Relationships Between Clinical Processes and Arteriovenous Fistula Cannulation and Maturation: A Multicenter Prospective Cohort Study

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Background: Half of surgically created arteriovenous fistulas (AVFs) require additional intervention to effectively support hemodialysis. Postoperative care and complications may affect clinical maturation.

Study Design: Hemodialysis Fistula Maturation (HFM) Study, a 7-center prospective cohort study.

Setting & Participants: 491 patients with single-stage AVFs who had neither thrombosis nor AVF intervention before a 6-week postoperative ultrasonographic examination and who required maintenance hemodialysis.

Predictors: Postoperative care processes and complications.

Outcomes: Attempted cannulation, successful cannulation, and unassisted and overall clinical maturation as defined by the HFM Study criteria.

Results: AVF cannulation was attempted in 443 of 491 (90.2%) participants and was eventually successful in 430 of these 443 (97.1%) participants. 263 of these 430 (61.2%) reached unassisted and 118 (27.4%) reached assisted AVF maturation (overall maturation, 381/430 [88.6%]). Attempted cannulation was less likely in patients of surgeons with policies for routine 2-week versus later-than-2-week first postoperative visits (OR, 0.21; 95% CI, 0.06-0.70), routine second postoperative follow-up visits (OR, 0.39; 95% CI, 0.15-0.97), and a routine clinical postoperative ultrasound (OR, 0.28; 95% CI, 0.14-0.55). Attempted cannulation was also less likely among patients undergoing procedures to assist maturation (OR, 0.51; 95% CI, 0.27-0.98). Unassisted maturation was more likely for patients treated in facilities with access coordinators (OR, 1.91; 95% CI, 1.17-3.12), but less likely after precannulation nonstudy ultrasounds (OR per ultrasound, 0.42 [95% CI, 0.26-0.68]) and initial unsuccessful cannulation attempts (OR per each additional attempt, 0.90 [95% CI, 0.83-0.98]). Overall maturation was less likely with infiltration before successful cannulation (OR, 0.44; 95% CI, 0.22-0.89). Among participants receiving maintenance hemodialysis before AVF surgery, unassisted and overall maturation were less likely with longer intervals from surgery to initial cannulation (ORs for each additional month of 0.81 [95% CI, 0.76-0.88] and 0.93 [95% CI, 0.89-0.98], respectively) and from initial to successful cannulation (ORs for each additional week of 0.87 [95% CI, 0.81-0.94] and 0.88 [95% CI, 0.83-0.94], respectively).

Limitations: Surgeons' management policies were assessed only by questionnaire at study onset. Most participants received upper-arm AVFs, planned 2-stage AVFs were excluded, and maturation time windows were imposed. Some care processes may have been missed and the observational design limits causal attribution.

Conclusions: Multiple processes of care and complications are associated with AVF maturation outcomes.

Complete author and article information (including a list of the members of the HFM Study Group) is provided before references.

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Am J Kidney Dis. 71(5): 677-689. Published online February 2, 2018.

doi: 10.1053/j.ajkd.2017.10.027

An arteriovenous fistula (AVF) is clinically mature if it can be reproducibly cannulated with 2 large-bore needles and provides sufficient blood flow for adequate hemodialysis. Progressive postoperative increases in vessel diameter and blood flow[1] are necessary, but insufficient, for clinical AVF maturation. Numerous care processes or complications may delay and/or prevent successful cannulation and/or maturation. Surgeons or nephrologists may be reluctant for less-experienced dialysis staff to attempt cannulation. Attempted cannulations may cause infiltrations, impeding successful AVF use. New AVFs may require diagnostic tests and/or surgical or percutaneous interventions to attain clinical maturation. Extended delays may lead to abandonment. AVF management without a dedicated vascular access coordinator may lower the chance of clinical maturation. Nevertheless, only a few single-center studies have investigated relationships between care processes and clinical maturation.[2-6]

The Hemodialysis Fistula Maturation (HFM) Study was a 7-center prospective cohort study of patients undergoing creation of new single-stage AVFs,[7] for which care processes constituted a protocol-specified investigational domain. Notable variations in care processes within and across centers were identified before patient enrollment. We examined the associations of AVF management care processes and complications with 3 critical events in

achieving maturation: attempted cannulation, successful cannulation, and clinical maturation.

Methods

Population, Access Management, and Data Collection

The HFM Study enrolled 602 patients with chronic kidney disease undergoing creation of a planned single-stage upper-extremity AVF[7] from March 2010 through August 2013. Participants provided written informed consent approved by the clinical center institutional review boards (see Item S1 for IRB numbers).

