Vascular Access Study Overview and Implementation

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Investigator Meeting & Workshop

Introduction

- Majority of HD patients in Lebanon are dialyzed using an AVF.

- No information exists on the extent of AVF failures in Lebanon, though many nephrologists proclaim that the problem is common.

- A permanent vascular access that delivers a flow rate sufficient for the dialysis prescription and associated with low complication rate, is key to prolonged HD .

- Early preoperative surgical assessment and increased use of vascular imaging improves fistula outcomes, prolong patient survival on dialysis and reduce morbidity.

Goal

- Evaluate current practices of AVF insertion in HD patients in Lebanon.

- Assess maturation and functionality of inserted fistulae

- Study practices and factors associated with failed and successful fistulae.

- Utilize the information to establish recommendations and guidelines for fistula construction, utilization and repair that facilitate a prolonged and hemodynamic blood exchange during HD.

Participating Centers

- RHUH – Beirut   142 patients
- Ein Wazein Hospital - Chouf   68 patients
- North Hospital Center   95 patients
- Saydet Zgharta   38 patients
- UMCRH – Beirut   62 patients
- Hammoud Hospital – Sidon   <u>165 patients</u>

                    TOTAL: 570 patients

- American Univ. of Beirut MC   80 patients

Projected number of patients meeting inclusion criteria over a two-year period: **Approximately 230 patients** **(260 with AUBMC)**

Objectives

- **Primary**

  Assess the proportion of AVFs in newly initiated HD patients that fail to mature or to function within the first three months of utilization.

- **Secondary**

  1. Identify blood vessel parameters and patient characteristics associated with successfully functioning AVFs for more than 6 months.

  2. Identify parameters and patient characteristics associated with failed AVFs:
     a. Early failure
        i. Fistula never matured enough to support dialysis.
        ii. Fistula fails within the first 3 months of utilization.
      b. Late failure: Fistula fails after over 3 months of utilization.

  3. Assess parameters documented by the vascular surgeons upon construction of the AVF.

  4. Utilize the learning from the above evaluations to devise recommendations and/or guidelines for optimal surgical construction of AVF in the Lebanese HD patient population.

Patient Enrollment & Data

Inclusion

- Patients age ≥ 18 years initiated on HD historically during the 12 months prior to June 1, 2012 (Cohort 1), or prospectively during the 12 months starting June 1, 2012 (Cohort 2).

Data Acquisition

- Cohort 1: Data abstracted from patient's chart. If patient is alive, consent to acquire follow up data.
- Cohort 2: Patient consented and data collected real time.

Follow Up

- Up to 12 months after date of first dialysis in both cohorts.

Termination

- If patient dies, receive a transplant or lost to follow up. Data is collected at baseline (dialysis initiation) and up to termination date.

Early AVF Failure

- AVF never matures to the point that it can be used for dialysis, or when it fails within the first 3 months of usage

- AVFs that structurally fail to mature usually do not grow in size and are prone to early thrombosis because of the significant flow restriction due to narrow vasculature.

- AVF may fail due to poor pre-surgical assessment resulting in:

  (a) Failure of arterial dilation

  (b) Failure of venous dilation and/or

  (c) accelerated venous neo-intimal hyperplasia

Clinical Predictors of Early AVF Failure

- Late patient referral

- Presence of cardiovascular disease

- Comorbidity such as diabetes and hypotension

- Smoking is associated with both early and late fistula failure.

- Patients who underwent 3 HD sessions per week without heparin administration

Regular Assessment of AVFs

Key parameters to be assessed on a monthly basis and as needed:

- Venous pressures
- Ease of cannulation (preferably evaluated by same nurse)
- AVF flow rate
- Palpable thrill (expected with low flow)
- Arm edema
- Changes in the audible bruits
- Physical signs of suspected stenosis by palpation of the entire AVF
- Ultrasound imaging parameters
- Lab Parameters: Pre-BUN, Post-BUN, calculated URR, Ca x P product
- Interdialytic weight gain (adjusted for changes in the dialysis prescription)

Outputs from Study

- Establish guidelines for AVF insertion

- Promote standards for pre-surgical surveillance

- Promote standards for optimal surgical AVF parameters

- Promote a post AVF insertion surveillance program

- Devise standard forms to capture these information

- Use the K-DIGO guidelines & recommendations as a reference for evaluation

- Develop national guidelines based on our own data

Study Profile

- **Principal Investigators:**
  - Salim Kabalan, MD   - RHUH
  - Jamal Hoballah, MD   - AUBMC
- **Primary University:** Lebanese University
- **Other Universities**: LAUMC, AUBMC, Arab University
- **Funding:** National Council for Scientific Research
- **Co-Investigators:**

  Nephrologists and Vascular Surgeons at each participating hospital
- **Timeline:** February 2012 – September 2014

Study Design & Schema

- This is a cohort study consisting of a historical component (Cohort 1) and a prospective component (Cohort 2).

- Cohort start is the date of first dialysis and has one year follow up.

