COMPARISON OF EARLY MECHANICAL AND INFECTIVE COMPLICATIONS IN FIRST TIME BLIND, BEDSIDE, MIDLINE PERCUTANEOUS TENCKHOFF CATHETER INSERTION WITH ULTRA-SHORT BREAK-IN PERIOD IN DIABETICS AND NON-DIABETICS: SETTING NEW STANDARDS

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◆ **Background:** There are no large studies that have examined ultra-short break-in period with a blind, bedside, midline approach to Tenckhoff catheter insertion.

◆ **Methods:** Observational cohort study of 245 consecutive adult patients who underwent percutaneous catheter insertion for chronic peritoneal dialysis (PD) at our center from January 2009 to December 2013. There were 132 (53.9%) diabetics and 113 (46.1%) non-diabetics in the cohort.

◆ **Results:** The mean break-in period for the percutaneous group was 2.68 ± 2.6 days. There were significantly more males among the diabetics (103 [78%] vs 66 [58.4%], $p = 0.001$). Diabetics had a significantly higher body mass index (BMI) (23.9 ± 3.7 kg/m² vs 22.2 ± 4 kg/m², $p < 0.001$) and lower serum albumin (33.1 ± 6.3 g/L vs 37 ± 6 g/L, $p < 0.001$) compared with non-diabetics. Poor catheter outflow was present in 6 (4.5%) diabetics and 16 (14.2%) non-diabetics ($p = 0.009$). Catheter migration was also significantly more common in the non-diabetic group (11 [9.7%] vs 2 [1.5%], $p = 0.004$). Primary catheter non-function was present in 17 (15%) of the non-diabetics and in 7 (5.3%) of the diabetics ($p = 0.01$). There were no mortality or major non-procedural complications during the catheter insertions. Among patients with 1 year of follow-up data, catheter survival (93/102 [91.2%] vs 71/82 [86.6%], $p = 0.32$) and technique survival (93/102 [91.2%] vs 70/82 [85.4%], $p = 0.22$) at 1 year was comparable between diabetics and non-diabetics, respectively.

◆ **Conclusions:** Percutaneous catheter insertion by practicing nephrologists provides a short break-in period with very low mechanical and infective complications. Non-diabetic status emerged as a significant risk factor for primary catheter non-function presumed to be due to more patients with lower BMI and thus smaller abdominal cavities. This is the first report that systematically compares diabetic and non-diabetic patients.

Safe and reliable access to the peritoneal cavity is of prime importance in chronic peritoneal dialysis (PD). The laparoscopic and peritoneoscopic techniques performed by surgeons have gained popularity over the blind, percutaneous technique due to concerns over procedural complications (1,2). However, it must be emphasized that the latter bedside technique carries several potential advantages, such as avoiding general anesthesia, shorter waiting periods, smaller incision sizes, shorter hospitalization time, and lesser cost, especially in resource-constrained settings (3,4). Another potential advantage of the percutaneous technique is the possibility of a shorter break-in period. A few recent studies have shown encouraging results, but were hampered by small numbers, potentially limiting the generalization of their results (4–6). In this report we describe the outcomes of blind, bedside midline, percutaneous Tenckhoff catheter insertion and compare diabetic and non-diabetic groups.

MATERIALS AND METHODS

This was an observational cohort study of patients initiated on chronic PD at Christian Medical College, Vellore, the largest private tertiary care center in South India, from January 2009 to December 2013. The study was designed, implemented, and reported in accordance with ICH Guidelines for Good Clinical Practice and the Helsinki Declaration 1975, as revised in 2000. The protocol was approved by the institutional review board and ethics committee. The article was prepared in accordance with the STROBE guidelines for observational studies (7). All consecutive adult patients (> 18 years) who underwent PD catheter insertion at our center were included, and follow-up data were collected from medical records until 31 December 2013.

