Critical Appraisal

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ORIGINAL RESEARCH • VASCULAR AND INTERVENTIONAL RADIOLOGY

Hemodialysis Arteriovenous Fistula and Graft Stenoses: Randomized Trial Comparing Drug-eluting Balloon Angioplasty with Conventional Angioplasty

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Conflicts of interest are listed at the end of this article.

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- **Title : mentioned clearly**
- **Published in relevant journal, updated publication (May 2018)**
- **Authors from relevant department (IR, Vas.Surg, Nephro, Radio)**

Objective

- Main objective - To compare lesion primary patency and restenosis rates between drug-eluting balloon (DEB) percutaneous transluminal angioplasty (PTA) and conventional balloon PTA (cPTA) in the treatment of arteriovenous fistula (AVF) and arteriovenous graft (AVG) stenosis.

- Hypothesis - 6-month lesion primary patency of arteriovenous fistulas (AVFs) and AVGs after DEB PTA would be superior to conventional balloon PTA (cPTA).

➢ Relevant but no specific objective stated

Method

Prospective randomised single centre clinical trial
January 2012 to May 2013
Participants: 119 patients (DEB PTA 59 vs cPTA 60)
Mean age: 59.2 years (Range: 25-83 years)
Sex: 79 male, 40 female

- Acceptable sample size for given study duration
- Wide age range

Method:

- Operational definitions: Clearly stated.
- Demographic data: Relevant.
- Performers: 2-20 years experience; Wide experience gap.
- Diagnostic AV fistulogram or AV graftogram in either ante- or retrograde fashion. No further explanation of each approach.

Inclusion and exclusion criteria:

- Specifically mentioned.

Inclusion criteria
Upper limb or groin malfunctioning AVF or AVG
AVF or AVG >3 months old (matured)
Native vessel 4–7 mm in diameter (corresponding to the sizes of the available DEBs)
Able to cross the lesion with a guidewire
Platelet count >50 × 10^9/L
PT/PTT <3 seconds above normal
Exclusion criteria
Thrombosed AVF or AVG
Evidence of systemic infection or local infection associated with the AVF or AVG
Age <21 years
Pregnancy
Uncorrectable coagulopathy (despite transfusion) or hypercoagulable state
Enrolled in another investigational study
Comorbid conditions limiting ability to comply with follow-up requirement
Life expectancy <6 months

Figure 1: Inclusion and exclusion criteria used in this study. *AVF* = arteriovenous fistula, *AVG* = arteriovenous graft, *DEB* = drug-eluting balloon, *PT* = prothrombin time, *PTT* = partial thromboplastin time.

Materials:

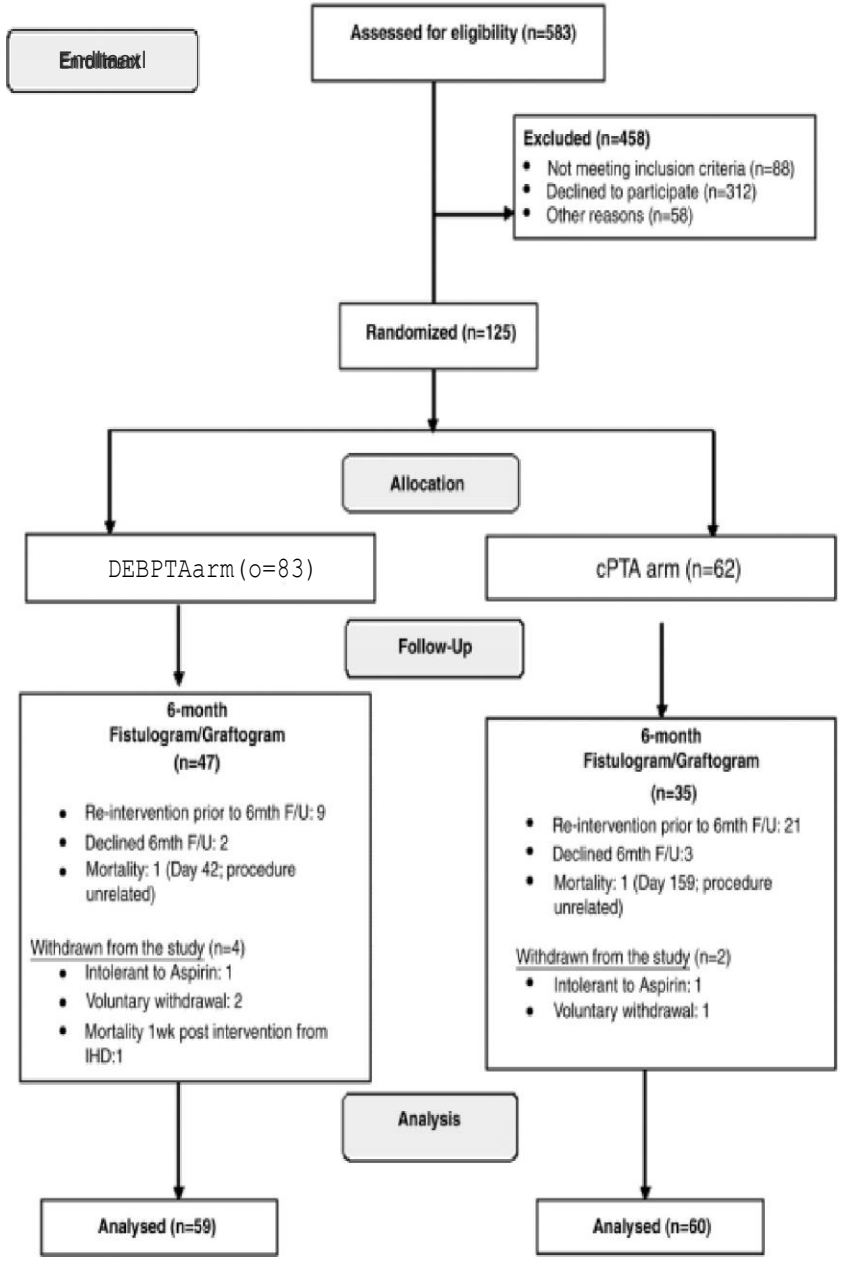
- Digital measuring software available on the angiographic machines (Artis Zeego or Artiz dMP; Siemensm, Erlangen, Germany)
- Vascular sheath (5–7 F)
- 4-F angled tip catheter (Berenstein; Cordis, Miami Lake, Fla)
- 0.035-in hydrophilic guidewire (Terumo Glidewire; Terumo Medical, Tokyo, Japan)
- 0.035-in Teflon guidewire (Starter Guidewire; Boston Scientific, Chaska, Minn)
- 1:1 randomization by research coordinators (2-5 years experience)
- Paclitaxel drug-eluting balloons (DEBs)