Patients underwent standardized preoperative sonographic vascular mapping, with results used by the surgeons in planning AVF surgery. The study protocol included standardized postoperative research ultrasounds at 1 day, 2 weeks, and 6 weeks. Results of these were not reported to the clinical centers except for 6-week ultrasounds at centers routinely obtaining them clinically. Beyond discouraging elective interventions before 6 weeks, the study did not stipulate a standard management protocol for new AVFs. Surgeons and dialysis units determined their own timing and frequency of postoperative visits and attempted AVF cannulation, use of nonstudy imaging studies, and type(s) and timing of interventions in nonmaturing AVFs. The specific functions of access coordinators, when present, varied by unit policy.

The HFM Study collected baseline patient demographics and comorbid conditions; surgeon and dialysis center practice policies, including surgeon clinical and ultrasound follow-up policies; ultrasounds as described; postoperative care processes and complications related to AVF management, that is, cannulations complicated by infiltration[7]; and use of additional diagnostic tests to assess and interventions to promote AVF maturation. Follow-up policies were studied without tracking patients' individual follow-up and clinical ultrasound visits, but detailed information including whether and when cannulation was attempted, whether and when the AVF was first successfully used for dialysis (by HFM Study definition), and whether attempted cannulation was complicated by an infiltration, was obtained for each dialysis session, beginning with the first attempted AVF cannulation and continuing until clinical maturation failure or success, whether unassisted or assisted by intervention, was determined.

Definitions of Study Outcomes

For patients receiving dialysis before AVF creation, clinical AVF maturation was defined as use with 2 needles for ≥75% of hemodialysis sessions during a continuous 4-week period commencing within 9 months of AVF surgery and including 4 consecutive sessions with mean blood pump flow >300 mL/min or, failing that, any Kt/V ≥ 1.4 or urea reduction ratio ≥ 70%. For patients initiating dialysis therapy more than 9 months after AVF creation, the first dialysis session meeting the pump flow, Kt/V, or urea reduction ratio criterion was required to be within 4 weeks of hemodialysis therapy initiation. Clinical maturation was subclassified as assisted if preceded by a percutaneous or surgical intervention to promote AVF maturation, and unassisted—the primary HFM Study clinical outcome—otherwise.

We focused on unassisted and overall (unassisted or assisted) clinical maturation and 2 related but distinct necessary intermediate outcomes: (1) the initial attempt to cannulate the AVF, and (2) successful cannulation, that is, completion of a 2-needle dialysis session.

Statistical Analysis

Measures of AVF physiologic maturation (AVF flow and vein diameter) and accessibility for cannulation (vein depth) may guide care processes and decisions of whether and when to cannulate the AVF, and are prognostic for clinical maturation,[8,9] thereby potentially confounding by indication the relationships of some care processes to cannulation and/or maturation. To avoid this, we both restricted analysis to the cannulation-eligible subcohort of patients with AVFs that survived without assistance to the point of 6-week ultrasonographic examination (491 patients), and controlled analyses for 6-week ultrasound flow, diameter, and depth. We studied associations of care processes, AVF infiltrations, and interventions with decisions to attempt cannulation in this group, and/or with clinical maturation in the further subset cannulated successfully, that is, the cannulated subcohort, as indicated in Table 1. For these analyses, we multiply imputed[10,11] races (black vs other) of 7 participants who omitted it; unassisted and overall AVF maturation outcomes of 6 and 10 participants, respectively, for whom they were unresolved by study closure; and 6-week AVF ultrasonographic measurements of 45 participants who missed this appointment or had technically unsatisfactory ultrasounds (missing measurements and/or poor image quality). We used 20 imputations and Rubin's formula.[10]

We treated kidney transplantation without cannulation and death without transplantation or cannulation as competing risks for cannulation analyses; treated death as a clinical maturation failure, as in other HFM Study analyses; and used the Fine-Gray cumulative-incidence approach[12] to describe times to cannulation and maturation. For patients in the cannulation-eligible subcohort and receiving maintenance dialysis at the time of AVF creation, we estimated and plotted cumulative incidences from AVF creation to first attempted cannulation and overall clinical maturation. For those who underwent cannulation, we similarly described times from first attempted to first successful cannulation and from then to overall clinical maturation. These descriptive analyses involved no imputation.

We used logistic regression to examine associations of care processes with outcomes. Influences of care processes that vary between clinical centers may partially manifest as