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UK Renal Registry 18th Annual Report: Chapter 11 2014 Multisite Dialysis Access Audit in England, Northern Ireland and Wales and 2013 PD One Year Follow-up: National and Centre-specific Analyses

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Key Words

Chronic kidney disease · Diabetes · Dialysis · End stage renal disease · Established renal failure · Haemodialysis · Peritoneal dialysis · Prevalence · Renal replacement therapy · Transplantation · Treatment modality · Vascular access

Summary

- Data are presented from the third combined vascular and peritoneal dialysis access audit.
- In 2014, 53 centres in England, Wales and Northern Ireland (out of 62) returned data on first access from 4,339 incident haemodialysis (HD) patients and 1,090 incident peritoneal dialysis (PD) patients.
- Of the 5,429 incident patients, 20.1% started dialysis on PD, 27.8% started with an arteriovenous fistula (AVF), 1.0% with an arteriovenous graft (AVG), 27.1% on a tunnelled line (TL) and 24.0% on a non-tunnelled line (NTL).
- Older patients (≥ 65 years) were more likely to start haemodialysis using AVF compared to their younger counterparts (36.2% vs. 32.8%).
- Thirteen of the nineteen centres (68%) using the physician led percutaneous insertion technique had over 20% of their incident patients starting on PD when compared to only seven out of fourteen centres (50%) which used single technique (open surgical or laparoscopic) for their PD catheter insertion.
- Wide variations were apparent between centres for use of AVF as the first haemodialysis access ranging from 10–54%.
- Eight of the 49 centres were achieving close to the 65% target for AV fistula in their incident patients.

- Length of time known to nephrology services and likelihood of commencing dialysis using either an AVF or a PD catheter are strongly associated. Patients who were known to a nephrologist for over one year were more likely to start dialysis with AVF, as compared to those who were referred between 90–365 days (39.2% vs. 24.6%). Similarly, patients who were known to a nephrologist between 90 days and one year were more likely to start on PD when compared to patients who were referred <90 days prior to dialysis start (26.9% vs. 9.1%). By comparison, amongst the late presenters, only 3.5% had first access documented as an AVF and 87.3% started dialysis on either a tunnelled line or a non-tunnelled line.
- Initial surgical assessment was a key determinant of the likelihood of AVF formation. Of the incident patients known to renal services for longer than three months and in those assessed by a surgeon at least three months prior to starting dialysis, 71.4% started dialysis with an AVF whereas of those who were not seen by a surgeon only 10.8% did.
- Thirty one of the 38 centres were 2 or 3 standard deviations below the 85% target for prevalent haemodialysis patients with an AV fistula.
- For centres returning data on one-year peritoneal dialysis outcomes, the majority of centres (28/32) maintained $\geq 50\%$ of patients on PD at one year, having censored for transplantation.
- This report demonstrates wide variations in practice between centres across several domains in the provision of dialysis access and further work will be required to understand the underlying reasons.

Introduction

High quality vascular access is a key modifiable risk factor for patients on dialysis and is an important measure of good clinical care. The third combined vascular and peritoneal dialysis access audit in England, Wales and Northern Ireland represents the findings from the 2014 data collection period for patients starting dialysis between 1st January 2014 and 31st December 2014. The combined access audit provides information on timely and appropriate access interventions in order to achieve permanent access based on the recommendations and quality requirements stated in Renal Association clinical practice guidelines and vascular access guidelines for haemodialysis and peritoneal access [1, 2]. The core principal of these audits has been to highlight the performance variation of renal centres across England, Wales and Northern Ireland and explore factors that may contribute to the provision of excellent quality vascular and peritoneal access.

The term established renal failure used within this chapter is synonymous with the terms end stage renal failure and end stage kidney disease, which are in more widespread international usage. Patients have disliked the term 'end stage', which reflects the inevitable outcome of this disease.

Methods

All adult renal centres in England, Wales and Northern Ireland were contacted regarding vascular and peritoneal access for all incident and prevalent dialysis patients (centre level only) in 2014. Data were collected using Microsoft Excel spreadsheets circulated by the UK Renal Registry (UKRR).

The records were also validated against the UKRR database to confirm that the population collected at each centre for the audit was the same as, or representative of, the incident population at that centre as collected via the usual UKRR quarterly return. Data checks were made by cross-referencing with the UKRR database. Any patients identified from the UKRR as not incident to dialysis between 1st January 2014 and 31st December 2014 were excluded. Patients were categorised as having AKI for the purposes of this audit and therefore excluded if they did not match to UKRR data and their access at three months was recorded as recovered renal function or not recorded. Similarly, where the reported prevalent numbers from the audit were more than 10% different to those in the UKRR database, those centres were excluded. The cross-referencing also enabled ascertainment of information on mortality within three months of commencing dialysis.

Centres who reported data on peritoneal dialysis (PD) patients in the 2013 vascular and peritoneal access audit were asked to

complete a one year follow up of their PD patients. Additional information was requested on the date of PD catheter failure, the reason for catheter failure, the number of catheters used during the year, and the modality in use at one year after starting PD.

Table 11.1 lists the summary of audit measures as stated in the Renal Association clinical practice guidelines, with explanation for why some of the audit measures were not reported.

Patients starting haemodialysis (HD) were grouped by type of first vascular access: arteriovenous fistula (AVF), arteriovenous graft (AVG), tunnelled dialysis line (TL), non-tunnelled dialysis line (NTL). Patients starting PD were categorised by the insertion technique: laparoscopic, peritoneoscopic, open surgery, percutaneous. Access at three months was defined as the type of access in use at three months after starting dialysis. If a patient was no longer receiving dialysis at three months then the reason was recorded instead, for example died or transplanted. Referral time was defined as the number of days between the date of first being seen by a renal physician and the date of commencing dialysis. A patient was classified as presenting late if they had a referral time of less than 90 days. In the analyses involving whether or not a patient had received surgical assessment at least three months before starting dialysis, patients were excluded if they were categorised as a late presenter.

Access failure was defined as the access no longer being usable for dialysis. Data about the date and cause of access failure was collected. For the purposes of analysis, access failures were grouped into five groups (maturation, mechanical, infection, other and unknown) for HD failures and six groups (infection, catheter related, solute/water clearance, leaks/hernia, other and unknown) for PD failures. Those grouped into 'other' included conservative management, dialysis withdrawn and line replaced. Access failure was censored for death, transplantation, withdrawal from renal replacement therapy (RRT) and elective switching of access type. It was the intention to only capture access failures relating to the first type of access. If the reason recorded for access failure was not related to the first type of access recorded, then the data was not included in this analysis.

Separate and combined analyses have been performed for incident HD patients and incident PD patients as appropriate. Due to the exploratory nature of the audit the analyses have been limited to descriptive statistics of frequencies, percentages and unadjusted associations between variables. If a centre had more than 50% missing returns for a particular data field, then all patients from that centre were excluded from analyses involving that data field. The data were analysed using SAS 9.3.

Results

Inclusion and exclusion criteria

Figure 11.1 is a flow diagram of exclusions. Of the 62 centres contacted, data were received from 54 centres. In the three years of the running of the combined audit, three centres have not contributed data (Carshalton, Coventry, Kent) with three centres having contributed only once (Bristol, Dudley, London Guys). Only one

Table 11.1. Summary of audit measures stated in Renal Association clinical practice guidelines for dialysis access

RA audit measure/guideline	Reported	Reason for non-inclusion
HD access		
1 Proportion of patients whose first haemodialysis treatment is with an arteriovenous fistula:	Yes	
1a Stratified by new patients with established renal failure and known to the nephrology team for >90 days	Yes	
1b Stratified by new patients with established renal failure and known to the nephrology team for ≤90 days	Yes	
1c Patients with a failed renal transplant	No	Not captured by the audit
1d Patients transferred permanently from PD to haemodialysis	No	Not captured by the audit
2 65% of all patients commencing haemodialysis should commence with an AV fistula	Yes	
3 A centre should measure the proportion of prevalent long term haemodialysis patients receiving dialysis via a fistula, an arteriovenous graft and a tunnelled or a non-tunnelled line	Yes	
4 85% of all prevalent patients on haemodialysis should receive dialysis via a functioning arteriovenous fistula	Yes	
5 Complications related to vascular access	Yes	
5a Rupture of vascular access (fistula and graft)	Partly	Incident patients only
PD access		
1 Catheter patency – more than 80% of catheters should be patent at 1 year (censoring for death and elective modality change)	Yes	
2 Complications following PD catheter insertion:	Partly	
2a Bowel perforation <1%	No	Not captured by the audit
2b Significant haemorrhage <1%	No	Not captured by the audit
2c Exit site infection within 2 weeks of catheter insertion <5%	No	Not captured by the audit
2d Peritonitis within 2 weeks of catheter insertion <5%	Yes	
2e Functional catheter problem requiring manipulation or replacement or leading to technique failure <20%	No	Not captured by the audit

centre was excluded due to poor data quality (Ipswich). Patients ($n = 558$) who did not match when cross-referencing with the UKRR database and whose access at three months was ‘recovered renal function’ were categorised as having AKI for the purposes of this audit and excluded. Fifteen patients were excluded from all analyses due to missing RRT start date or first access type.

Data completeness

Fifty-three centres returned data on first dialysis access for 4,339 incident HD patients and 1,090 incident PD patients. The UKRR incident patient data for the same year were 4,895 HD and 1,396 PD, thus there were access returns on 88.6% of HD and 78.1% of PD patients. The patient demographic returns via the access audit correlated well with the data returns made via the usual UKRR quarterly returns. The completeness of all variables in the audit was over 80% apart from body mass index (BMI) which was 54.3% (data not shown).

Variations in first dialysis access

Patient demographics

The median patient age when starting RRT was 68 years in the HD cohort and 61 years for patients commencing PD. Overall, 63.7% of the patients were male, 36.3% female; the proportional distribution of the sexes was similar for both the HD and PD subgroups.

A significant proportion of patients starting dialysis had diabetes (53.6%), however diabetes associated nephropathy was the primary renal disease (PRD) in only 26.2% (table 11.2).

Table 11.3 presents HD and PD patient subgroups stratified by age, dichotomised body mass index (BMI) (≤ 30 or >30), PRD, referral time (<90 or ≥ 90 days) and surgical assessment status.

There was an association between the access modality (HD vs. PD), referral time (<90 days vs. ≥ 90 days) and surgical assessment status in excess of three months prior to dialysis start. The following observations can be made:

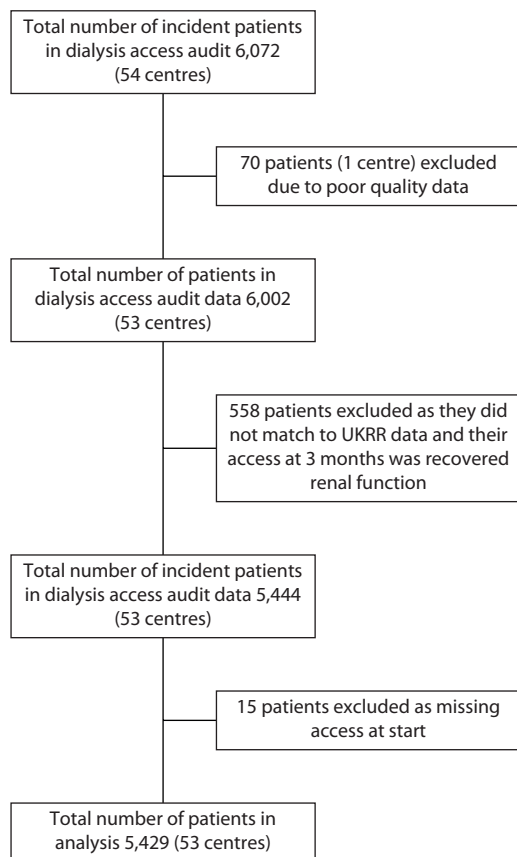


Fig. 11.1. STROBE flow diagram of exclusions

For HD:

- AVF was the initial access for 34.8% of patients, with 1.2% with an AVG, 34.0% on a tunnelled line and 30.0% on a non-tunnelled line. The percentage of patients starting with an AVF had been stable for the previous three years but has since fallen from 40.7% in 2013. The majority of centres are failing to achieve the target as stated in the Renal Association guidelines (65% of all patients commencing haemodialysis should commence with an AVF).
- Patients aged 65 or over were more likely to start RRT with an AVF (36.2%) when compared to patients <65 years (32.8%). Similarly, older patients were less likely to start on a tunnelled line (30.3% vs. 38.7%).
- BMI had a positive impact on vascular access with 48.9% of the patients with BMI >30 starting on AVF compared to 36.8% of the patients with BMI ≤30.
- Patients with polycystic kidney disease (PKD) as primary renal diagnosis were most likely to start with an AVF (66.1%).
- Patients, who were referred at least 90 days prior to commencing dialysis, were more likely to start on AVF compared to those starting more acutely (48.4% vs. 3.8%).
- A high proportion of patients who were referred at least 90 days prior to commencing dialysis, start

