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Fluoroscopic Guided Peritoneal Dialysis Catheter Placement: An Analysis of Pelvic Catheter Positioning and Early Catheter Flow Dysfunction

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Epidemiology and Biostatistics

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Abstract

Fluoroscopic peritoneal dialysis catheter (FPDC) positioning has not been thoroughly evaluated. Using a retrospective cohort of adult patients who underwent FPDC insertion in London, Ontario (Feb 1, 2010 - Aug 1, 2017); we retrieved procedural radiographs measuring the level of intraabdominal radiocontrast to pubic symphysis (IRPS), and catheter tip to pubic symphysis (CTPS). The median (Q1-Q3) distance (millimeters) of IRPS was larger in females [35(25-44)] than males [28(19-37); $P=0.001$]; but this distance was not associated with variables: Age (years), BMI (Kg/m^2), Race, PKD, abdominopelvic surgeries, in correlation/regression analyses. CTPS distance increased with BMI [$(\beta$; 95% Confidence Interval (CI); females: 0.79; 0.01,1.57; males: 1.08; 0.69,1.47)] and decreased with aging in males (-0.16; -0.29, -0.03). Predictors of early catheter dysfunction were assessed: CTPS, age, BMI, Race, ESKD, sex, break-in-period, abdominopelvic surgeries via backward-stepwise logistic regression, observing associations for higher BMI (Odds Ratio; 95% CI; 1.09; 1.01, 1.16), diabetic ESKD (0.39; 0.16, 0.93).

Keywords

Fluoroscopy, peritoneal dialysis catheter insertion, retrospective cohort study, peritoneal dialysis

Lay Summary

Patients with kidney failure who choose peritoneal dialysis require a permanent catheter inserted into their abdomen. Ideally, the catheter tip is positioned in the deep pelvis so that it fills and drains dialysis fluid easily. The pubic bone of the pelvis located in the mid-groin currently serves as the landmark for the pelvic cavity, and catheter inserters reference it to decide where they should insert the catheter. X-ray guided catheter insertion uses a sequence of real-time x-rays and contrast dye injected into the abdomen to help the catheter inserters visualize the deep pelvis and then position the catheter tip; however, the X-ray approach has not been well studied. We designed a study to understand how the practices unique to x-ray guided catheter insertion relate to the pubic bone landmark approach and if they are predictive of future catheter flow problems which are severe enough to require another procedure to reposition the catheter. Using stored procedure x-rays from adults who underwent x-ray guided catheter insertion in London, Ontario between 2010-2017, we used computer software to measure: 1. The distance between the pubic bone and the level of contrast which is injected into the abdomen and pools in the deep pelvis, 2. The distance between the pubic bone and the bottom of the catheter tip. We found that the distance between the pubic bone and injected contrast was larger in females than males, likely reflecting anatomical differences in the female versus male pelvis. The distance between the pubic bone and the bottom of the catheter tip increased with increasing body mass index (a calculation that uses height and weight to estimate how much body fat someone has, with higher values indicating higher body fat). We also found that the distance between the pubic bone and the bottom of the catheter tip decreased with aging in males. Finally, the distance between the pubic bone and the bottom of the catheter tip was not predictive of developing severe catheter flow problems.

Co-Authorship Statement

This thesis was primarily authored by David A. Clark. Contributions to the study design, data analysis, interpretation, and manuscript were provided by the supervisory committee and collaborators.

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Abbreviations

Peritoneal Dialysis (PD)

Peritoneal Dialysis Catheter (PDC)

End Stage Kidney Disease (ESKD)

Acute Kidney Injury (AKI)

Renal Replacement Therapy (RRT)

Hemodialysis (HD)

Body Mass Index (BMI)

Polycystic Kidney Disease (PKD)

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Kathy Koyle (K.K.)

International Society of Peritoneal Dialysis (ISPD)

Peritonitis, Organisms, Exit Site, and Tunnel (POET)

Difference in Beta Coefficients (DFBETA)

Variance Inflation Factor (VIF)

Chapter 1

1 Introduction

1.1 Background and Overview

Peritoneal dialysis (PD), a form of renal replacement therapy that patients can perform at home, requires the pre-requisite insertion of a peritoneal dialysis catheter (PDC).

Fluoroscopic PDC insertion is one of several methods available for inserting a PDC and is utilized by dialysis programs across Canada.¹

Placement of a proper functioning PDC begins with determining optimal PDC position, including achieving deep pelvic position of the PDC tip (rectovesical space for males or rectouterine space for females) to assure optimal function. Traditionally, the upper border of the pubic symphysis has been used as a landmark for the true pelvis (pelvic cavity) and thus referenced for PDC tip positioning.² This practice has been suggested for all methods of PDC insertion, including fluoroscopic guided. Performing PDC insertion under fluoroscopy offers additional advantage in that radiocontrast dye injected into the peritoneal cavity can also guide deep pelvic positioning of the PDC tip; however, the utility of this technique has not been studied; nor has it been evaluated as a possible risk predictor for a patient developing early PDC flow dysfunction.

We reviewed the literature, including the approach to PDC insertion, practices for pre-assessment landmarking, predictors of PDC flow dysfunction, and techniques unique to the fluoroscopic approach for PDC insertion. This review helped to identify knowledge gaps for further study. Using a retrospective cohort of patients having previously undergone fluoroscopic PDC insertion at a large tertiary care center in Ontario, Canada, this study analyzed radiographic images at the time of fluoroscopic-guided insertion, routinely acquired as part of the procedural maneuvers used to guide pelvic positioning of the PDC tip. Analyses of images including distance measurements: level of intraabdominal radiocontrast pooled in the deep pelvis to the upper border of the pubic symphysis, and PDC tip to the upper border of the pubic symphysis, were performed to

determine how fluoroscopic techniques for optimal PDC tip placement relate to traditional landmarking practices and additionally if predictive of early PDC flow dysfunction.

Chapter 2

2 Literature Review

2.1 Peritoneal Dialysis

2.1.1 Brief Overview

Peritoneal dialysis (PD) is one form of renal replacement therapy that can be used to treat patients with end-stage kidney disease (ESKD), manage patients with acute kidney injury (AKI) who need renal replacement therapy (RRT), and/or aid in ultrafiltration in patients with heart failure refractory to diuresis. To perform PD, a specified volume of dialysate is infused into the peritoneal cavity through a PDC and allowed to dwell for a prescribed time period. The peritoneum then acts as a membrane to allow excess fluid and waste products to pass from the bloodstream into the dialysate, which is subsequently drained via the PDC as dialysis effluent. The peritoneal cavity is then filled again with fresh dialysate and the process repeated, typically 4-5 times during the daytime via gravity-based methods, or via a cycler machine automatically overnight while the patient is sleeping. In contrast, hemodialysis (HD), the most common form of renal replacement, removes excess fluid and wastes by circulating the patient's blood outside the body through a specialized filter, which is typically performed for 3.5-4-hour sessions, three times per week.

2.1.2 Chronic Peritoneal Dialysis

As kidney function declines, patients who reach ESKD would die without RRT. Options for patients with ESKD include renal transplantation and chronic dialysis. Although renal transplantation is the ideal form of long-term RRT, the scarcity of available organs, and reduced eligibility for frail and aging individuals has led to chronic dialysis being the most common RRT.³ The two most common types of chronic dialysis are facility-based HD and home-based PD. In contrast to patients receiving facility-based HD, most patients receiving PD perform their dialysis at home and maintain their independence. Patients receiving PD have similar survival,⁴⁻⁹ are more likely to hold jobs or continue

working (28% for patients on peritoneal dialysis vs. 9% on hemodialysis),^{10, 11} and report a higher quality of life and satisfaction with their dialysis therapy.¹²

2.1.3 Chronic Peritoneal Dialysis in Canada

In Canada, the number of people with ESKD has tripled over the past 20 years. The incidence of ESKD continues to rise especially among individuals with diabetes and those older than 65.¹³ Of the available dialysis options, PD is the most cost-effective modality in Canada. In 2013, the total annual health-care cost of treating a patient with ESKD in Canada using facility-based HD versus PD was approximately \$95,000 – \$107,000 versus \$56,0000 respectively.¹⁴ Despite PD being substantially cheaper and patients receiving PD having similar (survival) or better (patient reported quality of life) health outcomes compared to facility-based HD,^{6, 12, 15} PD remains underutilized in Canada. In 2012, 4,249 patients (18% of total dialysis population) received chronic PD.¹³ In contrast, other developed countries with health care delivery similar to Canada (e.g. Denmark, Australia, Sweden, New Zealand), boast significantly higher rates of PD utilization (23-36% of total dialysis population).¹⁶ Of several factors which have been deemed responsible for PD underuse,^{17, 18} one of importance is the insertion of a properly functioning PDC.

