Primary Balloon Angioplasty versus Hydrostatic Dilation for Arteriovenous Fistula Creation in Patients with Small-Caliber Cephalic Veins: A Systematic Review and Meta-analysis

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No conflict of interest to disclose

Abbreviations and Terms

- **Primary Patency (intervention-free access survival) :**

The interval from dialysis access placement to date of one of the following events (whichever comes first): Thrombosis or any intervention to facilitate, maintain, or re-establish patency

- **Reintervention:**

Any intervention to facilitate, maintain, or establish the patency

- **Working AVF**

AVF useful for hemodialysis access

- **Immediate success:**

The presence of a thrill and a bruit associated with intraoperative duplex ultrasound finding of peak systolic velocity **(PSV) < 200 cm/s** at the site of anastomosis

- **AVF maturation time (per day) :**

The interval period from AVF creation to the first successful hemodialysis

- SSI :surgical site infection , Primary Balloon Angioplasty :PBA, Hemodialysis/Hydrostatic Dilation :HD, AVF: Arteriovenous Fistula, United States Renal Data System (USRDS), the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) , kidney replacement therapy KRT

ARTICLE HIGHLIGHTS

- **Research type : Systematic Review and Meta-analysis**

- **Key Findings:**

-Three studies were included / 6-month follow-up
-OR for

Primary patency was significantly higher in the PBA group (PBA) > **6.09**; 95% CI, **2.36-15.76**

Working AVF was higher in the PBA group > **4.22**; 95% CI, **1.31-13.59**

- **Take-home Message:**

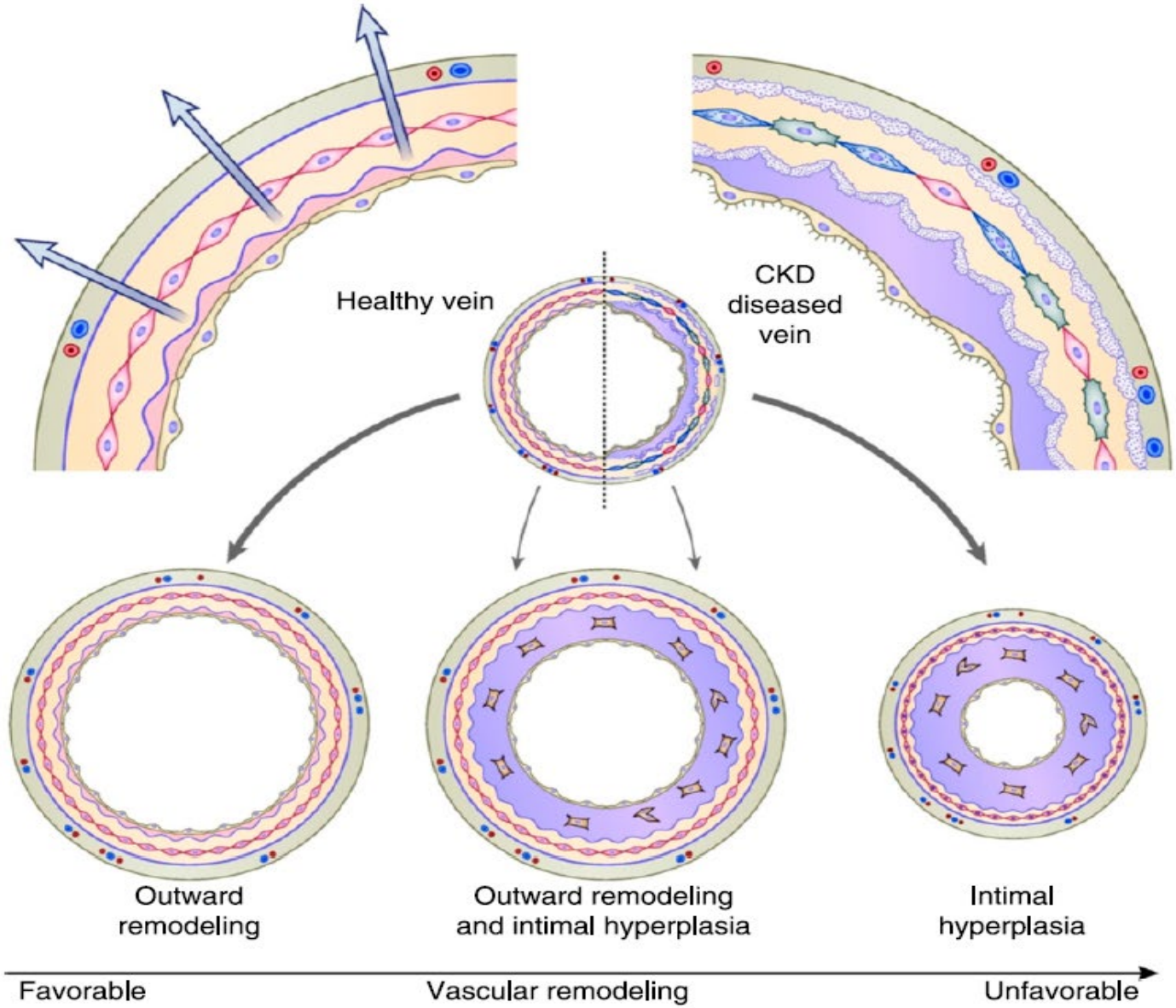
PBA of small cephalic veins (≤2.5 mm) is a safe, feasible, and efficacious augmentation method for AVF creation. This technique achieves favorable maturation outcomes, and PBA is superior to the standard hydrostatic dilatation technique.

