law. Furthermore, for physicians and medical institutions providing health care to persons with statutory health insurance in the German Health System (health care providers), German lawmakers have enacted a legal obligation for establishing and maintaining internal institutional QM and QA (§§135a ffsocial act V).

In order to ensure and document quality, it is not enough to have a presumption or a belief, one must know something about this quality in actual fact and demonstrably.

"We all believe in God. Everybody else has to deliver data" (N. J. Gilbert).

QA begins with the systematic prospective collection of data on structure, process, and outcome. The ideal instrument for this task is the registry. Collection of data alone, however, does not yet amount to QA. Rather, QA will only arise from the collection when indicators can be generated from that data which are suited through comparison with standards or bench marks to quantify the defined quality and there by allow an objective evaluation of specific parameters of performance [1]. This orientation of indicator-based QA allows statements to be made regarding quality at the level both of health care providers and the individual patient (microlevel) as well as at the system level (macrolevel) and thus regarding the quality of service in specific service areas (e.g. varicose vein therapy) [2].

Selection of the items for QA documentation begins naturally from the perspective of patient-centered medicine with outcome measures (quantitative analysis). But elements of structure and process quality are also extremely important for a final QA.

Data from classification systems (e.g. CEAP, VCSS, etc.) that document aspects of diagnostics and morbidity count per seas quality criterion (qualitative analysis), since the availability of such elements is essential for the creation of necessary stratifications or risk adjustments of the data on the documented clients.

In Germany the origin of a scientifically based and systematic QA in medicine is generally dated to the start of the Munich Perinatal Study (1975), first in Bavaria, soon thereafter throughout

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Germany, and also to the Quality Assurance in General Surgery (1977) [1,2]. In vascular medicine, the first efforts at QA began in the early 90s with the conceptualization and implementation of QA for varicose vein surgery by the Working Group of Vascular Surgeons in Private Practice in Germany (ANG), which later (2001) led to the worldwide first "QA Registry of Varicose Vein Surgery" of the German Society for Vascular Surgery and Vascular Medicine [3-5].

What is Quality?

Inherent in the concept of quality is a certain ambivalence. This is because human beings as a rule have a natural feeling for quality based on their everyday experience, which is why quality in this understanding is usually equated with excellence. "For most people, quality is like beauty; it has a positive connotation but denotes nothing measurable".

As terminus techniques, however, the term quality implies more than just excellence. As understood in QA, it implies a property of things or services which, regarded by different persons from different perspectives, can underlie very different assessments. Thus quality is not an absolute concept but a construct; it is original, indeterminate, and value neutral [1]. The logical consequence of this fact is that the assessed properties and the expectations of a product and/or service must be precisely defined in each case, including the limiting values within which the targeted quality goals can be regarded as having been achieved or not. Quality then is the broad agreement between requirements/expectations and reality. The greater the agreement, the higher the quality.

What are Quality Indicators?

- "Quality Indicators (QI) are instruments for measuring quality and are indispensable components of quality control and QA " [6].

- "Quality Indicators are auxiliary variables which indirectly depict the quality of an entity through numbers and/or numerical relationships. One could describe them as quality-related code numbers" [7].

To make an assessment in the QA process and, if appropriate, to evaluate the potential for improvement, quality must be amenable to objectification, i.e. it must be capable of being documented and measured. A feature of quality is that it cannot be directly observed or directly measured. Quality is only present or not present as defined and according to the stipulated limiting or reference values and/or reference ranges. In order to make the concept of quality operational, therefore, specific quality indicators are needed, which in the individual case can objectify and/or measure (quantitative analysis) the relation of the attained actual state or actual value to the required target state or value [1,6,8,9]. Reference values and reference ranges are not imminent properties of QI but empirically determined quality expectations and quality requirements that are derived from scientifically based facts and assessments.

