ANNEXES TO CHAPTER 6

Clinical Question XXVI. What is the best material and design for a tunnelled central venous catheter?

Long-term central venous catheters are usually tunnelled catheters anchored by a cuff. The materials and designs of these catheters are constantly evolving. Currently the two main biomaterials used to make catheters are polyurethane and silicone, while use of copolymers such as Carbothane is becoming increasingly common. Many catheters are coated with products such as heparin, antibiotics, or silver ions, to minimise the risk of thrombosis and infection. Lastly, different designs of lumen and tip are also available, with or without lateral holes.

As is described in the general reviews on this subject (Ash 2008; Tal 2008) there are multiple possible combinations, between the materials, the coatings to reduce risks of infection and thrombosis, and the different types of lumen and tip.

A number of RCT were located comparing different types of catheters, or a particular type of catheter and a special access system (LifeSite). The main findings are listed below, but the available evidence does not enable us to give a conclusive answer to our question, or to conclude that one material is better than another, or a particular make or model of catheter is superior to the others.

The RCT by Hwang (2012) compared a palindrome catheter (with symmetrical tip design) with a step-tip catheter in 97 patients followed up for two months. The catheter dysfunction-free survival rate was significantly longer for the palindrome catheter than for the step-tip catheter (78.9% vs 54.4% at two months, p=0.008). The overall survival rate of the catheter was also longer for the palindrome catheter than for the step-tip catheter (90.6% vs 68.8% at two months, p=0.015). No differences were found between the two catheters in adequacy of the flow for haemodialysis. There were no cases of bacteraemia during the study.	**Moderate quality**
The RCT by Trerotola (2002) compared two polyurethane catheters, the AshSplit (Medcomp) split-tip catheter and the OptiFlow (Bard Access Systems) *step-tip* catheter, in 132 patients referred for tunnelled haemodialysis catheter placement and followed up for 6 months. Flow rates within the acceptable range indicated by the Dialysis Outcomes Quality Initiative (300 ml/minute) were obtained with both catheters. Survival of the catheter at 6 months was better for the AshSplit catheter (22/64 = 34.4%) than for the OptiFlow (16/68 = 23.5%), with the difference being statistically significant (log-rank test p=0.02). There were fewer catheter-related infections with the AshSplit catheter (9/64 = 14.1%) than with the OptiFlow (15/68 = 22.1%), but the difference was not statistically significant (RR 0.64, 95% CI: 0.30 to 1.36; p=0.24). Rates per 100 catheter-days of 0.12 and 0.22 respectively.	**Moderate quality**

There were fewer infections leading to catheter removal with the AshSplit catheter (6/64 = 9.4%) than with the OptiFlow (11/68 = 16.2%), but the difference was not statistically significant (RR 0.58, 95% CI: 0.23 to 1.47; p=0.26). Rates per 100 catheter-days of 0.12 and 0.22 respectively.	
An earlier RCT by Trerotola (1999) compared a conventional silicone catheter (Bard Hickman 13.5 f) with a split-tip polyurethane catheter (Medcomp AshSplit 14.5 f) in 24 patients followed up for six weeks, only 19 of whom completed the study. In one patient who received an AshSplit catheter, the catheter malfunctioned, requiring it to be changed. One of the patients in the AshSplit group had S. aureus bacteraemia at four weeks which was successfully treated with antibiotics. According to the authors, flow rates within the acceptable range indicated by the Dialysis Outcomes Quality Initiative (300 ml/minute) were obtained with both catheters. The split-tip catheter provided higher flow rates than the conventional catheter.	**Low quality**
The Atherikul (1998) RCT compared three different catheters (PermCath, Tesio, VasCath Soft Cell) in 64 patients. The mean blood flow rates, measured as the mean of thirty dialysis sessions, of the PermCath and Tesio catheters were significantly higher than the VasCath (PermCath 383.6 ml/min, Tesio 396.3 ml/min, VasCath 320.4 ml/min); (p<0.005). No data are provided on catheter infection or malfunction.	**Low quality**
LifeSite vs Tesio-Cath catheter haemodialysis access systems	
The Rosenblatt (2006) RCT compared the LifeSite and Tesio-Cath catheter haemodialysis access systems, in 68 patients followed up for one year. Catheter survival at one year: 74% for LifeSite system and 48% for Tesio-Cath catheter, with the difference not being statistically significant (log-rank test p=0.062). After adjusting for different covariates, the difference became statistically significant (p=0.039). Infection-rate, per 1000 catheter-days: 3.1 for LifeSite system and 6.6 for Tesio-Cath catheter (p=0.008). Rate of device-related bacteraemia per 1000 catheter-days: 1.9 for LifeSite system and 3.4 for Tesio-Cath catheter (p=0.013).	**Low quality**
The RCT by Schwab (2002) compared the LifeSite haemodialysis access system with the Tesio-Cath catheter in 70 patients followed up for six months. Catheter survival at six months: somewhat lower with the LifeSite system (64.8%) than with the Tesio-Cath catheter (69.1%), after stratifying for diabetes and adjusting for age.	**Low quality**

