

# Primary Balloon Angioplasty Fistula Arteriovenosa pada Penyakit Ginjal Tahap Akhir: Kajian Maturitas Fistula, Hiperplasia Intima, Nitrit Oksida, Vascular Endothelial Growth Factor, dan Endothelial Microparticle = Primary Balloon Angioplasty in Arteriovenous Fistula in End Stage Renal Diseases: Study on Fistula Maturation, Intimal Hyperplasia, Nitrite Oxide, Vascular Endothelial Growth Factor, and Endothelial Microparticle

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## Abstrak

Untuk hemodialisis pasien Penyakit Ginjal Tahap Akhir (PGTA) akses vaskular terpilih adalah pembuatan fistula arteriovenosa (FAV) native, namun FAV memiliki angka kegagalan maturitas yang relatif tinggi. Primary balloon angioplasty (PBA) merupakan salah satu teknik dilatasi untuk membantu maturitas FAV. Teknik konstruksi FAV yang traumatis dan peregangan diameter lumen vena dengan balon dapat menyebabkan cedera fokal pada endotelium vena dan memberikan respons hiperplasia intima serta memengaruhi kadar NO, VEGF dan EMP yang dapat berdampak negatif pada maturitas FAV. Penelitian ini bertujuan untuk mengetahui efek PBA terhadap hiperplasia intima, kadar NO, VEGF, EMP serta maturitas FAV pada pasien dengan PGTA.

Desain penelitian adalah uji klinis tersamar acak tunggal di RSUPN Cipto Mangunkusumo, RSUPN Fatmawati, RSUD Kabupaten Tangerang, dan RS Hermina Depok pada bulan Desember 2019 sampai Februari 2022; dengan subjek penelitian 112 pasien. Setelah randomisasi sampel terstratifikasi, 48 pasien menjalani konstruksi FAV dengan PBA (intervensi) dan 64 pasien menjalani konstruksi FAV tanpa PBA (kontrol). Pengukuran meliputi intimal medial thickness (IMT) jukstaanastomosis, VF dan PSV draining vein 1, 2 dan 6 minggu pascaoperasi; kadar NO, kadar VEGF, kadar EMP pascaoperasi dan 2 minggu pascaoperasi serta maturitas FAV yang dievaluasi 6 minggu pascaoperasi. Terkait pandemi COVID-19, 32 pasien lost to follow-up dan 5 pasien kontrol dieksklusi karena trombus pada FAV sehingga subjek yang dianalisis 36 pasien intervensi dan 39 pasien kontrol.

Terdapat perbedaan bermakna antara grup kontrol dan intervensi pada maturitas, VF dan PSV draining vein 6 minggu pascaoperasi; kadar EMP 2 minggu pascaoperasi pada pasien PGTA yang menjalani operasi konstruksi FAV (Uji Mann Whitney U,  $p < 0,05$ ). Tidak didapatkan perbedaan bermakna IMT jukstaanastomosis serta kadar NO dan VEGF antara kelompok kontrol dan intervensi (Uji Mann Whitney U,  $p > 0,05$ ).

Simpulan: PBA meningkatkan maturitas FAV pada pasien PGTA yang menjalani operasi konstruksi FAV yang ditandai dengan peningkatan VF dan PSV draining vein hingga 6 minggu pascaoperasi tanpa memengaruhi ketebalan intima pada daerah jukstaanastomosis, kadar NO dan kadar VEGF. Terdapat peningkatan kadar EMP 2 minggu pascaoperasi pada FAV dengan PBA.

.....The preferred vascular access for hemodialysis for patients with end-stage renal disease (ESRD) is through the creation of a native arteriovenous fistula (AVF). The weakness of AVF is the relatively high maturation failure rate. Primary balloon angioplasty (PBA) is a dilation technique to assist AVF maturation. Traumatic AVF construction technique and diameter stretching of the vein lumen with balloons can cause

focal injury to the venous endothelium which will eventually affect intimal hyperplasia and NO, VEGF and EMP levels which can negatively impact AVF maturation. This study aimed to determine the effect of PBA on intimal hyperplasia, levels of NO, VEGF, EMP and AVF maturation in patients with ESRD who underwent AVF construction surgery.

This study used a single-blind randomized clinical trial design at RSUPN Cipto Mangunkusumo, RSUPN Fatmawati, RSUD Kabupaten Tangerang, dan RS Hermina Depok in December 2019 until February 2022 with 112 subjects. With stratified sample randomization method, 48 patients underwent AVF construction with PBA (intervention), 64 patients underwent AVF construction without PBA (control). Measurements included jukstaanastomosis intimal medial thickness (IMT), VF and peak systolic value (PSV) draining veins 1, 2 and 6 weeks postoperatively; NO, VEGF, EMP levels postoperative and 2 weeks postoperative; and AVF maturation evaluated 6 weeks postoperatively. Regarding the COVID-19 pandemic, 32 patients lost to follow-up and 5 control patients were excluded because of thrombus in the AVF so that analysis was carried out on 75 subjects (36 intervention patients and 39 control patients).

There were significant differences between control and intervention groups in maturity, VF and PSV draining vein 6 weeks postoperatively; EMP levels 2 weeks postoperatively in ESRD patients undergoing AVF construction (Mann Whitney U,  $p < 0.05$ ). There were no significant differences in jukstaanastomosis IMT; NO and VEGF levels between control and intervention groups (Mann Whitney U,  $p > 0.05$ ).

Conclusion: PBA increases the maturity of the arteriovenous fistula in ESRD patients undergoing AVF construction surgery which is characterized by an increase in VF and PSV draining veins up to 6 weeks postoperatively without affecting the IMT in jukstaanastomosis area, NO and VEGF levels. There was an increase in EMP levels 2 weeks postoperatively in AVF with PBA.