Every QI must exhibit specific properties with regard to the quality goal. A QI must reflect one or more elements of the investigated quality, and it must be able to truly, reliably, and reproducibly quantify the defined and associated quality, i.e. to measure and thereby to convert it to a defined measurement system that should make possible further analytic assessment procedures. This suitability requirement can be examined e.g. using the so-called RUMBA rule.

- Relevant for the selected problem.
- Understandable for providers and patients.
- Measurable with high reliability and validity.
- Behaviorable i.e. changeable by behavior.
- Achievable and feasible.

In recent years a comprehensive literature has a risen on the selection, development, design, and implementation of QI in medicine. The literature deals with the theory and practice of the development and validation of QI and has worked out rules for the design and evaluation of QI [2,6,8,9]. Lacking until now, however, are systematic and representative observations and investigations on the development and application of QI in vascular medicine in general and in the diagnosis and treatment of varicose veins in particular. Measured by the number of patients treated this fact is surprising.

Thus it is not surprising that even in 2009 a Rapid Report Commissioned by the Federal Joint Committee [10], with an admittedly inadequate overall -but especially for the German speaking world -search strategy examining publications mostly not listed on MEDLINE, came to the [following] result: „… There was identified only a current guideline on varicose veins [Finland]. No direct evidence of quality assuring measures in the field of„ varicose vein surgery". …"could be derived from the reviewed guideline and abstract [10].

Early QA development was limited almost exclusively to fields employing invasive treatment methods. This had the result that the generators of QI initially turned to that which had always lain within the purview of the health care providers and appeared most likely suited for the assessment of quality, namely the documentation, classification, and evaluation of complications of treatment. Only in recent years has the perspective expanded to include in the generation of QI aspects of diagnostics, diagnosis and confirmation of diagnoses, as well as quality of life and Patient Reported Outcome Measurement (PROM).

For general and systematic observation and evaluation of QI for varicose vein therapy, it is meaningful with regard to classification to follow the conceptual plan of the Donabedian model for examining the quality of health care (quality of structure, process, and outcome).

Generation of QI

QI can be generated from the following sources:

- Studies on varicose vein therapy.
- Studies on the development of QI.
- Guidelines.
- QA registries.

Studies on varicose vein therapy

Studies are always subject to the regime of a study design. The results therefore of studies evaluating an unselected, natural entire population are only applicable as guidelines that must be checked with reality. Studies are predestined to be sources of exemplary QI and are ideally suited to indicate innovative trends which could stimulate the expansion and perfecting of the arsenal of QI.

Studies on the development of QI

Studies dealing directly with the development of QI are rare. In an earlier investigation by the present authors [4], only 8 such studies

could be found, 3 of which had to be excluded from further analysis, leaving only 5 studies [7,11-14] with very different weightings of their relevance to the topic of QI in Phlebology. All of these studies deal with known parameters. New developments are lacking. The details will not be gone into further here. Special mention should be made of the 2 studies [11,13], that deal with the isolated or combined use of hemodynamic parameters as QI.

Guidelines

The 'Guidelines' of scientific medical societies are systematically developed to aid doctors in making decisions in specific situations. They are based on up-to-date scientific knowledge and on procedures that have been proven in [clinical] practice. They also ensure greater safety in medicine while also considering economic factors. The guidelines are not legally binding on doctors and do not therefore offer grounds for liability [claims] nor effect release from liability.

In line with the above definition and the mandate to guideline developers, a guideline is not primarily an instrument of QA, but a systematically developed documentation of the prevailing medical scientific opinions and standards. It defines a framework within which decisions can be made, without however being binding. It is therefore not surprising that e.g. the leading guidelines for treatment of varicose veins (D, USA, GB, EU) do not contain the terms 'quality assurance' and 'quality indicator' [4].

The National German Guideline: Guideline for the Diagnosis and Treatment of Varicose Veins [15] contains what are described as being merely "recommendations" summarizing key concepts from the prior textual presentation of the respective topics, which can be understood ideally as exhortations in the sense of qualitative recommendations. Quantitative data are only given on complications of treatment, the quota son this being taken from the general literature and also not agreeing across the different country-specific guidelines.

