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Vascular Access: Inukshuk

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EDITORIAL

Vascular Access: Inukshuk

An inukshuk (*pl*. inuksuit) is a figure constructed from unworked stones or boulders (Fig 1) that is used for communication among the Inuit in the Arctic.[1] In Inuktitut, the language of the Inuit, *inukshuk* means "to act in the capacity of a human." Inuksuit serve several functions including acting as hunting and navigational aids, coordination points, and messaging centers. In addition to their practical functions, inuksuit are venerated and possess spiritual connotations. For those who survive and thrive in the Arctic in the "Old Way," mindfulness and appreciation of the import of guidepost inuksuit are critical.

The need for guidepost inuksuit arises when considering hemodialysis (HD) vascular access, one of the most vexing problems of clinical nephrology. Vascular access failure results in an untimely burden for many: dialysis workers, healthcare providers, and, most importantly, patients. Failure of a vascular access portends multiple possibilities, none of them good. There are missed HD treatments, surgical revision(s), and their associated pain(s) and cost(s). There is blood loss, exposure to nephrotoxic contrast medium with possible reduction in residual kidney function, and macerated and propellant clots associated with pulmonary emboli during thrombectomy procedures. A forced and failed arteriovenous fistula (AVF) leads to morbidity for the patient in disfiguring scars and their ostracizing effects, loss of future vascular access options, and urgent requirement for alternative vascular access. The latter is arguably the worst scenario and requires temporary placement of an HD catheter that potentially leads to one of the 80,000 central line–associated bloodstream infections (CLABSIs) that occur in the United States annually.[2] These infections result in 28,000 intensive care unit deaths yearly and, on average, cost $45,000 per episode.[3] Even worse, some individuals will survive an episode of life-threatening sepsis only to encounter another as the fistula failure-to-dialysis catheter insertion cycle repeats itself.

The Centers for Medicaid and Medicare Services (CMS)–sponsored Arteriovenous Fistula First Breakthrough Initiative (FFBI) was developed as the National Vascular Access Improvement Initiative in 2003 and launched nationally in 2004.[4] This programmatic push for increasing AVF prevalence followed the 1997 National Kidney Foundation Kidney Disease Outcomes Quality Initiative recommendation for an incident autogenous AVF rate of 50%, with an ultimate 40% prevalence rate. The second, complementary guideline was a 10% prevalence of HD catheters.[5] This FFBI prevalence target of 40% was rapidly adopted as a quality metric by healthcare groups, hospitals, and the 18 end-stage renal disease (ESRD) networks in the United States. In 2009, the benchmark goal increased to 66% AVF use in prevalent HD patients, which was considered feasible, particularly because other countries boasted prevalences from 67% to 91% in Japan, Italy, and Germany.[6]

This laudable initiative likely failed because it was flawed in several aspects. In previous editorials, I had discussed the "systematization of harm"[7] and "misfears".[8,9] Both applied in this case. First, the FFBI evoked the specter of measurement and self-recrimination. Groups and institutions that embraced the initiative but scored below target AVF rates were considered less capable than others, which spurred an emotion-laden call to action to create AVFs on demand and without an optimized and individualized plan. Ironically, adoption of the FFBI led to an 80% incidence of temporary HD catheter insertions,[10] by inadvertently diverting attention from initiatives to decrease catheter use.[11] Thus, this sequence of events represented an inadvertent systematization of harm, and Lacson and colleagues proposed a solution of bridge grafts to subvert the dangers inherent to catheters. Elderly candidates who should not have undergone surgery to establish an AVF were moved to the front of the line for this delicate procedure, in many instances to increase the local AVF prevalence, but these individuals received grave disappointment when the AVF did not mature, resulting in a lost vein, non-recoverable time, and prolongation of central venous catheterization. This costly scenario was repeated ad infinitum and chalked up to "bad luck" and a search for improvement.

In elderly patients, there may be no clear-cut advantage to AVF over arteriovenous graft (AVG) construction. Here, the misfear—instinctive rather than factual—is that AVG placement will fail and the patient will require a future,

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Figure 1. Inukshuk at the mouth of the Great Whale River in the vicinity of Kuujjuarapik, the southernmost village of Nunavik. Photograph, courtesy of Nicolas M. Perrault.

secondary procedure. Consequently, an AVF is attempted although great doubt exists regarding the suitability of the AVF postsurgically. Not infrequently, a secondary procedure is required to facilitate its use. The data from the Dialysis Access Consortium trials demonstrated a high rate (~60%) of suitability failure for autogenous AVFs when defining suitability as "use of the AVF at a dialysis machine blood pump rate of 300 mL/min or more during 8 of 12 dialysis sessions."[12] Considered by many a benchmark trial, the outcome was not because vascular access surgeons have always understood that careful patient selection is fundamental to access. In a parallel trial, Dixon and colleagues demonstrated the difficulty inherent to successful graft constructions.[13] Graft failure occurred in nearly three-fourths of subjects after 1 year of observation, and the addition of long-acting pyridamole and aspirin did not offer a conclusive advantage over that of placebo for prophylaxis against thrombosis prevention.

