Evidence-Based Data for the Hemodialysis Access Surgeon

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ABSTRACT

The National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access (DOQI) have defined the access-related care for patients with end-stage renal disease (ESRD). However, the standard of care across the country has fallen short of the DOQI targets. One potential explanation for these shortcomings is the lack of compelling evidence in the literature to support the recommendations. This study was designed to compare the DOQI with the best available evidence in the literature for four clinical questions relevant to the hemodialysis access surgeon: the choice of access type (autogenous versus prosthetic), the type of prosthetic graft, management of the "failing" (nonthrombosed) access, and management of the thrombosed access. The electronic literature databases MEDLINE and Evidence-Based Medicine Reviews were searched and relevant randomized controlled trials or meta-analyses were identified for review. No randomized controlled trials comparing autogenous to prosthetic accesses were identified. However, a recent systematic review reported that the patency rates for upper extremity autogenous accesses were superior to their polytetrafluoroethylene (PTFE) counterparts. The identified randomized trials suggested that the patency rates for the different types of commercially available prosthetic grafts used for access appear comparable. They suggested that standard wall PTFE thickness and prosthetic anastomotic cuffs may be associated with better graft patency, while venous cuffs may be associated with worse patency. Furthermore, the trials suggested percutaneous angioplasty of "failing" prosthetic accesses with greater than 50% stenoses did not appear to improve patency and that routine use of intraluminal stents, as an adjunct to angioplasty, was not beneficial. They did suggest that patency after open surgical revision of "failing" prosthetic accesses was superior to that after percutaneous angioplasty. Lastly, the identified trials suggested that the patency rates after open surgical revision of thrombosed prosthetic accesses was better than after endovascular treatment. Despite the magnitude of hemodialysis-related access problems, the quality of the evidence supporting the clinical decisions relevant to the access surgeon is limited and further clinical trials are justified.

The National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access (DOQI) have defined the access-related care of patients with end-stage renal disease (ESRD) (1). However, the standard of care across the country has fallen short of the DOQI targets that included a 50% incidence of autogenous access for initial constructions and a 40% overall prevalence rate. Notably Reddan et al. (2) reported from the Centers for Medicare and Medicaid Services that only 28% of patients were dialyzed through autogenous accesses (prosthetic, 49%; percutaneous catheters, 23%) during 1999. The potential explanations for these shortcomings are multiple and include feasibility, relative ease of using prosthesis, the necessary time for autogenous access maturation, patient life expectancy, preference for prosthesis among dialysis technologists, and reimbursement. However, the most compelling explanation is likely the lack of evidence documenting the superiority of autogenous access.

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Despite the detailed scientific approach used to generate the DOQI (3), the data cited to justify the superiority of autogenous over prosthetic access were limited by Evidence-Based Medicine Standards (Table 1) (4) and included retrospective case series (5,6) and expert opinion (5–8). Indeed, many of the access patency and infectious standards defined by the DOQI were classified as opinion (rather than evidence) by the multidisciplinary task force that drafted the document. Importantly, the limitations of the data underlying the DOQI do not incriminate the scientific process, but rather serve to illustrate the deficiencies in the scientific literature dealing with vascular access. Furthermore, it is our opinion that many of the standards/guidelines defined by the DOQI are

TABLE 1. Hierarchy of Strength of Evidence for Treatment Decisions

N = 1	Randomized controlled trials
	Systematic review of randomized trials
	Single randomized trial
	Systematic review of observational studies addressing patient-important outcomes
	Single observational study addressing patient-important outcomes
	Physiologic studies
	Unsystematic clinical observations

unrealistic, and it has been our anecdotal impression that other committed access surgeons share these views.

This study was designed to compare the DOQI with the best available evidence in the literature for four clinical questions relevant to the hemodialysis access surgeon. These include the choice of access type (autogenous versus prosthetic), type of prosthetic graft, management of the "failing" (nonthrombosed) access, and management of the thrombosed access.