Only the no longer valid German Guideline Varicose Veins 2010 [16] present an unequivocal quality requirement that can be understood as a qualitative QI.

"In the diagnosis of venous diseases, an imaging procedure is required prior to invasive measures (venous surgery, radio frequency ablation, endovenous laser therapy, sclerotherapy)" [16].

This clear requirement was unfortunately clearly weakened in the Guidelines 2019 [15] to read "… an imaging procedure should be used. …".

The upshot of this is that guidelines only offer encouragement for the development of QI. Directly applicable QI are not found in guidelines due to this specific definition.

Registries

Due to their loose and non-selective structure, registries offer a suitable database for the generation and testing of QI. The two essential and most renowned registries for varicose vein therapy are the Vascular Quality Initiative Varicose Vein Registry (VQI VVR) in the USA and the Quality Registry for Invasive Varicose Vein Treatment of the German Society for Vascular Surgery (VR-DGG; VR-DGG-V1 and VR-DGG-V2) [3-5]. As a rule, registries are only directly accessible to registered users, which limit analysis of the registry structure to the slight possibility of an examination of publications from the databank of a given registry.

Practical Application of QI

Due to the developmental history of the Invasive Varicose Vein Treatment Registry DGG (VR-DGG), the authors have access to special insights into the history and structure of the registry, which means further statements will be based on our knowledge of these relationships [3,4,17,18].

Qualitative indicators are to be distinguished from quantitative indicators.

- Qualitative Indicators are properties whose attributes are described by estimations or assessments, e.g. yes/no or present/absent, etc.

- Quantitative (metrological) Indicators are properties that can be depicted numerically, which can then if needed be incorporated into further arithmetic operations.

Structural quality

"Structural quality is the quality necessary for accomplishing the necessary technical, methodological, materiel, and financial outfitting of an institution, including the excellence of the qualification of the medical staff" [1].

The determination of requirements for the structural quality of medical institutions in Germany lies within the competence and responsibility of regulators; the requirements are a prerequisite for acquiring the respective operating licenses and are subject to permanent monitoring and adapting to developments in the field. A special documentation of the structural quality in the context of the QA is therefore not necessary, at least for the area discussed here.

Process quality

"Process Quality is the quality of the services provided" [1].

The requirements for a comprehensive documentation of the services provided encompasses diagnosis, indications, informing patients, intervention, complications, outcomes, and the further aspect of health service research, also follow-up.

The process element "informing patients" is linked to specific and strict legal requirements, so that a separate documentation in the context of a QA registry is not necessary.

Qualitative process indicators in the diagnosis and treatment of varicose veins:

- Mandatory use of imaging diagnostic procedures prior to invasive measures

- Objectification of findings and diagnosis by means of coding: ICD, OPS.

Comment: The International Statistical Classification of Diseases and Related Health Problems (ICD) as well as the [German] Operation and Procedure Classification System (OPS) are themselves not direct indicators, they are however in view of the large number of QA to be expected from routine data, e.g. from health care payers, indispensable for the possibility of consolidating both systems.

- Compliance with the demand for stage-appropriate surgery/intervention: Record of venous reflux routes and the extent of the stripping and/or ablations.

Quantitative (metrological) process indicators in the diagnosis and treatment of varicose veins:

- Clinical Etiological Anatomical Pathophysiological (CEAP) classification.
- Venous Clinical Severity Score (VCSS).
- Disease related Quality of Life (DRQoL) or Patient Reported Outcome Measures (PROM) [19,4].
- Hemodynamic Parameters.

Comments: The above indicators [20] classify the documented clientele and upon repeated use post-intervention also become outcome indicators by means of the ρ.