Rate of device-related bacteraemia per 1000 catheter-days: 3.4 for the LifeSite system and 3.3 for the Tesio-Cath catheter. The blood flow rate was slightly higher with the LifeSite system than the Tesio-Cath catheter (358.7 vs 331.8 ml/min).	
Summary of evidence	
The available evidence, from comparisons between catheter models with few RCT and few patients, is not sufficient to recommend any one type of catheter over another from those compared in these studies.	**Low quality**
Patients' values and preferences *No relevant studies related to this aspect have been identified.*	
Use of resources and costs *No relevant studies related to this aspect have been identified.*	
Recommendations [Proposal]	
	There are no data in the literature to support the recommendation of any particular model or specific type of permanent central venous catheter for haemodialysis.

References

Ash SR. Advances in tunneled central venous catheters for dialysis: design and performance. Semin Dial. 2008 Nov-Dec; 21(6):504-15.

Atherikul K, Schwab SJ, Conlon PJ. Adequacy of haemodialysis with cuffed central-vein catheters. Nephrol Dial Transplant. 1998 Mar; 13(3):745-9.

Bonkain F, Racapé J, Goncalvez I, Moerman M, Denis O, Gammar N, Gastaldello K, Nortier JL. Prevention of tunneled cuffed hemodialysis catheter-related dysfunction and bacteremia by a neutral-valve closed-system connector: a single-center randomized controlled trial. Am J Kidney Dis. 2013 Mar; 61(3):459-65.

Hwang HS, Kang SH, Choi SR, Sun IO, Park HS, Kim Y. Comparison of the palindrome vs. step-tip tunneled hemodialysis catheter: a prospective randomized trial. Semin Dial. 2012 Sep-Oct; 25(5):587-91.

Kakkos SK, Haddad GK, Haddad RK, Scully MM. Effectiveness of a new tunneled catheter in preventing catheter malfunction: a comparative study. J Vasc Interv Radiol. 2008 Jul; 19(7):1018-26.

Oliver MJ, Edwards LJ, Treleaven DJ, Lambert K, Margetts PJ. Randomized study of temporary hemodialysis catheters. Int J Artif Organs. 2002 Jan; 25(1):40-4.

Power A, Singh SK, Ashby D, Cairns T, Taube D, Duncan N. Long-term Tesio catheter access for hemodialysis can deliver high dialysis adequacy with low complication rates. J Vasc Interv Radiol. 2011 May; 22(5):631-7.

Richard HM 3rd, Hastings GS, Boyd-Kranis RL, Murthy R, Radack DM, Santilli JG, Ostergaard C, Coldwell DM. A randomized, prospective evaluation of the Tesio, Ash split, and Opti-flow hemodialysis catheters. J Vasc Interv Radiol. 2001 Apr; 12(4):431-5.

Rocklin MA, Dwight CA, Callen LJ, Bispham BZ, Spiegel DM. Comparison of cuffed tunneled hemodialysis catheter survival. Am J Kidney Dis. 2001 Mar; 37(3):557-63.

Rosenblatt M, Caridi JG, Hakki FZ, Jackson J, Kapoian T, Martin SP, Moran J, Pedan A, Reese WJ, Ross JP, Ross J, Rushton F, Schwab SJ, Soundararajan R, Stainken B, Weiss MA, Work J, Yegge J. Efficacy and safety results with the LifeSite hemodialysis access system versus the Tesio-Cath hemodialysis catheter at 12 months. J Vasc Interv Radiol. 2006 Mar; 17(3):497-504.

Schwab SJ, Weiss MA, Rushton F, Ross JP, Jackson J, Kapoian T, Yegge J, Rosenblatt M, Reese WJ, Soundararajan R, Work J, Ross J, Stainken B, Pedan A, Moran JA. Multicenter clinical trial results with the LifeSite hemodialysis access system. Kidney Int. 2002 Sep; 62(3):1026-33.