2.2 Peritoneal Dialysis Catheter Insertion

2.2.1 Brief Overview

A pre-requisite to initiating a patient on PD is the insertion of a PDC. The typical PDC is soft and flexible (usually made of silicone) and has two Dacron (felt) cuffs (‘superficial’ and ‘deep’) which heal into abdominal wall tissues to anchor the PDC in place. Although PDCs vary in length and configuration, they can all be divided into three segments (named for in-situ position) and include the internal, tunnel, and external segments. Peritoneal access is attained by inserting the PDC internal segment into the peritoneal cavity, traversing through the abdominal wall (tunnel segment), and exiting the external segment through the skin at a location for easy patient use and self-care. A variety of methods are available for insertion of a PDC, including surgical (open or laparoscopic) and percutaneous (blind or image-guided).¹⁹

2.2.2 Methods of Insertion

Surgical methods of PDC insertion are performed in an operative setting and include either an open surgical method or laparoscopy.^{19, 20} Using the open surgical method, incisions are made through the anterior abdominal wall layers (skin, subcutaneous adipose tissue, rectus sheath, rectus abdominus muscle) and the peritoneal cavity is dissected open. The PDC is next inserted with or without a stylet, blindly advancing the internal PDC segment to the anticipated pelvic portion of the peritoneal cavity.¹⁹ In contrast, laparoscopic PDC insertion provides a less invasive approach and permits complete visualization of the peritoneal cavity throughout the PDC implantation procedure. The technique involves insertion of trocars into the abdominal wall via much smaller incisions which provide the operator working access to the peritoneal cavity. After insufflating the peritoneal cavity with gas, surgical instruments, a camera, and the PDC are inserted through the trocars and the PDC internal segment positioned under direct visualization.²¹ Laparoscopy also allows the option of simultaneous adhesiolysis, omentopexy, and rectus sheath tunneling.¹⁹

Percutaneous methods of PDC insertion employ minimally invasive techniques to gain access to the peritoneal cavity and are usually performed with adjunctive imaging guidance either in a radiology suite or at the bedside.¹⁹ After inserting a needle apparatus through the abdominal wall layers with the needle-tip entering the peritoneal cavity, a modified Seldinger technique is performed to insert a guidewire, serial dilators, and subsequently a peel-away sheath. The PDC is next advanced either over a wire or stylet with the internal segment directed to the pelvic portion of the peritoneal cavity, after which the sheath is removed.^{22, 23} Image guidance (real-time ultrasound and/or fluoroscopy) is typically used to aid initial needle entry into the peritoneal cavity, and subsequent PDC positioning.²⁴⁻²⁸ Of note, the otherwise blind percutaneous approach as well as a peritoneoscope technique (also known as Y-Tec procedure),²⁹ have generally fallen out of favor in North America.

Upon satisfactory placement of the internal segment of the PDC, the remainder procedural steps of PDC insertion are generally similar across surgical and percutaneous

methods. In all approaches, the end-tip of the external segment of the PDC is next passed through a subcutaneous tunnel before exiting the skin creating both the tunnel and external segments of the PDC. Care is taken to position the ‘superficial’ cuff of the PDC at least 2-4 cm proximal from the point of skin exit. Of note, the ‘deep’ PDC cuff is implanted within/deep to the rectus muscle via surgical methods versus superficial to rectus muscle via percutaneous methods.¹⁹

2.2.3 Fluoroscopic Peritoneal Dialysis Catheter Insertion

PDC insertion using fluoroscopic guidance is an image-guided percutaneous insertion method usually performed by interventional radiologists or nephrologists trained in the technique.^{22, 30} Either alone, or in combination with real-time ultrasound, fluoroscopy provides dynamic image guidance of key procedural steps of percutaneous PDC insertion to enhance the safety and success of the procedure.^{24, 31} Confirmation of peritoneal access and subsequent positioning of the PDC internal segment are key steps which are aided by fluoroscopy. Upon initial needle cannulation of the peritoneal cavity (which can also be aided by real-time ultrasound), 3-5 mL of radiocontrast dye is injected under fluoroscopy. Spreading of the injected contrast around bowel loops provides confirmation of successful entry into the peritoneal cavity, while inadvertent bowel puncture is demonstrated by contrast outlining the mucosal folds of either small bowel or colonic haustra. Radiocontrast dye can also be injected and/or withdrawn at subsequent steps of the procedure: 1) to ensure continued positioning in the peritoneal cavity during dilation and insertion of the peel away sheath; 2) pelvic positioning of the PDC internal segment 3) patency/function of the PDC and subcutaneous tunnel segment.^{24-27, 31}

2.2.4 Peritoneal Dialysis Catheter Insertion in Canada

In Canada, techniques for PDC insertion vary at the institutional level and include surgical or percutaneous methods performed by nephrologists, surgeons, and/or interventional radiologists.³⁰ Such variation in individual center practice reflects the convention that local expertise and available resources governs the choice of methodology for PDC insertion.³² Traditionally, PDCs have been inserted by surgeons using either an open laparotomy or laparoscopic technique, however, various barriers to

ubiquitous use of surgical insertion include logistical delays in PDC insertion, the need for general anesthetic for laparoscopic insertion, the need for additional resources to support PDC insertion in the operating room, and surgeon willingness to perform the procedure. In response, home dialysis programs across Canada have seen a rise in percutaneous PDC insertion programs; a practice paradigm which has been shown to increase rates of PD utilization.^{23, 27, 30, 33-35}

2.3 Optimal Peritoneal Dialysis Catheter Placement

2.3.1 Brief Overview

Optimal PDC placement entails the insertion of a well-functioning PDC in a safe and timely manner. Internationally recognized guidelines for PDC access creation detail practices to optimize PDC placement irrespective of the insertion method.¹⁹ These practices span the patient pre-assessment setting and the PDC implantation procedure (Table 1) and aim to reduce/avoid either of infectious and/or mechanical PDC complications. A key precept informing suggested practices is achieving optimal position of the PDC tip.

2.3.2 Optimal Positioning of the Peritoneal Dialysis Catheter Tip

Optimal PDC placement begins with proper positioning of the PDC tip, which should terminate in the deep pelvis.³⁶ Approximately 30% – 55% of dialysate rests in the pelvis when the patient is supine, as has been demonstrated by computerized tomographic peritoneography.³⁷ Positioning the PDC tip in the deep pelvis places the drainage side holes of the PDC tip beyond the reach of omentum and ensures optimal inflow and outflow of the dialysate.³⁸ Traditionally, the upper border of the pubic symphysis (Figure 1) has been used as a landmark for the true pelvis and is thus referenced for PDC tip positioning.^{34, 39} Therefore, during the insertion procedure the PDC tip is aligned with the upper border of the pubic symphysis; allowing the inserter to determine the insertion site and subsequently, the location of the exit site for the PDC. If the resultant exit site is sub-optimal for the individual patient (for reasons including body habitus, skin folds, scars, belt line, etc.) then either an alternative PDC type, or PDC extension is chosen.³⁸

2.3.3 Complications Related to a Mal Positioned Peritoneal Dialysis Catheter Tip

The most prominent complications which can arise from a mal positioned PDC tip are mechanical, of which primary concern is PDC flow dysfunction. A less common & still hypothesized mechanical complication is PDC tip pain (either constant or with draining) thought secondary to excessive deep positioning of the PDC tip in the pelvis.

PDC flow dysfunction has varying definitions in the literature but is most aptly defined as the failure to achieve sufficient effluent outflow to maintain any modality of PD.^{19, 40} Mal positioning of a PDC tip is but one of several mechanical complications which can manifest as PDC dysfunction, which are traditionally sub-classified by the clinical pattern of dysfunction (Table 2). Mal positioning of the PDC tip, as it relates to the PDC insertion procedure, is usually attributed to inappropriate tip placement during the insertion procedure or due to subsequent PDC tip migration. Inappropriate PDC tip placement leading to PDC flow dysfunction is more likely to occur when a PDC insertion is done without intraprocedural visualization for the positioning of the internal PDC segment, with expert consensus also suggesting a greater risk of dysfunction if the operator deviates from best practices for PDC implantation (i.e., not adjusting insertion to patient body habitus, PDC function test not performed at time of insertion). Likewise, expert consensus also warns of PDC tip migration when operators deviate from best placement practices and neglect to ensure that no excess torsion is applied to the PDC during placement.^{19, 41}

Other factors associated with risk of PDC flow dysfunction include a history of prior abdominopelvic surgeries, a prolonged PDC break in period, and etiology of ESKD. Surgical literature has traditionally cited the number of prior abdominopelvic surgeries as a predictor for the formation of intra-abdominal adhesions.^{42, 43} As such, a prior history of significant abdominopelvic surgery has generally been considered a contraindication to percutaneous methods of PDC insertion due to risk of placement failure;⁴⁴⁻⁴⁸ a standpoint reinforced by research demonstrating a higher incidence of PDC dysfunction in patients with history of prior surgeries versus not.^{49, 50} A prolonged PDC break in period, defined as the time from PDC insertion until first intended use, has also been associated with

increased risk for PDC flow dysfunction, specifically in PDCs that are embedded (the external segment is buried under the skin at the time of placement and externalized at the time of intended use).^{51, 52} Finally, large registry studies examining predictors of mechanical causes of PD technique failure (defined as a prolonged switch to hemodialysis secondary to one or more of: hernia, PDC dysfunction, leak) have noted risk associations with etiology of ESKD (referent group – glomerulonephritis), including an increased risk with polycystic kidney disease (PKD) and a decreased risk with diabetes.^{53, 54}

2.3.4 Corrective Measures for a Mal Positioned Peritoneal Dialysis Catheter Tip

A mal positioned PDC tip requires correction if it is felt to be impairing adequate PDC function to permit the desired peritoneal dialysis regimen. Corrective measures vary regarding the level of invasiveness, with the choice of measure(s) being dependent on the likely underlying cause(s) of the mal positioned PDC tip and the pattern of dysfunction manifested (i.e., flow dysfunction, tip/drain pain). Less invasive measures include modifications in the PD prescription (tidal peritoneal dialysis, conversion from cycler to ambulatory regimen) and laxatives (for management of constipation if PDC tip migration is secondary to resultant bowel distension).⁴⁰ Invasive measures include procedural interventions: PDC repositioning or simultaneous PDC removal/re-insertion. PDC repositioning represents the most common invasive measure to correct a mal positioned PDC tip and is commonly completed via a fluoroscopic or laparoscopic approach. Although fluoroscopic repositioning via wire manipulation is less invasive than laparoscopic repositioning surgery, the latter is generally favored given the distinct advantage of direct visualization and diagnosis-specific management (i.e., omentopexy in the case of omental wrapping).¹⁹