Literature Search

A reference librarian with an interest and training in evidence-based medicine (A.G.B.) searched the electronic databases MEDLINE and Evidence-Based Medicine Reviews (Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, Database of Abstracts and Reviews of Effectiveness, Cochrane Central Register of Controlled Trials) using the PubMed (U.S. National Library of Medicine, Bethesda, MD) and Ovid (Ovid Technologies, New York, NY) databases. The databases were searched from 1966 to March 2003 using the terms hemodialysis access, arteriovenous fistula, arteriovenous graft, arteriovenous shunt, access surgery, prosthetic access, and autogenous access in conjunction with the search filters "randomized controlled trials" or "meta-analyses." The search was further limited to full-text articles published in English. The abstracts of the articles identified by the search were then reviewed and the relevant articles identified for further in-depth review. Data were extracted during the in-depth review by a single investigator (T.S.H.) and independently confirmed by a second (J.M.S.).

Choice of Permanent Access: Autogenous versus Prosthetic

The DOQI (guideline 3) recommends autogenous radiocephalic and brachiocephalic as the first and second choices, respectively, for permanent access. They state that there is sufficient, quality evidence (*E*) to support the recommendation for radiocephalic access and justify the brachiocephalic access choice with a combination of evidence and opinion (*O*) (9). The third choice for permanent access was not clearly defined, and it was stated that either a prosthetic access (*E*) or an autogenous brachiobasilic access (*E*) could be constructed. Notably the DOQI emphasizes that percutaneous catheters should be strongly discouraged as a choice for permanent access. The DOQI recommends (guideline 29) that autogenous accesses should be constructed in at least 50% of all new ESRD patients (*O*) and that the prevalence among all hemodialysis patients should be 40% (*O*). The rationales provided by the DOQI for the preference of autogenous access are their superior long-term patency and lower complication rates, including conduit stenosis, infection, and hand ischemia.

The DOQI defines primary access failure rates (guidelines 33 and 35), cumulative access patency rates (guidelines 36 and 38), center-specific thrombosis rates (guideline 31), and infection rates (guideline 32) among their potential quality of care standards. The DOQI states that the annual cumulative patency rate for prosthetic accesses should be 70% (*E/O*) and that the thrombosis rate should not exceed 0.5 episodes per patient-year at risk (*E/O*). Furthermore, they state that the 30-day primary failure rates for prosthetic access in the forearm (loop configuration) and upper arm should not exceed 10% and 15%, respectively, and that the infectious complication rate should not exceed 10% over the functional life of the access (*O*). The DOQI also states that the failure rate for autogenous accesses should be less than 0.25 episodes per patient-year at risk (*O*). The DOQI did not define a cumulative annual patency rate (*O*) or primary failure rate (*O*) for the autogenous accesses as not to discourage surgeons from attempting their construction. Lastly, the DOQI states that the infectious complication rate for autogenous accesses should not exceed 1% over their functional life (*O*).

Despite the recommendations in the DOQI and their justifications based on the evidence in the literature, we were unable to identify any randomized controlled trials or meta-analyses comparing autogenous and prosthetic accesses. However, we recently published a formal systematic review of the literature comparing the patency rates of upper extremity polytetrafluoroethylene (PTFE) and autogenous accesses in adults that represents the next level down in the hierarchy of evidence (Table 1—systematic review of observational studies) (10). Studies were considered acceptable for inclusion if patency was reported using either the life table or Kaplan-Meier methods including the number of patients at risk (11).

Unfortunately there were only 34 studies that satisfied the inclusion criteria, with the majority comprised of cases series or nonrandomized controlled studies with the data collected in a retrospective fashion. There were five randomized controlled trials included. However, they compared characteristics of the graft materials or graft modifications and will be addressed in a subsequent section. The primary annual patency rates for the autogenous and PTFE accesses were approximately 60% and 40%, respectively, while the corresponding secondary patency rates were 80% and 60% (Fig. 1). Notably the annual secondary patency rate for the PTFE accesses is less than the cumulative annual patency rate (60% versus 70%) established by the DOQI in their quality of care standards. We were unable to determine accurate complication rates for the access types in our systematic review due to the fact that they were not described, the description was not standardized (e.g., hand ischemia—no quantification of severity), or the means of reporting were not amenable to meta-analysis (e.g., infection—incidence, but no event per patient-year at risk).