Introduction / Objectives

- per USRDS, The adjusted prevalence of ESRD patients has increased to 2242 cases per million population and > 70% need dialysis, of which HD continues to be the most common modality of KRT
- HD quality depends on the hemodialysis vascular access efficacy
- The preferable HD access modality in terms of efficacy, morbidities, and mortalities? AVF
- So, having a efficacious AVF is in need indeed!
- AVF maturation time ? 132 days in average / NKF-KDOQI (4-6 months before HD)
- AVF maturation **failure rate**? **20-60% (1/3 in average)**

Cont..

- AVF maturation reflects a balance between inward and outward remodeling
- Typically, failure of an AVF to mature is a characteristic juxta-anastomotic stenosis from either venous constriction or venous neointimal hyperplasia (NIH)
- Hypothesized pathophysiology : endothelial and smooth-muscle injury from shear stress, turbulent flow, and/or surgery > myofibroblasts and fibroblasts activation and cytokines/mediators expression > inflammatory response / proliferation > stenosis and AVF failure
- One of the major limiting factor of fistula functional maturation is **vein diameter**


Healthy vein
CKD diseased vein
Outward remodeling
Outward remodeling and intimal hyperplasia
Intimal hyperplasia
Favorable
Vascular remodeling
Unfavorable

Cont..

- The presence of a venous segment with adequate diameter is essential to maintain the efficacy of AVF. **But** not all patients have a descent one !

Therefore → **An augmentation technique is indicated**

- Several studies comparing the efficacy of PBA vs. HD for AVF creation in end-stage renal disease (ESRD) patients with small-caliber cephalic veins (≤2.5 mm)

- This systematic review seeks to determine which technique is preferable.

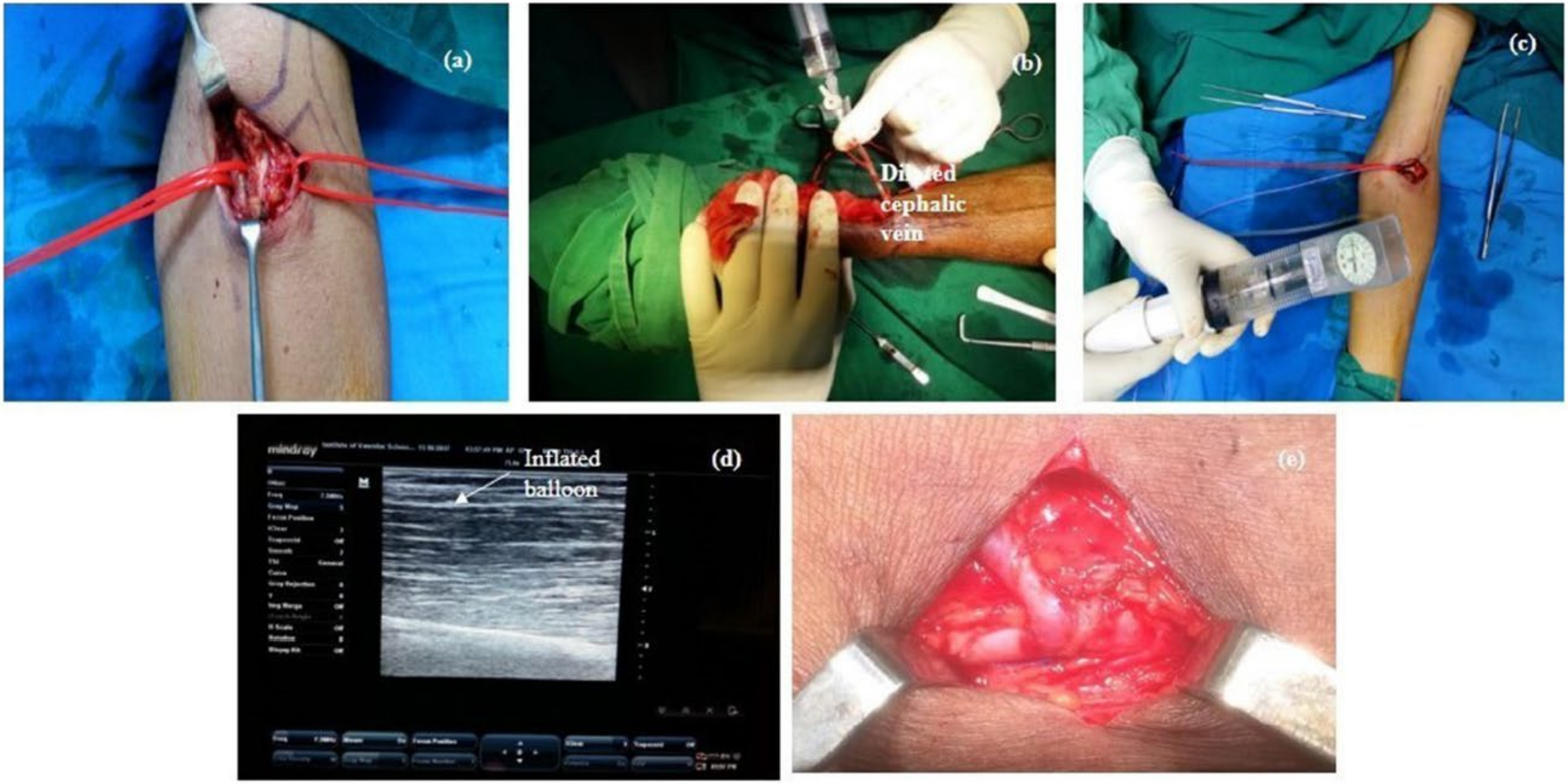


Figure 1. Arteriovenous fistula creation: hydrostatic dilatation and primary balloon angioplasty (a) exposed brachial artery and cephalic vein intraoperative photograph of hydrostatic, (b) dilatation of the vein done with 20G IV cannula inside the vein, (c) primary balloon angioplasty of cephalic vein, (d) inflated balloon seen in Doppler scan, and (e) completed arteriovenous fistula in the elbow.