2.4 Radiologic Methods for Optimal Positioning of the Peritoneal Dialysis Catheter

2.4.1 Brief Overview

Suggested approaches to optimize PDC placement using radiologic methods have included fluoroscopic and post-implantation x-ray imaging strategies.^{55,56} To date, post-implantation x-rays of PDCs have explored predictors of PDC dysfunction, serving mostly for education and audit purposes.^{56,57} In contrast, the fluoroscopic technique of injecting radiocontrast into the peritoneal cavity to guide deep pelvic positioning of the PDC tip occurs in real-time during the PDC insertion procedure; however, such strategies have yet to be validated.⁵⁵

2.4.2 X-Ray Imaging Post Peritoneal Dialysis Catheter Placement

Research efforts to optimize PDC placement and identify predictors of PDC dysfunction have included analyses of abdominal x-ray images performed immediately post PDC insertion.^{56,58-60} X-ray image predictors of PDC dysfunction have included PDC tip location on abdominal-pelvic films (within the true pelvis versus not), and specific in-situ PDC angle measurements on lateral x-ray films for Swan Neck style PDCs, with the latter suggested to evaluate maintenance of the preformed PDC tunnel configuration.^{59,60} To date, the clinical study of post-implantation x-rays to guide the use of preventative interventions to impact PDC dysfunction is generally limited,⁵⁸ and thus described x-ray predictors from retrospective observational studies are suggested for education and audit purposes.^{56,57}

2.4.3 Fluoroscopic Peritoneal Dialysis Catheter Insertion and Optimizing Catheter Position

Performing PDC insertion under fluoroscopy offers an additional advantage in that radiocontrast dye injected into the peritoneal cavity can also guide pelvic positioning of the PDC tip.⁵⁵ After confirmation of needle entry into the peritoneal cavity, it has been suggested that radiocontrast dye can be injected and pooled in the deep pelvic space, with subsequent manipulation of the pool of iodinated contrast media with the guidewire and PDC to serve as confirmation of a satisfactory position (Figure 2). However, this

maneuver has not been compared to the traditional landmarking strategy; nor has it been evaluated as a possible risk predictor of PDC flow dysfunction.

Table 1. Best Practices in Patient Preparation and Peritoneal Dialysis Catheter Implantation.

- Preoperative assessment performed by a multidisciplinary peritoneal dialysis access team to select the most appropriate catheter type, implantation technique, insertion site, and exit-site location⁶¹
- Implement bowel program to prevent perioperative constipation^{62, 63}
- Shower on the day of procedure with chlorhexidine soap wash of the planned surgical site⁶⁴
- If hair removal is necessary, use electric clippers⁶⁴
- Empty the bladder before procedure; otherwise, Foley catheter should be inserted⁶⁵
- Single preoperative dose of prophylactic antibiotic to provide anti-staphylococcal coverage⁶⁶
- Operative personnel are attired in cap, mask, sterile gown, and gloves⁶⁴
- Surgical site is prepped with chlorhexidine-gluconate scrub, povidone-iodine (gel or scrub), or other suitable antiseptic agent and sterile drapes applied around the surgical field⁶⁴
- Peritoneal catheter is rinsed and flushed with saline and air squeezed out of the Dacron cuffs by rolling the submerged cuffs between fingers²²
- Paramedian insertion of the catheter through the body of the rectus muscle with deep catheter cuff within or below rectus muscle⁶⁷⁻⁶⁹
- Pelvic location of the catheter tip³⁹
- Placement of purse-string suture(s) around the catheter at the level of the peritoneum and posterior rectus sheath and/or the anterior rectus sheath⁷⁰⁻⁷⁷
- Subcutaneous tunnelling instrument should not exceed the diameter of the catheter⁷⁸
- Catheter flow test performed to confirm acceptable function⁷⁹
- Exit site located ≥ 2 cm beyond superficial cuff⁸⁰
- Skin exit site directed lateral or downward^{76, 81}
- Exit site should be smallest skin hole possible that allows passage of the catheter⁷⁸
- No catheter anchoring sutures at the exit site (use medical liquid adhesive and sterile adhesive strips to secure the catheter)¹⁹
- Attach dialysis unit's requested catheter adapter and transfer set at time of procedure¹⁹
- Exit site protected and catheter immobilized by non-occlusive dressing⁸²

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Table 2. Common mechanical complications associated with peritoneal dialysis catheter dysfunction – sub-classified by pattern of dysfunction.

Inflow/Outflow dysfunction <i>Suggests intra-luminal problem</i>	Outflow Dysfunction Only <i>Suggests extra-luminal problem</i>
Fibrin Plug Catheter Kink Extrinsic Compression	Mal-positioned Internal Catheter Tip Constipation Adherent Intraperitoneal Tissues Peritoneal Cavity Dialysate Leak

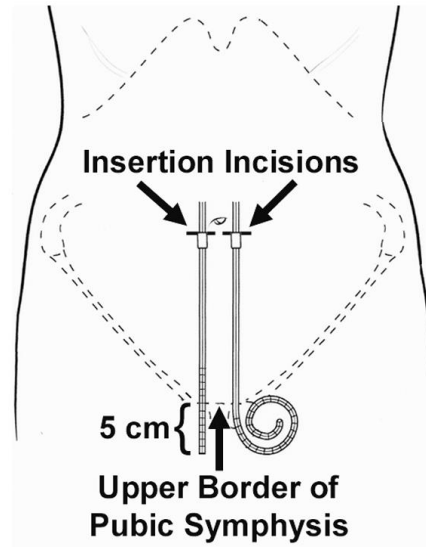


Figure 1: Schematic of traditional approach to position a peritoneal dialysis catheter with upper border of the pubic symphysis used as a landmark for the true pelvis and referenced for catheter tip positioning in the deep pelvis.

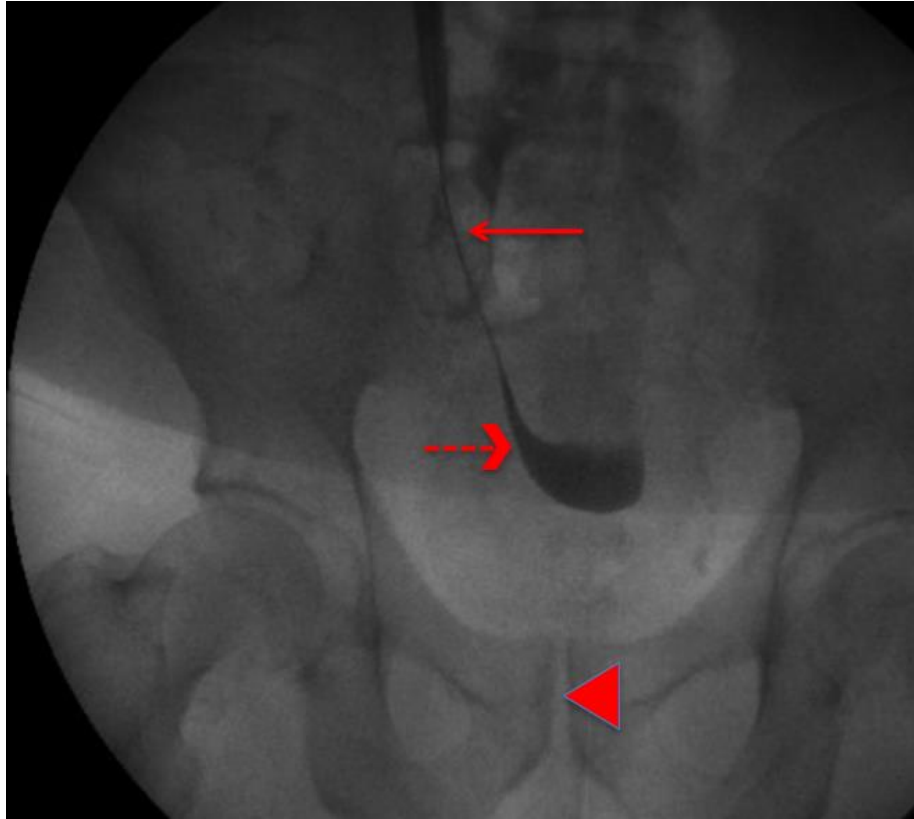


Figure 2: Fluoroscopic radiograph of peritoneal dialysis catheter insertion; Injection of radiocontrast followed by modified Seldinger technique. Standard anterior-posterior pelvic view, with the patient in the supine position (solid arrow – needle & guidewire, dashed arrow – pooled radiocontrast, arrowhead – pubic symphysis).