Table 11.2. Patient demographics

Variable		Total N = 5,429	HD N = 4,339	PD N = 1,090
Age	Median (IQR)	66 (53, 76)	68 (55, 77)	61 (48, 72)
BMI	Median (IQR)	27 (24, 32)	27 (24, 32)	27 (24, 31)
Gender		N (%)	N (%)	N (%)
	Female	1,972 (36.3)	1,588 (36.6)	384 (35.2)
	Male	3,457 (63.7)	2,751 (63.4)	706 (64.8)
Diabetes	Missing	625 (11.5)	528 (12.2)	97 (8.9)
	Yes	2,908 (53.6)	2,267 (52.2)	641 (58.8)
	No	1,896 (34.9)	1,544 (35.6)	352 (32.3)
PRD	Missing	247 (4.5)	202 (4.7)	45 (4.1)
	Diabetes	1,423 (26.2)	1,124 (25.9)	299 (27.4)
	Glomerulonephritis	624 (11.5)	448 (10.3)	176 (16.1)
	Hypertension	324 (6.0)	261 (6.0)	63 (5.8)
	Other	1,090 (20.1)	957 (22.1)	133 (12.2)
	Polycystic kidney	243 (4.5)	165 (3.8)	78 (7.2)
	Pyelonephritis	264 (4.9)	225 (5.2)	39 (3.6)
	Renal vascular disease	347 (6.4)	283 (6.5)	64 (5.9)
	Uncertain	867 (16.0)	674 (15.5)	193 (17.7)

IQR = interquartile range; BMI = body mass index; PRD = primary renal diagnosis; HD = haemodialysis; PD = peritoneal dialysis

Table 11.3. Patient characteristics stratified by type of first dialysis access

Variable	HD patients					PD patients					
	HD N	AVF	AVG	TL	NTL	PD N	Open surgery	Laparoscopic	Peritoneoscopic	Percutaneous	Missing
Total patients	4,339	1,508	54	1,474	1,303	1,090	415	197	20	309	149
%		34.8	1.2	34.0	30.0		38.1	18.1	1.8	28.3	13.7
Age at first dialysis		%					%				
<65	1,889	32.8	1.2	38.7	27.3	640	38.3	18.1	2.2	28.6	12.8
≥65	2,450	36.2	1.3	30.3	32.2	450	37.8	18.0	1.3	28.0	14.9
BMI (kg/m²)											
≤30	1,403	36.8	1.9	36.3	25.1	423	43.7	14.9	3.8	22.7	14.9
>30	745	48.9	1.3	29.4	20.4	161	49.1	18.0	1.9	14.9	16.1
No BMI	605	18.5	1.0	29.6	50.9	84	44.0	20.2	1.2	23.8	10.7
PRD											
Diabetes	1,124	40.9	1.3	37.5	20.2	299	36.5	18.4	1.7	29.1	14.4
GN	448	34.2	0.4	41.5	23.9	176	39.8	19.9	2.8	27.8	9.7
Hypertension	261	50.6	0.8	28.4	20.3	63	33.3	17.5	1.6	34.9	12.7
No PRD	202	17.8	0.5	33.2	48.5	45	31.1	8.9	0.0	40.0	20.0
Other	957	15.7	0.8	30.8	52.7	133	35.3	21.1	1.5	24.1	18.0
PKD	165	66.1	3.0	26.1	4.8	78	56.4	19.2	1.3	14.1	9.0
Pyelo	225	41.3	2.2	33.3	23.1	39	35.9	20.5	2.6	25.6	15.4
RVD	283	38.2	1.1	31.1	29.7	64	43.8	9.4	3.1	28.1	15.6
Uncertain	674	39.6	1.9	33.2	25.2	193	35.2	18.1	1.6	32.1	13.0
Referral time (days)											
<90	1,275	3.8	0.2	37.3	58.7	127	26.0	22.0	1.6	38.6	11.8
≥90	3,002	48.4	1.7	32.6	17.3	962	39.7	17.6	1.9	27.0	13.8
No ref	62	8.1	1.6	32.3	58.1	1	0.0	0.0	0.0	0.0	100
Assessed by surgeon											
Missing	59	25.4	0.0	42.4	32.2	81	66.7	13.6	0.0	18.5	1.2
No	2,290	5.6	0.5	44.8	49.1	439	29.6	14.1	2.5	41.2	12.5
Yes	1,910	70.2	2.0	21.2	6.7	557	39.3	22.3	1.6	20.3	16.5

Patients from centres with more than 50% missing data for a variable are excluded from the table for that variable

AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; GN = glomerulonephritis; BMI = body mass index; PRD = primary renal diagnosis; PKD = polycystic kidney disease; Pyelo = pyelonephritis; RVD = renal-vascular disease

dialysis on a tunnelled (32.6%) or a non-tunnelled (17.3%) line.

- Patients who had been seen by a surgeon at least three months before starting dialysis were more likely to start with an AVF than those not assessed (70.2% vs. 5.6%).

For PD:

- For 1,090 first PD catheters, the insertion techniques were 38.1% open surgical, 18.1% laparoscopic, 1.8% peritoneoscopic and 28.3% percutaneous. Insertion technique was not reported for the remaining 13.7%.
- There was a greater proportion of patients who underwent percutaneous PD catheter insertion in the BMI ≤30 group in comparison with those with BMI >30 (22.7% vs. 14.9%).

- Referral time had an influence on PD catheter insertion technique; 38.6% of patients referred less than 90 days before starting dialysis underwent percutaneous insertion compared to 27.0% of patients known longer to the service. These data were reversed for general surgical insertion: 26.0% of patients who presented late versus 39.7% of patients who did not present late.
- Patients who were assessed by a surgeon at least three months before starting dialysis were more likely to undergo open surgical placement (39.3% vs. 29.6% for non-surgical assessment).

Figure 11.2 shows haemodialysis access stratified by PRD. The proportional distribution of PD access was reasonably similar for different primary renal disease

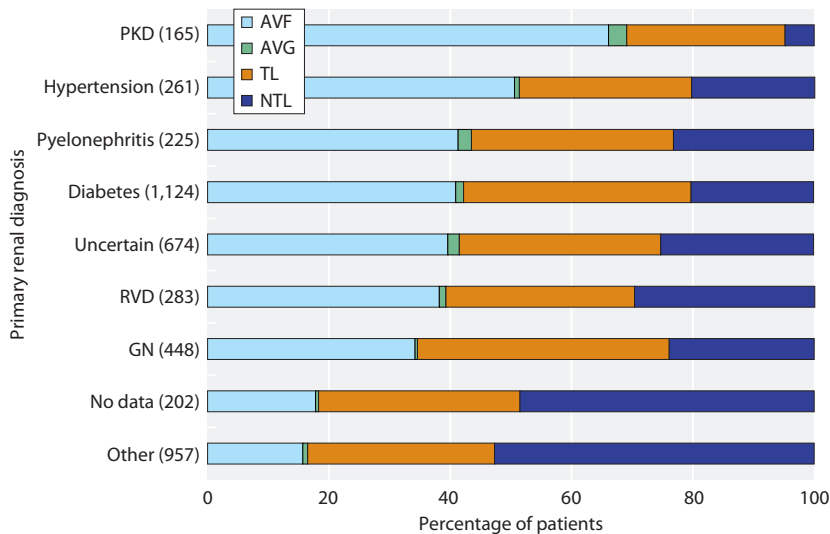


Fig. 11.2. Type of haemodialysis access stratified by primary renal disease
 Number of patients in each primary renal diagnosis group in brackets
 Primary renal diagnosis groups sorted by percentage of arteriovenous fistula
 AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; GN = glomerulonephritis; RVD = reno-vascular disease; PKD = polycystic kidney disease

but varied for HD access modality. Of note, patients with polycystic kidney disease were more likely to start HD with an AVF (66.1%). Where no primary renal diagnosis was available, patients were more likely to start dialysis with a non-tunnelled dialysis venous catheter (48.5%).

Figure 11.3 shows the distribution of haemodialysis access modality and PD catheter insertion technique stratified by BMI. As noted in table 11.2, unexpectedly BMI had a positive impact on type of vascular access with only 49.8% of the patients with BMI >30 kg/m² starting on a catheter compared to 61.4% of the patients with BMI ≤30 kg/m². In relation to peritoneal dialysis access,

patients with BMI >30 kg/m² were more likely to undergo open surgical placement (58.5%) than those with BMI ≤30 kg/m² (51.4%). The percutaneous approach was less likely to be used in patients in the higher BMI category (17.8%) compared to those with a lower BMI (26.7%). The peritoneoscopic or laparoscopic approach was used in a similar proportion of patients in both BMI groups. It should be noted that the analysis was limited due to a high proportion of missing data for BMI.

Figure 11.4 shows PD catheter insertion technique by centre. Centres reporting less than five patients on PD were not considered for analysis (n = 8). Seven centres

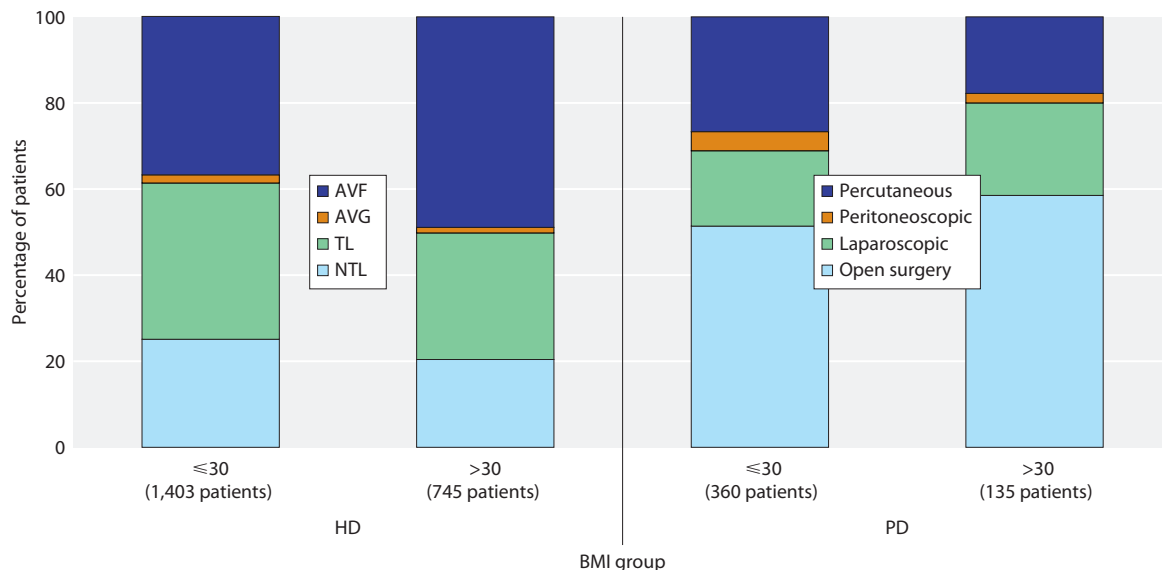


Fig. 11.3. Distribution of haemodialysis access modality and PD catheter insertion technique stratified by body mass index
 BMI = body mass index