If an individual, usually elderly with suboptimal caliber and quality veins, is subjected to "failure to mature" (FTM) testing and will predictively fail AVF maturation and use, an AVG is the first choice or the alternative of peritoneal dialysis. Perversely, failure of AVF construction enriches those who perform them. Driven by pressure to achieve an AVF prevalence metric, first 50% then 66%, AVF constructions that were likely to fail did so, leading to secondary synthetic AVG constructions after intervening catheter insertions—all executed and billed by the same individual. Finally, even the best AVFs may bear unforeseen consequences including aneurysmal dilation with erosion, left ventricular hypertrophy, high output cardiac failure, or a vascular "steal" syndrome.

Could we reduce these potentially lethal events by following our own inuksuit? Such a rhetorical question begs no answer, and there are and have been inuksuit that exist and facilitate the goal of optimal vascular access for each individual who requires one. These tools assist nephrologists to navigate the vascular access landscape in the same way that inuksuit situated throughout the Arctic landscape act as "helpers" to the Inuit. Three of these tools have been validated and may be easily implemented.

FAILURE TO MATURE INDEX

Lok and colleagues offer a solution to determining a priori the best vascular access for each patient in a timely fashion. Certainly, AVFs may sustain greater blood flow than AVGs, but that is not the only qualifying criterion for success. A simple, rigorously validated scoring system, developed by Lok and colleagues, predicts a preoperative AVF FTM rate using clinical parameters.[14] FTM is a function of age, coronary artery disease, peripheral vascular disease, and race. In terms of peripheral vascular disease, it is known that neointimal hyperplasia may be surreptitiously present before vascular access investigations are even contemplated.[15] The FTM prediction equation (score $= 3 + 2 \times$ [years $\geq$ 65] $+ 3 \times$ [PAD, peripheral arterial disease] $+ 2.5 \times$ [CAD, coronary artery disease] $- 3 \times$ [white]) was externally validated in 461 patients from 4 Canadian and 1 US dialysis centers and scored from 0 to 10.5 along the following 4 risk categories: $<$2.0, low risk; 2.0 to 3.0, moderate risk; 3.1 to 7.9, high risk; and $\geq$8.0, very high risk. The primary outcome was AVF FTM, operationally defined as an AVF that was unable to consistently provide prescribed dialysis via 2-needle cannulation for 1 month within 6 months of its creation. Interventions that promoted AVF maturation were permitted at the discretion of the treating provider(s), including nephrologists, interventionalists, and vascular surgeons. As anticipated, older black individuals had greater FTM risks, which was amplified by the presence of cardiovascular disease. Half of patients graded at high risk experienced FTM, and 69% of individuals with very high risk for FTM experienced AVF failure. The financial savings of calculating the risk prediction score in very high–risk individuals are substantial, notwithstanding the benefits to the patients who can avert an unfavorable surgical outcome(s). Because surgical opinion plays a significant role preoperatively, education regarding the appropriateness of AVF construction surgery represents an opportunity for meaningful collaboration, fortified by a robust vascular access database.

VASCULAR ACCESS SURVEILLANCE

Physical examination is the prototypical vascular access "monitoring" modus operandus, but it is a dying art. Physical examination of vascular access has been extended to include clinical clues such as symptoms and recirculation.[16] Rapid throughput medicine and the lack of hands-on teaching, attributable to a paucity of skilled examiners trained in this fundamental skill, have instigated this sorry state of affairs. Compounding this suboptimal situation, vascular access evaluation has physical and operator-dependent limitations. Certain key physical findings are contextually dependent on blood flow, a dynamic characteristic that may be inconstant, for example, in atrial fibrillation. In addition, physical findings

predictive of vascular access dysfunction may require achievement of thresholds of obstruction before detection.