Chapter 3

3 Rationale for Research Approach

3.1 The Need for Research

Performing PDC insertion under fluoroscopic guidance offers advantage over blind insertion strategies in that radiocontrast dye injected into the peritoneal cavity during the procedure can help guide pelvic positioning of the PDC tip.⁸³⁻⁸⁵ This unique aspect of fluoroscopic guidance has not been evaluated in prior efforts to assess practices for optimal PDC placement.³⁸ Accordingly, studies relating radiographic measures of PDC position at the time of fluoroscopic-guided insertion and prediction of PDC-related outcomes are lacking.⁶⁰

3.2 Our Research Approach

Since 2013, the London Health Sciences Center (LHSC) Renal Program in London, Ontario has averaged at least 50 patients per year who have undergone fluoroscopic PDC insertion. For each of these patients, comprehensive health data has been routinely collected for clinical purposes, including standardized pre-assessment evaluations, and stored radiological images from fluoroscopic procedures. Subsequent tracking of PDC-related outcomes is collected for clinical as well as audit/quality assurance purposes.

To evaluate suggested fluoroscopic techniques for pelvic positioning of the PDC tip, we devised a method for performing radiographic measurements relating the distance between the level of intraabdominal radiocontrast pooled in the deep pelvis and the pubic symphysis (an accepted landmark for the true pelvis) as well as the final PDC tip position and the pubic symphysis and analyzed these measurements in a cohort of patients who underwent fluoroscopic PDC insertion spanning 2010-2017. We then examined the relationship between radiographic measures of PDC tip position at the time of fluoroscopic-guided insertion and early PDC flow dysfunction - a clinically important PDC outcome which can relate to PDC mal-positioning at the time of placement.

3.2.1 Radiographic Measurements: True Pelvis & Final Catheter Tip Position

Radiographic measurements to characterize the true pelvis and PDC tip position in patients who undergo PDC insertion using fluoroscopic guidance were proposed by operators with expertise in performing the procedure (D.A.C., A.K.J.) and with consideration for potential future integration into the procedural technique/clinical care. Measurements included: the distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis (Figure 3); and the distance between the cranial border of the pubic symphysis and the bottom of the PDC tip (Figure 4). Proposed measurements from procedural fluoroscopic radiographs (anterior-posterior pelvic view, taken with the patient in supine position) reference the midline pubic symphysis, noting that physical-exam palpation of this bone landmark closely approximates the radiographic location (Appendix A).

Biologic factors which impact pelvic structure and therefore the proposed radiographic measures, were also reviewed in the literature. Of primary consideration, was the known anatomical differences which exist between the male and female pelvis,^{86, 87} including differences in the pelvic cavity reproductive organs and the skeletal pelvis; Females having a wider pelvis as well as a larger pelvic outlet to facilitate childbirth. Additionally, anthropologic and forensic literature has detailed Racial differences in the dimensions (height/breadth) of component bones comprising the pelvis,^{88, 89} as well as impacts of aging on both growth of component bones and their articulations.^{90, 91} Lastly, in individuals with autosomal dominant polycystic kidney disease, a described complication of enlarged kidneys includes their compressive/mass effects on the bony pelvis.⁹²

3.2.2 Strengths of LHSC Fluoroscopic PDC Insertion Health Data

There are several advantages to using this data. The practice of fluoroscopic PDC insertion at LHSC follows recommended best practices for optimal PDC placement and has consistently satisfied suggested audit targets for procedural complications and PDC outcomes.¹⁹ The operator at LHSC is a nephrologist highly experienced in the technique, which is known to be associated with higher rates of PDC utilization.⁹³ From 2010

onward, serial radiographic images from each fluoroscopic PDC insertion procedure, including the pelvic positioning maneuver using injected radiocontrast, have been routinely archived, permitting systematic analysis and ensuring study feasibility. Furthermore, health data collection for each patient is derived from routine scheduled encounters as part of peritoneal dialysis program delivery and allows for a range of variables to be ascertained.

3.2.3 Limitations of LHSC Fluoroscopic PDC Insertion Health Data

Acknowledging LHSC fluoroscopic PDC insertion health data is intended to guide clinical care and perform quality assurance – the data is not collected for the original purpose of research and information gaps in history, physical examination, stored fluoroscopic radiographs etc., do occur. Missing stored fluoroscopic radiographs often secondary to technology issues or tech personnel unfamiliar with image archiving. Collected data reflects both single operator and center experience, however, both the technique & center approach to fluoroscopic PDC insertion is comparable to that offered by other Canadian programs. Furthermore, LHSC is one of several centers in Ontario that provide the service of PD care, and thus a percentage (albeit small) of patients are lost to follow-up to other renal programs elsewhere in Ontario or outside the province. Lastly, PDC outcomes data is routinely maintained by administrative personnel without specialized medical training and thus misclassification of some outcomes may occur. Of note, this misclassification is typically ‘nondifferential’ as the acquisition of data is independent of any research question and thus not subject to recall bias.

3.3 Challenges of Optimal Peritoneal Dialysis Catheter Placement Analyses

Existing analyses for optimal PDC placement have examined physical examination landmarks and were performed to help inform optimal PDC configuration and exit site location prior to insertion. Positioning the PDC tip in the deep pelvis (most dependent portion of the peritoneal cavity) informed these analyses, concluding that the upper border of the pubic symphysis serves as the ideal landmark for the anatomical brim of the true pelvis.³⁸ To date, studies evaluating fluoroscopic maneuvers of PDC placement have

not been evaluated and therefore the approaches suggested in this study are exploratory, reflect the opinions of individuals with expertise in Fluoroscopic PDC insertion, and the continued notion that the PDC tip be positioned in the deep pelvis to attain optimal function.

3.4 Challenges of Peritoneal Dialysis Catheter Outcomes Analyses

There are analytic challenges to consider when conducting PDC outcome studies. Foremost is the lack of consistent definitions of mechanical PDC dysfunction in the literature.^{41, 60, 94-99} Only recently has there been improved efforts to standardize definitions for the purposes of quality assurance/research.⁴⁰ The relationship between patient characteristics, optimal PDC placement, and PDC outcomes is complex. Many of these variables are highly correlated and there is limited data to support assumptions about the pathophysiologic pathway that represents the relationship between suspected risk factors, confounders, and outcomes, and the directionality of these associations. For that reason, the purpose of this study was not to establish causality, but rather to explore the direction and magnitude of associations between patient characteristics and PDC placement and catheter dysfunction.

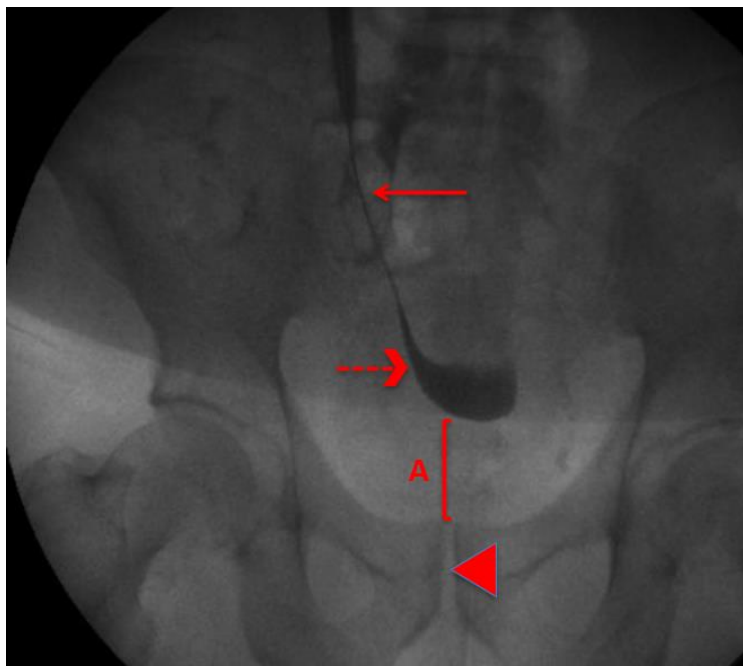


Figure 3. Fluoroscopic radiograph of staged peritoneal dialysis catheter insertion (injection of radiocontrast followed by modified Seldinger technique) with proposed radiographic measurement: A) Cranial border of the pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis – referencing midline, in a standard anterior-posterior pelvic view, with the patient in the supine position (solid arrow – needle & guidewire, dashed arrow – pooled radiocontrast, arrowhead – pubic symphysis)

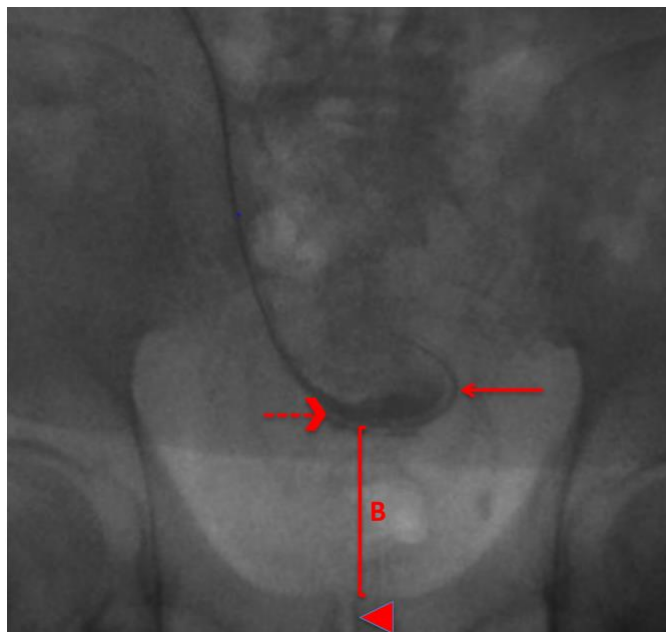


Figure 4. Fluoroscopic radiograph of staged peritoneal dialysis catheter insertion (Insertion of peritoneal segment of peritoneal dialysis catheter) with proposed radiographic measurement: B) Cranial border of the pubic symphysis to bottom of catheter tip – referencing midline, in a standard anterior-posterior pelvic view, with the patient in the supine position (solid arrow – catheter tip, dashed arrow – pooled radiocontrast withdrawn, arrowhead – pubic symphysis).