All patients from centres with more than 50% missing data for BMI were excluded

AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line

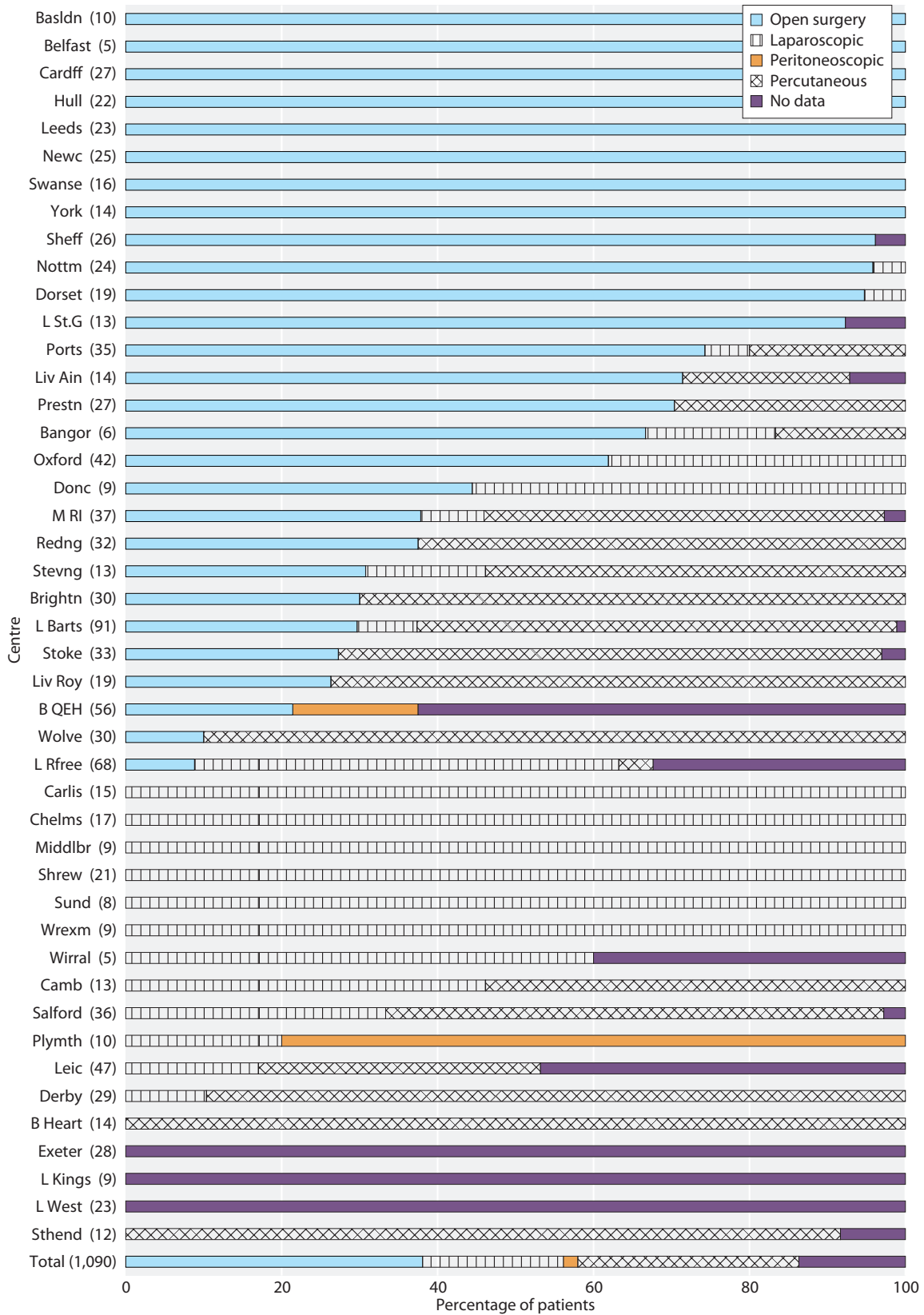


Fig. 11.4. PD catheter insertion technique stratified by centre

reported less than five patients using PD catheters for first dialysis in 2013. There continues to be a strong tendency for many centres to rely on one single approach to PD catheter placement, with 15 centres reporting use of a single technique for all of their patients mainly open surgical or laparoscopic. Two centres (Birmingham Heartlands, Southend) used percutaneous technique close to all of their PD catheter insertions with a further two centres (Derby, Wolverhampton) employing this technique in about 90% of cases. Fifteen other centres reported using the physician led percutaneous insertion technique. Thirteen of the nineteen centres (68.4%) using the physician led percutaneous insertion technique had over 20% of their incident patients starting on PD with three centres (Southend, Derby, Wolverhampton) having close to 40% of their incident patients starting on PD. By comparison only seven out of fourteen centres (50.0%) using single technique (open surgical or laparoscopic) had over 20% of their incident patients starting on PD (figure 11.5).

First dialysis access by renal centre

Figure 11.5 shows type of first dialysis access by centre. Approximately a quarter of the patients started with an AVF (27.8%) with over half of patients starting with a TL or NTL (51.2%) with approximately a 50–50 split between the two access types. Variations were apparent between centres when considering patients commencing dialysis via an AVF, ranging from <15% (London West, Carlisle) to >50% (Doncaster, Clwyd). Some centres had over 50% of patients starting dialysis on a tunnelled line (London West, Colchester). The use of arteriovenous graft as the first dialysis access was between 0–11 percent with only 21 of the 53 centres opting to use this.

Use of a PD catheter as first access varied between >40% (Derby, Southend) and 0% (Clwyd).

The Renal Association (RA) guidelines on vascular access for haemodialysis recommends 65% of all patients commencing haemodialysis should commence with an AV fistula. This is depicted in figure 11.6 with patients who presented late excluded for this analysis. Eight of the 49 centres (Chelmsford, York, Basildon, Derby, Liverpool Aintree, Doncaster, Stoke, Sheffield) reporting incident vascular access data were achieving close to the RA recommendations (>60%) with one centre achieving above 2 standard deviations (Stoke). However, there were 12 centres below 2 standard deviations and a further 15 centres below 3 standard deviations. These centres can be identified using figure 11.11. The results have to be cautiously interpreted due to non-adjustment for any patient related factors.

First dialysis access and referral time

Figure 11.7 shows a clear association between time known to a nephrologist and a patient starting haemodialysis with an AVF. A greater proportion of patients who were known to a nephrologist for over one year started dialysis with an AVF, as compared to those who were referred between 90–365 days (39.2% vs. 24.6%). Similarly, patients who were known to a nephrologist between 90 days to one year were more likely to start on PD when compared to patients who were referred <90 days prior to dialysis start (26.9% vs. 9.1%).

Figure 11.8 shows PD catheter insertion technique by referral time. Patients who were first seen by a nephrologist <90 days before starting RRT were more likely to undergo percutaneous insertion when compared to patients who were known between 90–365 days and >365 days (38.6% vs. 32.8% vs. 25.6%). These results may be due to centre effect and a reflection of practice patterns within the centre. Of the 13 centres that used the percutaneous insertion technique for over 50% of their PD catheters, five (Derby, London Barts, Manchester Royal Infirmary, Stoke, Wolverhampton) had over 20% of their patients presenting late starting on PD (figures 11.4 and 11.10). Open surgical technique was less likely to be used in the patients presenting late when compared to the patients who were known over 365 days, probably because of having a lesser likelihood of seeing a surgeon (26.0% vs. 40.2%).

Figure 11.9 shows first access for centres providing data for patients presenting to a nephrologist ≥ 90 days prior to dialysis start. Amongst the 4,027 patients, only 36.2% started with an AVF, below the Renal Association target and 23.9% started with a PD catheter. Despite being known to a nephrologist for over three months 38.6% of the patients started on a TL or NTL. As illustrated in figure 11.9 there was a significant variation between centres.

Figure 11.10 shows first access for centres providing data for patients presenting late (known to renal services for <90 days). Amongst the 1,402 patients for whom data were reported, 33.9% started dialysis on a tunnelled line, 53.4% on a non-tunnelled line and 9.1% using a PD catheter with only 3.5% having first access documented as an AVF.

In nine centres, more than 15% of patients presenting late had a peritoneal dialysis catheter inserted for use as first dialysis access and as a result had a lower requirement for tunnelled or non-tunnelled lines. The overall proportion of patients presenting late starting with an AVF for all of the centres was 3.5%. Three centres

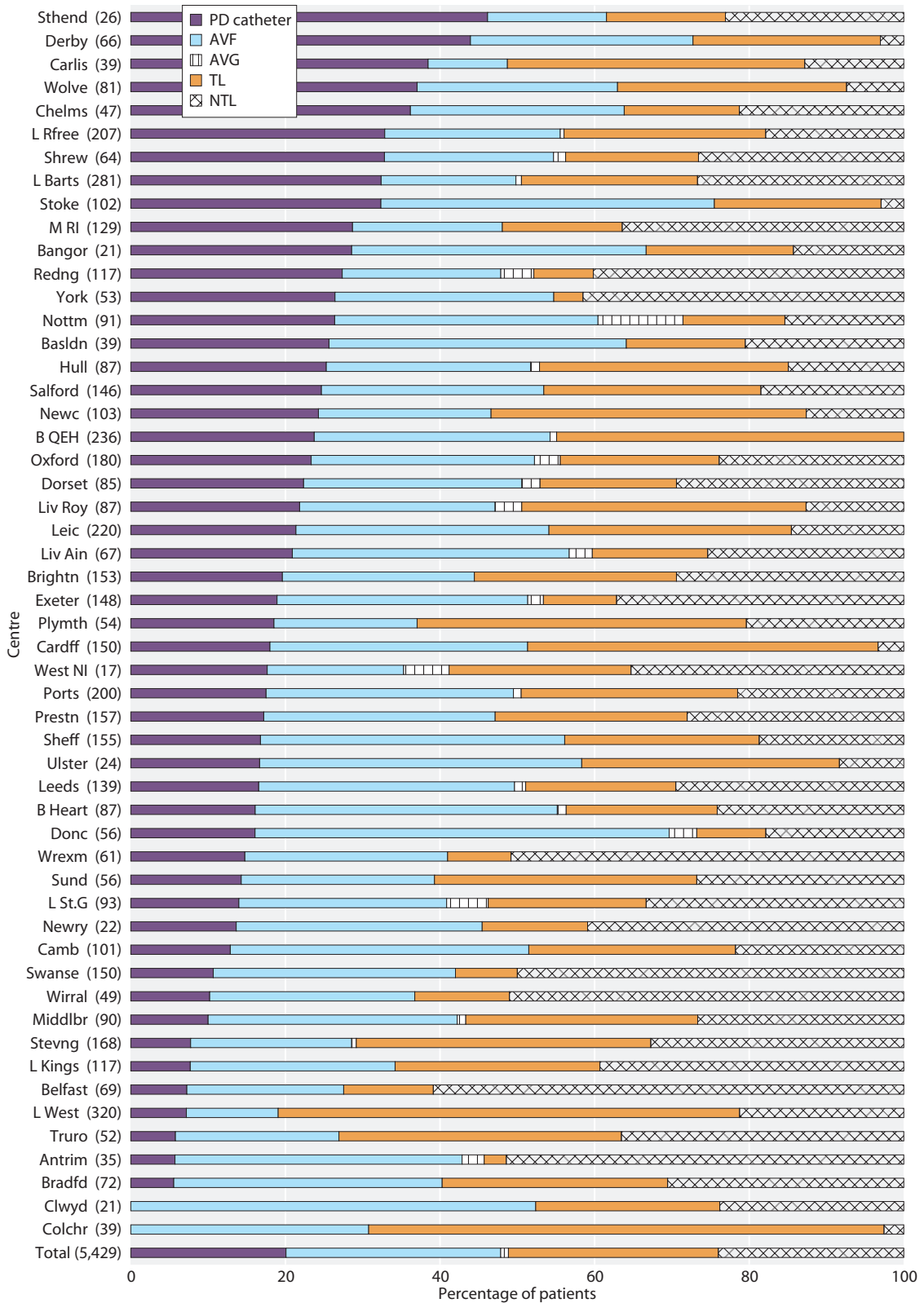


Fig. 11.5. Type of first dialysis access stratified by centre
 Centres are ordered by the percentage of patients starting dialysis with a PD catheter
 PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunneled line; NTL = non-tunneled line

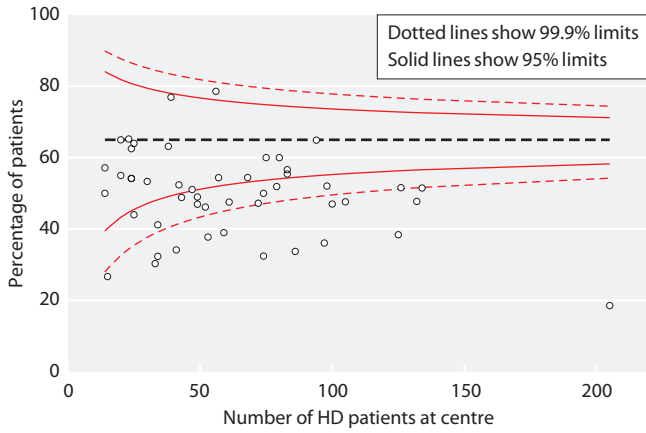


Fig. 11.6 Funnel plot of the percentage of HD patients who commenced dialysis using an AVF

however had over 15% of the patients who presented late starting with an AVF (Shrewsbury 27.5%, Colchester 20.0%, Derby 17.6%). This could be explained by a multitude of factors ranging from surgical access assessment and formation to ongoing evaluation of an AVF to enhance maturation and earlier cannulation. The number of patients presenting late reported in some centres was extremely small and it is difficult to make firm observations about clinical pathways for the development of dialysis access in this cohort.

Figure 11.11 shows the type of haemodialysis access in patients known to the renal service for at least 90 days. There was variation for patients starting haemodialysis with an AVF, with five centres (Ulster, Stoke, Doncaster, York, Chelmsford) achieving 65% or over with London West and Shrewsbury at the other end at <20%. The centres with highest tunnelled line use were London West (72.7%), Colchester (67.6%) and Carlisle (66.7%)

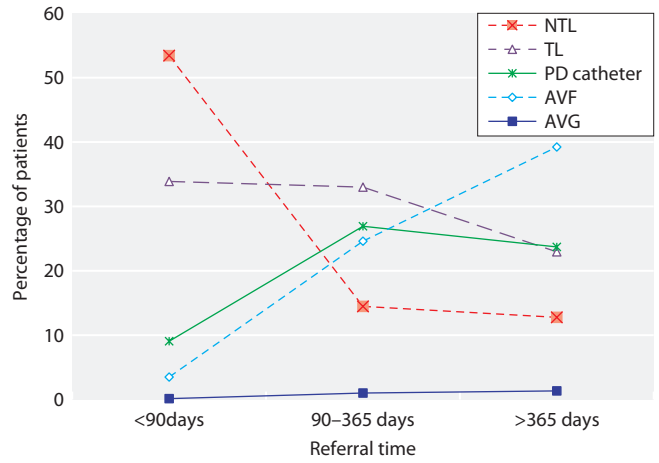


Fig. 11.7. Type of first dialysis access by referral time
NTL = non-tunnelled line; TL = tunnelled line; PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft

with over twice the overall proportion of all the centres combined (32.6%). There were eleven centres who reported over 30% of patients as starting on non-tunnelled lines despite being known to the centre for at least 90 days (Shrewsbury (40.0%), London St Georges (39.2%), Belfast (48.8%), London Kings (34.9%), Wrexham (33.3%), Wirral (33.3%), Reading (38.8%), Antrim (37.5%), Manchester Royal (32.7%), Swansea (32.0%), York (30.4%). It will be important to understand the variations in practice patterns that lie behind these statistics, which were not provided by current data.