The patients were fully educated about PD including exchange technique and catheter care. Informed consent was obtained prior to the procedure. Those with a past history of severe peritonitis, midline laparotomy scars, hernias, suspected adhesions and morbid obesity were referred for open surgical insertion, at the treating physician's discretion. Previous hysterectomy, cholecystectomy, or appendectomy was not considered a contraindication for percutaneous insertion (8). The double-cuffed, swan-neck Tenckhoff straight catheter (Quinton Instrument Company, Seattle, WA, USA) was used for

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all. Intravenous vancomycin 1 g and pre-medication with intramuscular pethidine (25 – 50 mg) and promethazine (25 mg) were given prior to the procedure. All patients were catheterized to drain the urinary bladder to prevent accidental injury, and the catheter was removed immediately post procedure. All patients had bowel preparation with soap and water enema the previous evening.

The blind, bedside percutaneous technique was performed using the Seldinger technique (9) under local anesthesia (2% lignocaine) in the dialysis unit procedure room under strict asepsis. All catheters were inserted by consultant nephrologists or senior trainees under direct supervision. A 0.5- to 1.0-cm incision was made below the umbilicus in the midline, with blunt dissection until the linea alba (supplementary file). A Veress needle was inserted into the peritoneal cavity, which was filled with 1.5 to 2.0 L of saline. A 0.035-inch guide wire was advanced into the abdomen through the Veress needle, following which a dilator and peel-away sheath assembly was threaded over the wire into the abdominal cavity. The wire and the dilator were removed and the Tenckhoff catheter was advanced through the sheath until the inner cuff was located just above the linea alba. A subcutaneous tunnel was created to the selected exit site 2 cm distal to the outer cuff (supplementary file). The midline incision site was closed in layers, and the exit site covered with an adherent dressing. Diathermy was not used during the percutaneous procedure. Catheter function was checked by instilling 2 L heparinized PD fluid and subsequently ensuring adequate drainage. Heparinized flushing was continued if there was any bloody drain until the fluid cleared. The catheter was flushed the following day and low-volume supine exchanges started within 2 days depending on the degree of dissection. Any dialysate leak was treated conservatively with resting the peritoneum for 1 – 2 weeks followed by starting low-volume supine exchanges.

A break-in period of 2 to 3 days was followed for percutaneously inserted catheters. Weekend insertions had longer break-in periods (3 – 4 days) due to staffing shortage. Mupirocin prophylaxis for exit-site dressing was advised in all patients, and stool softeners were administered to avoid constipation.

OUTCOME VARIABLES

1. Early mechanical complications within 4 weeks of catheter insertion were divided into (a) poor outflow, defined by the presence of a low flow dialysate rate (less than 500 mL flow in 5 minutes during the infusion and/or draining of dialysate solution) for any reason and not resolved with conservative management including laxatives (10); (b) failed insertion, defined as inability to insert catheter by percutaneous method; (c) dialysate leak, defined as dialysate fluid draining from the exit site or central wound; (d) visceral injury; (e) bleeding complications further sub-divided into bleeding from exit site or rectus hematoma; and (f) primary catheter non-function, defined as catheter reinsertion/repositioning or catheter removal

and switching of dialysis modality. Failed insertions were not counted as primary catheter non-function as there was no attempt at intra-abdominal placement of catheter (Table 2). Wherever feasible, the reasons for poor outflow were determined and recorded.

2. Early infective complications were peritonitis, exit-site or tunnel infection as defined by the International Society for Peritoneal Dialysis (ISPD) guidelines occurring within 4 weeks of catheter insertion (11).
3. End-points studied were: (a) mortality, (b) catheter survival at 1 year, (c) technique survival at 1 year, (d) PD-related infection episodes per patient-year.

