



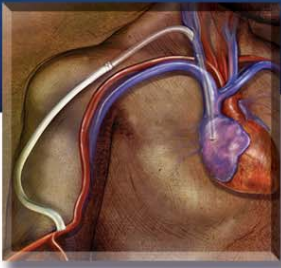
HeRO™ VASCULAR ACCESS DEVICE CLINICAL OUTCOMES BY ACCESS TYPE

AV FISTULAS

DATA POINT	REFERENCE
Bacteremia rate	Hajjar, J., Girard, R., Marc, J-M., Ducruet, L., Beruard, M., Fadel, B., et al. Surveillance des Infections Chez les Hemodialysis Chroniques en Centre. <i>Nephrologie</i> 2004;25:133-40.
Adequacy of dialysis (1.57)	2007 ESRD CPM Report. Adequacy of Hemodialysis Table 7.
Blood flow rate -normalized data within articles when blood flow rate by fistula type was reported (rather than overall mean), then normalized across articles.	Back RM, Maynard M, Winker A, Bandyk DF. Expected flow parameter within hemodialysis access and selection for remedial intervention of nonmaturing conduits. <i>Vascular and Endovascular Surgery</i> 2008;42(2):150-8. Pietura R, Janczarek M, Zaluska W, Szymanska A, Janicka L, Skublewska-Bednarek A, Szczerbo-Trojanowska M. Colour doppler ultrasound assessment of well-functioning mature arteriovenous fistulas for haemodialysis access. <i>Eur J Radiol</i> 2005;55(1):113-9.
Intervention rate (1.3-1.7)	Biuckians A, Scott EC, Meier GH, Panneton JM, Glickman MH. The natural history of autologous fistulas as first-time dialysis access in the KDOQI era. <i>J Vasc Surg</i> 2008;47(2):415-21. Keuter XH, De Smet AA, Kessels AG, van der Sande FM, Welten RJ, Tordoir JH. A randomized multicenter study of the outcome of brachial-basilic arteriovenous fistula and prosthetic brachial-antecubital forearm loop as vascular access for hemodialysis. <i>J Vasc Surg</i> 2008;47(2):395-401
Primary and secondary patency rates at 12 months (60 and 81%)	Huber TS, Carter JW, Carter RL, Seeger JM. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: a systematic review. <i>J Vasc Surg</i> 2003;38:1005-11. (extrapolated from figure)

CLINICAL CITATIONS

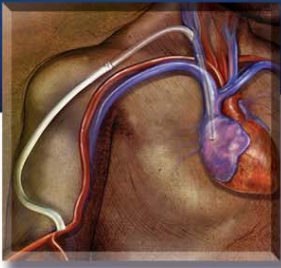




HeRO™ VASCULAR ACCESS DEVICE CLINICAL OUTCOMES BY ACCESS TYPE

AV GRAFTS	
DATA POINT	REFERENCE
Bacteremia rate (0.11/1,000 days)	Hajjar, J., Girard, R., Marc, J-M., Ducruet, L., Beruard, M., Fadel, B., et al. Surveillance des Infections Chez les Hemodialysis Chroniques en Centre. <i>Nephrologie</i> 2004;25:133-140.
Adequacy of dialysis (1.37-1.62)	Centers for Medicare & Medicaid Services. 2007 Annual Report, end stage renal disease clinical performance measures project. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards & Quality, Baltimore, Maryland, December 2007. Sehgal AR, Snow RJ, Singer ME, Amini SB, DeOreo PB, Silver MR, et al. Barriers to adequate delivery of hemodialysis. <i>Am J Kidney Dis</i> 1998;31(4):593-601. Tonelli M, Muirhead N. Access type as a predictor of dialysis adequacy in chronic hemodialysis patients. <i>ASAIO J</i> 2000;46:279-82. 2001 Annual Report: ESRD clinical performance measures project. <i>Am J Kidney Dis</i> 2002 May;39(5Suppl1):S4-98. Centers for Medicare and Medicaid Services, Kinney R. 2005 Annual Report, end stage renal disease clinical performance measures project. <i>Am J Kidney Dis</i> 2006 Oct;48(4Suppl2):S1-106.
Blood flow rate (1,169 ml/min)	Rittgers SE, Garcia-Valdez C, McCormick JT, Posner MP. Noninvasive blood flow measurement in expanded polytetraethylene grafts for hemodialysis access. <i>J Vasc Surg</i> 1986; 3(4):635-42.
Intervention rate (1.6–2.4/year)	Katzman HE, Glickman MH, Schild AF, Fujitani RM, Lawson JH. Multicenter Evaluation of the Bovine Mesenteric Vein Bioprotheses for Hemodialysis Access in Patients with an Earlier Failed Prosthetic Graft. <i>Journal of the American College of Surgeons</i> . 2005;201:223-230. Madden RL, Lipkowitz GS, Browne, BJ, Kurbanov A. A Comparison of Cryopreserved Vein Allografts and Prosthetic Grafts for Hemodialysis Access. <i>Ann Vasc Surg</i> 2005;19:686-691. Hurlbert SN, Mattos MA, Henretta JP, Ramsey DE, Barkmeier LD, Hodgson KJ, Sumner DS. Long-term patency rates, complications and cost-effectiveness of polytetrafluoroethylene (PTFE) grafts for hemodialysis access: a prospective study that compares Impra versus Gore-tex grafts. <i>Cardiovasc Surg</i> 1998 Dec; 6(6):652-6. Bosman PJ, Blankestijn PJ, van der Graaf, Heintjes RJ, Koomans HA and Eikeboom BC. A Comparison Between PTFE and Denatured Homologous Vein Grafts for Haemodialysis Access: a Prospective Randomized Multicentre Trial. <i>Eur J Vasc Endovasc Surg</i> 1998 Aug;16:126-132.
Primary and secondary patency rates at 12 months (42 and 65%)	Huber TS, Carter JW, Carter RL, Seeger JM. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: a systematic review. <i>J Vasc Surg</i> 2003;38:1005-11. (extrapolated from figure)