➢ Relevant and clearly mentioned.

Technique:

- Size and brand of balloon, burst pressure, timing, number of angioplasty was clearly stated for both cPTA and DEB PTA.
- Dose of Paclitaxel 3 micrOGRAM/MM2
- Post procedure medications: 100MG aspirin and 75mg clopidogrel daily for 1 month and then continue 100MG aspirin for 5 months until follow up 6 month angiography.
- 6 month angiography: assess target lesion for restenosis and dialysis circuit patency and stenotic lesions.
- At 1 year follow up, lesion and circuit primary patency rate.

➢ Clearly mentioned management.



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Study Factors:

- Lesion primary patency and restenosis rate at 6 months
- Lesion primary patency at 1 year
- Anatomic and clinical success after PTA
- Circuit primary patency at 6 months and 1 year

➢ Clearly mentioned and specific.

Confounding:

- age, sex, smoking history, type and site of dialysis access, age of dialysis access, number of previous PTAs, length and percentage stenosis of the target lesion, and number of lesions in the dialysis circuit.

- comorbidities of hyperlipidemia, hypertension, ischemic heart disease, and diabetes mellitus were excluded from analysis, as these conditions were treated and controlled differently in participants, hence increasing the noise and confounding the results.

Statistical Analysis:

- Kaplan-Meier product-limit estimator curves were used to compare primary patency of DEB PTA and cPTA at 6 months and 1 year.
- Cox proportional hazards regression analysis test for calculating hazard ratio for DEB PTA versus cPTA.
- Fisher exact test to compare restenosis rate and clinical success rates between DEB PTA and cPTA.
- A p-value of less than 0.05 was considered statistically significant.
- SPSS statistical software (Version 17 and 21; SPSS, Chicago,III)

➢ Clearly mentioned

Results:

- Estimated lesion primary patency in the DEB PTA and cPTA arms was 0.81 and 0.61, respectively, at ***6 months (P = .03)*** and 0.51 and 0.34, respectively, at ***1 year (P = .04).***
- Estimated circuit primary patency in the DEB PTA and cPTA arms was 0.76 and 0.56, respectively, at ***6 months (P = .048)*** and 0.45 and 0.32, respectively, at 1 year (*P* = .16).
- Restenosis rate was **34.0% (16 of 47) for DEB PTA** and **62.9% (22 of 35) for cPTA at 6 months (*P* = .01).**

➢ Answer the objective.

Limitation of the study:

- Unblinded nature of study
- Absence of independent core laboratory adjudication: measurement bias favoring DEB PTA arm.
- Treating single most severe stenosis in the dialysis circuit with DEB PTA (Asian known to have multiple lesions within dialysis circuits)
- 1 year follow up by record review only, no clinical assessment under strict protocol.

Conclusion:

- DEB PTA is able to significantly prolong 6-month and 1-year lesion primary patency, as well as 6-month circuit primary patency, in participants with AVF or AVG stenosis when compared with cPTA.

- Further prospective trials investigating the use of DEB PTA in selected groups of participant (eg, those with mature AVFs, those with multiple previous PTAs) and in treating all significant stenoses within the dialysis circuit will be required.

Overall

- Acceptable journal with some modifications:
  - Specific age group
  - Procedurists with similar experience and discipline
  - Treating multiple stenoses in selected groups
  - Long term regular follow up plan to maintain patency

- Applicable ? Costly and readily accessible

THANK YOU

Reference :

- Critical Appraisal Presentation by Prof Dr Syed Hatim Noor