Cont..

- Other techniques have been used to enhanced fistula functions:

Angioplasty, thrombectomy, stent placement, venous branch ligation, fistula superficialization, banding, interposition vein grafts, and transposition

- However, the outcomes have not met expectations, because none of those techniques addressed the **vein size** at the time of AVF creation.

Methods

➢ **Study Design :**

- Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines

- “Patient, Intervention, Comparison, Outcome (PICO)” format

- The patients :

ESRD individuals who were a candidate for AVF creation and had small-caliber cephalic vein, the intervention was primary balloon angioplasty, and the comparator was hydrostatic dilation.

Cont..

➢ Outcome

- The primary outcomes :

✓ **primary patency**

✓ **Reintervention**

✓ **working AVF**

- The secondary outcomes :

✓ **Immediate success**

✓ **AVF maturation time (per day)**

✓ **SSI**

Cont..

➢ **Eligibility Criteria**

- **Inclusion Criteria :**

Randomized controlled trials comparing PBA versus HD for AVF creation in ESRD patients with cephalic vein diameter ≤ 2.5 mm

- **Exclusion Criteria:**

Single-arm trials, non-randomized studies, case-report, non-full text articles, non-English records, and review articles

Cont..

➢ **Search Strategy (**Inception date to September 26th, 2021)

-Medline and PubMed were searched with the "arteriovenous fistula, cephalic vein, angioplasty".

-Embase was searched by ('arteriovenous fistula'/exp OR 'arteriovenous fistula') AND ('angioplasty'/exp OR 'angioplasty') AND ('cephalic vein'/exp OR 'cephalic vein')

-Google Scholar was searched with "arteriovenous fistula, cephalic vein, balloon angioplasty, hydrostatic dilatation".

-We supplemented our search by screening the texts and references of the eligible studies.

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➢ **Data Extraction**

- Two authors (SAS and ARS) independently reviewed the included articles and extracted data in two separate sheets, and then the sheets were crossed checked. In case of any disagreement, the corresponding author (MWA) would adjudicate.

➢ **Risk of Bias Assessment**

- Cochrane risk-of-bias tool (RoB2)

➢ **Certainty in Evidence**

- Certainty in evidence was evaluated using GRADE approach [23] and was demonstrated by using GRADEpro GDT Software, 2021, McMaster University, and Evidence Prime Inc, Ontario, Canada.

Cont..

➢ **Statistical Analysis (**2-sided, and a P-value <0.05)

- Baseline demographic and clinical characteristics > were presented using descriptive statistics
- The meta-analyses of outcomes > the Review Manager, version 5.4.1
- The odds ratio (OR) of dichotomous data and the mean difference (MD) of continuous data with associated 95% confidence interval (CI) were calculated by the Mantel-Haenszel method and the generic inverse-variance method, respectively
- The random effect model was applied (Considering the clinical diversities and methodological differences)
- The heterogeneities between studies were detected using the I^2 test statistic