CLINICAL CITATIONS



HeRO™ VASCULAR ACCESS DEVICE CLINICAL OUTCOMES BY ACCESS TYPE

LONG-TERM CATHETER REFERENCES

DATA POINT	REFERENCE
<p>Bacteremia rate (2.3/1,000 days) from Mathew Oliver MD meta analysis: an internal meta-analysis was performed from previous publications. This meta-analysis of internal jugular TDC-related bacteremia rates was based on data published in 15 articles that met the following criteria: prospective studies, including prospective cohort and randomized controlled trials of tunneled, cuffed catheters with at least 20 patients. Studies of the Lifesite® hemodialysis access system and Dialock® hemodialysis access system were excluded. The final normalized cumulative TDC bacteremia control rate was 2.3/1,000 catheter days.</p>	Dunn J, Nylander W, Richie R. Central venous dialysis access: experience with a dual-lumen, silicone rubber catheter. <i>Surgery</i> 1987 Nov;102(5):784-9.
	Schwab SJ, Buller GL, McCann RL, Bollinger RR, Stickel DL. Prospective evaluation of a Dacron cuffed hemodialysis catheter for prolonged use. <i>Am J Kidney Dis</i> 1988;11(2):166-9.
	De Meester J, Vanholder R, De Roose J, Ringoir S. Factors and complications affecting catheter and technique survival with permanent single-lumen dialysis catheters. <i>Nephrol Dial Transplant</i> 1994; 9:678-83.
	Marr KA, Sexton DJ, Conlon PJ, Corey GR, Schwab SJ, Kirkland KB. Catheter-related bacteremia and outcome of attempted catheter salvage in patients undergoing hemodialysis. <i>Ann Intern Med</i> 1997;127(4):275-80.
	Trerotola SO, Johnson MS, Shah H, Kraus MA, McKusky MA, Ambrosius WT et al. Tunneled hemodialysis catheters: use of a silver-coated catheter for prevention of infection--a randomized study. <i>Radiology</i> 1998;207(2):491-6.
	Beathard GA. Management of bacteremia associated with tunneled cuffed hemodialysis catheters. <i>J Am Soc Nephrol</i> 1999;10:1045-9.
	Saad TF. Bacteremia associated with tunneled, cuffed hemodialysis catheters. <i>Am J Kidney Dis</i> 1999;34(6):1114-24.
	Perini S, LaBerge JM, Pearl JM, Santiestiban HL, Ives HE, Omachi RS et al. Tesio catheter: radiologically guided placement, mechanical performance, and adequacy of delivered dialysis. <i>Radiology</i> 2000;215(1):129-37.
	Richard HM, III, Hastings GS, Boyd-Kranis RL, Murthy R, Radack DM, Santilli JG et al. A randomized, prospective evaluation of the Tesio, Ash split, and Opti-flow hemodialysis catheters. <i>J Vasc Interv Radiol</i> 2001;12(4):431-5.
	Rocklin MA, Dwight CA, Callen LJ, Bispham BZ, Spiegel DM. Comparison of cuffed tunneled hemodialysis catheter survival. <i>Am J Kidney Dis</i> 2001;37(3):557-63.
	Ewing F, Patel D, Petherick A, Winney R, McBride K. Radiological placement of the AshSplit haemodialysis catheter: a prospective analysis of outcome and complications. <i>Nephrol Dial Transplant</i> 2002;17:614-9.
	Trerotola SO, Kraus M, Shah H, Namyslowski J, Johnson MS, Stecker MS et al. Randomized comparison of split tip versus step tip high-flow hemodialysis catheters. <i>Kidney Int</i> 2002;62:282-9.
	Cetinkaya R, Odabas AR, Unlu Y, Selcuk Y, Ates A, Ceviz M. Using cuffed and tunneled central venous catheters as permanent vascular access for hemodialysis: a prospective study. <i>Ren Fail</i> 2003;25(3):431-8.
	Lok CE, Stanley KE, Hux JE, Richardson R, Tobe SW, Conly J. Hemodialysis infection prevention with polysporin ointment. <i>J Am Soc Nephrol</i> 2003;13:169-79.
	O'Dwyer H, Fotheringham T, O'Kelly P, Doyle S, Haslam P, McGrath F et al. A prospective comparison of two types of tunneled hemodialysis catheters: the Ash Split versus the PermCath. <i>Cardiovasc Intervent Radiol</i> 2005;28:23-9.