By contrast, vascular access "surveillance," functionally continuous access monitoring, requires specialized tests and instruments, which are employed periodically. Accordingly, additional detection methods for vascular access dysfunction have been explored. This conduit complication when slowly progressive may be signaled by escalation of blood urea nitrogen and verified by the classical, tripartite, blood urea nitrogen recirculation study. Because of this procedure's exacting and time-intensive nature, this technique is rarely performed on a routine basis today by any in-center HD units. Fortunately, the proxies of conductivity testing and observation of sodium dialysance monitoring have supplanted the classical recirculation study. Elevated intra-access pressure (IAP) has been studied as a warning sign for vascular access dysfunction and impending thrombosis. Static IAP of AVFs and AVGs as an original surveillance mechanism was developed by Besarab and colleagues more than 2 decades ago.[17] This parameter normalized by the systolic blood pressure correlated with access recirculation, AVF and AVG thrombosis, reduced blood flow, requirement for surgical intervention, and access failure. Its positive predictive value was sufficiently high to promote its adoptability, but the scrupulous technique required for widespread deployment limited adoptability.

Similarly, periodic, duplex ultrasonographic probing of vascular accesses and the ultrasound dilution technique proved successful in the early detection of vascular access thrombosis in a study by May and colleagues.[18] Ultrasonography has 2 intrinsic costs: purchase of a relatively costly device and personnel. The latter cost stems from the time and dedicated manpower that is intrinsic to establishing technique precision and reproducibility. Typically, a single individual in an HD unit was entrusted with the responsibility of ultrasonic detection of vascular access dysfunction, and this became a full-time job. Due to time constraints, most patients could not even undergo surveillance weekly or monthly, greatly dissipating the capability of the instrument to detect access dysfunction. For now, cost considerations and dedication to the craft of ultrasonography preclude its widespread applicability. Ram and colleagues could not demonstrate superiority of ultrasonographic surveillance compared with aggressive clinical monitoring in a randomized, controlled trial.[19]

Amplifying the strengths of IAP observation, surveillance of vascular accesses is feasible. The IAP can be rapidly and proxy calculated using accessible, hemodialysis machine-based data collected automatically and frequently.[20] A computerized algorithm (Vasc-Alert) dynamically determines venous intra-access pressure from the venous drip chamber pressure during hemodialysis machine operation. This parameter is derived from the venous drip chamber pressure, blood pump flow data, and a recent hematocrit (viscosity index). Periodic extraction of individual treatment data is fed forward to a remote database. Similar to the systolic pressure-normalized IAP, a venous access pressure ratio (VAPR) is defined as the ratio of the venous intra-access pressure (VAP) to the mean arterial pressure (MAP). This ratio is termed the vascular access pressure ratio (VAPR). VAPRs are iteratively calculated whenever timed blood pressure measurements are carried out and averaged per dialytic session. Data within the final 60 minutes of a dialysis treatment are excluded to eliminate the effect of ultrafiltration on hematocrit, blood pressure, and consequential alterations of resistances in the systemic and vascular access circuits. Abnormal mean VAPRs are those that surpass a prespecified upper bound in trended fashion, namely during 3 consecutive treatments.

Elevated VAPRs correlate with vascular access dysfunction in AVGs, and similar correlations are anticipated in AVFs. Anomalous AVG flow is also detectable by dynamic access pressure surveillance. Importantly, hemodialysis is never interrupted by this technique, and large amounts of patient-level and unit-level data are autoreported to in-center dialysis unit healthcare providers for rapid interpretation. When high venous access pressure ratio warnings are transmitted, the healthcare provider is alerted to the presence of vascular access dysfunction and access evaluation by a vascular access surgeon can be facilitated. Zasuwa and colleagues delineated the effectiveness of automated intravascular surveillance.[21] Using a computerized algorithmic approach, thrombosis rates declined progressively in AVGs and AVFs, with the magnitude of effect greater in AVGs than autogenous AVFs.

ANTIMICROBIAL/ANTIBIOTIC HD CATHETER LOCKS

When all else fails, a hemodialysis catheter becomes necessary unless the patient opts for peritoneal dialysis—an excellent upfront choice. Excellent catheter care in a given hemodialysis unit does not translate to 24/7 vigilance, and catheter infection rates escalate slowly for 90 days before achieving a steep upward trajectory. The source of a catheter infection—itself a misnomer—is biofilm that progressively forms on the catheter. This microorganism-manufactured matrix dually confers antibiotic resistance while providing a nutrient environment for its residents, which alternate between a sessile, slime-making existence in a condominium constructed of an extracellular polymeric substance and a flagellar, planktonic lifestyle in the bloodstream. Catheters impregnated with substances such as silver[22] are designed to prevent microorganism colonization or disrupt biofilm formation have also been combined with anti-infectives such as chlorhexidine in successful clinical trials that did not include hemodialysis patients.[23] However, hemodialysis catheters that are instilled with high concentrations of antimicrobials at the end of a dialysis session—antimicrobial locks—have proven the most effective strategy in the reduction of CLABSIs. This particular strategy is 3 decades old.[24]