Chapter 4

4 Research Questions

4.1 Fluoroscopic Peritoneal Dialysis Catheter Insertion - Landmarking the True Pelvis

By analyzing procedural fluoroscopic radiographs from a retrospective cohort of patients who underwent incident fluoroscopic PDC insertion at LHSC spanning 2010-2017, we aimed to describe the distribution of the distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis (referencing midline in a standard-anterior posterior pelvic view, with the patient in the supine position; Figure 3). We aimed to determine what patient factors associate with a greater distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis. Acknowledging anatomical differences between the male and female pelvis (section 3.2.1), as well as sex-specific abdominopelvic pathology/surgery – all analyses were stratified according to sex.

Hypothesis: 1) We expected that a prior history of abdominopelvic surgeries would lead to increased distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis in both males and females.

4.2 Fluoroscopic Peritoneal Dialysis Catheter Insertion and Final Catheter Tip Position

By analyzing procedural fluoroscopic radiographs from a retrospective cohort of patients who underwent incident fluoroscopic PDC insertion at LHSC spanning 2010-2017; we aimed to describe the distribution of the distance between the cranial border of the pubic symphysis and the bottom of the PDC tip (referencing midline in a standard anterior-posterior pelvic view, with the patient in the supine position; Figure 4); We aimed to determine what patient factors associate with a greater distance between the cranial border of the pubic symphysis and the bottom of the PDC tip. Acknowledging anatomical

differences between the male and female pelvis (section 3.2.1), as well as sex-specific abdominopelvic pathology/surgery – all analyses were stratified according to sex.

Hypothesis: 1) We expected that higher BMI and/or a history of prior abdominopelvic surgeries would lead to increased distance between the cranial border of the pubic symphysis and the bottom of the PDC tip in both males and females.

4.3 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Final Catheter Tip Position and Early Catheter Flow Dysfunction

By analyzing procedural fluoroscopic radiographs from a retrospective cohort of patients who underwent incident fluoroscopic PDC insertion at LHSC spanning 2010-2017, we aimed to determine if the measured distance between the cranial border of the pubic symphysis and the bottom of the PDC tip (referencing midline in a standard anterior-posterior pelvic view, with the patient in the supine position; Figure 4) associates with a higher incidence of PDC flow dysfunction in the first three months of PDC use.

Hypothesis: We expected that the incidence of PDC flow dysfunction in the first three months would be higher if the PDC tip was distanced further from the cranial border of the pubic symphysis.

Chapter 5

5 Methods

5.1 Design and Setting

We conducted a retrospective cohort study of adult patients who underwent percutaneous PDC insertion using fluoroscopic guidance at a large tertiary care center in Ontario, Canada to describe pelvic positioning of the PDC tip using fluoroscopic methods and to determine if aspects of the positioning associate with the risk for early PDC flow dysfunction. Study conduct and reporting follow guidelines (STROBE)¹⁰⁰ for observational studies (Appendix B). The study was approved by the Western University Health Science Research Ethics Board, London, Ontario (Appendix C).

5.1.1 LHSC Renal Program & Peritoneal Dialysis Catheter Insertion

The LHSC Renal Program in London, Ontario, averages 50-70 patients per year who undergo PDC insertion. Approximately two-thirds of all patients undergo percutaneous PDC insertion using fluoroscopic guidance while the remainder are inserted via laparoscopic surgery. Since 2010, the percutaneous insertion procedure using fluoroscopic guidance has been routinely performed by a single operator (A.K.J.) who has incorporated recommended best practices for optimal PDC placement.¹⁹ All patients who require PDC insertion (percutaneous or surgical) are routinely first seen in pre-assessment by A.K.J. This encounter incorporates best practices for optimal PDC placement, including pre-planned PDC mapping to inform the choice of either percutaneous or surgical placement. Patients identified as more suitable for surgical PDC insertion are subsequently seen by dedicated surgeons with expertise in laparoscopic PDC insertion technique.

5.1.2 Fluoroscopic Peritoneal Dialysis Catheter Insertion Procedure

Percutaneous PDC insertion using fluoroscopic guidance is performed in a dedicated fluoroscopy suite at LHSC, Victoria Campus. Prior to the insertion procedure, all patients

routinely complete a bowel cleansing protocol and empty their bladder to reduce the risk of bowel/bladder injury. Pre-planned sites for PDC entry and exit site creation are marked beforehand with a marking pen. In accordance with the International Society of Peritoneal Dialysis (ISPD) Guidelines for PD related infections, pre-procedural prophylaxis with intravenous antibiotics is given.¹⁰¹ With the patient placed in the supine position, preliminary bedside ultrasonography of the abdomen is performed to ascertain the safety of the chosen entry (puncture) site for PDC entry. To facilitate insertion of the PDC through rectus muscle and implantation/approximation of the deep cuff within rectus muscle, a paramedian PDC entry site is chosen to reduce the risk of leak, hernia, and PDC migration.^{67, 102-104} Color doppler ultrasonography is used to confirm the absence of any larger arteries (inferior epigastric artery and branches) usually coursing through rectus muscle or anterior to the posterior rectus sheath. Greyscale ultrasonography is used to assess the layers of the anterior abdominal wall and approximate the depth of the peritoneum relative to the skin surface to aid initial entry and tunnel creation. Maximal sterile barrier precautions are enforced: staff wear a surgical mask covering mouth and nose, sterile gown, sterile gloves, surgical cap/hood; the patient is masked to cover mouth and nose. The abdomen is prepped with an antiseptic scrub and sterilely draped, allowing exposure of the insertion site and expected exit site. The PDC is prepped for insertion by flushing it with fluid (e.g., saline) and placing it into a surgical bowl filled with fluid, ensuring to extrude any trapped air in either cuff (via manual compression) which might inhibit tissue ingrowth. Typically, intravenous conscious sedation is administered according to local governance procedure and local anesthesia using Lidocaine (with or without epinephrine) is infiltrated in the skin at the proposed exit site, and within the skin and subcutaneous/deep tissues of the anterior abdominal wall at the anticipated puncture site. A horizontal incision, 2-4 cm in length is made in the skin at the puncture site. Blunt dissection of the subcutaneous tissue to the level of the abdominal rectus sheath is completed to facilitate needle entry into the peritoneum and deep cuff placement. Confirmation of peritoneal cavity access is visualized using fluoroscopy. Upon injecting 3-5 mL of radiocontrast under fluoroscopy, spreading of the contrast around the bowel loops confirms successful entry into the peritoneal cavity. Inadvertent bowel puncture demonstrates contrast outlining the

mucosal folds of either small bowel or colonic haustra. Additional evidence for peritoneal cavity access includes non-painful, steady flow of peritoneal fluid as visualized by an attached drip chamber. After the peritoneal cavity is cannulated, a modified Seldinger technique is applied to introduce a guide wire and subsequent dilator and peel-away sheath. Serial dilation may be required but is often omitted to promote a tight seal with the goal of decreasing the risk of leak. The wire and the dilator are removed, and the PDC is advanced through the sheath on either a stylet or stiff guide wire in the deep pelvic direction. To avoid any torsion on the PDC, precautions are taken to ensure the PDC is not twisted, as visualized by the integrated radiopaque line. The intraperitoneal segment is advanced until the proximal cuff is abutting rectus muscle, and then the stylet (or stiff wire) and peel-away sheath are removed. Under fluoroscopy, using anterior-posterior pelvic views, radiocontrast dye is injected and/or withdrawn at interval steps to assure 1) continued positioning in the peritoneal cavity during dilation and insertion of the peel away sheath; 2) pelvic positioning of the PDC tip 3) patency/function of the inserted PDC and/or subcutaneous tunnel. Radiocontrast dye pooled in the target rectovesical (male) or rectouterine (female) space with subsequent manipulation of the pool of iodinated contrast media with the guidewire and PDC is utilized as a confirmation of pelvic positioning. Once the intraperitoneal segment of the PDC is in satisfactory position, PDC function is assessed by filling and draining the abdomen using dialysate. After the intraperitoneal segment of the PDC is in adequate position and function is assessed, the end of the PDC is tunneled subcutaneously to an exit site in the lateral abdominal wall. To accomplish this, the proximal end of the PDC is attached to a tunneling stylet and the PDC is tunneled in an arcing configuration, bringing the PDC out at the exit site; Again, avoiding torsion on the PDC by ensuring the PDC is not twisted by inspecting the radiopaque line integrated into the PDC. The exit site is created with a downward or lateral direction to avoid accumulation of debris and reduce the risk of PDC related infection.¹⁰⁵ Care is also taken to ensure the superficial cuff is at minimum 2-4 cm from the exit site to prevent future cuff extrusion. To rule out a kink in the newly created subcutaneous tunnel, fluid is routinely instilled and withdrawn from the extruded tunneled PDC. To aid prevention of fibrin formation, the PDC is capped with heparin [100 units/1 mL]. The PDC entry incision is closed using an absorbable suture for the

subcutaneous tissue, followed by skin closure. The exit site is covered with a non-occlusive dressing and is not changed for 1-week post-insertion. The PDC and attached transfer set is immobilized and taped securely to the abdomen to avoid inadvertent trauma or dislodgement.