CLINICAL CITATIONS



HeRO™ VASCULAR ACCESS DEVICE CLINICAL OUTCOMES BY ACCESS TYPE

LONG-TERM CATHETER REFERENCES (CONTINUED)

DATA POINT	REFERENCE
Adequacy of dialysis (1.29 – 1.46)	<p>Centers for Medicare & Medicaid Services. 2007 Annual Report, end stage renal disease clinical performance measures project. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards & Quality, Baltimore, Maryland, December 2007.</p> <p>Sehgal AR, Snow RJ, Singer ME, Amini SB, DeOreo PB, Silver MR, et al. Barriers to adequate delivery of hemodialysis. <i>Am J Kidney Dis</i> 1998;31(4):593-601.</p> <p>Tonelli M, Muirhead N. Access type as a predictor of dialysis adequacy in chronic hemodialysis patients. <i>ASAIO J</i> 2000;46:279-82.</p> <p>2001 Annual Report: ESRD clinical performance measures project. <i>Am J Kidney Dis</i> 2002 May;39(5Suppl1):S4-98.</p> <p>Centers for Medicare and Medicaid Services, Kinney R. 2005 Annual Report, end stage renal disease clinical performance measures project. <i>Am J Kidney Dis</i> 2006 Oct;48(4Suppl2):S1-106.</p>
Blood flow rate – not applicable	<p>Not applicable</p>
Intervention rates (5.8/year) and patency (36 and 37%)	<p>Rocklin MA, Dwight CA, Callen LJ, Bispham BZ, Spiegel DM. Comparison of cuffed tunneled hemodialysis catheter survival. <i>Am J Kidney Dis</i> 2001;37(3):557-63.</p> <p>Duszak R, Haskal ZJ, Thomas-Hawkins C, Soulen MC, Baum RA, Shlansky-Goldberg RD et al. Replacement of failing tunneled hemodialysis catheters through pre-existing subcutaneous tunnels: a comparison of catheter function and infection rates for de novo placements and over-the-wire exchanges. <i>J Vasc Interv Radiol</i> 1998;9(2):321-7.</p> <p>Hodges TC, Fillinger MF, Zwolak RM, Walsh DB, Bech F, Cronenwett JL. Longitudinal comparison of dialysis access methods: risk factors for failure. <i>J Vasc Surg</i> 1997;26(6):1009-19.</p> <p>Lund GB, Trerotola SO, Scheel PF, Savader SJ, Mitchell SE, Venbrux AC, et al. Outcome of tunneled hemodialysis catheters placed by radiologists. <i>Radiology</i> 1996;198(2):467-72.</p> <p>Schwab SJ, Weiss MA, Rushton F, Ross JP, Jackson J, Kapoian T, et al. Multicenter clinical trial results with the LifeSite hemodialysis access system. <i>Kidney Int</i> 2002;62:1026-33.</p> <p>Trerotola SO, Johnson MS, Harris VJ, Shah H, Ambrosius WT, McKusky MA et al. Outcome of tunneled hemodialysis catheters placed via the right internal jugular vein by interventional radiologists. <i>Radiology</i> 1997;203(2):489-95.</p>

CLINICAL CITATIONS