Choice of Prosthetic Access

The DOQI (guideline 4) recommends PTFE over other prosthetic or biologic conduits for patients that are not candidates for autogenous accesses (*E/O*). They did not recommend any specific type or modification (e.g., thin wall, elastic, tapered) of the PTFE (*O*) and state that

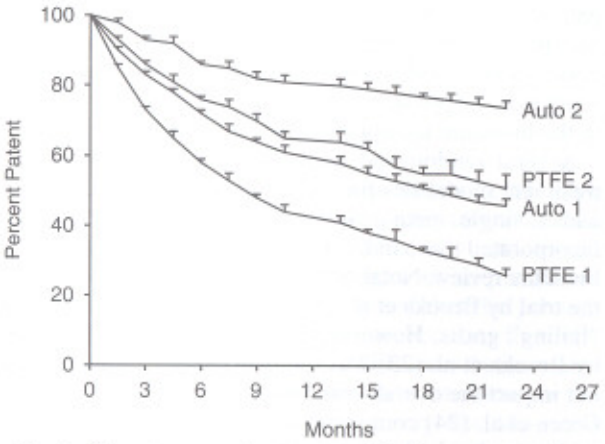

FIG. 1. The patency rates (percent patent) for the autogenous (Auto) and PTFE (PTFE) upper extremity arteriovenous hemodialysis accesses are plotted against time (months) with the positive standard error bars. Both the primary [auto 1 (N = 1849), PTFE 1 (N = 1245)] and secondary [auto 2 (N = 1336), PTFE 2 (N = 703)] patency rates for the two access types are shown. The patency rates for the autogenous accesses were better than their corresponding PTFE counterparts with the one exception of the initial (1.5 months) time point for the primary patency comparison. (From Huber TS, et al. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis access: a systematic review. *J Vasc Surg*, 39: 491–496, 2003.)

the access may be configured straight, looped, or curved, with the ultimate objective of optimizing the surface area available for cannulation (O). Furthermore, they recommend that the specific anatomic location of the access should be based on the individual patient's anatomy, the surgeon's skill, and the anticipated period of time the access will be required (O).

Our literature search identified several randomized controlled trials dealing with commercially available prosthetic accesses. Glickman et al. (12) reported from a multicenter trial (N = 142) that there was no difference in patency between polyurethane urea (Vector, Thoratec Industries, Pleasanton, CA) and standard wall PTFE (W. L. Gore, Flagstaff, AZ; or Impra, Tempe, AZ) accesses. Of interest is that Glickman et al. (12) also reported that the polyurethane urea grafts took less time for hemostasis after decannulation and that a larger percentage were cannulated before 9 days postoperatively. However, these endpoints were not examined in a randomized controlled fashion.

Both Kaufman et al. (13) (N = 131) and Hurlbert et al. (14) (N = 190) reported no difference in either patency or complications between the Gore and Impra brands of PTFE (standard wall). Tordoir et al. (15) (N = 37) reported that the patency rates for stretch PTFE (Gore) were superior to those for standard wall PTFE (annual primary patency 59% versus 29%), while Lenz et al. (16) (N = 108) reported that patency rates for standard wall PTFE (Gore) were superior to those for the thin wall, stretch PTFE (annual primary patency 49% versus 31%) in a significantly larger study. Sorom et al. (17) (N = 48) recently reported that PTFE grafts configured with a PTFE cuff (Venaflo, Impra) had superior patency (annual secondary patency 64% versus 32%) to noncuffed stretch PTFE grafts (Gore). Notably none of the cuffed PTFE grafts failed as a result of venous outflow stenosis.

Dammers et al. (18) (N = 109) reported that there was no difference in patency rates between 6 mm and 4 and 7 mm tapered thin wall, stretch PTFE (Gore) grafts. The 4–7 mm tapered grafts offer the theoretical advantage that they may reduce fistula flow and thereby the incidence of hand ischemia. Somewhat surprisingly, Dammers et al. (18) reported a significantly higher mean fistula flow rate at 12 months in the tapered grafts. They found no difference in the incidence of hand ischemia between the two graft types, although the overall incidence (3/109) in the series was too small for any type of statistical comparison.

Lastly, Lemson et al. (19) (N = 120) reported that a venous anastomotic cuff (Tyrell collar) did not improve patency when used in conjunction with thin wall, stretch PTFE (Gore) grafts. However, Gagne et al. (20) (N = 17) reported a similar study where the cuff resulted in such a dramatic decrease in patency (9 months primary patency 80% versus 17%) that the study had to be stopped prematurely. Of interest is that the studies reported contradictory findings with respect to the impact of the cuff on the development of stenosis at the venous anastomosis.