Results

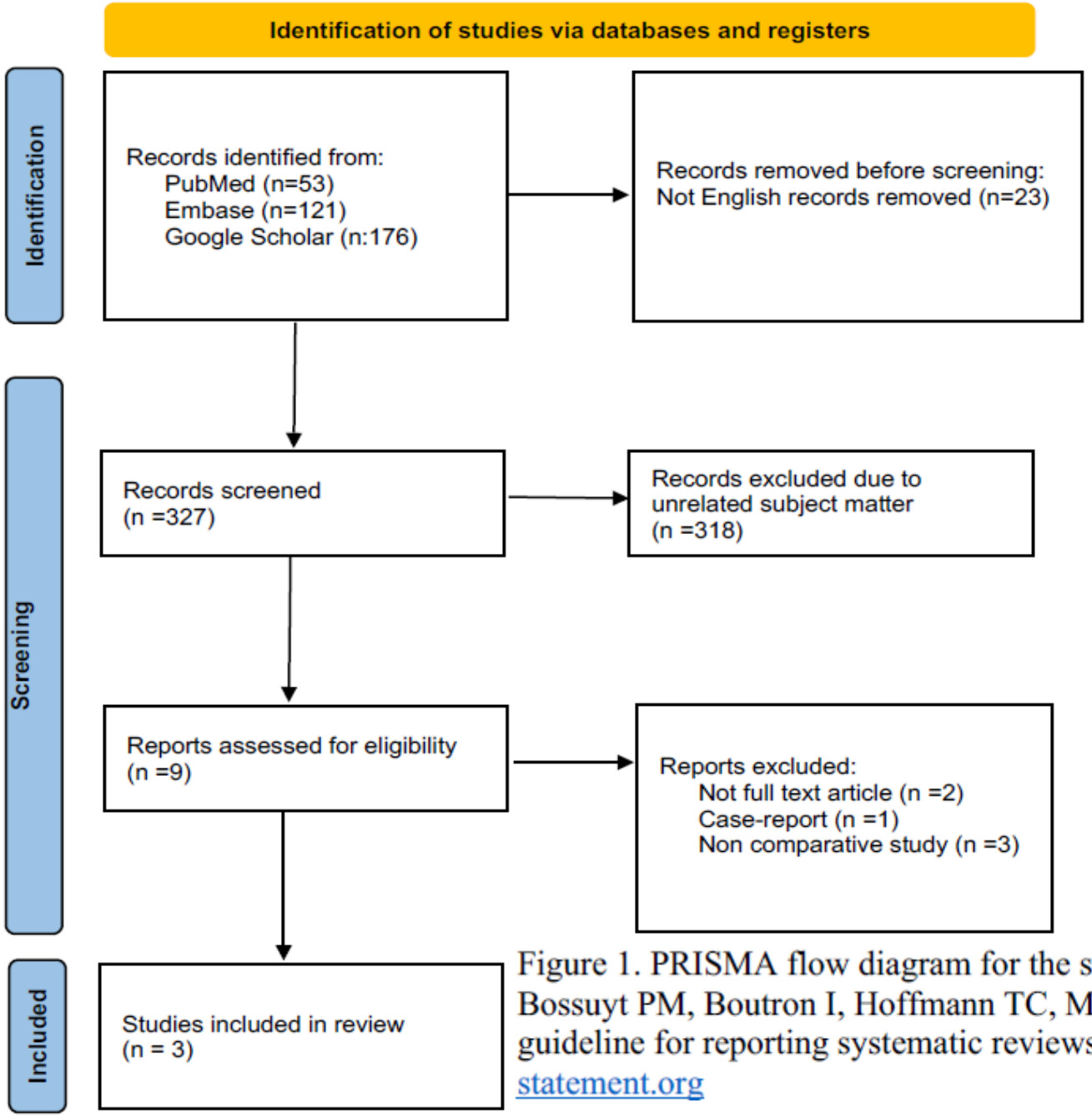


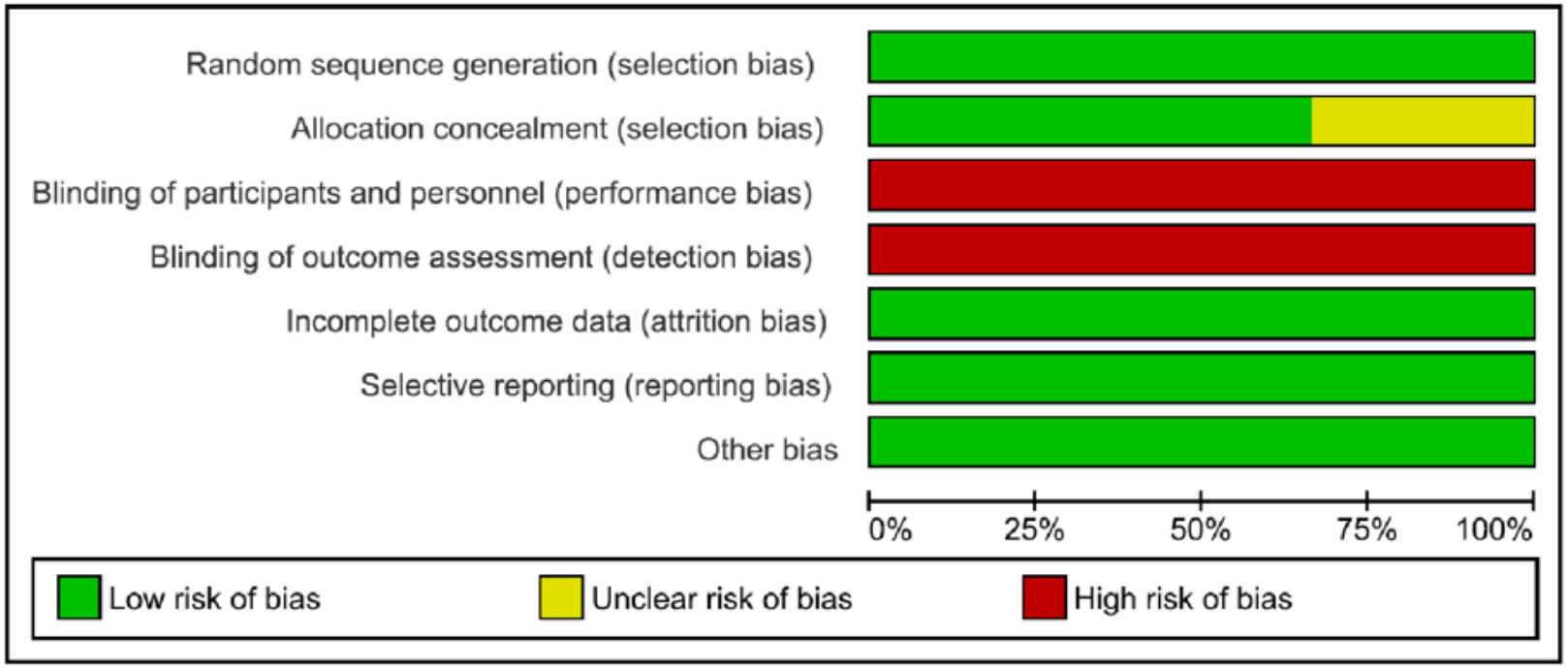
Figure 1. PRISMA flow diagram for the study search and inclusion. Source: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. http://www.prisma-statement.org