Routine use of hemodynamic monitoring methods in Phlebology has been increasingly abandoned in recent years. Unfairly so, if one considers that the indication for invasive treatment of varicose veins in no way arises from the expectation of curing the disease, but only from the hope of improving the venous hemodynamics. The studies by Lee et al. 2016 and Ahmed et al. 2019 [13,11] give hope that the actual prospects and possibilities of this methodology for the purposes of QA could lead to a renaissance of hemodynamic monitoring.

- American Society of Anesthesiologists (ASA).

Comment: The risk classification of the American Society of Anesthesiologists (ASA) physical status classification system [20,21] has proved to be insufficiently differentiated for its original purpose. However, for the registry-relevant function of contributing to an easily applicable stratification of a clientele, its simplicity of definition and ease of use make it still ideally suited.

- Intraoperative Complications: Aggregates, as they are broadly used for the total complication rate in some studies, are not suited for QA under the aspect of continual improvement. For this purpose very detailed data are needed.

Quality of Outcome

"Quality of Outcome" is the result of structural and process quality. It involves the evaluation of the subsequent and/or resultant outcome [1].

Quantitative (Metrological) Outcome Indicators:

- CEAP.
- Validation of Venous Severity Score (VCSS).
- QoL sive PROM [4,20].
- Postoperative complications.
- Postoperative Wound infections: Centers for Disease Control (CDC) coding system [20].
- Hemodynamic Parameters.

Date Analysis

Data analysis follows a mutually agreed upon plan and usually begins with a check of the completeness of the dataset, of the internal plausibility, etc. With today's data collection software, however, this as a rule has already been accomplished [during collection].

There follows next the checking for the completeness of the documented clientele, which usually requires a survey of [health care] providers, but also e.g. can be done by a comparison with internal or external statistics or billing data, followed by checking for the homogeneity and/or for distribution imbalances of the documented clientele plus a search for and identification of any data outliers.

Next the QI of the sample is calculated and compared with outcomes in the base set according to a qualified plan for the use of statistical methods. The analysis ends with a qualifying evaluation of the quality of the individual health care provider, followed if needed by consultation in light of the findings.

Results of the German Quality Registry Varicose Vein Surgery

Data from a total of 89,647 patients was collected in the varicose -QA project of the German Society for Vascular Surgery over the years 2001-2009. 49,204 patients were statistically evaluated in 2001-2005 and 40,443 patients in 2006-2009. 95,214 surgical procedures were performed on 105,296 limbs. 114,991 vascular territories were operated on. The proportion of men was 30.6% (n=27,463), the proportion of women was 69.4% (n=62,184). The average age of the patients was 52.8 years (range 15 to 96 years) [18].

50.35% (n=45,145) of patients were treated as outpatients, 49.65% (n=44,502) as inpatients.

1.83% (n=1,931) of treated limbs were in stage C 1, 52.65% (n=55,442) in stage C 2, 29.72% (n=31,304) were in stage C 3, 12.06 % (n=12,700) in stage C 4, 1.66% (n=1,749) in stage C 5 and 2.06% (n=2,170) in stage C 6.

47,253 of patients undergoing surgery were ASA I (52.71%), 36,222 patients were ASA II (40.51%), 5,920 ASA III (6.60%), 184 patients ASA IV (0.17%) and 4 patients were miscoded as ASA V (0.01%).

An imaging method was used in almost 100% of cases preoperatively. In the time period 2006-2009 duplex sonography alone was performed on 85.5% of patients (n=34,574), venography alone on 4.4% of patients (n=1,765) and both methods on 9.3% (n=3,778). Only 0.8% of patients (n=326) underwent surgery without the use of an imaging method. Duplex sonography use increased with time: In 2001 duplex ultrasound was used in 70%, in 2009 in 95% of the patients.

Most procedures were performed under general anesthesia (82.74%). The number of regional anesthesia was significantly lower (10.21%), and 6.32% procedures were performed under local anesthesia. Other anesthetic methods were used in 0.73% of cases.