Management of the Failing Access

The DOQI recommends (guidelines 17–19) intervention for hemodynamically significant stenoses in prosthetic and autogenous accesses (E). They define these stenoses as a ≥ 50% reduction in the normal vessel diameter in the presence of a "hemodynamic, functional, or clinical abnormality," as determined by a variety of different techniques including recirculation time and decreased blood flow. Intervention is justified in this setting, with the rationale that these stenoses are associated with an increased risk of thrombosis and that therapeutic intervention reduces this risk, thereby prolonging access life. The DOQI also recommends (guideline 18) intervention for autogenous accesses when the flow is inadequate for the prescribed dialysis regimen (E/O), and they emphasize that significant stenoses in autogenous accesses are not necessarily associated with elevated dynamic or static pressures.

The DOQI recommend (guideline 19) that the choice of intervention (endovascular versus open surgical) for "failing" prosthetic and autogenous accesses should be dictated by local expertise (E/O); quality control standards are provided. They state that the unassisted primary patency after percutaneous transluminal angioplasty (PTA) of these lesions should be 50% at 6 months (E), while those for open surgical revision should be 50% at 1 year (O). The higher standard for the open surgical approach was justified by the fact that it is usually associated with a revision of the venous anastomosis and thereby consumes more vein. The DOQI also recommends (guideline 19) the use of intravascular stents as an adjunct to PTA in select cases, including limited access options and poor operative candidates (E).

The literature search identified three randomized controlled trials examining the treatment of "failing" accesses. Lumsden et al. (21) (N = 64) compared prophylactic PTA to no intervention in patients with greater

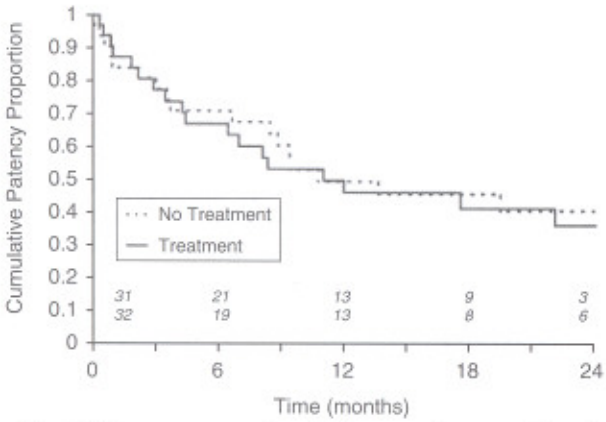

FIG. 2. The patency rates (cumulative proportion patent) for the prosthetic access grafts with more than 50% stenosis randomized to percutaneous angioplasty (treatment, $N = 32$) or observation alone (no treatment, $N = 32$) are shown. There were no significant differences in the patency rates between the two groups at any time point. The 6-month patency rates were 69% and 70% for the treatment and no treatment groups, respectively. (From Lumsden AB, et al. Prophylactic balloon angioplasty fails to prolong the patency of expanded polytetrafluoroethylene arteriovenous grafts: results of a prospective randomized study. *J Vasc Surg* 26:382, 1997.)

than 50% stenoses in PTFE prosthetic accesses and found no difference in access patency. The stenotic lesions were detected by color flow duplex ultrasonography and confirmed by arteriography prior to randomization. Furthermore, patients randomized to intervention underwent repeat arteriography and repeat PTA if stenoses greater than 50% were detected during follow-up imaging. Notably the 6-month cumulative access patency rates for both the treatment and nontreatment groups (69% versus 70%, respectively) (Fig. 2) exceeded the recommended DOQI standards for PTA (50%). Beathard (22) ($N = 58$) compared PTA alone and in conjunction with a self-expanding stent (Gianturco) for stenoses at the venous anastomoses of PTFE accesses and found that the stent did not provide any additional benefit. Lastly, Brooks et al. (23) ($N = 43$) compared open surgical repair (patch angioplasty or interposition graft) with PTA for either PTFE or bovine accesses with stenoses at the venous anastomoses and found that the patency rates were significantly better in the surgical group (annual cumulative patency 65% versus 25%).