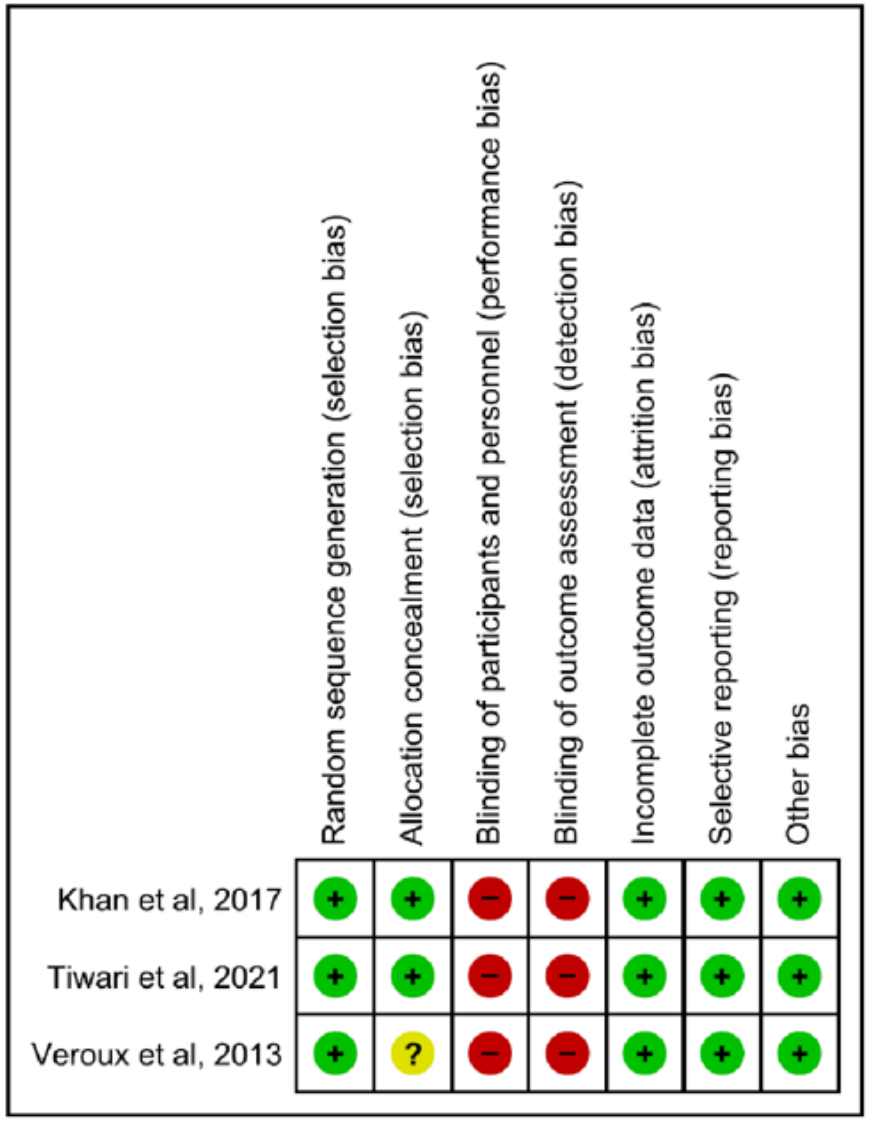
Table 1. Studies' design and patients' demographic and clinical characteristics

Study and Year	Design	Country	Total No. of Patients and Treatment Groups	Mean (SD) or Range of Age (year)	Male Sex N (%)	DM N (%)	HTN N (%)	Smoker N (%)	PAD N (%)	Dialysis N (%)
Veroux et al, 2013	RCT	Italy	Total 40 PBA 19 HD 21	54.5 55 (18) 54 (8)	19 (47.5) 13 (68) 16 (76)	10 (25) 6 (32) 4 (19)	40 (100) 19 (100) 21 (100)	22 (55) 11 (58) 11 (52)	14 (35) 8 (42) 6 (29)	17 (42) 13 (68) 4 (19)
Khan et al, 2017		India	Total 60 PBA 30 HD 30	51-60	44 (73) 21 (70) 23 (76)	19 (32)	37 (62)	NR	NR	48 (80)
Tiwari et al, 2021		India	Total 80 PBA 40 HD 40	40-70	59 (73) 28 (70) 31 (77)	48 (60) 23 (57) 25 (62)	62 (77) 29 (72) 33 (82)	38 (47) 20 (50) 18 (45)	29 (36) 16 (40) 13 (32)	61 (76) 31 (77) 30 (75)

Abbreviations: RCT, Randomized Controlled Trial; No, Number; PBA, Primary Balloon Angioplasty; HD, Hydrostatic Dilation; DM, Diabetes Mellitus; HTN, Hypertension; PAD, Peripheral Arterial Disease.

Risk-of-Bias Assessment





PICO

Study and Year	Sample Size	PICO				Follow-up
		Patients	Intervention: PBA	Comparison: HD	Outcomes	
Veroux et al, 2013	T 40 I 19 C 21	ESRD patients with normal radial artery on DUS and cephalic vein's diameter ≤ 2 mm. All patients received acetyl salicylic acid per day from 1 week before to 4 weeks after the procedure. All patients received a systemic anticoagulation using 2500 IU of heparin 3 minutes before clamping the cephalic vein and the radial artery.	After isolation of 3 to 4 centimeters of cephalic vein, a guidewire 0.018 inches was introduced through the cephalic vein and advanced up to the elbow under direct palpation, or DUS in cases of deep cephalic vein. A noncompliant balloon, 4 mm×150 mm was introduced and gently inflated to 12 atmospheres of pressure for a period of 60 seconds, from the elbow to the level of the anastomosis, to achieve the final diameter of 4 mm. The anastomosis was performed end-to-side with 7/0 polypropylene running sutures.	After isolation of about 5 cm of cephalic vein at the wrist with ligation of collateral veins, the vein was dilated by injection of high-pressure sterile solution through a syringe 20 mL and 16-gauge plastic cannula to achieve the final diameter of 4 mm. The anastomosis was performed end-to-side with the radial artery, with 7/0 polypropylene running sutures.	Primary: primary patency, reinterventions, and functioning AVF. Secondary: immediate success rate and maturation time. Tertiary: None.	7 months