5.2 Study Population

5.2.1 Overview

We established a cohort of adult (>18 years) patients with end stage kidney disease (ESKD) affiliated with the London Health Sciences Center (LHSC) Renal Program who underwent percutaneous PDC insertion using fluoroscopic guidance spanning 2010-2017. All patients had a coiled tip, 2-cuff, 62 cm length Tenckhoff PDC inserted during this period.

5.2.2 Patient Inclusions/Exclusions

For research questions examining: Landmarking of the true pelvis (section 4.1) and final PDC tip position (Section 4.2) we included patients who underwent PDC insertion for the purpose of chronic dialysis therapy and excluded those lacking sufficient radiologic images (see section 5.4) or with a prior history of PDC insertion (acknowledging prior PDC insertion increases the risk of prior PD peritonitis and adhesion formation and has an influence on subsequent PDC mapping/placement).⁷⁹ For the primary analysis addressing the research question examining final PDC tip position and early PDC flow dysfunction (section 4.3), we further excluded patients who died or experienced attrition/technique failure within 3 months of PD initiation for reasons other than early PDC flow dysfunction.

5.3 Sample Size

Timelines for the availability of archived radiologic images as well as inclusion of patients in the Baxter Canada Peritonitis, Organisms, Exit Site, and Tunnel (POET) database influenced the chosen convenience sample. After excluding patients with a history of prior PDC insertion (estimated to be at most 10% of patients); we anticipated there would be 315 patients between 2010-2017. After a further 5% deduction to account

for the possibility of missing radiographic images, we estimated ~300 patients available for study. Acknowledging that females comprised approximately 40% of all peritoneal dialysis patients in Ontario spanning 2010-2015,¹³ we expected roughly 120 females and 180 males. We further estimated approximately 30-45 patients (10-15%) experiencing PDC flow dysfunction as per prior reported studies of PDC complication rates in patients who undergo fluoroscopic guided PDC insertion.¹⁰⁶⁻¹¹¹

5.4 Radiographic Measurements

For each patient, distance (millimeters) measurements included: cranial border of the pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis (Figure 3); cranial border of the pubic symphysis to bottom of the PDC tip (Figure 4). Measurements were calculated from fluoroscopic anterior-posterior pelvic radiographs taken with the patient in supine position and referencing the midline pubic symphysis. Measurements were performed using Citrix Imaging software (version 12.8.1), with the image width of the standardized PDC introducer needle as a reference frame [physically measured with a Vernier caliper measurement (Scienceware, 6"/150mm)]. All radiographic measurements were performed by two study personnel (K.K., D.A.C.) following a standardized sequence protocol (Appendix D), and without any knowledge of the outcome of interest (see section 5.6) at the time of measurement.

5.5 Patient Characteristics

We collected information on the following patient characteristics routinely collected at the time of procedure pre-assessment and subsequent week of PD training: age, sex, race, cause of ESKD, prior number and type of abdominopelvic surgeries, height, and weight (BMI), PDC insertion procedure (fluoroscopic vs. laparoscopic), date of PDC insertion procedure, and initial date of PD training (elapsed time between PDC insertion and PD training representing the PDC break-in period). In the case of missing data, missing values were obtained from electronic medical records by two study personnel (D.A.C., K.K.) using a fixed lookback window of 3 months prior to the procedure date. This lookback window was fixed to avoid information bias based on cohort entry date.

5.6 Peritoneal Dialysis Catheter Flow Dysfunction

In alignment with current practice approach as well as prior published studies,^{40, 112} PDC flow dysfunction was defined as the failure to achieve sufficient inflow/outflow to maintain any modality of PD (continuous ambulatory PD or automated PD); refractory to non-procedural interventions (i.e. aggressive bowel regimen), and necessitating a repositioning procedure or otherwise causing technique failure. PDC flow dysfunction attributed to sub-optimal PDC tip placement during the insertion procedure usually manifests early into PDC use. Therefore, the outcome of PDC flow dysfunction necessitating a repositioning procedure, and/or otherwise leading to technique failure was evaluated within three months of initiating PD; a time period that aligns with prior published reports noting highest incidence of mechanical causes of PD technique failure in the first three months.⁵⁴ PDC flow dysfunction outcomes are routinely captured for all PD patients by the London PD program. The repositioning procedure (fluoroscopic vs. surgical), is routinely performed at the London Health Sciences Center, and the cause of PDC dysfunction reported at the time of repositioning (i.e., omental wrapping, small bowel wrapping, PDC tip migration etc.). A subset of patients who do not undergo repositioning for PDC flow dysfunction and instead permanently switch to HD are also captured, with reasons for PDC flow dysfunction identified as per clinical judgement/x-ray imaging. In alignment with consensus opinion regarding simultaneous PDC removal and reinsertion via fluoroscopic guidance for PDC dysfunction, local practice approach has generally reserved this maneuver for select infectious PDC related complications and not flow-related PDC dysfunction.

5.7 Data Sources

5.7.1 PACS (Picture Archiving and Communication System)

Stored radiographs from each percutaneous PDC insertion procedure under fluoroscopic guidance are routinely electronically archived in PACS, including sequence images for pelvic positioning of the PDC tip. We retrieved sequence images for pelvic positioning of the PDC tip for all patients who underwent PDC insertion with fluoroscopic guidance at

LHSC during the study period for the purpose of performing radiographic measurements to characterize the true pelvis and PDC tip position (section 5.4).

5.7.2 POET (Peritonitis, Organisms, Exit Site, and Tunnel)

POET electronic database (Baxter Healthcare) is a clinical monitoring system which includes prospectively collected data on incident PD patients at any given center. Information contained within the POET database includes patient demographics, cause of infection, PDC complications, and therapy transfers. Patients who underwent PDC insertion at LHSC prior to 2018 were routinely recorded in the POET electronic database. Dedicated nurses and/or clinical administrators with extra knowledge/training of peritoneal dialysis and the POET database prospectively entered and maintained data.

5.7.3 Patient Health Records

Information on patients' characteristics and outcomes is routinely collected in the clinical record. This information is stored in both paper charts and the electronic medical record: Cerner Millennium PowerChart Electronic Health Record (Lenexa, KS, USA).

5.8 Statistical Analysis

5.8.1 Baseline Characteristics

Standard descriptive statistics were used to describe baseline characteristics and stratified by sex. For continuous variables, we summarized symmetrically distributed data by the mean and standard deviation, and skewed distributions by the median and interquartile range. For categorical and binary variables, we summarized data by the various strata using counts and proportions. Fisher's exact tests were used to compare categorical data and either t-tests (normally distributed) or Wilcoxon rank-sum tests (non-normally distributed) to compare continuous data.

5.8.2 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Landmarking the True Pelvis & Final Catheter Tip Position

To account for anatomical differences between the male and female pelvis (section 3.2.1) as well as sex-specific abdominopelvic pathology/surgery; analyses were stratified

according to sex. Standard descriptive statistics were used to describe radiographic measures and summarized visually via histograms. Spearman rank correlation methods were used to assess for correlation between suggested radiographic measurements and each of age, BMI, and number of abdominopelvic surgeries. Joint relationships of radiographic measurements and covariables were analyzed via multiple linear regression models, with checks of model assumptions and fit [collinearity (analyses not shown), normality, constant variance, linearity, and outlying points]. Variables included in the analyses were defined a priori and determined based on a review of the literature, including biologic factors affecting pelvic structure, and consideration of both clinical significance and biological plausibility. Selected variables were collected at baseline and included age, BMI, PKD ESKD, Race (White race versus other), and number of prior abdominopelvic surgeries. A list of the variables and how they were coded for analyses can be found in Table 3. Regression coefficient estimates and 95% confidence intervals were displayed graphically contrasting univariate and multivariate model results. Within each sex strata we tested for statistical interaction between any statistically significant predictor and all other variables included in the multiple regression model with an a priori plan for subsequent subgroup analyses for any significant interactions. Missing data for radiographic measurements were deemed missing completely at random (i.e., missing or not does not depend on observed and unobserved data) and therefore were handled through a complete case analysis.¹¹³

5.8.2.1 Sensitivity Analyses

Comparisons of multiple linear regression models including and excluding potential outliers/influential data points were performed using DFBETA statistics.

5.8.3 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Final Catheter Tip Position and Early Catheter Flow Dysfunction

Primary analyses of final PDC tip position and early PDC flow dysfunction excluded patients who experienced attrition in the first three months for reasons other than PDC flow dysfunction (Figure 5); Baseline characteristics of these excluded patients were contrasted against those included in the primary analyses. The outcome of early PDC

flow dysfunction versus final PDC tip position was displayed graphically via box plots. The measure of final PDC tip position was informed by prior analyses (section 5.8.2): and defined as the distance between the patient's pubic symphysis and bottom of the PDC tip. Single predictor logistic regression analyses were conducted for the outcome of early PDC flow dysfunction versus each of final PDC tip position, and variables defined a priori and determined based on a review of the literature, including biologic factors affecting pelvic structure, and consideration of both clinical significance and biological plausibility. Selected variables were those collected at baseline and included age, BMI, Sex, cause of ESKD, Race (White race versus other), break in period, and number of prior abdominopelvic surgeries. Variables that affected the outcome were included in multivariable logistic regression analyses examining the outcome of early PDC flow dysfunction versus final PDC tip position; being selected for inclusion via backward elimination process and using a liberal P-value criterion (0.2) given the smaller data set.¹¹⁴ A list of the variables and how they were coded for analyses can be found in Table 4. To accommodate backward elimination, cause of ESKD was categorized using dummy variables: Diabetic, Ischemic, Glomerulonephritis, PKD, Other, Unknown. Odds Ratios and 95% confidence intervals were displayed graphically contrasting results of single predictor and multiple predictor models. Acknowledging anatomical differences between the male and female pelvis (section 3.2.1), as well as sex-specific abdominopelvic pathology/surgery, statistical interaction was tested between all variables selected for inclusion in multiple predictor models and sex. For all models, checks of model assumptions/fit [variance inflation factor (VIF) - multicollinearity, DFBETAs – outlying/influential points, Hosmer–Lemeshow test – goodness of fit] were completed.