First dialysis access and surgical assessment

Figure 11.12 highlights the proportion of patients referred for surgical assessment at least three months prior to starting dialysis. There was considerable

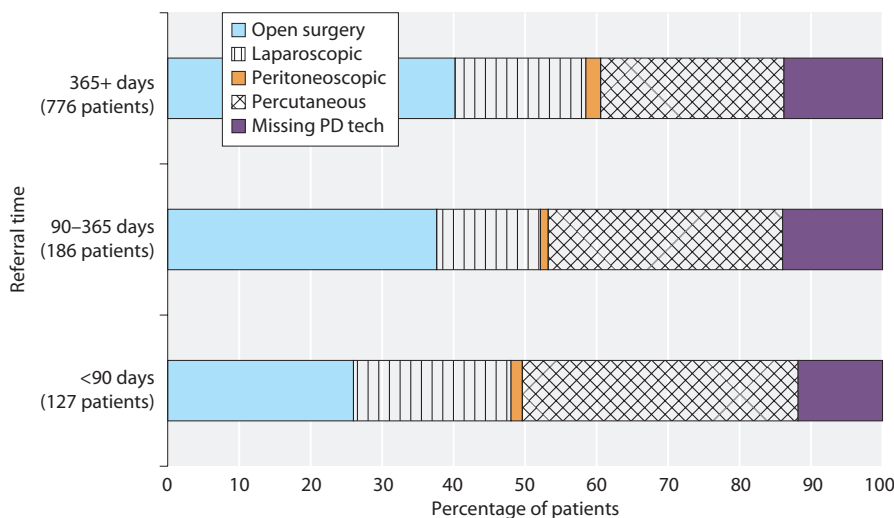


Fig. 11.8. PD catheter insertion technique by referral time

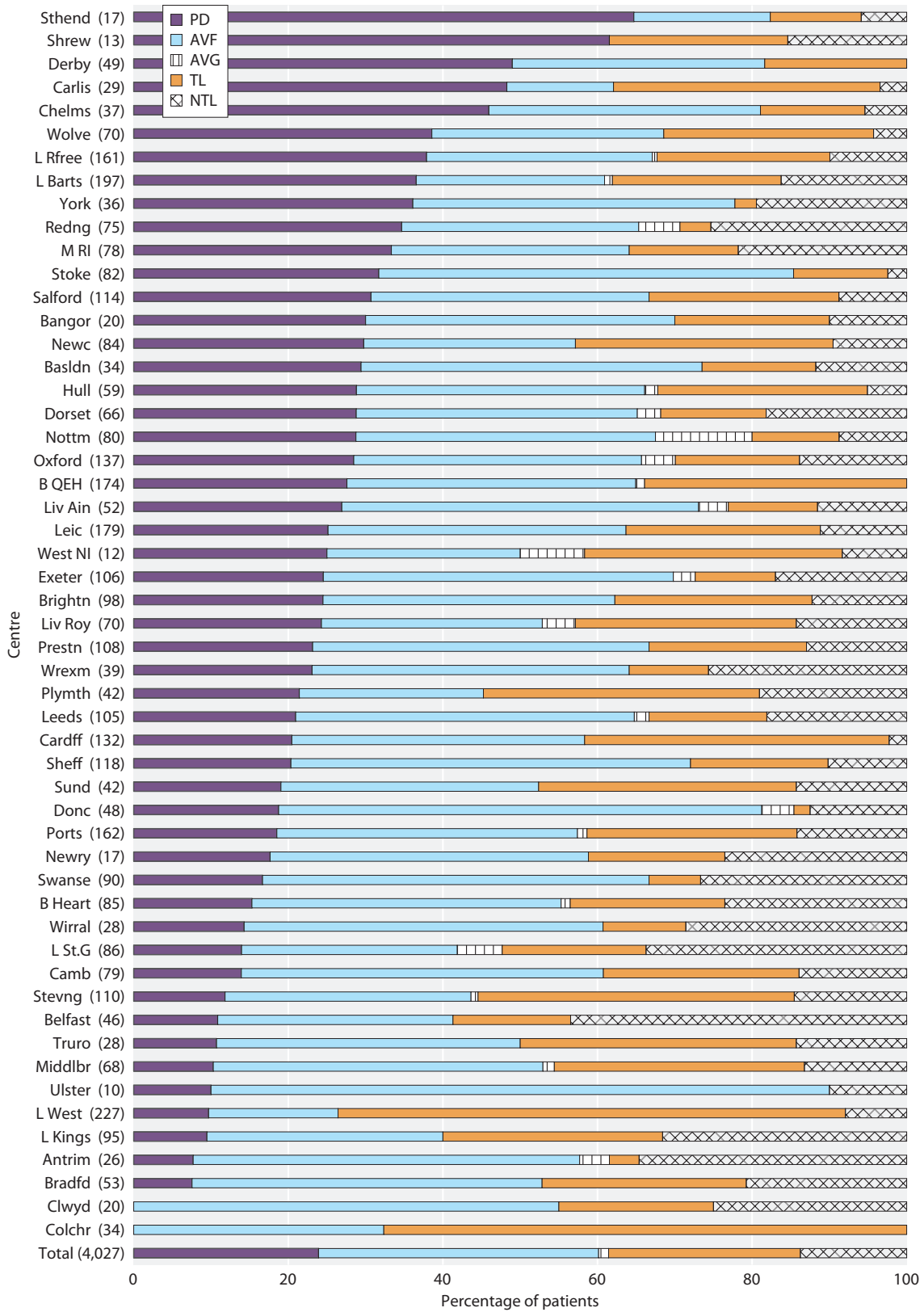


Fig. 11.9. Type of access used for first dialysis in patients presenting to a nephrologist ≥ 90 days prior to dialysis start
 PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunneled line; NTL = non-tunneled line

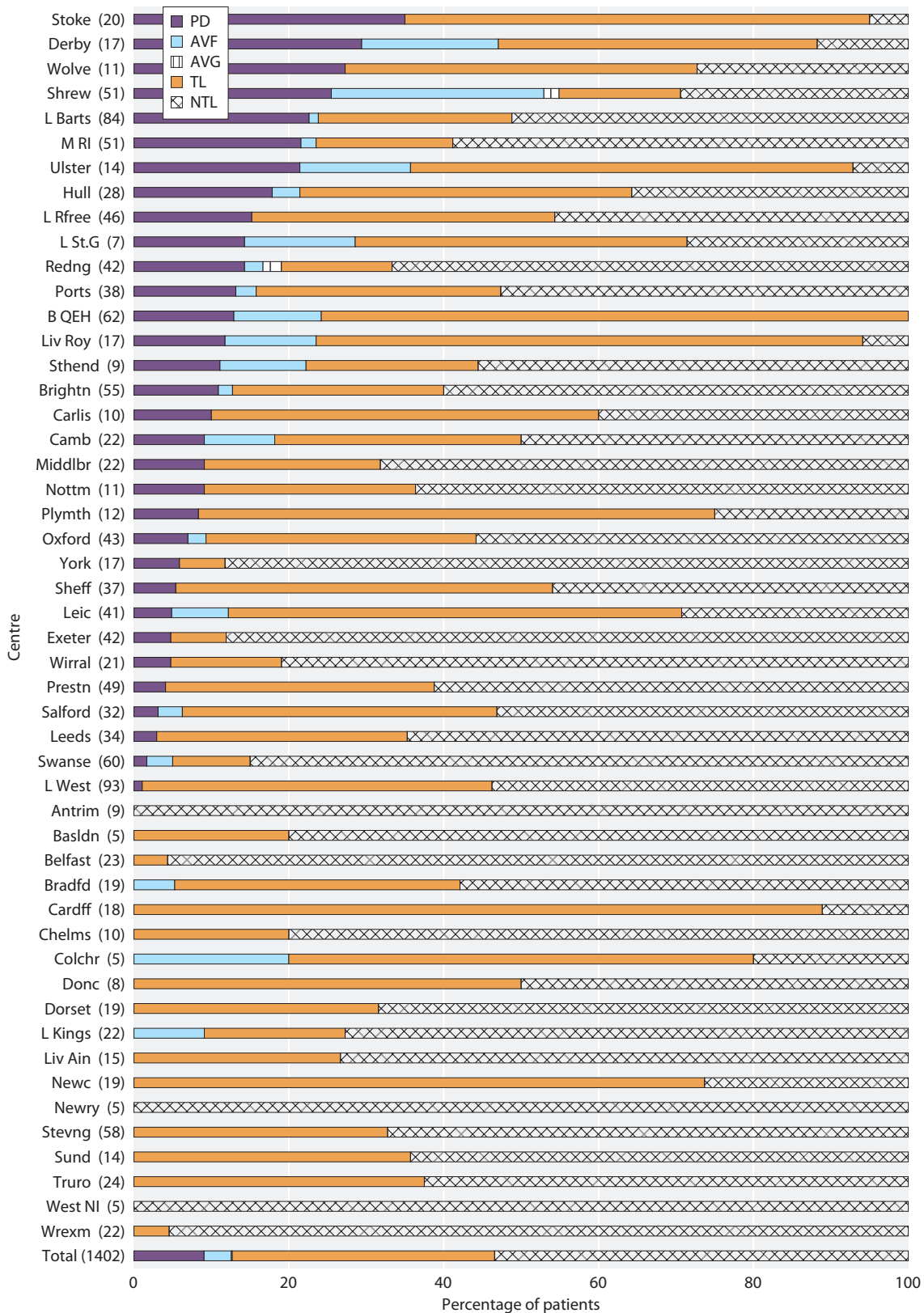


Fig. 11.10. Type of access used for first dialysis in patients presenting to a nephrologist <90 days prior to dialysis start
 PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunneled line; NTL = non-tunneled line

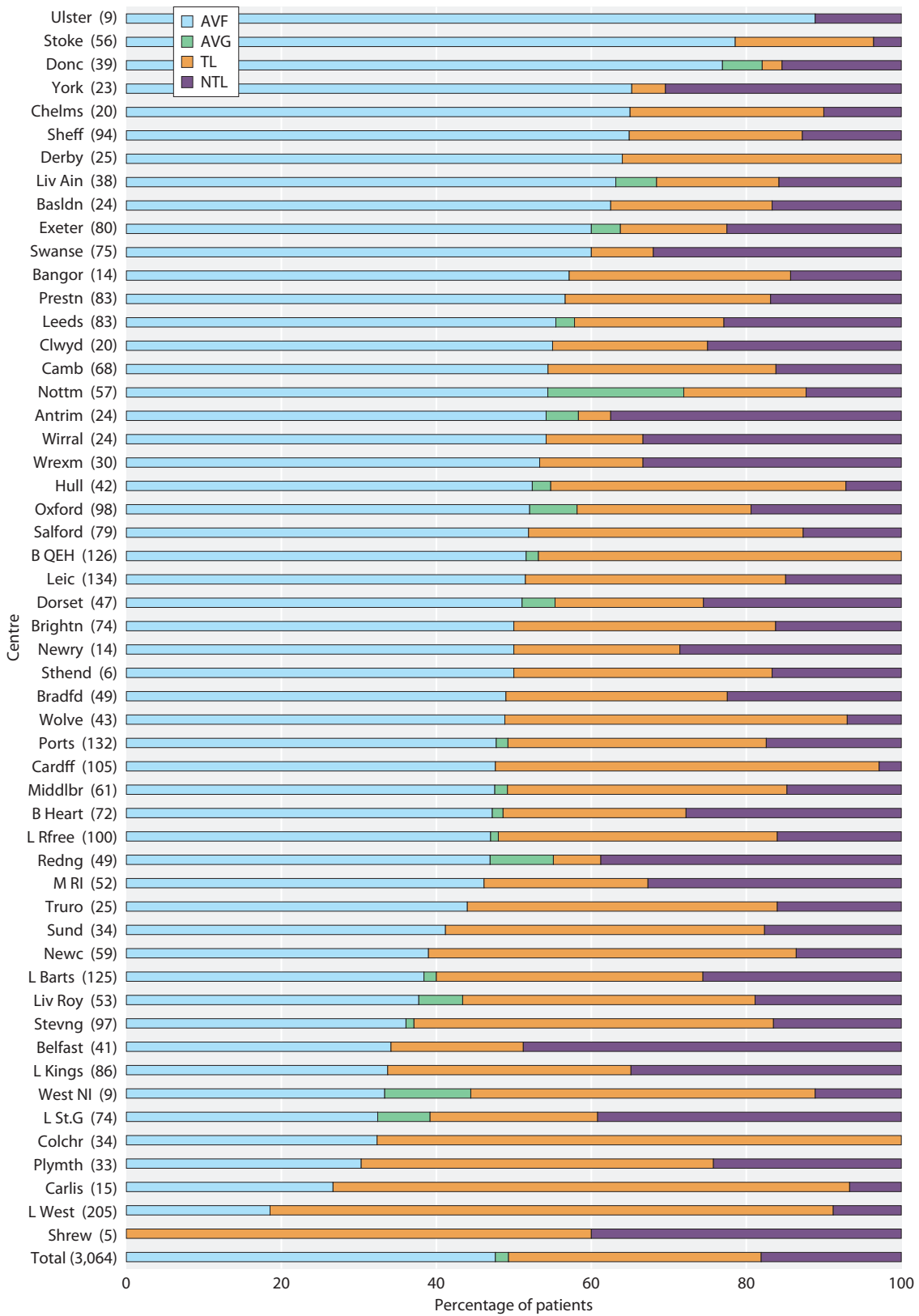


Fig. 11.11. Type of first access for haemodialysis patients stratified by centre restricted to patients known at ≥ 90 days prior to dialysis start
 AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line

