

Quality assessment of vascular access procedures for hemodialysis: a position paper of the Vascular Access Society based on the analysis of existing guidelines.

Short title: Quality assessment in angioaccess surgery

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Abstract:

Quality assessment in vascular access procedures for hemodialysis is not clearly defined. The aim of this article is to compare various guidelines regarding recommendation on quality control in angioaccess surgery.

The overall population of end stage renal disease patients and patients in need for hemodialysis treatment is growing every year. Chronic intermittent hemodialysis is still the main therapy. The formation of a functional angioaccess is the cornerstone in management of those patients. Native (autologous) arteriovenous fistula is the best vascular access available. A relatively high percentage of primary failure and fistula abandonment raises the need for quality control in this field of surgery.

There are scarce recommendations of quality assessment on creation of a vascular access for hemodialysis in searched guidelines. Some guidelines recommend the proportion of native AVF in incident and prevalent patients as well as the maximum tolerable percentage of central venous catheters and complications. According to some guidelines, surgeon's experience and expertise have a considerable influence on outcomes. There are no specific recommendations regarding surgeon's specialty, grade, level of skills and experience.

In conclusion, there is a weak recommendation in guidelines on quality control in vascular access surgery. Quality assessment criteria should be defined in this field of

surgery. According to those criteria, patients and nephrologist could choose the best vascular access center or surgeon. Centres with best results should be referral centres and centres with poorer results should implement quality improvement programmes.

Keywords: Hemodialysis, Vascular access procedures, Guidelines, Quality assessment

Introduction

Overall population of end-stage renal disease (ESRD) patients is growing every year. More than 70% of those patients are treated by chronic intermittent hemodialysis (HD) (1). Functional vascular access (VA) to the circulation is necessary for adequate HD. All guidelines recommend native (autologous) arteriovenous fistula (AVF) as the preferred access because of a low complication rate, durability and lower cost in comparison to arteriovenous graft (AVG) or central venous catheter (CVC) (2-9). A relatively high percentage of primary failure and fistula nonmaturation rate is the most negative aspect of VA surgery. Quality assessment and quality indicators are not clearly defined in angioaccess surgery.

Guidelines are comprehensive and hard-laboring work of experts. Recommendations are based on the most reliable source of high-quality evidence. Evidence – based in surgery can be developed from different sources. Large randomized controlled trials (RCTs) are generally considered the gold standard of evidence-based practice in surgery. Other sources are: meta-analyses, systematic literature reviews, observational studies, expert opinions and other (10). Various clinical practice

guidelines exist on VA surgery but there are no controlled randomized trials regarding quality assessment.

The aim of this article is to search the most cited guidelines and find out the recommendations for quality control in VA procedures for HD, especially regarding the quality assessment of VA surgeons.

Methods

We searched Medline and Web of Science databases for published VA guidelines of various scientific societies with the special interest in quality assessment. When more guidelines of the same society were available the most recent one was selected. The special interest was given to the following criteria: 1. surgeon's experience; 2. the rate of functional VA in incident patients; 3. the rate of functional VA in prevalent patients; 4. access survival; 5. percentage of dialysis catheters.

Results and Discussion

Eight guidelines from various parts of the world were found and included into the analysis. Table 1.

The impact of surgeon's experience

Substantial variations of outcomes in VA surgery exist between countries. The DOPSS study have shown great differences in prevalence of AVF, AVG and CVC between facilities in United States (US) and Europe even after adjustment of age, gender, body mass index and comorbidities (11). There are also marked variations in the prevalence of AVFs and primary failure rate in small geographical areas. A study

conducted in the Netherlands revealed that primary failure rate varied from 8% to 50% among 11 centres (12). Even in Japan, the nation with the highest prevalence of AVFs and the lowest prevalence of CVCs, great differences in outcomes was found. The primary failure rate was reported to be 0.8–23.6% in 23 facilities (13). Some authors called this phenomenon as a „center effect“ (12). Spergel concluded that surgical judgment and technique are the most important factor affecting outcomes and called it the „surgeon effect“ (14). But, how can we measure quality of a vascular access surgeon?