Management of the Thrombosed Access

The DOQI states (guideline 21) that thrombosed prosthetic accesses could be treated either with open surgical, mechanical, or pharmacomechanical thrombolysis, with the choice contingent on the local expertise (no level of evidence provided). They recommend that all residual stenoses be corrected (*E*) and justify this approach stating that thrombosis is a result of venous outflow stenosis more than 85% of the time. Furthermore, they define the quality control standard for percutaneous lysis/PTA by a 3-month unassisted patency rate of 40% (*E*) and that for surgical thrombectomy/revision by a 6-month unassisted patency rate of 50% (*O*). The DOQI states (guideline 22) that the outcome after thrombolysis of autogenous accesses is not good and they propose that each institution adopt its own approach. They note that there is little evidence in the literature to support the various treatment options.

Several randomized controlled trials comparing the treatment modalities for thrombosed prosthetic accesses and a single meta-analysis of randomized trials that incorporated these individual trials were identified in the literature review. Notably this meta-analysis also included the trial by Brooks et al. (23) examining the treatment of "failing" grafts. However, the samples size in the study by Brooks et al. (23) was relatively small and likely did not impact the overall conclusions. In the meta-analysis, Green et al. (24) compared open surgical thrombectomy with mechanical or chemical thrombectomy and included seven trials with a total of 479 patients. The patency rates for the open surgical treatment were better for every time point examined (30 days, 60 days, 90 days, and 1 year), with the corresponding relative risks ranging from 1.22 to 1.34. There were no differences in the complication rates between the open surgical and endovascular approaches. However, the technical failure rate was significantly higher in the endovascular group, with a relative risk of 1.90. Notably the 3-month patency rate after endovascular treatment (24%) and the 6-month patency rate after open surgical treatment (34%) reported from one of the larger trials within the meta-analyses [Marston et al. (25) ($N = 115$)] were significantly lower than the DOQI standards (Fig. 3). Unfortunately

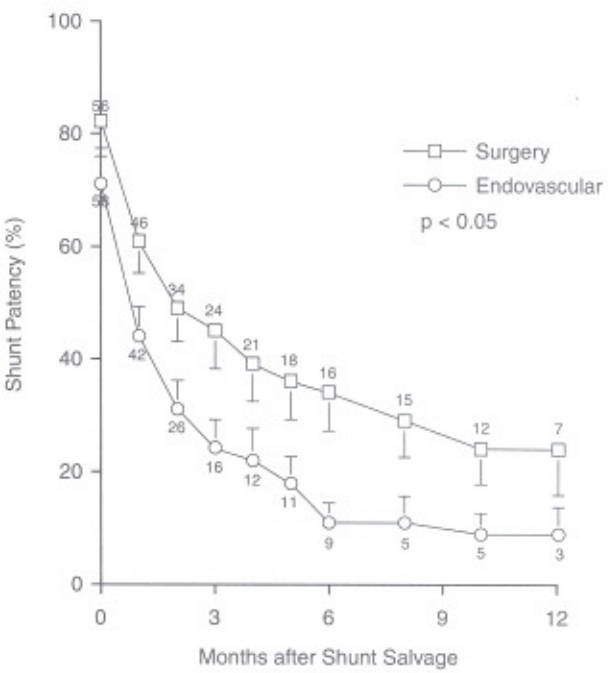

FIG. 3. The shunt patency rates (percent patent) for the thrombosed prosthetic access grafts randomized to open surgical (surgery, $N = 56$) or endovascular (endovascular, $N = 59$) treatment are shown. The graft patency after salvage was significantly better in the surgery group. The 6-month patency rate was 34% for the surgery group and only 11% for the endovascular group. (From Marston WA, et al. Prospective randomized comparison of surgical versus endovascular management of thrombosed dialysis access grafts. *J Vasc Surg* 26:373, 1997.)

no studies comparing the various treatments for thrombosed autogenous accesses were identified.

Discussion

Autogenous access appears to be the best choice for permanent hemodialysis access given the available data. Although we were unable to find any randomized controlled trials comparing autogenous to prosthetic accesses, our systematic review found that the patency rates for upper extremity autogenous accesses in adults were better than those for their PTFE (prosthetic) counterparts and corroborated the similar contentions in the DOQI. However, access patency is only one of several clinically relevant endpoints that factor into the decision of selecting the most appropriate access type, despite the fact that it has been the focus of the most intense investigation. The other factors include cost, patient/technologist preference, obligatory time that temporary catheters are required, failure of autogenous accesses to mature, need for remedial procedures to facilitate access maturation, infectious complications, hand ischemia, and subsequent access options after abandonment of the initial configuration. Unfortunately none of these endpoints, with the potential exception of infectious complications, has been closely examined.