DATA SOURCE AND STATISTICAL METHODS

Demographic, clinical, and laboratory data were collected from the centralized hospital information processing system and from individual patient records. The number of consecutive cases that met the inclusion criteria within the study period (January 2009 – December 2013) determined the sample size. Frequency distributions were provided for categorical variables. Continuous variables were described using mean, standard deviation (SD), minimum, maximum, median, and interquartile range (IQR) based on the distribution. Two independent groups were compared using unpaired Student's *t*-test or Mann-Whitney U test for continuous variables, and chi-square test or Fisher's exact for categorical variables. Incidence of peritonitis was reported in number of episodes per patient-year. Univariate analyses and multivariable logistic regression were used to assess risk factors of primary catheter non-function. Two-sided $p < 0.05$ was considered statistically significant. Data analysis was carried out using SPSS 16.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

A total of 245 patients were included in the study. There were 132 (53.9%) diabetics and 113 (46.1%) non-diabetics in the cohort.

Diabetic patients were older than non-diabetics (56.7 ± 8.5 vs 42.3 ± 14.5 , $p = 0.001$) (Table 1). There were significantly more males among diabetics than non-diabetics (103 [78%] vs 66 [58.4%], $p = 0.001$) (Table 1). Diabetics had significantly higher body mass index (BMI) (23.9 ± 3.7 kg/m² vs 22.2 ± 4 kg/m², $p < 0.001$) and lower serum albumin (33.1 ± 6.3 g/L vs 37 ± 6 g/L, $p < 0.001$) compared with non-diabetics (Table 1). Diabetic patients had more comorbidities than non-diabetics, as shown in Table 1. All insertions were first attempts. There were no mortality or major non-procedural complications during the catheter insertions.

The mean break-in period for the diabetic group was 2.5 ± 2.3 days (median 2; IQR 1 – 3) and for the non-diabetic group was 2.9 ± 3 days (median 2; IQR 1 – 3), $p = 0.98$. Early complications occurring within 4 weeks of PD catheter insertion are shown in Table 2. Poor catheter outflow was present in 6 (4.5%) diabetics and 16 (14.2%) non-diabetics ($p = 0.009$). Catheter

TABLE 1
Baseline Characteristics of Non-Diabetic and Diabetic Groups

Parameter	Non-diabetic N=113	Diabetic N=132	P value ^a
Age (years)	42.3±14.5	56.7 ± 8.5	<0.001
Male:Female	66:47	103:29	0.001
Weight (kg) ^b	56.6 ± 11.8	62.8 ± 10.9	<0.001
Body mass index (kg/m ²) ^c	22.2±4	23.9±3.7	<0.001
Serum albumin (g/L) ^d	37±6	33.1±6.3	<0.001
CKD-EPI eGFR (mL/min/1.73 m ²)	6.2±11.2	6.3±2.3 ^e	<0.001
Underlying renal diseases			
Diabetic nephropathy	0 (0%)	120 (90.9%)	<0.001
Glomerular diseases	27 (23.9%)	3 (2.3%)	<0.001
Interstitial diseases	9 (8%)	5 (3.8%)	0.16
Others	11 (9.7%)	2 (1.5%)	0.004
Unknown	65 (57.5%)	2 (1.5%)	<0.001
Comorbidities			
Hypertension	38 (33.6%)	98 (74.2%)	<0.001
Coronary artery disease	7 (6.2%)	35 (26.5%)	<0.001
Vascular access failures	16 (14.2%)	14 (10.6%)	0.40
Chronic liver disease	1 (0.9%)	3 (2.3%)	0.40
Blood-borne virus positivity	15 (13.3%)	15 (11.4%)	0.65
HCV-positive status	12 (10.6%)	3 (2.3%)	0.007
HBV-positive status	3 (2.7%)	4 (3%)	0.86
HIV-positive status	1 (0.9%)	10 (7.6%)	0.012
Right sided exit-site placement	2 (1.8%)	2 (1.5%)	0.88
Mean duration of follow-up (months)	14.5±13.8	14.9±12.2	0.39
Median duration of follow-up (months)	9 (IQR 4–23)	11 (IQR 5–22.75)	
Cumulative duration of follow-up (patient-years)	91	111	

CKD-EPI eGFR = chronic kidney disease epidemiology collaboration estimated glomerular filtrate rate; HCV = hepatitis C virus; HBV = hepatitis B virus; HIV = human immunodeficiency virus; IQR = interquartile range.