Khan et al, 2017	T 60 I 30 C 30	ESRD patients with normal radial or brachial arteries on DUS and cephalic vein's diameter ≤ 2 mm. All patients received acetyl salicylic acid per day for 4 weeks after the procedure. All patients received a systemic anticoagulation using 2500 IU of heparin 3 minutes before clamping the cephalic vein and the radial artery.	Same as the above technique was applied at writs (Radiocephalic AVF) and elbow (Brachiocephalic AVF) and a noncompliant balloon, 4mm × 120 was used.	Same as the above technique was applied at writs (Radiocephalic AVF) and elbow (Brachiocephalic AVF) and 18- or 20-gauge plastic cannula was used.	Primary: primary patency, reinterventions, and functioning AVF. Secondary: immediate success rate and maturation time. Tertiary: None.	6 months

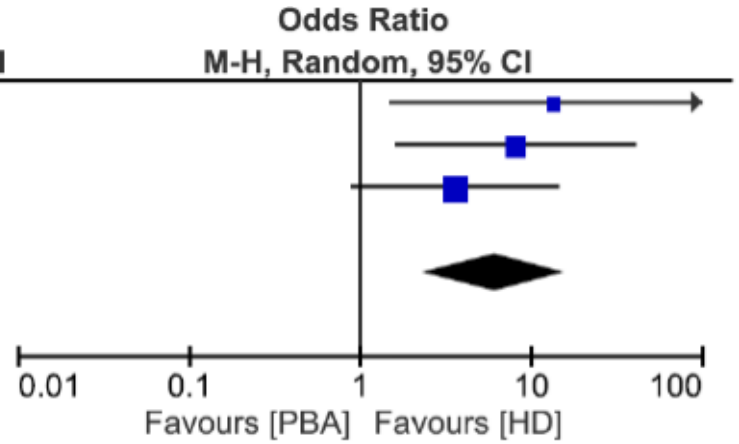
Tiwari et al, 2021	T 80 I 40 C 40	ESRD patient with normal radial artery on DUS and cephalic vein's diameter ≤ 2.5 mm. All patients received acetyl salicylic acid per day for 6 months after the procedure.	Same as the above technique was applied at elbow and a noncompliant balloon, 4 × 150 mm was used and finally the anastomosis was performed end-to-side with 6–0 polypropylene running suture.	After isolation of about 5 cm of cephalic vein at the elbow, the vein was dilated with a 20-ml sterile heparinized saline solution injection. Then, segmental HD was done at 5, 10, 15 cm and the anastomosis was performed end-to-side, with 6–0 polypropylene suture.	Primary: primary patency, reinterventions, and functioning AVF. Secondary: immediate success rate and maturation time. Tertiary: Surgical site infection.	6 months

Abbreviations: PBA, Primary Balloon Angioplasty; HD, Hydrostatic Dilation; T, Total; I, Intervention; C, comparison; ESRD, End Stage Renal Disease; DUS, Duplex Ultra Sonography.

A) Primary Patency

Study or Subgroup	PBA Events	PBA Total	HD Events	HD Total	Weight	Odds Ratio M-H, Random, 95% CI
Veroux et al, 2013	18	19	12	21	18.8%	13.50 [1.51, 120.78]
Khan et al, 2017	28	30	19	30	34.6%	8.11 [1.61, 40.77]
Tiwari et al, 2021	37	40	31	40	46.6%	3.58 [0.89, 14.39]
Total (95% CI)		**89**		**91**	**100.0%**	**6.09 [2.36, 15.76]**
Total events	83		62			

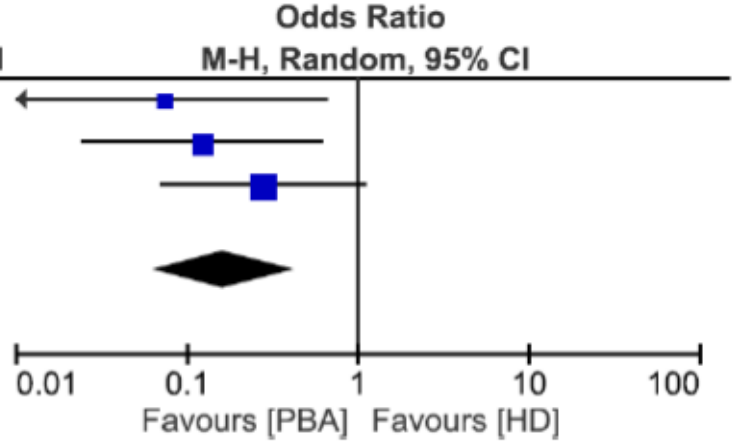
Heterogeneity: Tau² = 0.00; Chi² = 1.20, df = 2 (P = 0.55); I² = 0%
Test for overall effect: Z = 3.73 (P = 0.0002)



B) Reintervention

Study or Subgroup	PBA Events	PBA Total	HD Events	HD Total	Weight	Odds Ratio M-H, Random, 95% CI
Veroux et al, 2013	1	19	9	21	18.8%	0.07 [0.01, 0.66]
Khan et al, 2017	2	30	11	30	34.6%	0.12 [0.02, 0.62]
Tiwari et al, 2021	3	40	9	40	46.6%	0.28 [0.07, 1.12]
Total (95% CI)		**89**		**91**	**100.0%**	**0.16 [0.06, 0.42]**
Total events	6		29			