5.8.3.1 Sensitivity Analyses

Pre-planned sensitivity analyses comprised models that 1) included patients who experienced attrition in the first three months for reasons other than early PDC flow dysfunction; 2) included patients who experienced attrition in the first three months for reasons other than early PDC flow dysfunction and assumed these patients all experienced the outcome of interest.

5.8.4 Statistical Software

All statistical analyses were conducted using Stata/SE software version 17.0 (StataCorp. 2021 (Appendix E). Stata Statistical Software: Release 17.0. College Station, TX: StataCorp LLC). For all analyses, a p value < 0.05 was considered statistically significant and there was no adjustment for multiple statistical comparisons.

Table 3. Included variables, and how they were coded, for analyses assessing fluoroscopic peritoneal dialysis catheter insertion: landmarking the true pelvis & final catheter tip position.

Variable	Definition and Coding
Age (per year)	Continuous variable
BMI (per Kg/m ²)	Continuous variable
PKD ESKD	0= no (ref) 1= yes
Race (White race versus other)	0= Other (ref) 1= White
Number of Prior Abdominopelvic Surgeries	Continuous variable
BMI, Body Mass Index; PKD, Polycystic Kidney Disease; ESKD, End Stage Kidney Disease	

Table 4. Included variables, and how they were coded, for analyses assessing fluoroscopic peritoneal dialysis catheter insertion: final catheter tip position and early catheter flow dysfunction.

Variable	Definition and Coding
Age (per year)	Continuous variable
BMI (per Kg/m ²)	Continuous variable
*Diabetic ESKD	0= no (ref) 1= yes
*Ischemic ESKD	0= no (ref) 1= yes
*GN ESKD	0= no (ref) 1= yes
*PKD ESKD	0= no (ref) 1= yes
*Other ESKD	0= no (ref) 1= yes
*Unknown ESKD	0= no (ref) 1= yes
Race (White race versus other)	0= Other (ref) 1= White
Number of Prior Abdominopelvic Surgeries	Continuous variable
Sex	0= Male (ref) 1= Female
Break in period (per day)	Continuous variable
*cause of ESKD categorized as dummy variables; BMI, Body Mass Index; ESKD, End Stage Kidney Disease; GN, Glomerulonephritis; PKD, Polycystic Kidney Disease	

Chapter 6

6 Results

6.1 Study Cohort and Baseline Characteristics

A total of 286 adult patients underwent first-time PDC placement via fluoroscopic insertion and had archived radiologic images available for study over the 7-year study period at the LHSC in London, Ontario, Canada (patient selection into the cohort is presented in Figure 5). The average age for the entire cohort was 61 ± 16 (std. dev.) years. Median BMI (Q1-Q3) was 27 (24 – 31) Kg/m^2 . Baseline characteristics of patients stratified according to sex are displayed in Table 5. Female patients comprised 31% of the cohort. Etiology of ESKD and Race were comparable between sexes. A higher percentage of male patients (60%), compared to females (37%) had no prior history of abdominopelvic surgery prior to fluoroscopic PDC insertion ($P < 0.001$). The classification of abdominopelvic surgeries for the cohort is displayed in Table 6. Of the types of surgeries that are not unique to either sex, only inguinal hernia repair surgeries were more common in males versus females (23% vs. 1%, $P < 0.001$).

6.2 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Landmarking the True Pelvis & Final Catheter Tip Position

The frequency distribution of the radiographic measurements, according to sex, are displayed in Figure 6. The median distance (interquartile range) between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis was larger in females than in males (Table 7). Age, BMI, and the number of prior abdominopelvic surgeries were weakly correlated with the distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis, as well as the distance between the cranial border of pubic symphysis to the bottom of the PDC tip, in both males and females (Table 8). Multiple linear regression modelling: age, BMI, PKD, Race, and number of prior abdominopelvic surgeries was not associated with the variance in the measured distance (mm) between the cranial border of the pubic symphysis to caudal border caudal border of intraabdominal radiocontrast pooled in the deep pelvis in either

males ($F(5,183) = 0.86$, $p = 0.5$, $R^2 = 0.02$, $R^2_{\text{Adjusted}} = -0.003$; Table 9, Figures 7-9) or females ($F(5,81) = 1.20$, $p = 0.32$, $R^2 = 0.07$, $R^2_{\text{Adjusted}} = 0.01$; Table 10, Figures 10-12). None of age, BMI, PKD, Race, or number of prior abdominopelvic surgeries were associated with the measured distance (mm) between the cranial border of the pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis in either males (Figure 7) or females (Figure 8). A higher BMI was associated with a greater distance between the cranial border of the pubic symphysis and bottom of the PDC tip in males in both univariate [$F(1,187) = 1.55$, $p = 0.21$, $R^2 = 0.01$, $R^2_{\text{Adjusted}} = 0.002$], and multiple linear regression modeling [$F(5,179) = 7.39$, $p = <0.001$, $R^2 = 0.17$, $R^2_{\text{Adjusted}} = 0.15$; Table 10; Figures 13-15]. Increasing age was associated with a lesser distance between the cranial border of the pubic symphysis and bottom of the PDC tip in males in multiple linear regression modeling only (Table 11; Figures 13-15). In females, a higher number of prior abdominopelvic surgeries was associated with a lesser distance between the cranial border of the pubic symphysis and bottom of the PDC tip in univariate [$F(1,86) = 4.9$, $p = 0.03$, $R^2 = 0.05$, $R^2_{\text{Adjusted}} = 0.04$], but not multiple linear regression modeling [$F(5,81) = 2.01$, $p = 0.04$, $R^2 = 0.11$, $R^2_{\text{Adjusted}} = 0.06$; Table 12, Figures 16-18]. A higher BMI was associated with a greater distance between the cranial border of the pubic symphysis and bottom of the PDC tip in females in multiple linear regression modeling (Table 12, Figures 16-18).

6.2.1 Sensitivity Analyses - Influential Data Points

For multiple linear regression modeling of the cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis, removal of influential points did not substantially alter model coefficients in either males (Table 13) or females (Table 14). Similarly, removal of influential points did not substantially alter multiple linear regression models of the cranial border of pubic symphysis to bottom of the PDC tip in either males (Table 15) or females (Table 16).

6.3 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Final Catheter Tip Position and Early Catheter Flow Dysfunction

All 286 patients included in this cohort were trialed on PD. Of 35 patients who experienced early PDC flow dysfunction, 31 underwent a reposition procedure (Table 17). Another 32 patients experienced attrition within three months for non-PDC flow dysfunction reasons and demonstrated comparable baseline characteristics to those with early PDC flow dysfunction (Table 18). Of patients who underwent a reposition procedure (28 laparoscopic, 3 fluoroscopic) for early PDC flow dysfunction, cases resolved surgically noted omental wrapping plus PDC migration for 16/28 (57%) patients, four (14%) patients had omental wrapping only, and the remainder eight (29%) patients had PDC tip migration only. The median distance (interquartile range) between the cranial border of the pubic symphysis and the bottom of the PDC tip was comparable between those who experienced early PDC flow dysfunction versus not [37mm (29-53) vs. 38mm (26-49); $P=0.62$; Figure 19]. Multiple logistic modelling using stepwise backward variable selection to examine the outcome of early PDC flow dysfunction retained BMI, Age, and diabetic ESKD ($n=242$, Likelihood ratio statistic=9.03, $P=0.03$, pseudo $R^2 = 0.04$). Testing of model assumptions demonstrated VIFs ranging 1-1.5 for analyzed variables (suggesting low risk for multicollinearity), DFBETA analyses did not suggest outliers/influencing points (Figure 20), and the model was of good fit (Hosmer–Lemeshow, 10 groups, $p=0.54$). None of age, BMI, or diabetic ESKD reached statistical significance for predicting early PDC flow dysfunction in single predictor models. A higher BMI was associated with significantly increased odds of early PDC flow dysfunction in multi-predictor modeling while Diabetic ESKD demonstrated significantly lower odds of early PDC flow dysfunction (Figure 21). None of age, BMI, or diabetic ESKD demonstrated statistical interaction with sex (Table 19).