It is not completely clear that autogenous access is the obvious choice when/if these other components are considered, and it is also not clear that the order of choices outlined by the DOQI (radiocephalic autogenous → brachiocephalic autogenous → brachiobasilic autogenous or prosthetic) is optimal. In our own recently validated algorithm designed to optimize autogenous access, 16% of the autogenous accesses failed to mature sufficient for cannulation, 24% needed some type of remedial intervention to facilitate maturation, and it took a mean of 3 months until they were sufficient for cannulation (26). Furthermore, some surgeons have contended that all forearm options including prosthetic configurations should be exhausted before moving to the arm, since the presence of a forearm prosthetic access leads to dilation of the veins in the arm, thereby facilitating additional autogenous options. A randomized controlled trial comparing autogenous to prosthetic accesses is necessary to definitively determine the optimal access configuration and address these multiple questions. Indeed, it is surprising that one has not been performed already given the staggering number of patients with ESRD and the associated costs of renal replacement therapy. Admittedly it is unclear whether the necessary clinical equipoise exists. The DOQI guidelines are very pro-autogenous access and it has been our anecdotal impression that the nephrology community has used the guidelines to encourage access surgeons to create autogenous accesses. However, it is important to note that many of the standards defined by the DOQI were classified as opinion. Furthermore, the fact that the prevalence of autogenous access across the county has fallen short of the DOQI targets suggests that the information has either not been widely disseminated or widely accepted.

The optimal choice for prosthetic accesses among the commercially available grafts remains unresolved. The DOQI recommends PTFE as the prosthetic material of choice, and it is likely the most widely used conduit material. However, there was no difference in patency between the PTFE and polyurethane urea grafts in the study by Glickman et al. (12) Two nice randomized trials demonstrated that the specific brand of PTFE does not make a difference in graft performance (13,14). However, several of the fabric characteristics or modifications to the PTFE grafts may confer a patency advantage, although the available evidence is somewhat contradictory and the study sample sizes relatively small (15–18). Further investigation is necessary before more definitive recommendations can be made. The reported improved patency rates associated with the PTFE anastomotic cuff are intriguing in light of the fact that none of the grafts failed due to venous outflow stenosis, the usual cause of failure (17). Furthermore, it was surprising that the addition of a venous anastomotic cuff did not appear to improve graft patency, and indeed may have had the opposite effect (19,20). It is unfortunate that the trial examining the use of tapered grafts was not sufficiently powered to determine whether they reduced in the incidence of hand ischemia, since they may afford this theoretic advantage (18). Unfortunately we were unable to identify any randomized controlled trials examining the various locations or configurations for the prosthetic grafts. The DOQI recommends that the configuration should optimize surface area and the location should be dictated by patient anatomy, surgeon preference, and the anticipated duration of dialysis; all these recommendations seem reasonable, although largely opinion.

Randomized controlled trials suggest that prophylactic percutaneous angioplasty and routine use of intraluminal stents do not improve patency for prosthetic grafts with more than 50% stenoses. These findings appear to contradict the recommendations by the DOQI. Admittedly only two randomized controlled trials (one each) were identified that addressed these issues, and the sample sizes were relatively small. One possible explanation for the differences with regard to the treatment of these "failing grafts" may be the caveat in the DOQI that the stenoses should be associated with a "hemodynamic, functional, or clinical abnormality" as detected by a variety of techniques. Although somewhat nebulous, this caveat suggests that the presence of a stenosis alone is not sufficient to merit intervention. In the study by Lumsden et al. (21), the graft stenoses were identified simply by color flow duplex ultrasonography and confirmed by arteriography. They stated in the open meeting discussion included with the manuscript that they examined a variety of techniques to confirm the significance of the stenoses, although they did not find any particularly helpful.