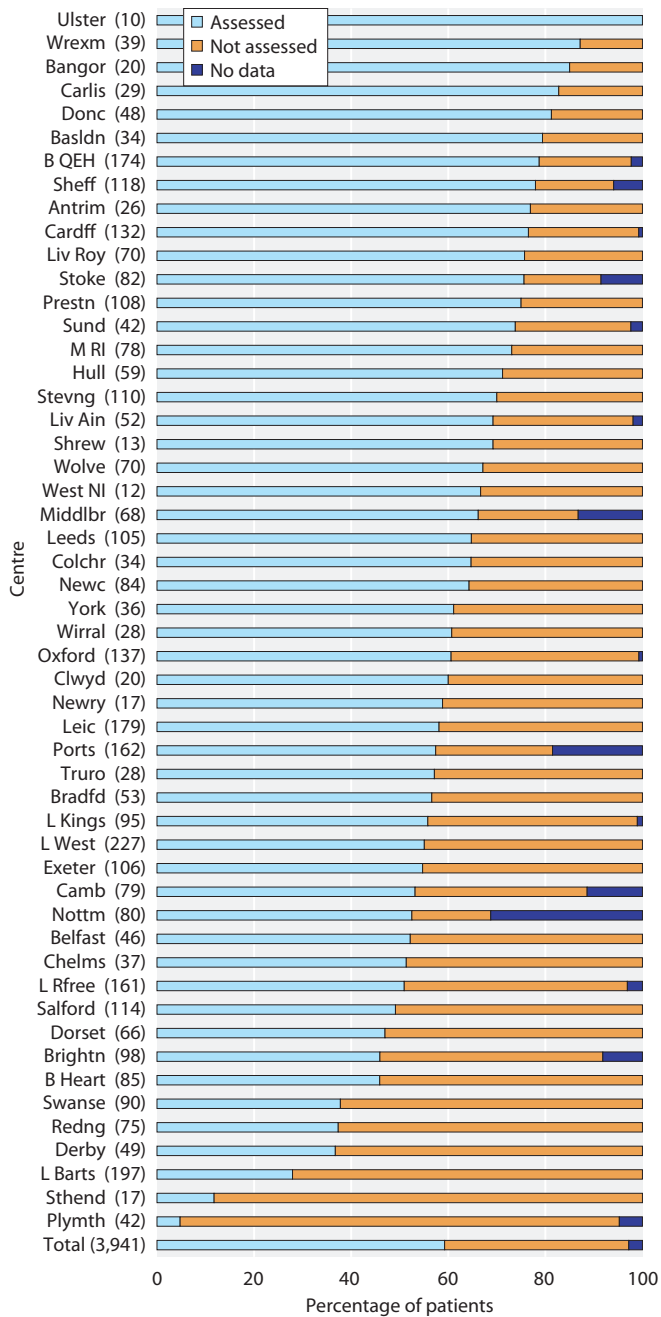


Fig. 11.12. Proportion of patients undergoing surgical assessment more than three months prior to starting dialysis

variation between the renal centres. Overall, the proportion referred to a surgeon was highest in Ulster (100%), Wrexham (87.2%), Bangor (85.0%), Carlisle (82.8%) and Doncaster (81.3%). This usually resulted in a high proportion of patients starting with either an AVF or PD catheter. Carlisle had only 13.8% starting with an AVF but had 48.3% starting on PD (refer to figure 11.9). Conversely, some centres despite having

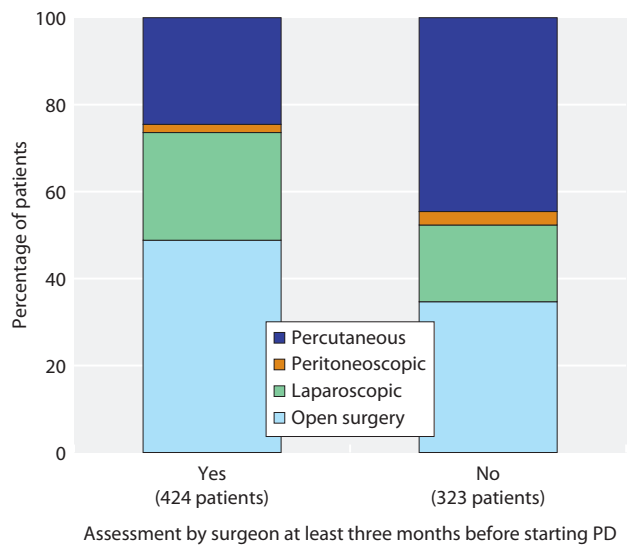


Fig. 11.13. PD catheter insertion technique stratified by surgical assessment

low rates of surgical assessment, performed well on their PD catheter rates (figure 11.9) as they utilised percutaneous PD catheter insertion technique (figure 11.4). For example, three of the centres with lowest surgical assessment, Derby (36.7%), London Barts (27.9%) and Southend (11.8%) all achieved high PD rates in their patients who were known to the centre for over three months (Derby 49.0%, Southend 64.7%, London Barts 36.5%) as these centres utilised percutaneous PD catheter insertion technique (Derby 89.7%, Southend 91.7%,

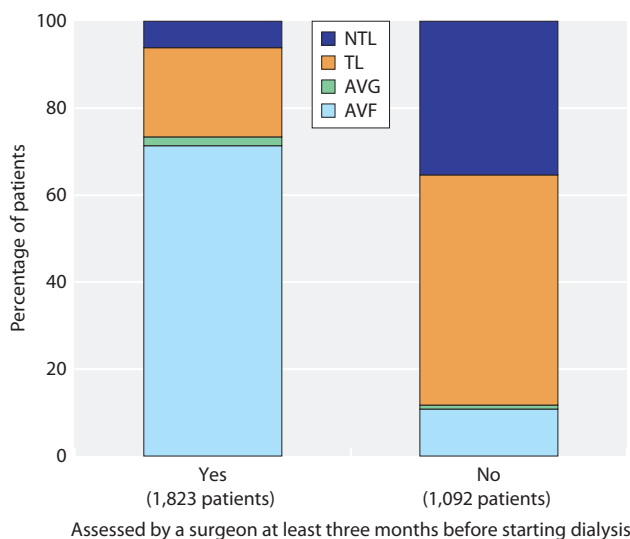


Fig. 11.14. Type of haemodialysis access stratified by surgical assessment

AVF = arteriovenous fistula; NTL = non-tunnelled line; TL = tunnelled line; AVG = arteriovenous graft

Table 11.4. Type of dialysis access at three months since dialysis start stratified by first access type

Access in use at first dialysis (N)	Access in use at three months (%)								
	AVF	AVG	TL	NTL	PD catheter	Transplanted	Died	Stopped/LTFU	No data
AVF (1,494)	88.4	0.3	4.8	0.1	0.1	1.1	3.6	1.2	0.3
AVG (54)	3.7	79.6	5.6	0.0	0.0	3.7	5.6	1.9	0.0
TL (1,455)	9.8	0.5	74.8	0.3	3.3	0.8	7.4	2.7	0.3
NTL (1,288)	6.1	0.3	54.1	2.7	5.4	0.2	22.9	7.8	0.5
PD (1,082)	0.7	0.0	6.0	0.4	84.3	2.2	1.6	1.3	3.5

AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; PD = peritoneal dialysis; LTFU = lost to follow up

London Barts 61.5%). The end point of achieving definitive access (AVF or PD catheter), is being used here as a surrogate of the surgical pathway. However, the variation seen may not be solely or indeed largely down to the surgical assessment. Firstly, a detailed understanding of factors that prevent patients from being assessed for access in a timely fashion is required. Secondly, the variation may be due to organisational factors e.g. if physicians insert Tenckhoff catheters then patients starting on PD may not be referred to the surgeons and therefore those centres will show lower rates of surgical assessment for AVF in the audit.

In the 2014 audit returns, a greater proportion of patients who received surgical assessment at least three months prior to commencing dialysis underwent open surgical insertion (48.8% vs. 34.7%) compared to those who did not (figure 11.13). This figure also provides evidence that the percutaneous PD catheter insertion technique is utilised where surgeons have not seen the patient, since it is surgeon independent.

Figure 11.14 demonstrates a strong relationship between being assessed by a surgeon at least three months before starting dialysis and the likelihood of starting with an AVF. This relationship was much stronger than that between surgical assessment and method of PD catheter placement. This suggests that the role of surgical assessment was more important in relation to AVF placement. Of those assessed by a surgeon at least three months prior to starting dialysis, 71.4% started dialysis with an AVF whereas of those who were not seen by a surgeon only 10.8% did.

Dialysis access at three months after starting RRT

The type of access used three months after starting dialysis gives an important insight into the responsiveness of the access formation pathway. Table 11.4 expresses the proportion of patients still dialysing using a particular form of access as a percentage of the access

they originally started dialysis with. For example, 88.4% of patients starting dialysis with an AVF were still using this at three months and 84.3% of patients starting on PD remained on this modality at three months. Of patients starting dialysis via a tunnelled line, the majority continued to use this form of access at three months (74.8%) and of 1,288 patients who commenced dialysis via a non-tunnelled line, 697 (54.1%) were dialysing through a tunnelled line at three months with a significant proportion 22.9% ($n = 295$) dying within three months. This data suggests that obtaining definitive access for HD (AVF/AVG) within three months of starting treatment continues to remain a big challenge.

Figure 11.15 demonstrates the differences in access outcomes stratified by centre. By three months, 33.2% of patients were dialysing using an AVF (range 12.8% London West to 55.6% Doncaster); 1.3% were using an AVG (0% many sites to 10.1% Nottingham); 41.2% tunnelled lines (8.2% York to 79.2% London West); 1.0% non-tunnelled lines; 22.1% were using a PD catheter (0% Leicester to 51.6% Carlisle) and 1.2% transplanted (0% many sites to 8.1% Leeds).

Access at three months in patients referred to renal centres <90 days before starting dialysis was analysed. Only 45 centres were included in this analysis. The majority (71.9%) of patients presenting late were being dialysed using tunnelled lines at three months after dialysis start (figure 11.16). The between centre range was from 21.4% in York to 98.9% at London West. Amongst patients presenting late, only 9.9% were using an AVF at three months (individual centres ranged from 0% in 14 centres to 42.9% in York). PD catheters were used by 15.5% of patients (range 0% in six centres to 44.4% in Nottingham). It is interesting to note that in some centres late presentation was not always associated with a temporary access such as a TL or a NTL, for instance in York despite presenting late, 42.9% of their HD patients were dialysing via AVF at three months.