- Study Schema:

Historical	Enrollment	Follow Up

Prospective		Enrollment	Follow Up

Study Start
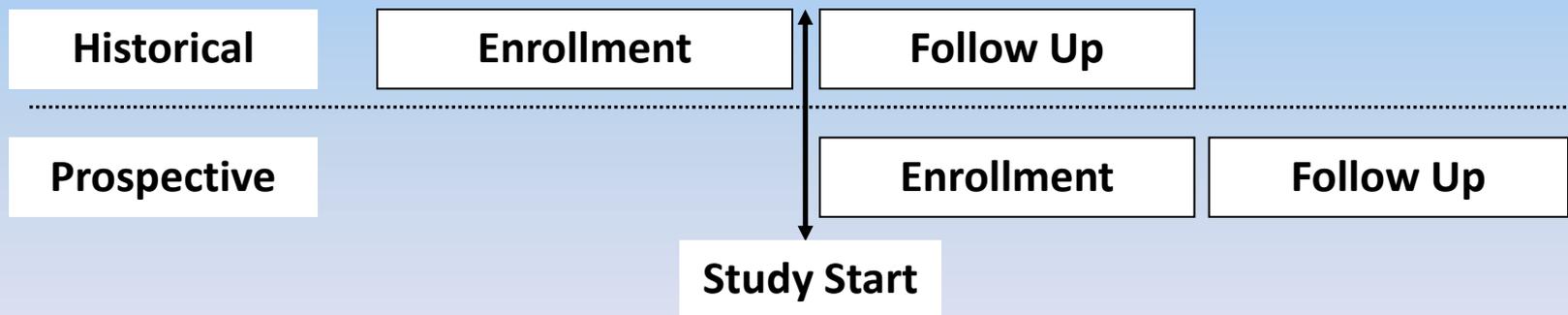
Clinical Methods

Historical Cohort 1

- **Abstract data from charts**
- **Contact & consent patients**
- **Collect follow up Data**

Workshop on advanced standards:

1. **AVF construction**
2. **AVF monitoring, care & complications**
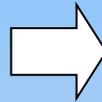
Prospective Cohort 2

- **Real time data on AVF construction, monitoring, care and complications**
- **Collect follow up AVF outcomes data**

Compare outcomes data for

Cohort 2 (Practice after workshop)

relative to

Cohort 1 (Existing practice)

Schedule of Data Parameter Acquisition

STUDY ROUTINE	BASELINE	MONTHLY	12 MONTHS
INCLUSION/EXCLUSION	X		
CONSENT PATIENT	X		
MEDICAL HISTORY / RISK PROFILE	X		
ANTHROPOMETRIC MEASUREMENTS	X		X
VITAL SIGNS*	X	X	X
PHYSICAL EXAM*	X	X	X
LABORATORY TESTING*	X	X	X
PRE-SURGERY VASCULAR ASSESSMENTS	X		
ULTRASOUND AVF STRUCTURE DATA	X	3 months	X
HEMODYNAMIC OPERATIONAL DATA	X	X	X
LOG OF AVF COMPLICATIONS	X	X	X
LOG OF VASCULAR ACCESS TYPES USED	X	X	X

What's after the Workshop: Cohort-1

- General Study Tasks
  - Finalize forms for data collection
  - Construct data entry screens
  - Convey study recommended procedures to all participating nephrologists & surgeons

- COHORT – 1
  - Finalize list of eligible patients at each center
    - Started dialysis June 1, 2011 until May 31, 2012
    - Regardless whether patient is dead or alive today
  - Consent living patients
  - Collect available data
    - Have complete registry data
    - Obtain available surgical data
    - Abstract remaining data from patient chart
  - Eligible patients identified so far: 90 patients
  - Additional patients expected through end of May 2012: 15 – 20
  - Projected total for cohort-1: 105 – 110 patients
  - Surgical practice continue as usual through end of May 2012

What's after the Workshop: Cohort-2

- New patients started on chronic dialysis as of June 1, 2012

- Ongoing enrollment of new patients through May 31, 2013

- Each patient follow-up for 1 year after first dialysis date

- AVF or AVG constructed for these patients after the workshop are expected to follow the study procedures

- Consent patient in the dialysis unit during first week on dialysis

- Enter patient data into kidney registry

- Use standard forms to document additional data:
  - AVF or AVG construction / Repair form
  - Monthly access monitor check list

Study Data in the National Kidney Registry

A clear example of how the registry functions as a centerpiece for the research program:

- Demographics
- Dialysis Initiation data

Monthly updates for:
- Vascular access complications
- Adequacy of dialysis
- Laboratory data
- Comorbidity and complications
- Outcome measures

Live registry access: www.kidneyregistrylb.com

Forms Used for Data Collection

- Standard form to document real-time structural parameters of the constructed fistula and pre-operative assessments that were done

- Standard form to document the physical exam of the AVF and the arm, and the hemodynamic parameters of operational AVFs:
    - Between construction & first use
    - Monthly after first use
    - Recommended based on screening criteria

- A standard form to capture detail of repair / treatment for ongoing complications in the AVF documented in the registry

Workshop Schedule

Topic	Presenter(s)
Vascular Access in Hemodialysis: An Overview	Jamal Hoballah, MD
Clinical & Surgical Considerations in Vascular Access Insertion	Joe Naoum, MD
Routine Maintenance of Vascular Access	Ammar Serawan, MD
Nursing Care of Vascular Access	Ibtissam Sabbah, PhD
Access Failure & Complications	Joe Naoum, MD Joe Khouri, MD
Standard Forms and Protocols / KDOQI (2008) + Fistula First Initiative	Elie Arbid, MD