All values mean±SD or median with IQR or number with percentages.

^a Bold *p* values indicate *p*<0.05

^b N=237

^c N=234

^d N=241

^e N=131

migration was also significantly higher in the non-diabetic group (11 [9.7%] vs 2 [1.5%], *p* = 0.004). Catheter reinsertion/repositioning was significantly lower in the diabetic group (5 [3.8%]) than in the non-diabetic group (16 [14.2%]), *p* = 0.004. The reasons for catheter reinsertion/repositioning are given in Table 2.

Two (1.5%) in the diabetic group and 2 (1.8%) in the non-diabetic group were lost to follow-up. The outcomes comparing both groups are shown in Table 3.

Non-diabetic status emerged as a significant risk factor for primary catheter non-function in the multivariable logistic regression assessing pre-insertion factors (gender, age, BMI, diabetes) (odds ratio [OR] = 3.07, *p* = 0.037) (Table 4).

DISCUSSION

The indwelling peritoneal catheter was first developed by Henry Tenckhoff in 1968 and was placed using an open

surgical technique (12). The percutaneous technique of catheter placement was described as early as 1984 (13). We compared the blind, bedside, midline, percutaneous technique for PD catheter insertion between diabetics and non-diabetics in 245 patients. The proportion of diabetics and non-diabetics was comparable (53.9% vs 46.1%). The diabetic group had more men and higher BMI. The proportion of blood-borne virus-positive patients was 12.2% (30/245), reflecting effective utilization of resources. The expense saved in terms of major operating room use, anesthesia, personnel and cost of consumables is likely to be substantial. There was also money saved due to shorter break-in period and reduced hospital stay. This should be an important determinant in considering percutaneous catheter insertion as the preferred method in developing countries. Overall primary catheter non-function requiring manipulation or replacement or leading to technique failure was present only in 24 (9.8%) patients, but it was significantly higher among non-diabetics (Table 2). This

TABLE 2
Early Complications of Catheter Insertions in Non-Diabetics versus Diabetics

Early complications	Non-diabetic N=113	Diabetic N=132	P value	Comments
Failed catheter insertion	1 (0.9%)	1 (0.8%)	0.91	Neither patient cooperated and the catheters were inserted surgically
Poor outflow	16 (14.2%)	6 (4.5%)	0.009	
Catheter migration	11 (9.7%)	2 (1.5%)	0.004	One patient also had dialysate leak. Another was on anti-coagulation and also had rectus sheath hematoma. All had catheter reinsertion/repositioning.
Omental wrap	4 (1.6%)	1 (2.6%)	—	All but 1 patient in percutaneous group had catheter reinsertion/repositioning. One patient switched to hemodialysis as he was against catheter reinsertion/repositioning.
Catheter kink	0	2 (5.1%)	—	Both patients had catheter reinsertion/repositioning.
Catheter luminal clot	1 (0.4%)	0	—	This patient had catheter reinsertion.
Intra-abdominal adhesions	2 (0.8%)	0	0.14	Both patients had catheter reinsertion/repositioning.
Cause unidentified	2 (0.8%)	1 (2.6%)	—	All but 1 patient in percutaneous group had catheter reinsertion/repositioning. This patient was switched to hemodialysis elsewhere and catheter was removed.
Dialysate leak	4 (3.5%)	12 (9.1%)	0.08	All but 1 was managed conservatively with peritoneal rest. One patient in the percutaneous group had associated catheter migration and underwent reinsertion.
Visceral injury				
Mesenteric tear	1 (0.9%)	1 (0.8%)	0.91	One patient had catheter reinsertion and another was switched to hemodialysis.
Paralytic ileus	0 (0%)	0 (0%)	—	
Bleeding				
Exit-site bleeding	1 (0.9%)	0	0.28	This patient had thrombocytopenia and was managed conservatively.
Rectus sheath hematoma	1 (0.9%)	0	0.28	This patient was on anti-coagulation, had associated poor flow due to catheter migration and underwent reinsertion/repositioning.
Early peritonitis	0 (0%)	3 (2.3%)	0.11	All were diabetic and managed conservatively. One had a negative culture and the other 2 had <i>Pseudomonas</i> species and <i>Klebsiella</i> species in the peritoneal fluid culture, respectively.
Overall early mechanical complications	22 (19.5%)	18 (13.6%)	0.22	Excludes early peritonitis
Primary catheter non-function	17 (15%)	7 (5.3%)	0.01	Includes all cases of catheter repositioning/reinsertion, catheter removal and switching to hemodialysis. Excludes failed insertions.