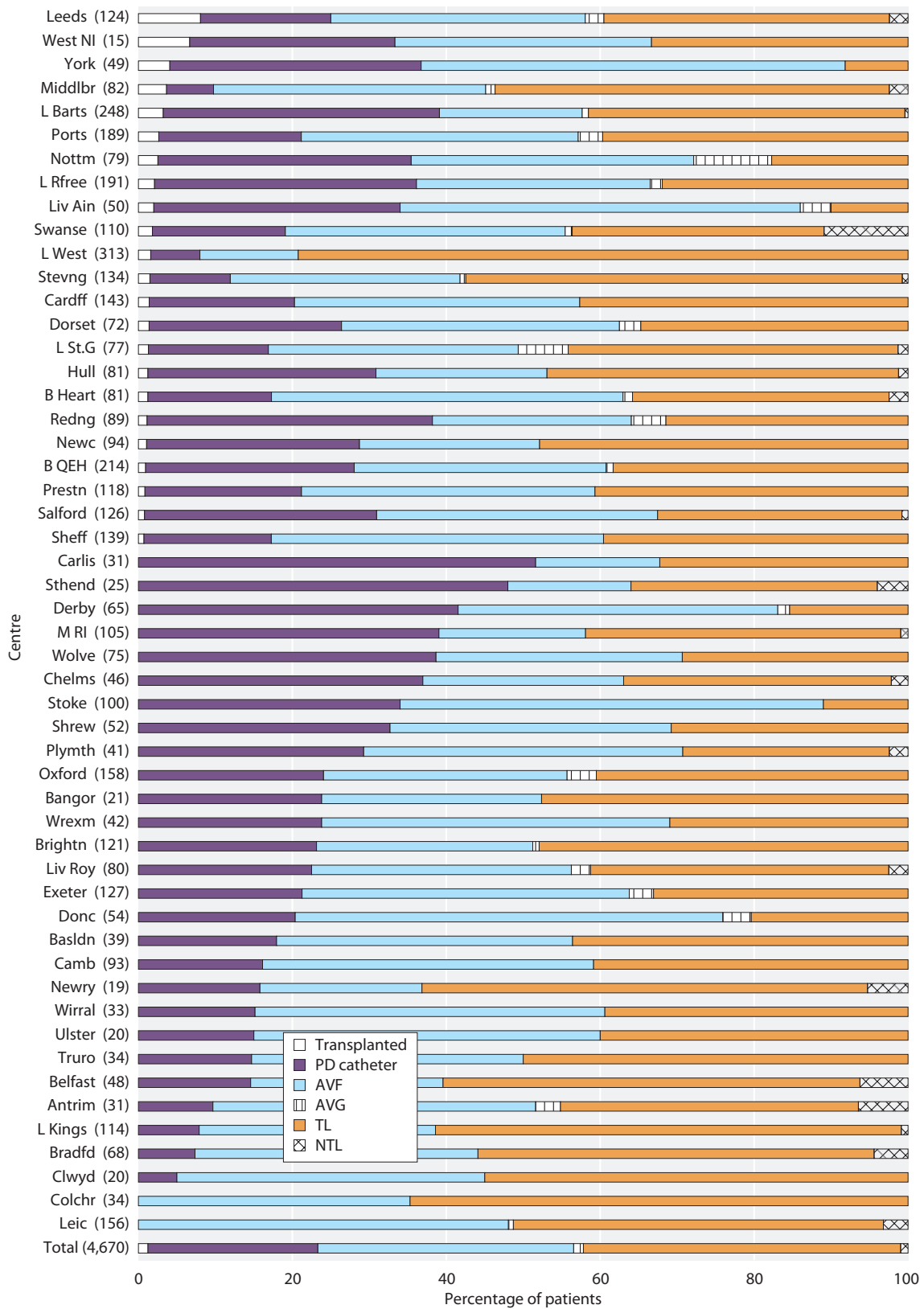


Fig. 11.15. Type of dialysis access at three months stratified by centre
 AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; PD = peritoneal dialysis

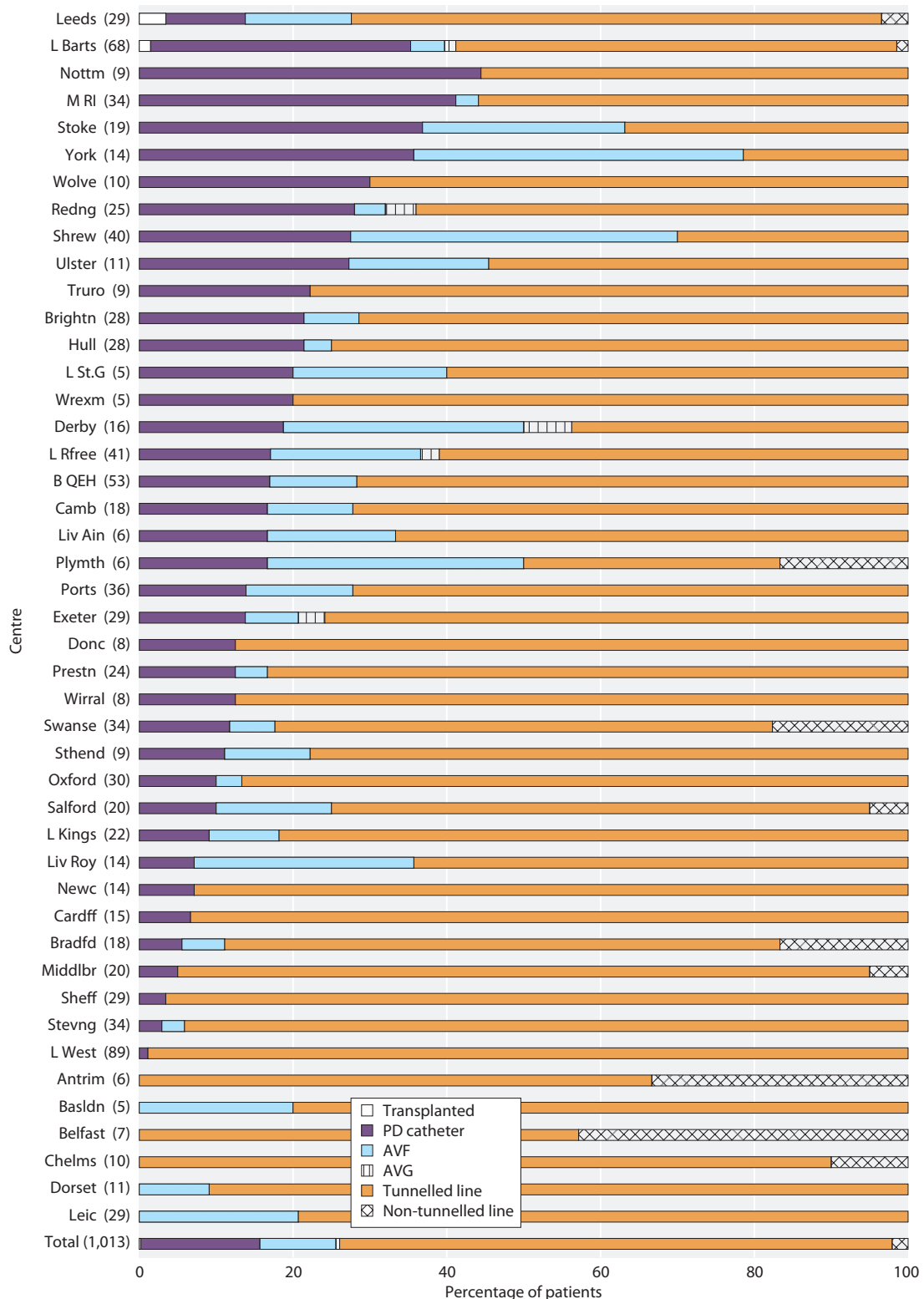


Fig. 11.16. Type of dialysis access at three months in patients referred to renal services less than 90 days before starting dialysis, stratified by centre

Centres reporting on fewer than five patients were excluded

PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft

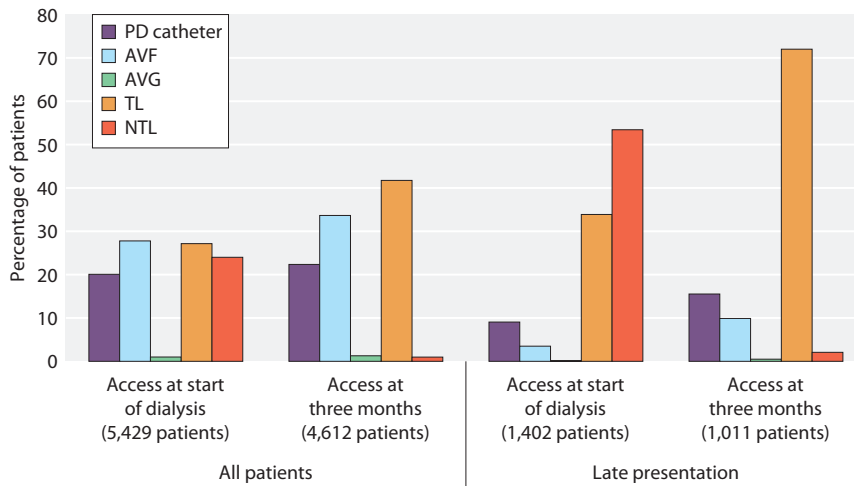


Fig. 11.17. Access in use at start of dialysis and after three months for those still on dialysis, displayed for all patients and also restricted to patients presenting late PD = peritoneal dialysis; AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line

Whilst the reported numbers of patients presenting late tended to be low in many centres, it will be interesting to examine the practice pattern that underlies these data.

Figure 11.17 shows access in use at start of dialysis and at three months after commencing dialysis, displayed for all patients and also restricted to patients presenting late. There was a small increase in the proportion of patients dialysing with an AVF at three months for all patients, 27.8% to 33.7%. In the late presenters, patients dialysing with an AVF, increased from 3.5% at dialysis start to 9.9% at three months. Use of a tunnelled line increased at three months in all patients by 14.6% and in late presenters by 38.1%, which is a reflection of conversion from NTL to TL. PD catheter use saw only a small increase for all patients (2.3%) and for late presenters (6.5%).

Figure 11.18 shows the percentage access type at dialysis start from 2012 to 2014 with the analysis restricted to patients referred at least 90 days prior to

start of dialysis and patients who have not been transplanted by three months. The use of an AV fistula as the incident access dropped by 1.7% between 2012 and 2014 despite the publication of the Renal Association guidelines in 2011. Reported use of AV graft, tunnelled line, non-tunnelled line and peritoneal dialysis catheter has been fairly static over the three-year period.

Prevalent access

Nine centres did not submit prevalent numbers and six centres were excluded from the analysis as the reported prevalent access numbers did not match with the number of prevalent patients at each of the centres in the UKRR database.

The Renal Association guidelines on vascular access for haemodialysis recommends 85% of all prevalent patients on haemodialysis should dialyse using an AV fistula. Only seven of the 38 centres (Birmingham Heartlands,

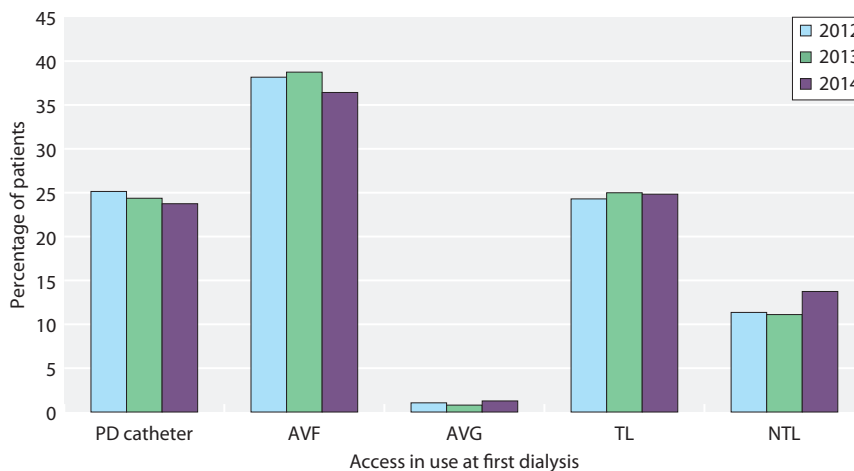


Fig. 11.18. Percentage trend in incident dialysis access use at first dialysis PD = peritoneal dialysis catheter; AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line

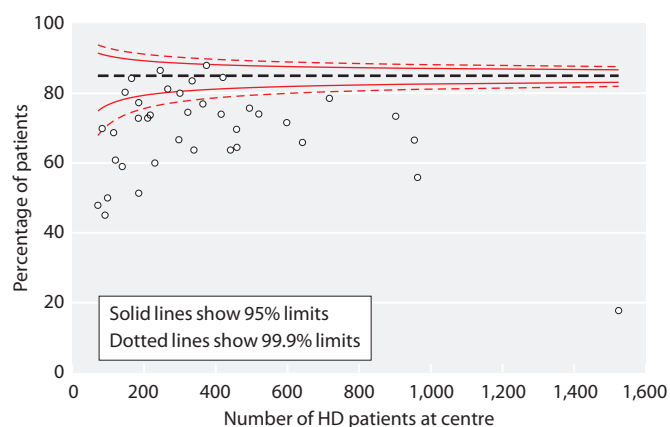


Fig. 11.19. Funnel plot of the percentage of prevalent HD patients dialysing using an AVF

Derby, Stoke, Truro, York, Dorset, Salford) reporting prevalent data were achieving close to the RA recommendations. Twenty-eight centres were more than three standard deviations and three centres were more than two standard deviations below this target (figure 11.19). The significant variation between centres could be possibly due to factors in the vascular access pathway (system factors) which can be modified. Equally, there has to be some caution exercised in interpreting these results due to non-adjustment for any of the measured and unmeasured confounders (patient related factors) and warrants further analysis.

Figure 11.20 shows type of dialysis access in prevalent patients by centre. Variations were apparent between centres when considering prevalent patients with an AV fistula, ranging from less than 20% (London West) to over 65% in 13 centres. One centre had over 70% of prevalent patients on a tunnelled or non-tunnelled line (London West) with two centres (Birmingham Heartlands, Derby) at the other end of the spectrum with less than 10% of patients. The use of an AV graft was between 0% and 10.8% with 35 centres opting to use this.