The proportion of redo surgery was 17%. We found a steady increase in the proportion of redo surgery with time. Where as in 2001 only 15% of procedures performed were redo surgery, by 2007 and 2008, this proportion rose to 20% and 19% respectively. In the redo group 58% of the cases had to undergo a ligation of the SFJ or SPJ again.

From 2006 to 2009 open varicose vein surgery with ligation of SFJ/SPJ and stripping was performed in 79.9% (n=31,898), Radio Frequency Ablation (RFA) in 9.7% (n=3,259), Endovenous Laser Treatment (ELT) in 2.9% (n=939) and other procedures in 7.5% of cases (n=3,120).

Intra-operative complications occurred very rarely. With reference to vascular beds operated on, intra-operative complications were reported in 0.18% (n=209) of cases. The following types of intra-operative complications for the period 2006 to 2009 were described: damage to the deep venous system in 0.03% (n=13), damage to arteries

in 0.01% (n=4), nerve damage in 0.02% and other complications in 0.07% (n=34) of cases.

There was a difference in the postoperative complication rate for the years 2006 to 2009, depending on whether inpatient or outpatient surgery was performed. General complications occurred in 0.25% (n=52) of cases for outpatient surgery, where as the complication rate for inpatient surgery was higher at 0.67% (n=117), this difference was statistically highly significant ($p<0.0001$, chi^2-square-test).

There was a clear correlation between postoperative complications and preoperative ASA stages. Whereas the complication rate for stages ASA I and ASA II was at 0.2% and 0.5% respectively, it increased to 1.2% in stage ASA III, to 2.2% in stage ASA IV. The differences in the complication rates between the ASA classes were statistically highly significant ($p<0.0001$, Cochrane Armitage-Test) (Table 4).

There were differences amongst the individual surgical procedures with respect to postoperative local complications. Thus the complication rate after RFA was the lowest with 0.25%, while the rate for the other procedures was 4.62%, but the difference between high ligation and stripping in comparison to RFA was statistically not significant. Also there were no statistical significant differences between stripping and ELT, or stripping and other operative procedures [22].

We observed a rising incidence of local complications in relation to the C stages. For surgery of the GSV, local complications occurred in stage C2 in 1.22% (n=307), in stage C3 in 1.38% (n=191), and in stage C4 in 1.42% (n=89) of cases; they increased significantly in the C5 stage at 4.58% (n=27) and in stage C6 at 3.73% (n=48). A similar tendency was observed for surgery of the SSV in the years 2006-2009. No statistical analysis was performed, because of the unbalanced numbers in the different groups.

Medical thromboprophylaxis with Low-Molecular-Weight Heparin (LMWH) was given to the vast majority of patients (n=80,653, 89.97%). Thromboprophylaxis with LMWH was given to 61,322 patients (68.40%) for 1 to 5 days, and in 19,331 cases (21.56%) it was used for longer than 5 days. In the evaluation period 2001-2005, a Deep Vein Thrombosis (DVT) occurred in 0.1% (n=51 patients) and a Pulmonary Embolism (PE) in 0.02% (n=11 patients) of cases. In the period 2006-2009 DVT was reported in 0.099% (n=40 patients) and PE in 0.017% (n=8 patients). For the period 2006 to 2009, the occurrence of DVT in relation to the administration of a LMWH was evaluated. DVT occurred in 0.03% of patients without a LMWH. DVT was reported in 0.01% of patients receiving thromboprophylaxis for up to 5 days, and in 0.12% of patients receiving thromboprophylaxis for more than 5 days. Due to the unbalanced numbers in each group, no statistical analysis was performed.

General complications occurred very rarely. We carried out a differentiated evaluation for the period 2006-2009: Pulmonary complications occurred in 5 patients (0.012%), and cardiovascular complications in 25 patients (0.062%). Other complications were reported in 93 patients (0.23%). A total of 32 patients had to be given a blood transfusion over the entire reporting period 2001-2009, which corresponds to a rate of 0.035%.