Tal MG, Ni N. Selecting optimal hemodialysis catheters: material, design, advanced features, and preferences. Tech Vasc Interv Radiol. 2008 Sep; 11(3):186-91.

Trerotola SO, Kraus M, Shah H, Namyslowski J, Johnson MS, Stecker MS, Ahmad I, McLennan G, Patel NH, O'Brien E, Lane KA, Ambrosius WT. Randomized comparison of split tip versus step tip high-flow hemodialysis catheters. Kidney Int. 2002 Jul; 62(1):282-9.

Trerotola SO. Re: A randomized, prospective comparison of the Tesio, Ash Split, and Opti-flow hemodialysis catheters. J Vasc Interv Radiol. 2002 Mar; 13(3):342-3.

Trerotola SO, Shah H, Johnson M, Namyslowski J, Moresco K, Patel N, Kraus M, Gassensmith C, Ambrosius WT. Randomized comparison of high-flow versus conventional hemodialysis catheters. J Vasc Interv Radiol. 1999 Sep; 10(8):1032-8.

Table 1. STUDIES EXCLUDED

Study	Cause for exclusion
Bonkain 2013	RCT comparing a connector (Tego Needlefree Haemodialysis Connector) with a citrate lock solution. Does not compare different catheters with each other.
Kakkos 2008	Non-randomised retrospective study. Case study and controls.
Oliver 2002	RCT comparing two temporary catheters, non-permanent.
Power 2001	Non-randomised study. Retrospective cohort.
Richard 2001	Although in the title they classify it as randomised, treatment assignment was not random. In the methods section it says, "Catheters were placed in a revolving order, so the first patient received an Ash split, the second an Opti-flow, the third a Tesio, the fourth an Ash split, the fifth an Opti-flow, and so on". In a letter to the editor, Trerotola (2002) directly criticises the methods of that study, even questioning ethical and legal aspects. [see: Trerotola SO. Re: A randomized, prospective comparison of the Tesio, Ash Split, and Opti-flow hemodialysis catheters. J Vasc Interv Radiol. 2002 Mar; 13(3):342-3.]
Rocklin 2001	Non-randomised study.

GRADE TABLES

Date: 2014-01-27
Question: Should Ash-Split catheter (Medcomp) vs Opti-Flow catheter (Bard Access Systems) be used in tunnelled catheter for haemodialysis ?
Bibliography: Trerotola SO, Kraus M, Shah H, Namyslowski J, Johnson MS, Stecker MS, Ahmad I, McLennan G, Patel NH, O'Brien E, Lane KA, Ambrosius WT. Randomized comparison of split tip versus step tip high-flow hemodialysis catheters. Kidney Int. 2002 Jul; 62(1):282-9.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ash-Split catheter (Medcomp)	Opti -Flow catheter (Bard Access Systems)	Relative (95% CI)	Absolute		
Catheter-related infections (follow-up 6 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/64 (14.1%)	15/68 (22.1%)	RR 0.64 (0.3 to 1.36)	79 fewer per 1000 (from 154 fewer to 79 more)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Infections which caused catheter removal (follow-up 6 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	6/64 (9.4%)	11/68 (16.2%)	RR 0.58 (0.23 to 1.47)	68 fewer per 1000 (from 125 fewer to 76 more)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		

[1] Allocation concealment not clear, and probably not blind.

Date: 2014-01-28
Question: Should palindrome catheter vs step-tip catheter be used in tunnelled catheter for haemodialysis?
Bibliography: Hwang HS, Kang SH, Choi SR, Sun IO, Park HS, Kim Y. Comparison of the palindrome vs. step-tip tunneled hemodialysis catheter: a prospective randomized trial. Semin Dial. 2012 Sep-Oct; 25(5):587-91.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Palindrome catheter	Step-tip catheter	Relative (95% CI)	Absolute		
Survival rate free of catheter dysfunction (follow-up 2 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	42/47 (89.4%)	34/50 (68%)	RR 1.458 (1.084 to 1.96)	311 more per 1000 (from 57 more to 653 more)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Overall catheter survival rate (follow-up 2 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	42/47 (89.4%)	34/50 (68%)	RR 1.31 (1.06 to 1.63)	211 more per 1000 (from 41 more to 428 more)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		

[1] They do not report on the randomisation method or allocation concealment, nor on the blinding.