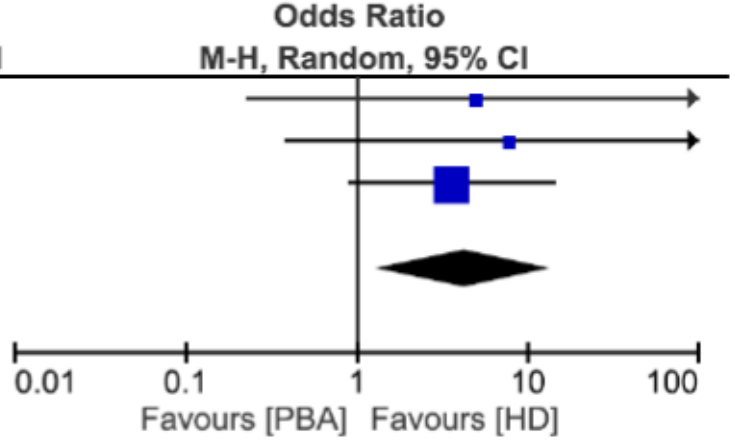
Heterogeneity: Tau² = 0.00; Chi² = 1.20, df = 2 (P = 0.55); I² = 0%
Test for overall effect: Z = 3.73 (P = 0.0002)



C) Working AVF

Study or Subgroup	PBA Events	PBA Total	HD Events	HD Total	Weight	Odds Ratio M-H, Random, 95% CI
Veroux et al, 2013	19	19	19	21	14.2%	5.00 [0.23, 111.05]
Khan et al, 2017	30	30	27	30	15.1%	7.76 [0.38, 157.14]
Tiwari et al, 2021	37	40	31	40	70.7%	3.58 [0.89, 14.39]
Total (95% CI)		**89**		**91**	**100.0%**	**4.22 [1.31, 13.59]**
Total events	86		77			

Heterogeneity: Tau² = 0.00; Chi² = 0.23, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.41 (P = 0.02)

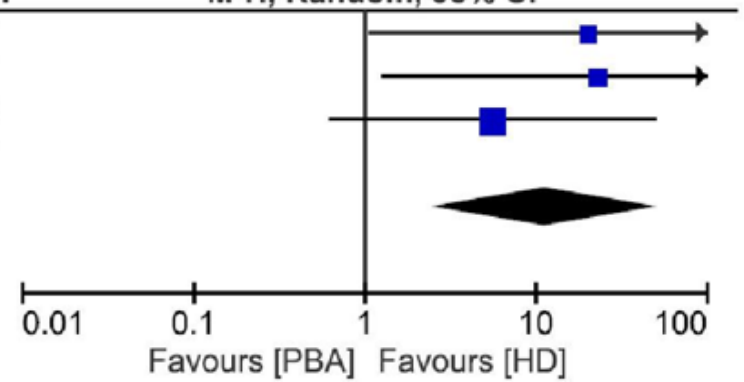


D) Immediate Success

Study or Subgroup	PBA Events	PBA Total	HD Events	HD Total	Weight	Odds Ratio M-H, Random, 95% CI
Veroux et al, 2013	19	19	14	21	26.2%	20.17 [1.06, 382.45]
Khan et al, 2017	30	30	22	30	26.9%	23.04 [1.26, 420.37]
Tiwari et al, 2021	39	40	35	40	47.0%	5.57 [0.62, 50.03]
Total (95% CI)		**89**		**91**	**100.0%**	**11.42 [2.54, 51.42]**
Total events	88		71			

Heterogeneity: Tau² = 0.00; Chi² = 0.80, df = 2 (P = 0.67); I² = 0%

Test for overall effect: Z = 3.17 (P = 0.002)

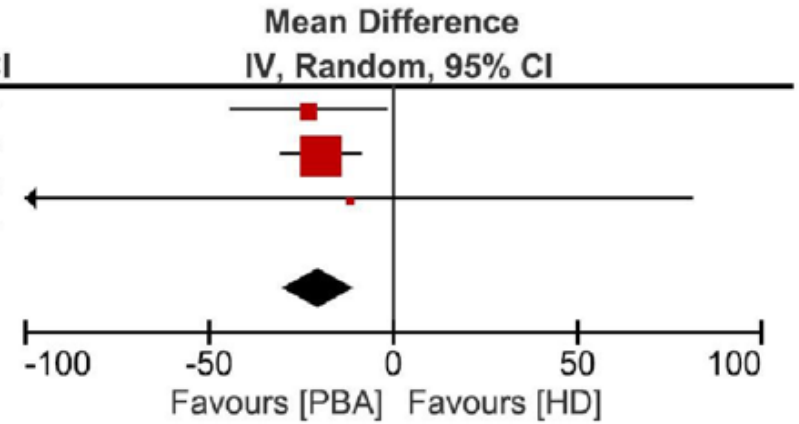


E) AVF Maturation Time

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Veroux et al, 2013	-23	10.81	21.4%	-23.00 [-44.19, -1.81]
Khan et al, 2017	-19.7	5.68	77.5%	-19.70 [-30.83, -8.57]
Tiwari et al, 2021	-11.77	47.44	1.1%	-11.77 [-104.75, 81.21]
Total (95% CI)			**100.0%**	**-20.32 [-30.12, -10.52]**

Heterogeneity: Tau² = 0.00; Chi² = 0.11, df = 2 (P = 0.95); I² = 0%

Test for overall effect: Z = 4.06 (P < 0.0001)



Study or Subgroup	PBA Events	PBA Total	HD Events	HD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Tiwari et al, 2021	2	40	4	40	100.0%	0.47 [0.08, 2.75]
Total (95% CI)		**40**		**40**	**100.0%**	**0.47 [0.08, 2.75]**
Total events	2		4			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.83 (P = 0.40)