To date, the great majority of trials that investigated the safety and utility of antimicrobial locks have been positive. Various antimicrobial locks have been successfully investigated in clinical trials including minocycline,[25] taurolidine,[26] gentamicin/citrate solutions,[27] a mixture of citrate/methylene blue/parabens.[28] Ethanol at a concentration of 70% has also been studied, but published data do

not yet support routine utilization of ethanol antimicrobial locking.[29] In the Heparin vs EthAnol Lock THerapY for the prevention of Catheter Associated infecTion in Haemodialysis trial, a definitive conclusion could not be drawn as the study was underpowered by under-recruitment. Heparin was used in some trials with the thought that high, local concentrations might preclude or forestall biofilm formation. This strategy was ineffective in vitro with citrate/methylene blue/parabens, and Hemmelgarn and colleagues in the PreClot study posited that heparin nurtured the development of biofilm.[30] Later, Moore and colleagues delineated a reduction of CLABSI of 73% in a single-center study of 555 participants and 1350 catheters using an antimicrobial lock of gentamicin/citrate solution vs a heparin-control group (0.45 per 1000 catheter days vs 1.68 per 1000 catheter days; $P = 0.001$).[31] Furthermore, a mortality benefit of gentamicin/citrate was revealed (hazard ratio, 0.32), whereas no increase of antibiotic resistance was found (antibiotic lock group, 0.22 per 1000 person years vs heparin-control, 0.45). In a study antedating that of Moore's, Landry and colleagues disclosed the emergence of gentamicin resistance in their investigation of a gentamicin-heparin lock,[32] prompting discontinuation of heparin after 6 months. Overall, citrate substitution for heparin, or the omission of heparin, appears fundamental to the avoidance of antibiotic resistance.

Despite the positive outcomes of clinical trials of antimicrobial locks, this easy-to-learn, adoptable, and implementable technique has few devotees despite an unambiguous admonition by Landry and Braden to practicing nephrologists that the important decision is not if but when to implement an antibiotic lock strategy.[33] Fears of the development of antibiotic resistance from implementation of a "lock" were not irrational, but negating the evidence that resistance clearly has not been the natural consequence of their use and ignoring their positive benefits during a dire clinical circumstance is illogical. This is a type 2 clinical error. Principally, the concept that an antibiotic lock must engender microbial resistance is a *non sequitur*.

The conflation of the necessary physical and biological characterization of AVFs will hopefully optimize vascular access modality choice and increase the AVF rate *in those who will benefit* from AVF construction. Only in this way will the true prevalence of mature AVFs be established. Greater predictive accuracy than the FTM risk score provides may eventuate from a computational approach, with robust decision matrices that interrogate for all that can be known about a patient's vascular access preoperatively, and facilitate pragmatic AVF outcomes. Currently, 2 predictive models that use ultrasonographic findings and non-gadolinium contrast-enhanced magnetic resonance angiography provide anticipated vascular access blood flow rates before vascular access surgery is attempted.[34,35] Such predictive models offer the way forward in conjunction with excellent clinical judgment that considers the individual clinical and functional characteristics, life circumstances, and preferences of patients.

I cannot fathom an Arctic aboriginal ignoring an inukshuk assembled by another experienced traveler-pioneer communicating a warning or sage advice from centuries ago. In terms of vascular access, we have our own pioneers with their inuksuit and should heed those who built them to act in the capacity of a physician with the best interests of patients at heart. The FFBI essentially sets a "one size fits all" standard, always a flawed approach. Nonetheless, the AVF rate remains within the scope of work of the ESRD networks. This harangue is promulgated by the implementation of the 2014 CMS "Five Star" rating system, which was added to the CMS Dialysis Facility Compare Web site.[36] All told, FFBI has made us aim higher, and our contemporary inukshuk, the FTM risk scoring system, dynamic vascular access surveillance, and antimicrobial locks, will improve functioning vascular access rates and optimize the desired "Patient First" approach as espoused by Lok and colleagues. The traditional meaning of "inukshuk" is "you are on the right path," and now we are.

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