Discussion

Society, which is represented by state institutions, has expectations of the quality of health. To guarantee that this expectation is met at the highest possible level, regulatory authorities introduced QA as mandatory. QA in the diagnosis and treatment of varicose veins in Germany had its beginnings in the 90s, even before the enactment of the legal regulation by social act V. This was a direct result of the dispute among medical professionals regarding the quality of outpatient varicose vein surgery. That dispute was settled and is past, while QA remains and is if also for other reasons more necessary than ever. Treatment options for varicose veins involve only improvement of venous hemodynamics and there by the amelioration of patient discomfort and suffering, and in the final analysis the prevention or lessening of the severe and irreversible end stages, which can result from complete decompensation of the venous hemodynamics. Associated with the high prevalence and consequent high number of treatments is the compelling need for QA in light of the limited health care system resources available to this area. The Rapid report of 2009 shows that the diagnosis and treatment of varicose veins lies definitely within the purview of lawmakers and thus of the German Federal Joint Committee (GBA).

The early Initiative of the American Venous Forum (AVF) 2011 with a first "American Venous Registry" (AVR), which probably contributed not a little to the creation of the Vascular Quality Initiative (VQI), shows that also in the USA the significance of QA in this area of care is and was highly valued. The instruments, registry, and QI are available and tested; practical implementation of the intra- and inter-institutional QA is working.

The Institute of Quality Assurance and Transparency in the Health Care System (IQTIG) states the following in its paper on the methodological foundations of QA. Assessment of quality by means of quality indicators requires the appropriate survey methods with the utmost standardization, whose high objectivity and reliability can lay the foundation for a standardized, quantitative assessment of outcomes. In addition, the survey methods must be so selected that in spite of the large number of health care providers and treatments given, they are feasible, i.e. the effort per case is acceptable.

For this are suited especially standardized, written, or electronic surveys, such as case-based and institution-based QA documentation, and patient surveys, as well as secondary data analyses such as the social data analyses of health insurance companies, which again represent highly standardized data [2].

If this thought is pursued further, it arrives at a point which for about 30 years now has not been fully thought through. How comprehensive should a QA system be: Comprehensive, selective, permanent, and random? The Vascular Quality Initiative (VQI) of the Society for Vascular Surgery (SVS) Patient Safety Organization (PSO) in the USA currently has 14 major vascular procedure registries; the German Vascular Society has 4 to 5, each with a growing trend, participation voluntary. The problem for users of the DR-QA systems arises from the need for QA documentation in addition to the cased-based routine documentation and the costs for construction and maintenance accruing to the publisher and operator of the QA platform. The current solutions are not viable in their extent or over the long term. What person or institution is capable of maintaining and administrating 14 or more QA registries in addition to the daily tasks of patient care and, often, medical research and teaching?

These questions should not be understood as arguments against QA; they have much more to do with the methodology. The solution can only lie in the retrieval and analysis of routine data. For this there is lacking accessible, uniform documentation. In the past, the

development of a uniform, standardized system for documenting outcomes in vascular medicine was certainly considered. Such a standardized system would enable the retrieval and/or release of a qualified dataset on variable topics and time periods for use in a super ordinate analysis. It is clear that such considerations cannot remain without consequence in light of questions of general acceptance but also of costs. The only systematized data which is accessible under today's conditions but not generally accessible are the relevant billing data of the payers of the German Statutory Health Insurance and the accredited doctors' associations. Relevant billing data, however, means that only a narrow slice of the information on a given patient is available compared to what a registry's dataset could provide.

So, what do we really need for a meaningful and effective QA? Lawmaker and health insurers prefer the fewest possible, if feasible a single QI for all purposes. The quality improvement immanent in QA, also from the view point of the IQTIG, requires precise identification of deficiencies, i.e. without the most detailed possible documentation of process and outcome, without detailed indicators, there can be no starting point for an improvement in quality.

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