was much less than the audit standard of 20% recommended by the ISPD (14). Chow *et al.* reported a low primary catheter failure rate of 2.8% in 250 patients using an open dissection technique (15). Danielsson and McCormick *et al.* have proposed a reasonable benchmark of < 10% primary catheter non-function within 4 weeks of insertion (16,17), similar to this study.

The incidence of overall mechanical complications in our study was 16.3% (40/245) and was comparable between diabetics and non-diabetics (Table 2). However, the incidence of dialysate leak was higher in the diabetic group compared with the non-diabetic group though not significant (Table 2). This can be explained by the higher BMI and thus greater abdominal obesity among diabetics. The dialysate leak rate of 6.5% in our

TABLE 3
Follow-Up Outcomes in Non-Diabetic versus Diabetic Groups

Outcomes	Non-diabetic N=113	Diabetic N=132	P value ^a
Lost to follow-up	2 (1.8%)	2 (1.5%)	0.88
Mortality	22 (19.8%)	46 (35.4%)	0.007
Renal transplant	15 (13.5%)	8 (6.2%)	0.053
Switched to hemodialysis ^b	15 (13.5%)	14 (10.8%)	0.51
Catheter survival at 1 year ^c	71 (86.6%)	93 (91.2%)	0.32
Technique survival at 1 year ^c	70 (85.4%)	93 (91.2%)	0.22
Peritoneal dialysis-related infection (episodes per patient year)	0.30	0.43	

^a Bold *p* values indicate *p*<0.05

^b Based on data from 111 patients in the non-diabetic and 130 patients in the diabetic group with status known at last follow-up.

^c Based on data from 82 patients in the non-diabetic and 102 patients in the diabetic group who had at least 1 year of follow-up data.

TABLE 4
Predictors of Primary Catheter Non-Function in Multivariable Regression

Baseline characteristics	Univariate analysis		P value	Multivariable logistic regression analysis		
	Primary catheter non-function Yes	No		OR	95% CI	P value
Age (yrs)	46±14.4	50.9±13.7	0.06			
Male:female (<i>n</i>)	16:8	153:68	0.80			
BMI (kg/m ²) ^a	23±5.2	23.3±4	0.28			
Non-diabetic status <i>n</i> (%)	17 (15%)	96 (85%)	0.011	3.072	(1.07–8.84)	0.037

OR = odds ratio; CI = confidence interval; BMI = body mass index.

^a N=245

study is comparable to that reported in literature varying from 2.6% to 22% (18–22).

Catheter migration occurred in 13 patients (5.3%) in our study. These rates are lower than those reported in previous studies, ranging from 7.6% to 24% (23–26). Catheter re-insertion was required in 21 patients (8.6%) and was significantly higher among non-diabetics. The most common cause for catheter re-insertion was poor outflow secondary to catheter migration. Similar catheter reinsertion rates have been reported in other studies (27). Since the non-diabetic group had a greater proportion of patients with lower BMI, we hypothesize that our technique of percutaneous insertion leads to more mechanical complications in individuals with smaller abdominal cavities. None of them developed bowel injury during catheter insertion in this study. This finding is reassuring because this technique is still not widely adopted by nephrologists due to fear of visceral injury. However, there were 2 instances of mesenteric hematoma (0.8%), 1 of which required emergency laparotomy. The rates of bowel injury and significant hemorrhage in this study are well within the rates (<1% each) stipulated by the ISPD (14).