Use of a PD catheter in prevalent patients varied between 27.0% (Carlisle, Derby) and 3.7% at Middlesbrough (Colchester does not have any PD patients).

Figure 11.21 shows the percentage of prevalent dialysis patients with each access type, by year. The percentage of prevalent patients on PD has shown a decline in trend, in the three years of the combined access audit with use of PD declining at 1% every year. The observed fall in AVF use might be due to a different cohort of centres having contributed to the prevalent access data. For example, a large centre such as London West which has 82.2% (1252/1524) of its haemodialysis patients that

dialyse via a catheter could be potentially skewing the data.

Access failure

Figure 11.22 shows comparative access failure for the different access types within three months of start. Access failure was defined as a documented date of failure/discontinuation recorded within three months of starting dialysis unless a centre comment indicated that it was a planned discontinuation. However there were deficiencies in the way that failure was recorded in this audit. Failure rates were generally higher in the peritoneal dialysis group with fairly similar failure rates between open surgical and percutaneous at 10%. Failure rates were generally around 5% for AVF and AVG demonstrating its superiority with failure rates for tunnelled line similar to PD (close to 10%).

The number of HD access failures reported were small. This may reflect poor local documentation procedures and these data are not included in this report.

Again, numbers of PD access failure were small and hence drawing any inferences is difficult. However, it can be seen from figure 11.23 that peritoneoscopic technique had one documented failure within three months. As previously mentioned, percutaneous technique had fairly comparable failure rates compared to either open surgical or laparoscopic technique. There was no evidence to suggest differences in failure rates due to leaks or hernia between the different insertion techniques. Twelve out of 941 (1.3%) PD patients were reported as failure of PD due to infection with no obvious difference in infection rates between the different PD insertion techniques. This was significantly lower than the national target of 5%.

2013 PD access audit one-year follow-up

Centres who reported on PD patients in the 2013 vascular and peritoneal access audits were asked to complete a one year follow up of their PD patients. The additional information requested was the date of catheter failure, the reason for catheter failure, the number of catheters used during the year, and the modality in use at one year after starting PD. Of 57 centres who reported data on PD patients in 2013, 32 completed the one year follow up, returning data on 753 (73.7%) patients. Plymouth was excluded from analysis due to over 50% missing data. The analysis therefore included 719 patients from 31 centres. In these patients, 402 (55.9%) were still on PD at one year with 87% of these (280/322) still on their first catheter.

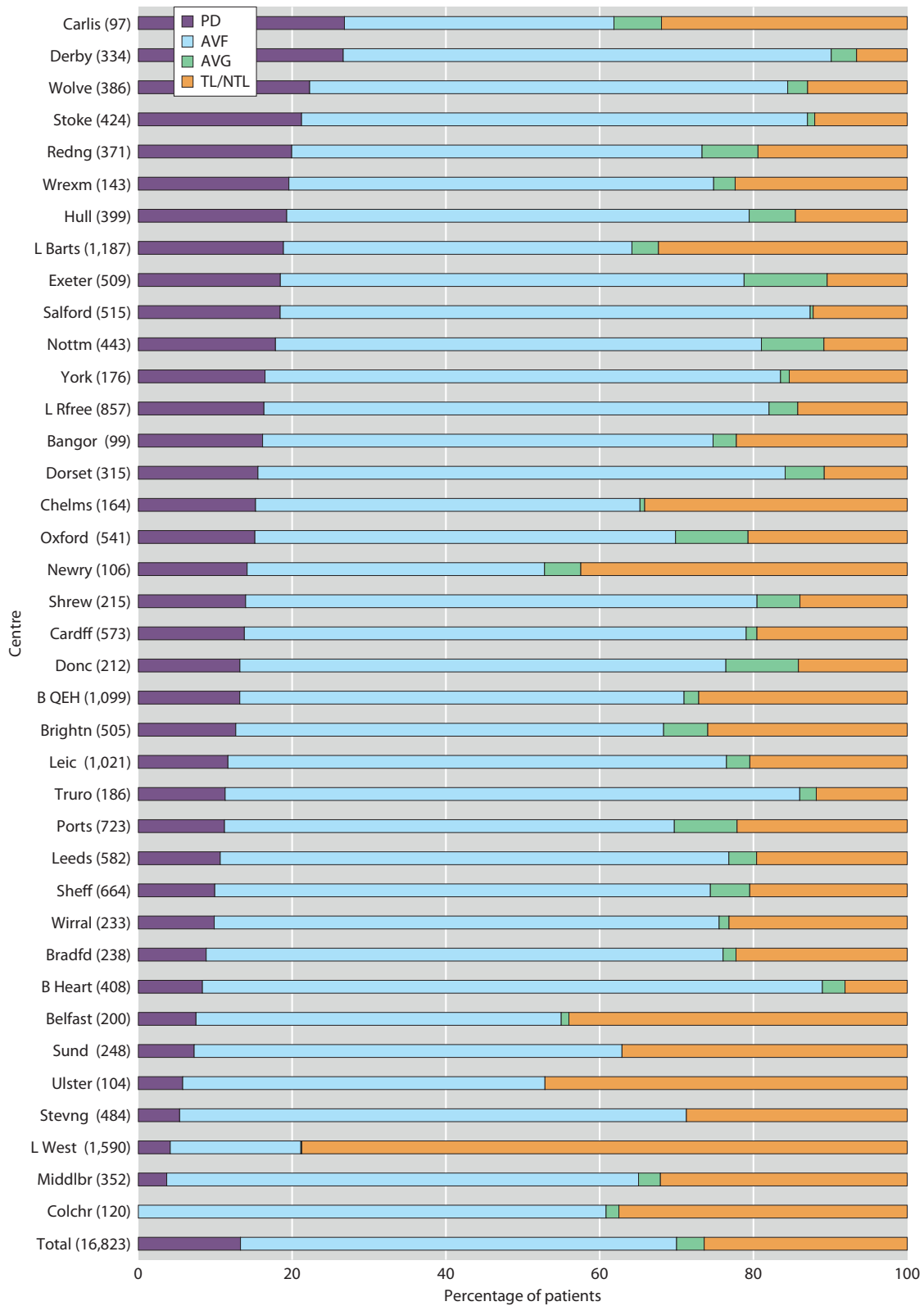


Fig. 11.20. Type of dialysis access in prevalent patients stratified by centre
 Centres are ordered by the percentage of patients starting dialysis with a PD catheter
 AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; PD = peritoneal dialysis

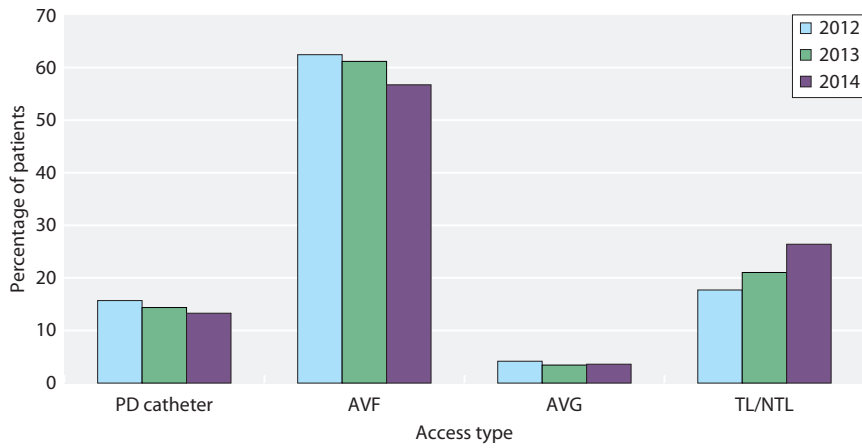


Fig. 11.21. Percentage of prevalent dialysis patients with each access type, by year
 PD = peritoneal dialysis catheter;
 AVF = arteriovenous fistula;
 AVG = arteriovenous graft; TL = tunnelled line;
 NTL = non-tunnelled line

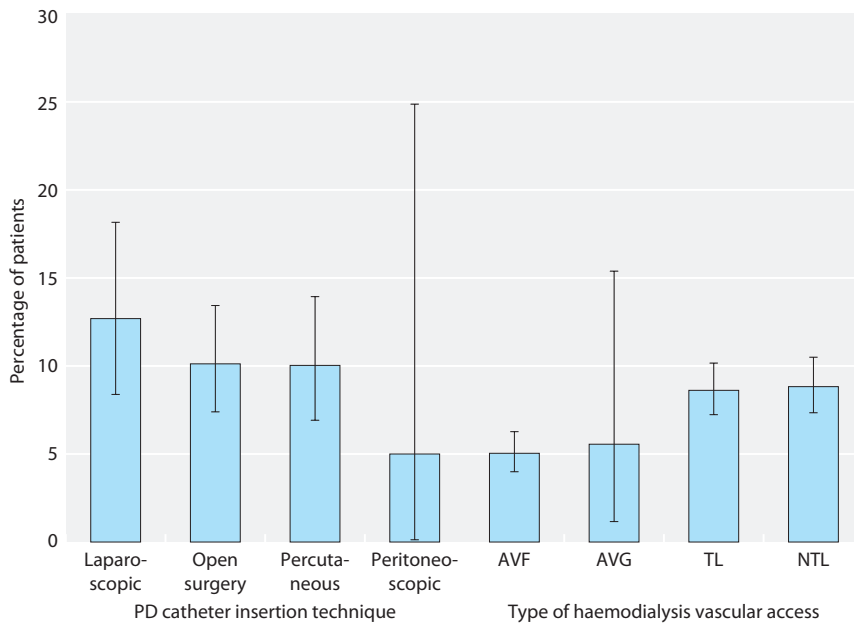


Fig. 11.22. Percentage of patients experiencing failure of first access within three months, by type of first access
 AVF = arteriovenous fistula; AVG = arteriovenous graft; TL = tunnelled line; NTL = non-tunnelled line; PD = peritoneal dialysis catheter

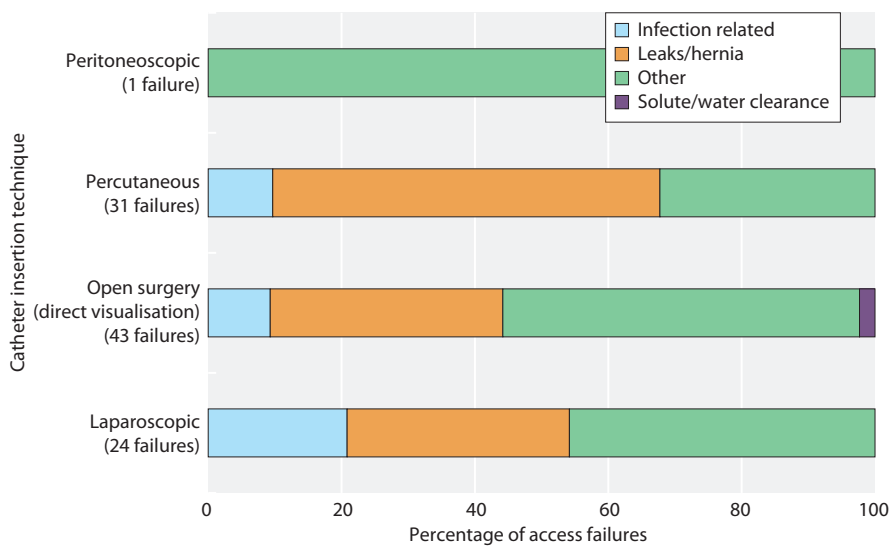


Fig. 11.23. Reported causes of peritoneal dialysis access failure within three months stratified by catheter insertion technique

There was a significant variation in PD technique survival with the majority of centres ($n = 21$) maintaining $\geq 50\%$ of patients on PD at one year, however only one centre maintained $\geq 80\%$ on PD at one year (York). Although in general where it is particularly low, transplantation seems to be the main beneficiary with variation between centres ranging from 0% to 42.9%. Having censored for transplantation the proportion of patients who were on PD was 66.1% with 28 centres maintaining $\geq 50\%$ of patients on PD at one year. Modality change to haemodialysis varied from 0% (Middleborough, Swansea) to $>25\%$ (Birmingham Heartlands, Sheffield, Doncaster, Dorset, Sunderland, Leeds) (figure 11.24).

Causes of PD access failure within one year of starting on PD were analysed. There was no evidence to suggest a difference in the PD failure rates when analysed by percutaneous and all of the three other techniques combined. The reported numbers were too low to draw firm conclusions ($n = 152$). Unsurprisingly the principal causes of catheter failure were mechanical or infection related (figure 11.25).

Figure 11.26. is a funnel plot which graphically displays the unadjusted percentage of PD patients experiencing a catheter failure within one year of commencement of RRT across multiple renal centres. PD catheter failure was censored for transplantation, elective transfer to HD or death. The results have to be cautiously interpreted due to the extent of and variation in missing data, small numbers of patients in some centres and non-adjustment for any patient related factors.