The importance of surgeon experience in VA procedures for HD was already recognized (15,16). The problem occurs, when the specific factors influencing surgeon's quality are trying to be objectivised. Some of the quality indicators actually depend on the caring nephrologist more than on the VA surgeon. The specialty, grade, level of education, skills and experience of VA surgeon may influence outcomes. The impact of specialty of VA surgeon on quality of procedures is difficult to reveal. Worldwide, various specialists are involved in construction of VA for HD: vascular surgeons, general surgeons, urologists, transplant surgeons, interventional radiologists, cardiothoracic surgeons and nephrologists as a non-surgical specialty. Interventional nephrologists construct about 85% of the AVFs in Italy and about 25% of the AVFs in Japan, the nations with the highest proportion of prevalent patients using an AVF (17). Worldwide, it has been reported that interventional nephrologists have comparable or even better results than surgeons (18 - 22). It seems reasonable to state that dedication to angioaccess surgery is more important than specialty of VA surgeon. The grade of operating surgeon may also influence outcomes. One of the results in a DOPPS study was that the likelihood of the AVF use was 40% lower in dialysis unit in which surgery trainee either performed or assisted permanent VA

placements (11). There was an opposite finding that involvement of surgical trainees did not influence outcomes (23).

Globally, the formal education and certification in VA surgery is often an exception than rule. Younger surgeons learn from experienced surgeons and, not so rarely, from their own mistakes. The main question is: which factors influence skill and experience. The years of surgical training are less important in comparison to the number and complexity of procedures performed per year. O'Hare et al. have found that AVF placement were over three times as high at high-volume centres (>30 procedures per year) compared to low-volume centres (<10 procedures per year). (24). An experienced and dedicated surgeon can achieve good results even in patients with severe comorbidities (25).

What guidelines suggest?

There are no specific recommendations regarding surgeon grade, specialty or level of skills and experience in searched guidelines. Japanese guidelines suggest, as an opinion, that the access surgeon is required to have sufficient experience and expertise. The patency of the VA is clearly affected by the surgeon's ability. Also the insertion of CVC should be performed by an experienced surgeon or under guidance of an experienced surgeon (6). European Best Practice Guidelines (EBPG) stated, without grade of recommendations, that experience and detection of the physician performing VA surgery have a considerable influence on outcome. Catheter insertion must be performed by trained and senior physician (3). The UK Guidelines stated that AVG require planning and surgical expertise, the number of possible configurations ultimately depends on the expertise of the surgeon (9).

Canadian Guidelines suggest that the location for the graft placement is determined by each patient's unique anatomic restrictions, previous access history, and surgeon's skill (8). KDOQI Guideline mentioned that longevity of AVG function might be influenced by surgical techniques (2). Some guidelines only recommend the rate of AVFs in incident and prevalent HD patients and acceptable percentage of long-term CVCs and catheter related complications. All guidelines recommend creation of native AVF as the first choice (2-9). It is crucial to stress that the rate of usable (functional) fistulas is the target outcome, not the construction rate (2). Among searched guidelines, only Spanish guidelines referred to the suggested standards as quality indicators. Five quality indicators were formulated. The percentage of patients who initiate HD with usable AVF or AVG (standard 75%), the percentage of prevalent patients using AVF (standard 80%), the annual thrombosis rate of AVF (standard 0.25) and AVG (standard 0.50), the percentage of prevalent patients with tunneled CVC (standard <10%) and the percentage of infection of tunneled CVC (standard <10% in the first 3 months after insertion and <50% infections annually) (7).

The latest UK renal association guidelines recommend that at least 60% of incident patients should have functioning AVF or AVG and at least 80% of all prevalent patients should receive dialysis treatment via definitive access: AVF, AVG or Tenckhoff catheter (9). Japanese Guidelines set the survival expectations of AVG. The goal for primary patency rates 1 year after surgery is 60%. The goal for secondary patency rates (assisted patency) is 80%, 60%, and 40% for 1 year, 3 years, and 5 years, respectively (6). Canadian guidelines suggest that more than 60% of prevalent patients should have a native AVF. Quality care standards are according to the Canadian guidelines defined as following target rates: the rate of graft thrombosis should not exceed 0.5 thrombotic episodes per patient year at risk,

after adjusting for initial failures (e.g., failures within the first 2 months of fistula use), the rate of thrombosis of native AV fistulae should be <0.25 episodes per patient year at risk, the rate of infection should not exceed 0.01 episodes per patient year at risk for primary AV fistula and 0.1 episodes per patient year at risk for AV grafts, for tunneled cuffed catheters, the recommended target rate of systemic infection is <0.5 episodes per patient year at risk, the primary access failure rates of dialysis AV grafts in the following locations and configurations should not be <15% in forearm straight grafts, 10% in forearm loop grafts, and 5% in upper arm grafts. The cumulative patency rate of all dialysis AV grafts should be at least 70% at 1 year, 60% at 2 years, and 50% at 3 years (8). Other searched guidelines and initiatives do not recommend specific quality criteria in construction of native VA. Many nephrologists established their own quality indicators of surgeon's quality and refer patients to the surgeon with good outcomes (26,27). Nguyen et al. suggested that nephrologists should choose the VA surgeon who is willing to create more than 50% functional fistulas (28).