Another potential advantage of the blind, percutaneous technique is the possibility of a shorter break-in period. Traditionally, a break-in period of 2 to 4 weeks is practiced for both surgical and percutaneous insertion techniques, to allow

for healing of the exit site and fibrosis around the external cuff to prevent infection (2,28,29). The use of a shorter break-in period in percutaneous insertion has been evaluated in a few small studies, with encouraging results. An earlier study from our center involving 34 patients had a break-in period of 3 days, and there were no exit-site or incision-site leaks (4). Sampathkumar *et al.* reported a break-in period of 4.6 ± 2.44 days using a paramedian approach (5). A study by Banli *et al.* involving 41 patients had a break-in period of 6 days with 2 pericatheter leaks (4.8%) (30). Jo *et al.* reported paramedian percutaneous catheter insertion with no break-in period in 51 patients (6). In surgically inserted patients, Yang *et al.* evaluated the possibility of an early break-in period. Time to PD initiation was shorter in the early group (2.0 ± 2.7 days) than in the late group (40.6 ± 42.8 days) (*p* < 0.001). Overall, 33 early-group (14.6%) and 11 late-group patients (13.1%) developed catheter-related complications within 6 months (*p* = 0.74) (31).

In our study, the mean break-in period was ultra short (2.68 ± 2.63 days). Despite this, the occurrence of dialysate leak rate of 6.5% in our study is among the lowest in the literature (18–22). Moreover, only 3 diabetic patients (1.2%) had early peritonitis, which was treated conservatively. This rate is much lower than that reported in other studies (18,20,32). These findings suggest that early PD initiation

following blind, bedside, midline percutaneous catheter insertion is safe and significantly decreases the time to initiation of PD. The use of prophylactic antibiotics (vancomycin in this study) decreases the rate of peritonitis but not exit-site and tunnel infection rates according to the meta-analyses done by Cochrane Collaboration (33). We had no early exit-site or early tunnel infections in this study. This is a new standard in early PD-related infections and suggests that the exit-site infection (< 5%) and peritonitis rates (< 5%) as recommended in the clinical practice guidelines of the ISPD can be obtained (14).

Catheter survival and technique survival at 1 year was comparable between diabetics and non-diabetics (Table 3). This is better than the minimum (80%) primary catheter patency at 1 year recommended by the ISPD (14). It is reported that mechanical catheter malfunction accounts for about 20% of technique failure and transfers to hemodialysis (17). The 1-year catheter survival and technique survival rates seen in our study are better than those reported by Henderson *et al.*, where the 6-month catheter survival was 83% in the percutaneous group and 59% in the surgical group (18).

To our knowledge, this is the largest study to date examining the safety of a short break-in period in patients undergoing a blind, midline approach of percutaneous PD catheter insertion using smaller skin incisions (0.5 – 1.0 cm) and without the use of diathermy. This finding has significant implications in patient management because early initiation of PD obviates the need for prolonged temporary hemodialysis with a venous catheter, thereby averting its associated risks. This should translate into a shorter hospital stay and decreased cost to the patient, as mentioned in a previous study from our center (4), where the cost savings on surgical charges alone was approximately USD 323 for each patient. Also, treating nephrologists can undertake the procedure with minimal training and procedure requirements.

The results of our study have to be interpreted in the light of certain limitation. The study is a retrospective observational cohort design.

Blind, midline percutaneous insertion of Tenckhoff catheter by the treating nephrologist has good patient safety and compliance and is cosmetically appealing, with minor procedural complications. The significantly shorter break-in period helps to initiate PD early. Non-diabetic status emerged as a significant risk factor for primary catheter non-function, presumed to be due to more patients with lower BMI and thus smaller abdominal cavities (Table 4). This is the first report that systematically compares diabetic and non-diabetic patients. Nephrologists the world over and especially in resource-poor settings should be encouraged to adopt this technique for maximum utilization of healthcare facilities.

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DISCLOSURES

The authors have no financial conflicts of interest to declare.

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