Of the centres for which data were available ($n = 27$), no outlier centres were identified with failure rates above

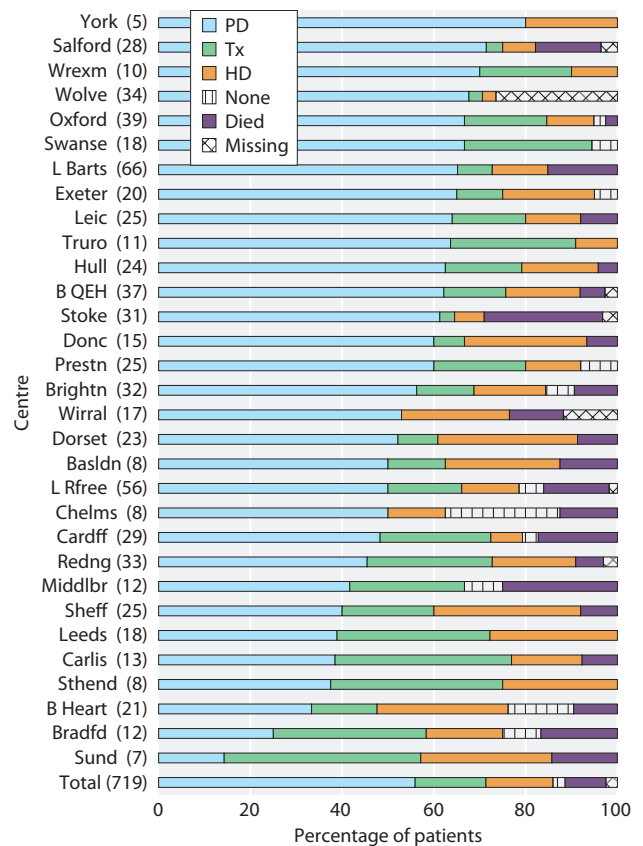


Fig. 11.24. Modality at one year after commencing PD, by centre PD = peritoneal dialysis catheter; Tx = transplanted; HD = haemodialysis

the upper 95% 'alert' or 99.9% 'alarm' limits for PD catheter failures. Two renal centres reported one-year catheter failure rate below the 99% control limit (Truro, Bradford). The mean one-year catheter failure rate was

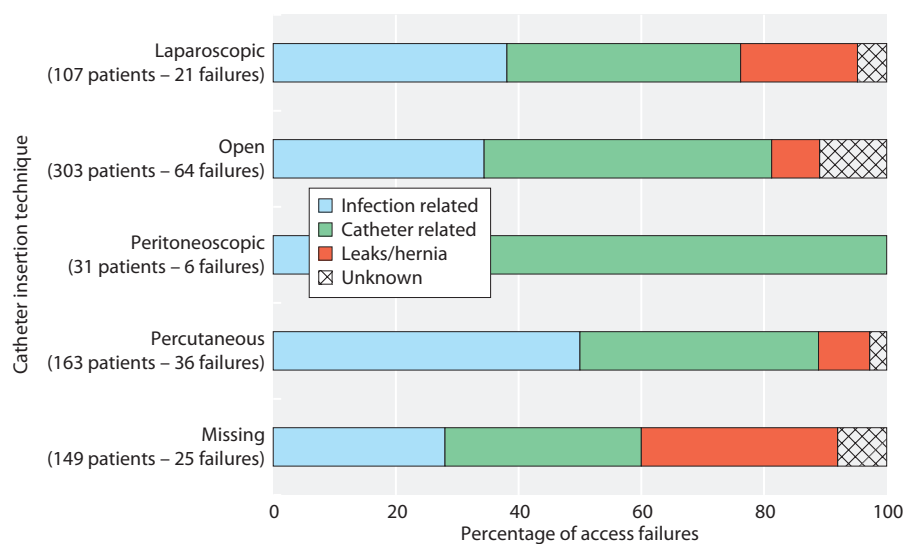


Fig. 11.25. Causes of PD access failure within one year of PD catheter insertion

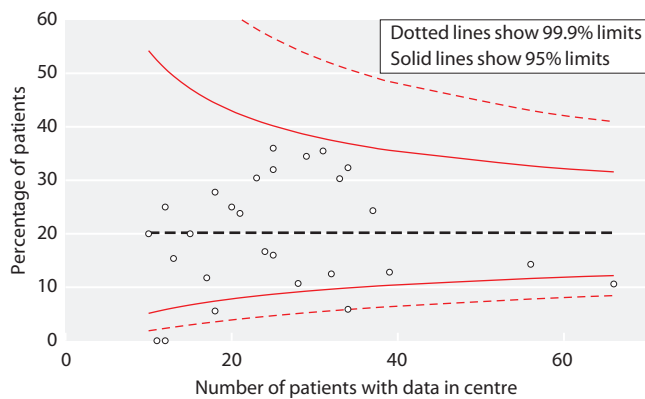


Fig. 11.26. Funnel plot of the percentage of PD catheter failures within one year of insertion

20.2% which all but met the rate recommended in the guidelines issued by the RA (20%).

Conclusions

This third multisite dialysis access audit from England, Wales and Northern Ireland has provided important information regarding the variation in access provision and failure. Data collection is still not optimal, as missing data across a range of fields exist.

Haemodialysis catheter (TL, NTL) use continued to remain high in incident and prevalent haemodialysis patients. In incident dialysis patients, tunnelled lines were used in approximately 41% of patients three months' post dialysis start and this figure was higher for patients presenting late. Particularly in the late presenters, this report highlights an opportunity for use of percutaneous PD access technique in order to increase the uptake of PD and reduce catheter use.

This audit has shown that age had a bigger impact on the type of vascular access but not on PD access with older patients more likely to start dialysis with an AVF and less likely using a tunnelled line. This data is contrary to what has been published in the literature with the HEMO study showing a lower likelihood of having a fistula in the elderly (37.5% in <65 years vs. 27.8% in >65 years; OR 0.64, 95% CI, 0.52 to 0.79) [3]. The distribution of patients starting RRT in the 2014 incident cohort was 46.6% vs. 53.4% in the under 65's and over 65's respectively when compared to 64.7% vs. 35.3% in the HEMO study. Hence the above observation in the audit could be down to elderly patients more likely to start RRT on haemodialysis via an AVF when compared

to the younger patients who have a higher likelihood of starting with a transplant and may use haemodialysis via a catheter as a bridge to transplantation. Patients with polycystic kidney disease were more likely to start HD with an AVF and demonstrate the effect of PKD as a marker for planned care, as these patients are often known to renal services for many years before dialysis is required.

An interesting finding from the vascular access audit over the last couple of years has been the relationship between BMI and AVF rates. The 2013 and 2014 audits have shown that there were a higher proportion of patients starting haemodialysis on an AVF in the BMI >30 category when compared to the BMI ≤30 group with a difference of 12% between the two groups (audit 2013: 54.9% vs. 42.6%; audit 2014: 48.9% vs. 36.8%) [4]. There has been conflicting evidence in the literature, with the HEMO study showing a lower likelihood of having a fistula (adjusted odds ratio 0.76, 95% CI, 0.65 to 0.87) [3]. On the other hand, recent studies have shown that obesity may not be associated with increased failure rates except at the highest BMI quartile and with the use of peri-operative vein mapping similar success may be achieved in the higher BMI group [5, 6].

Several guideline statements such as the US Fistula First Breakthrough Initiative, NKF-KDOQI (National Kidney Foundation Kidney Disease Outcomes Quality Initiative), and European Renal Best Practice (ERBP) Guidelines strongly promote the use of arteriovenous fistulae (AVF) and discourage the use of catheters (CVC); with UK Renal Association recommendations for a centre to achieve AVF in >65% of the incident patients and over 85% in prevalent patients [1, 7–9]. A few centres have demonstrated that these targets are indeed achievable; the majority of these centres have implemented local quality improvement projects directed at the vascular access pathway. The differences in AVF use in both incident and prevalent patients may be due to variation in local processes for access planning and delivery which needs further investigation.

This audit has highlighted that there has been a fall in the AVF rates both in incident and prevalent patients. There is also a significant disparity between the data from this audit and the DOPPS data with regards to prevalent haemodialysis access, with audit data showing AVF 65.4%, AVG 4.1% and catheter 30.5% respectively when compared to the DOPPS 4 data for the UK showing AVF 75%, AVG 6.6% and catheter 18.5% [10–12]. The vascular access tariff returns have also suggested a AVF/AVG rate of approximately 75%. The reason for

this disparity is likely to be due to sampling errors. Firstly, DOPPS only samples 20 UK centres and secondly, due to a slightly different group of centres contributing to the data in this year's and in previous years' data UKRR returns.

The latest Renal Association vascular access guidelines published in May 2015 reduced the targets to 60% of all incident patients commencing planned haemodialysis via AVF/AVG and 80% of all prevalent dialysis patients should dialyse via definitive access AVF/AVG/PD [13]. The reduction in targets were intended to encourage more centres to dialyse their patients using definitive access rather than to make it easier for the centres to achieve the new targets. These targets have not been used in the funnel plots since they were published in the period not covered by the report. Despite the revised targets most renal centres continued to fall significantly below the recommendations. There needs to be a consolidated effort from all specialties that are involved with provision of vascular access if the vascular access standards are to be achieved.

This audit has shown that in many centres percutaneous insertion of PD catheters is not used at all or is underutilised with 42% of the centres using this technique. However, in those centres using the physician led percutaneous insertion technique, 68% of them had over a fifth of their incident patients starting on PD. The audit data has also shown that patients who were first seen by a nephrologist <90 days before starting RRT, were more likely to undergo percutaneous insertion when compared to patients who were known between 90–365 days and >365 days. Therefore, some centres that are unable to place PD access in their unplanned starts probably resort to TL use, clearly this pathway is unresponsive and presents an ideal opportunity for a percutaneous initiative in order to increase PD uptake. Centres with a successful percutaneous PD pathway (Derby, Stoke, Southend, Wolverhampton), were able to achieve less than 40% catheter use (TL/NTL) in their incident patients when compared to a national average of 51%. Therefore, in centres with low PD penetrance a successful percutaneous pathway at those centres might have a big impact on PD uptake and reduce TL use. Another important point noted in this audit is that many centres rely only on one technique, usually a general surgical approach, which may limit responsiveness to PD. Several studies have demonstrated equivalent outcomes between percutaneous and surgical insertion [14–16]. Hence, the use of the percutaneous technique pathway whilst being safe, might have a better impact

on achieving responsive PD access service. The work of Castledine et al has shown that in the UK, PD access use is multifactorial and depends not only on the ease of PD catheter placement but also individual patient characteristics and is also associated with modifiable centre factors [17]. Therefore, improving the ease of PD catheter placement via implementation of percutaneous insertion technique in more centres might help to get over the first hurdle towards improving the uptake of PD.

The audit has shown that without surgical assessment, patients are more likely to require temporary haemodialysis access such as a tunnelled or non-tunnelled dialysis catheter. Timely surgical assessment is a key component of the clinical pathway to fistula placement which usually leads to a successful procedure followed by successful cannulation. The other improvements identified by the DOPPS practice patterns were better prevalent AVF rates, better skilled surgeons, quicker referral to operation time and earlier cannulation [12, 18]. The relationship between surgical assessment and AVF formation was very different from that of PD catheter placement. It is quite possible that the time required to plan PD catheter placement is shorter because there are fewer steps on the PD pathway compared to that required for AVF formation. For instance, the need for vein mapping may influence the timing of AVF placement. Many of the centres that are not able to arrange timely surgical review resort to TL, this presents an opportunity to recommend percutaneous PD access to avoid complications related to the use of haemodialysis catheters.

This audit has also shown that both AVF and the PD catheter offer similar sustainability in terms of access at three months. Percutaneous PD catheter technique had similar failure rates to the other techniques combined and hence is a recommendable technique that should be better exploited.

Several DOPPS studies looked into understanding the variation in provision of vascular access. In these studies, time to surgery, cannulation and willingness to take on more difficult cases came out as very powerful factors [12, 19]. Similarly, the UKRR needs to firstly consider, a survey of the practice patterns and staffing for provision of vascular and PD access, in all the renal centres to explore the reason behind the wide variation in haemodialysis access provision between centres which could lead to potential improvements in access service provision. Secondly, using statistical techniques such as Instrument Variable (IV) analysis to explore variations in centre level survival stratified by AVF rates at the

centres with adjustments made for the captured practice patterns at the centre along with comorbidity, ethnicity, and deprivation. This approach is the subject of the UK PD Catheter Study (UKCRN ID 17940) [20].

Similarly, it would be valuable to undertake a case study exploring the role of percutaneous PD catheter insertion for primary access comparing high performing with low performing centres to understand differences in pathways of care. This presents a quality improvement opportunity in line with recommendations from CG125 (NICE technology appraisal) with the potential to increase PD uptake and reduce TL use with beneficial effects on MSSA bacteraemia rates and cost.

In summary, 100 percent coverage and better data returns in the subsequent audits from all renal centres

is needed. There were still significant variations between centres in provision of dialysis access in patients with established renal failure. Further work is needed to explore the reasons behind these variations in order to define the best practice.

Acknowledgement

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Conflicts of interest: the authors declare no conflicts of interest

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