The DOQI does not recommend the routine use of stents, but rather suggests that they may be beneficial for patients with limited options or those who are poor operative risks. It is notable that two additional randomized controlled trials (27,28) comparing percutaneous angioplasty alone to angioplasty plus intraluminal stents in patients with both "failing" and thrombosed prosthetic

grafts reached similar conclusions to Beathard et al. (22), namely that the stents did not provide additional benefit. It is unfortunate that we were unable to identify any randomized controlled trials examining the treatment of "failing" autogenous accesses. In the absence of level 1 evidence, the DOQI recommendations seem reasonable.

It has been our anecdotal impression that, unlike prosthetic accesses, autogenous accesses present as "failing" accesses rather than thrombosed ones and that it is usually possible to intervene to maintain functional patency. The role of treatment in this setting is likely comparable to that for "failing" lower extremity bypass grafts, which has been shown to dramatically improve patency (29–31). The randomized trial by Brooks et al. (23), documenting the superiority of open surgical intervention for the treatment of "failing" prosthetic and biologic grafts, is consistent with the differential standards for percutaneous and open surgical revision defined by the DOQI and suggests that open surgical intervention may be the treatment of choice. However, this treatment choice is usually contingent upon multiple factors other than access patency, such as local expertise, treatment availability, and patient/provider preference. It should be noted that the postintervention patency rates reported in the trials by Lumsden et al. (21) and Brooks et al. (23) exceed the standards defined by the DOQI for percutaneous transluminal angioplasty and open surgical revision, respectively.

The meta-analysis of the randomized controlled trials suggested that patency after open surgical revision of thrombosed prosthetic accesses is better than after endovascular treatment, despite no difference in the complication rates. These findings are indirectly supported by the differential outcome standards defined by the DOQI which are more rigorous for open surgical revision. Similar to the treatment of "failing" prosthetic accesses, these findings would suggest that the open surgical treatment is superior. However, the decision about the specific treatment modality is influenced by more factors than long-term patency. In the study by Marston et al. (25) (Fig. 3), it should be noted that only 34% and 11% of the grafts treated with open surgical and endovascular therapies, respectively, were still functional at 6 months. These findings suggest that once the grafts thrombose, their long-term outcome is dismal and subsequent access options should be explored. Furthermore, they suggest that the outcome criteria defined by the DOQI in this setting (endovascular, 40% at 3 months; open surgical, 50% at 6 months) may be unrealistic.

The optimal treatment for thrombosed autogenous accesses remains unresolved. Indeed, the DOQI states that the outcomes for both endovascular and open surgical treatment are poor, and they challenge individual centers to define the best modality. However, it has been our anecdotal impression that the outcome is not quite so poor, and we would strongly recommend chemical lysis provided there are no contraindications. Autogenous accesses frequently fail secondary to an underlying critical stenosis that is potentially amenable to percutaneous angioplasty or they fail secondary to technical problems related to cannulation or compression, which may be treated by thrombectomy alone.

There are a few limitations of the study that merit further comment. First, the search strategy that we used to identify the randomized trials was not as rigorous as frequently used in formal systematic reviews. Specifically, we reviewed only full-text articles written in English that we identified by MEDLINE or Evidence-Based Medicine Reviews. Admittedly we may have identified additional trials if we utilized other databases, abstracts, or non-English publications. However, we would contend that the search represented a reasonable, practical approach that likely identified the critical articles. Furthermore, a reference librarian with an interest in evidence-based medicine performed the search in an unbiased fashion. Second, the randomized controlled trial is the "gold standard" for clinical investigation as defined by evidence-based medicine. However, it is not the only study design, and basing clinical decisions solely upon the results from these types of trials is clearly not possible given the limited number of studies and the multitude of clinically relevant access questions. Furthermore, just because a study was conducted in a randomized controlled fashion does not mean that the results are necessarily valid or relevant. Indeed, the Evidence-Based Medicine Working Group has established a methodology to evaluate articles about therapy and prevention (32,33) and it was our initial intention to use their criteria. However, the requisite information was not contained in most of the trials identified. An article describing the methodologic approach of the DOQI summarized the opinions of its authors stating that just because "a report is based on the results of an RCT [randomized controlled trial] does not by itself mean that the reported evidence constitutes strong evidence" (3).

Despite the debates about the strengths of various trial designs, it is apparent that the quality of the evidence supporting clinical decision making relevant to access is limited. It is incumbent upon us as clinicians to continue to identify the best possible evidence and to conduct the necessary trials to answer the critical questions in order to provide the best possible care for our patients.

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