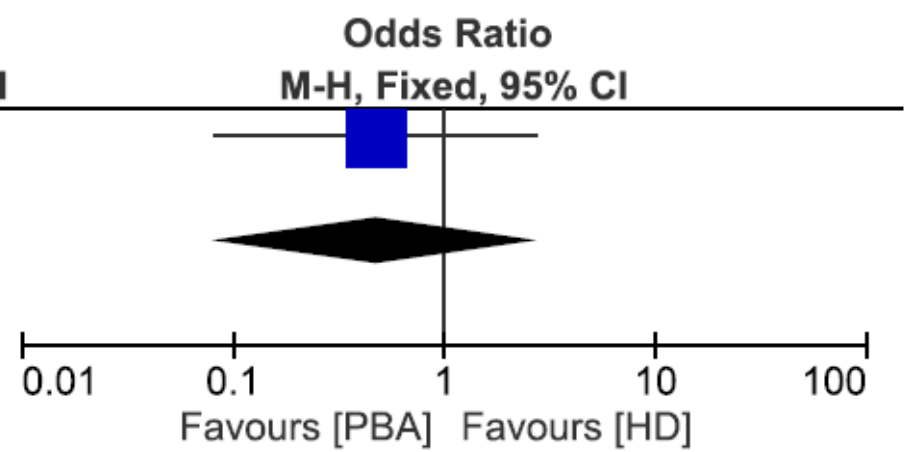


Fig. 5 Forest plot comparing the Odds of surgical site infection between primary balloon angioplasty (PBA) and hydrostatic dilation (HD) groups.

Primary Balloon Angioplasty compared to Hydrostatic Dilation for AVF Creation in ESRD Patients with Small-Caliber Cephalic Vein

Patient or population: AVF Creation in ESRD Patients with Small-Caliber Cephalic Vein

Setting: Hospitals in Italy and India

Intervention: Primary Balloon Angioplasty

Comparison: Hydrostatic Dilation

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Hydrostatic Dilation	**Risk with Primary Balloon Angioplasty**				
Primary Patency	681 per 1,000	**929 per 1,000** (835 to 971)	**OR 6.09** (2.36 to 15.76)	180 (3 RCTs)	⨁⨁⨁⨁ High[a]	A higher score indicates the greater chance of primary patency at the 6 months follow-up.
Reintervention	319 per 1,000	**70 per 1,000** (27 to 164)	**OR 0.16** (0.06 to 0.42)	180 (3 RCTs)	⨁⨁⨁⨁ High[a]	A lower score indicates the lower risk of intervention at the 6-months follow-up.
Working AVF	846 per 1,000	**959 per 1,000** (878 to 987)	**OR 4.22** (1.31 to 13.59)	180 (3 RCTs)	⨁⨁⨁⨁ High[a]	A higher score indicates the greater chance of working AVF at the 6 months follow-up
Immediate Success	780 per 1,000	**976 per 1,000** (900 to 995)	**OR 11.42** (2.54 to 51.42)	180 (3 RCTs)	⨁⨁⨁⨁ High[a]	A higher score indicates the greater chance of intraoperative immediate success.
AVF Maturation Time	The mean AVF Maturation Time was **51.16** days	MD **20.32 days lower** (30.12 lower to 10.52 lower)	-	180 (3 RCTs)	⨁⨁⨁⨁ High[a]	A lower score indicates the shorter AVF maturation time following primary balloon angioplasty versus hydrostatic dilation.
Surgical Site Infection	100 per 1,000	**50 per 1,000** (9 to 234)	**OR 0.47** (0.08 to 2.75)	80 (1 RCT)	⨁⨁◯◯ Low[a,b]	A lower score indicates a lesser risk of surgical site infection.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

Discussion /Critical Appraisal

- PBA augmented AVFs had greater primary patency, required few reinterventions, and remained more functional

- The AVFs' primary patency rate has been reported at 60% at one year, with the vein diameter being the major determining factor of the patency

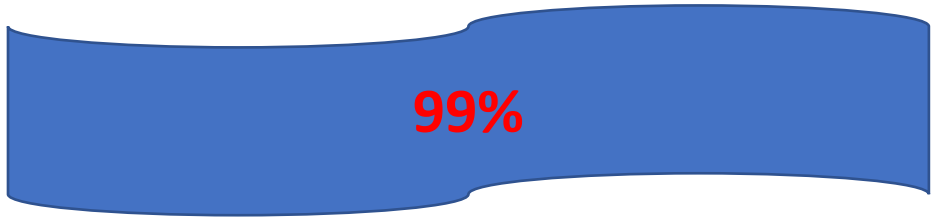
- In the subcategory of patients, the meta-analysis revealed PBA augmented AVFs attained 93% primary patency

- Following AVF creation, the anastomosis and venous segment are being exposed to hemodynamic changes and undergo adaptive outward remodeling and vessel wall thickening > **venous diameter expansion** is a critical element predicting clinical success

- PBA can exert sufficient force against the venous wall, while the hydrostatic dilation employs less effective radial force; therefore, **those of HD were more susceptible to failure**.

- **Short segment** of the cephalic vein (i.e., from mid-forearm to wrist) VS. **longer segment** of the cephalic vein (i.e., from wrist to elbow), Does it matter ?

- Intraoperative technical success rate?



- **Mean fistula maturation time** following PBA VS. standard HD ?

Limitation

- **Three eligible** studies were found and enrolled in the meta-analysis. However!

- Surgical site infection/ Sample size

- Existing literature reported the **medium**-term outcomes

Conclusion

- PBA is a safe, feasible, and efficacious augmentation technique for autogenous AVF creation in patients with small-caliber cephalic veins, and it is preferable to the standard HD method.

- We recommend the PBA augmentation technique for this category of patients

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Thank you for your attention
Questions ?