Established and new concepts to create a stable access for chronic hemodialysis

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
Nephrologists aim: stable and easy
Hämodialysis 3-4 hours 3 X/week
Need for a stable Access
Average flow of CVC and AV-Fistulas

Minimal required flow for effective hämodialysis 250-300ml/min

• Central venous catheters (CVC):
  • Type of Catheter:
    • Shaldon
    • Demers
    • Hickman

• Arteriovenous Fistulas:
  • AV-Fistel forearm 250ml/min
  • AV-Fistel upper arm 300-400 ml/min
  • Prosthetic shunt 400-600 ml/min
AV fistulas are the preferred method of vascular access

2. USRDS Annual Report 2011 (2007 data). Reoperation rate includes only angioplasty for AVF and AVG, and CVC replacement for CVC. Complication rates are reported per patient-year. Complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access.
Venous Catheters

- For less than 3 weeks duration
- Cuff/uncuffed
- For patients with AKI, poisoning, in the ICU setting for CRRT
- Short-term bridge until more permanent access in CKD
- Preferred site - right internal jugular vein
- **Complications:** Thrombosis, Infection, Risk of permanent central venous stenosis or occlusion, Discomfort and cosmetic, Lower blood flow rates
- Use of subclavian venous catheters is generally contraindicated in dialysis patients except as a last resort.
Tunneled central venous catheters
Classical Access Surgery

• Fistula first Movement
• „Safe the veins“

• Minimal anatomical requirements for AV fistulas:
  – Ultrasound:
    – Cephalic vein  forearm  >2,5-3 mm
    – Cephalic vein  upper arm  >4 mm
    – Basilic vein  >5 mm
    – Radial artery  >1,5 mm
    – Ulnar artery  >1,5 mm
    – Brachial artery  >3 mm
Fore arm AV-fistulas
Brescia-Cimino-fistula

Arteria side to vein end anastomosis of cephalic vein and distal radial artery
– Golden-standard
Upper arm AV-fistulae

• **Cephalic-brachial-fistula:**
  End-vein side arterial–anastomosis with cephalic vein und brachial artery
  – Good patency
  – High patients comfort

• **Basilic-brachialis-fistula:**
  End-vein-side arterial-anastomosis between basilic vein and brachial artery
  – Discomfort for patient while dialysis
  – Often need for second operation to transpose the vein

• **Gracz-fistula:**
  End-vein side arterial anastomosis with perforator vein to basilic vein and cephalic vein and either brachial, radial or ulnar artery
  – Puncture area cephalic and basilic vein
  – Less risk of inducing HAIDI
  – Best patency (Vgl. Gracz, Konner)
Cephalic-brachial-fistula:

Gracz-fistula:
Prosthetic Loop Shunt

- Forearm loop, straight prosthetic graft, axillo-axillary grafts in case of minor quality veins
  - 6mm PTFE-prosthesis usually first puncture within 14d
  - High risk of infection twice as high as native fistula
  - Patency worse compared to native arteriovenous fistula
Patency comparable to standard prosthetic grafts
Hybrid Graft

HeRO Graft Arterial Graft Component has a 6mm inner diameter (ID), 7.4mm outer diameter (OD), and is 53cm long, inclusive of the connector. It consists of an ePTFE hemodialysis graft.

HeRO Graft Venous Outflow Component has a 5mm ID, 19F (6.3mm) OD, and is 40cm long. It consists of radiopaque silicone with braided nitinol reinforcement.
Hybrid Graft

AVF to HeRO Graft anastomosis

Fistula Salvage

CryoLife
Life Restoring Technologies
Limitations of Surgical AV Fistulas

### Clinical Outcomes

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Primary failure rate</td>
<td>20-60%</td>
</tr>
<tr>
<td>Mean maturation time</td>
<td>4-9 months</td>
</tr>
<tr>
<td>Average re-interventions</td>
<td>2-3</td>
</tr>
<tr>
<td>Occlusions (thrombosis)</td>
<td>17-25%</td>
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Need for an improved method of AV fistula creation

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Penetrating trauma occasionally results in AV fistula formation.

TVA everlinQ Endovascular AVF

**Potential Advantages**

**Percutaneous AVF creation**

- Consistent hemodynamic anastomosis
- No vessel trauma, torque or tension
- No surgical anastomosis / Side-to-Side
- Enables smaller vessel AVFs
- No implant at anastomosis level
Venous catheter

Arterial catheter

Radiofrequency electrode creates fistula

6 Fr over the wire and RX system

Magnets align catheters

Flexible spacers

RF Generator
everlinQ procedure

- Ultrasound based puncture of brachial artery and brachial vein and angiography and phlebography
everlinQ procedure
everlinQ procedure

- Transarterial angiography
Advantage of percutaneous technique

- No scar
- Early dilatation of basilic and cephalic vein
Clinical Experience: FLEX Study

Study Overview

Single center, prospective design

Paraguay

33 patients, 4 cohorts

6 month follow-up

Study endpoints:

• Technical success

• Patency

• Safety

Study completed Q1 2014

Patient Demographics

| Gender male | 61% |
| Age (years) | 51.0±11.4 |
| BMI | 24.3±3.8 |
| BMI > 25 | 30.3% |
| Race | 100% |
| Hispanic | |
| Predialysis at enrollment | 6.1% |
| Previous AVF | 12.1% |
| Diabetes | 58% |

Clinical Results: FLEX Study

<table>
<thead>
<tr>
<th>Clinical Endpoint</th>
<th>FLEX Study Result</th>
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<tbody>
<tr>
<td>AVF maturation time</td>
<td>58 days</td>
</tr>
<tr>
<td>Interventions/patient-year</td>
<td>0.15**</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>4% (1/26)</td>
</tr>
<tr>
<td>Stenosis</td>
<td>0%</td>
</tr>
<tr>
<td>Access infection/patient-year</td>
<td>0%</td>
</tr>
<tr>
<td>Serious device-related adverse events</td>
<td>3% (1/33)*</td>
</tr>
</tbody>
</table>

+ 1 patient developed venous hypertension at 37 days from a central vein stenosis. Patient received balloon angioplasty. EndoAVF occluded at 106 days.
**1 patient developed pseudoaneurysm during procedure due to arm motion from neuromuscular stimulation. Pseudoaneurysm was resolved with thrombin injection. A procedure modification to limit arm motion mitigated this risk in subsequent cases.
** Interventions for Groups C & D (coil embolization performed at index procedure). 1 intervention in 14 patients, median follow-up time 177 days. Rate reported per patient-year.
Novel Endovascular Access Trial (NEAT)

- Multicenter, single arm, prospective design: CA, AU, NZ
- **80 patients with 12 months follow-up**
- Primary endpoint:
  - Fistula Usability @ 3mo
- Secondary endpoints:
  - Procedural success
  - Safety
  - Re-intervention rate
  - Primary & secondary patency
  - Others
Summary

- CVC should possibly be avoided as long term access
- Golden standard access is a arteriovenous fistula preferable in fore arm position
- Prosthetic grafts are an option for older patients with a minor vein quality
- Early canulation prosthetic grafts might reduce the quantity of CVC
- Hybrid grafts can be used for complicated end stage cases
- Endovascular techniques for creating av access expand the spectrum of AV fistula surgery
- Patients with no option for a fore arm fistula can be considered
- Endovascular AV-fistula do not prevent further surgical options
Thank you for your attention!
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