Generally, there is no consensus about quality assessment criteria in VA procedures for HD. Searched guidelines do not recommend speciality and grade of operating surgeon as well as the number of procedures per year needed for having acceptable experience and skills.

Despite the lack of evidence from randomized controlled trials (RCTs) about quality assessment in angiaccess surgery, according to some standard criteria, it is possible to indirectly measure the quality of vascular access care but not surgeon's quality directly.

Should criteria for quality assessment be unique worldwide?

VA community should try to define realistic standards and criteria for assessment of quality in VA procedures for HD at national level according to local practice patterns and available resources. The latest UK guidelines define more realistic standards related to percentage of incident and prevalent patients using AVF or AVG in comparison to guidelines published in 2011. Former guidelines suggest the use of AVF in 65% of incident and 85% in prevalent patients (29). The latest guidelines decrease this demand to 60% in incident and 80% in prevalent patients not only using AVF but also AVG (9). Roca-Tey et al. have found a stable percentage of patients who initiate HD with a fistula (around 50%) in eleven years time span without tendency for increase (30). In Spanish guidelines the percentage of incident patients using AVF was set as high as 75% (7).

Improvement in VA care should be a continuous process and quality assessment could be one of the steps towards better outcomes. Van der Veer et al. conducted an electronic survey among national experts from 37 European countries and have found that factors commonly believed to negatively affect the quality of VA care were: (lack of) surgical capacity; reimbursement system for establishing or maintaining VA; (lack of) training and education of health professionals and (lack of) requirements for minimum number of procedures for those creating VA (31).

Some of the possible measurable criteria could be: specific education in VA surgery and license, number of procedures per year, the time between the presentation of patients to VA surgeon and construction of a VA, the percentage of autogenous fistulas, AVGs and CVCs in prevalent HD patients, the percentage of functional fistulas in incident HD patients, the percentage of creation of functional fistula in the first attempt, primary patency or intervention-free period, primary failure rate and number of intervention to allow patency, the percentage of patients switching from

CVC to AVF or AVG, the number of catheter days, maturation time and durability of an access may be some of the outcomes which can be measured. VA surgeon's dedication seems to be very important but can not be measured. A dedicated surgeon is open to continuous education, does not consider VA procedures as a minor surgery and prepare himself for each operation which includes quality preoperative examination and communication with the patient. Quality VA surgeon is familiar with all vascular access techniques and follow up patients in order to achieve the best outcomes. The possible characteristics of a quality VA surgeon are shown in Table 2.

Table 2. Characteristics of a quality vascular access surgeon.

Education	Skills	Outcomes
Academic or referral centre Vascular access courses Training on phantom model Strict mentor supervision	Ultrasound Vascular access procedures Microsurgery Endovascular techniques	Proportion of AVF, AVG and CVC Switching rate: CVC to AVF/AVG Maturation rate and time Proportion of functional VA on the first attempt

AVF – arteriovenous fistula, AVG – arteriovenous graft, CVC – central venous catheter, VA – vascular access

Conclusion

Because of a lack of valid trials regarding quality assessment in VA procedures, there are only weak recommendations in searched guidelines. According to the recommended proportion of native AVF in incident and prevalent HD patients and acceptable percentage of CVC and complication rate, it is possible to indirectly measure outcomes of VA surgeon(s) or VA centre(s). The outcomes mainly reflect the surgeon's ability to create functional VA for HD, despite some unmeasurable and unknown factors influencing outcomes. Also, results may be influenced by other

participants in care of HD patients as well as patients' characteristics and local resources. Vascular access care should be individualised and the best vascular access for each individual patient should be considered having in mind that it would not always be a native fistula. Vascular access community should try to define criteria which reflect quality in VA surgery in order to allow comparison of outcomes. VA centres with best results should become referral centres, while centres with inferior results should implement quality improvement programs. The final results of quality improvement in angioaccess surgery will be decrease of morbidity and mortality, as well as costs.

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