6.3.1 Sensitivity Analyses

Including patients who experienced attrition in the first three months for non-PDC flow dysfunction reasons, the median distance (interquartile range) between the cranial border of the pubic symphysis and the bottom of the PDC tip was comparable between those

who experienced early PDC flow dysfunction [37mm (29-53)] versus those who did not experience early catheter flow dysfunction [38mm (26-50); $P=0.6$; Figure 22]. Multiple logistic regression modelling with stepwise backward variable selection also retained BMI, Age, and diabetic ESKD ($n=272$, Likelihood ratio statistic=9.59, $P=0.02$, pseudo $R^2 = 0.05$). Testing of model assumptions demonstrated VIFs ranging 1-1.7 for analyzed variables (suggesting low risk for multicollinearity), DFBETA analyses did not suggest outliers/influencing points (Figure 23), and the model was of good fit (Hosmer–Lemeshow, 10 groups, $p=0.43$). None of Age, BMI, and diabetic ESKD reached statistical significance for predicting early PDC flow dysfunction in single predictor models. A higher BMI was associated with significantly increased odds of early PDC flow dysfunction in multi-predictor modeling while Diabetic ESKD demonstrated significantly lower odds of early PDC flow dysfunction (Figure 24). None of age, BMI, or diabetic ESKD demonstrated statistical interaction with sex (Table 20). Including patients who experienced attrition in the first three months for non-PDC flow dysfunction reasons and treating as if all experienced the outcome of interest, the median distance (interquartile range) between the cranial border of the pubic symphysis and the bottom of the PDC tip was comparable between those who experienced early PDC flow dysfunction [37mm (27-50)] versus not [38mm (26-49); $P=0.82$; Figure 25]. Multiple logistic regression modelling for early PDC flow dysfunction using stepwise backward variable selection retained only BMI ($n=272$, Likelihood ratio statistic=1.98, $P=0.16$, pseudo $R^2 = 0.007$), which did not reach statistical significance for predicting early PDC flow dysfunction ($p=0.16$), nor demonstrate statistical interaction with sex ($p=0.21$).

Table 5. Baseline characteristics of patients.

Characteristic	Males <i>n</i> = 196	Females <i>n</i> = 90	<i>P</i> Value
Age (years \pm SD)	62 \pm 16	58 \pm 16	0.08
BMI [median Kg/m ² (Q1-Q3)]*	28 (25-31)	26 (23-32)	0.45
White Race, n (%)	170 (87)	81 (90)	0.85
Cause of ESKD, n (%)			0.08
Diabetes	87 (44)	27 (30)	
Ischemic/Hypertension	30 (15)	14 (15)	
Glomerulonephritis	32 (17)	16 (17)	
Polycystic Kidney Disease	12 (6)	10 (11)	
Other	24 (12)	20 (24)	
Unknown	11 (6)	3 (3)	
Number of Prior Abdominopelvic Surgeries, n (%)			<0.001
0	118 (60)	33 (37)	
1	61 (31)	31 (34)	
2	16 (8)	16 (18)	
3	1 (1)	6 (7)	
4	0	4 (4)	
SD, Standard Deviation BMI, Body Mass Index ESKD, End Stage Kidney Disease *n = 196 males; 89 females			

Table 6. Summary of abdominopelvic surgeries by sex, n (%).

Surgery Type	Male 96 Surgeries	Female 97 Surgeries	<i>P</i> Value
Appendectomy	26 (27)	19 (20)	0.24
Inguinal Hernia Repair	22 (23)	1 (1)	<0.001
Cholecystectomy	17 (18)	12 (12)	0.32
Renal Transplant	8 (8)	3 (3)	0.13
Nephrectomy	7 (7)	5 (5)	0.52
Umbilical Hernia Repair	4 (4)	0	0.06
Esophageal Hernia Repair	1 (1)	0	0.49
Splenectomy	0	1 (1)	0.99
Cystectomy	0	2 (2)	0.49
Suprapubic Catheter	0	1 (1)	0.99
Ureter Reimplantation	0	1 (1)	0.99
Liver Transplant	1 (1)	0	0.49
Unknown	6 (6)	3 (3)	0.33
Prostatectomy	4 (4)	-	-
Uterine Suspension	-	1 (1)	-
Ovarian Cyst Removal/Oophorectomy	-	2 (2)	-
Cesarian Section	-	16 (17)	-
Tubal Ligation	-	14 (14)	-
Hysterectomy	-	16 (16)	-

Table 7. Radiographic measures.

Radiographic Measure [median (Q1-Q3)]	Males		Females		<i>P</i> Value
	<i>n</i>	Distance (mm)	<i>n</i>	Distance (mm)	
Cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis	189	28 (19-37)	86	35 (25-44)	0.001
Cranial border of pubic symphysis to bottom of peritoneal catheter tip	185	38 (30-50)	88	37 (24-49)	0.43

Table 8. Correlation analyses of predictor variables and radiographic measures.

Variable	Cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis (mm)		Cranial border of pubic symphysis to bottom of peritoneal dialysis catheter tip (mm)	
	ρ		ρ	
	Males n=189	Females n=86	Males n=185	Females n=88
Age (per year)	-0.10	-0.18	-0.16	-0.11
BMI (per Kg/m ²)	0.08	0.14	0.37	0.23
Number of Prior Abdominopelvic Surgeries	0.04	-0.08	-0.11	-0.26
<p>ρ, Spearman Rank Correlation Coefficient BMI, Body mass index</p>				

Table 9. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Males, n=189.

Variable	Coefficient (β)	SE	95% CI	Wald χ^2	p value
Age (per year)	-0.08	0.07	-0.21 to 0.06	-1.13	0.26
BMI (per Kg/m ²)	0.31	0.21	-0.97 to 0.71	1.50	0.14
PKD	4.21	4.70	-5.07 to 13.49	0.90	0.37
White Race	0.93	3.21	-5.41 to 7.26	0.29	0.77
Number Of Prior Abdominopelvic Surgeries	1.56	1.60	-1.59 to 4.71	0.98	0.33
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease					

Table 10. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Females, n=85.

Variable	Coefficient (β)	SE	95% CI	Wald χ^2	p value
Age (per year)	-0.15	0.12	-0.39 to 0.08	-1.27	0.11
BMI (per Kg/m ²)	0.53	0.33	-0.12 to 1.18	1.63	0.11
PKD	6.61	5.61	-4.6 to 17.81	1.17	0.24
White Race	-0.55	2.61	-12.28 to 11.19	-0.09	0.93
Number Of Prior Abdominopelvic Surgeries	-0.67	1.65	-3.83 to 2.54	-0.42	0.68
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease					

Table 11. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Males, n=185.

Variable	Coefficient (β)	SE	95% CI	Wald χ^2	p value
Age ^a (per year)	-0.16	0.07	-0.29 to -0.03	-2.36	0.02
BMI ^b (per Kg/m ²)	1.08	0.19	0.69 to 1.47	5.46	<0.001
PKD	1.45	4.15	-6.74 to 9.65	0.39	0.73
White Race	5.12	3.13	-1.07 to 11.31	-1.63	0.1
Number of Prior Abdominopelvic Surgeries	-2.23	1.53	-5.26 to 0.81	-1.45	0.15
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease Interaction (#):					
^a Age#PKD, BMI, White Race, Number of Prior Abdominopelvic Surgeries; p=0.97					
^a Age#White Race, BMI, PKD, Number of Prior Abdominopelvic Surgeries; p=0.13					
^a Age#Number of Prior Abdominopelvic Surgeries, BMI, PKD, White Race; p=0.19					
^{a,b} Age#BMI, PKD, White Race, Number of Prior Abdominopelvic Surgeries; p=0.51					
^b BMI#PKD, Age, White Race, Number of Prior Abdominopelvic Surgeries; p=0.25					
^b BMI#White Race, Age, PKD, Number of Prior Abdominopelvic Surgeries; p=0.41					
^b BMI#Number of Prior Abdominopelvic Surgeries, Age, PKD, White Race; p=0.46					

Table 12. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Females, n=87.

Variable	Coefficient (β)	SE	95% CI	Wald χ^2	p value
Age (per year)	-0.13	0.14	-0.41 to 0.15	-0.94	0.35
BMI ^a (per Kg/m ²)	0.79	0.39	0.01 to 1.57	2.01	0.04
PKD	-6.91	6.89	-20.61 to 6.81	-1.00	0.32
White Race	0.94	7.19	-13.37 to 15.24	-0.13	0.90
Number Of Prior Abdominopelvic Surgeries	-3.44	1.97	-7.37 to 0.48	-1.75	0.09
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease Interaction (#):					
^a BMI#Age, PKD, White Race, Number of Prior Abdominopelvic Surgeries; p=0.71					
^a BMI#PKD, Age, White Race, Number of Prior Abdominopelvic Surgeries; p=0.61					
^a BMI#White Race, Age, PKD, Number of Prior Abdominopelvic Surgeries; p=0.62					
^a BMI#Number of Prior Abdominopelvic Surgeries, Age, PKD, White Race; p=0.31					

Table 13. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep; Males – omission of nine outlier/influential points.

Variable	All Observations, n=189		Omitting 9 Observations, n=180	
	Coefficient (β)	95% CI	Coefficient (β)	95% CI
Age (per year)	-0.15	-0.21 to 0.06	-0.11	-0.23 to 0.01
BMI (per Kg/m ²)	0.53	-0.97 to 0.71	0.36	-0.01 to 0.73
PKD	6.61	-5.07 to 13.49	1.59	-11.34 to 8.16
White Race	-0.55	-5.41 to 7.26	0.13	-5.68 to 5.94
Number of Prior Abdominopelvic Surgeries	-0.67	-1.59 to 4.71	1.23	-1.72 to 4.17
CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease				

Table 14. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Females - omission of five outlier/influential points.

Variable	All Observations, n=85		Omitting 9 Observations, n=80	
	Coefficient (β)	95% CI	Coefficient (β)	95% CI
Age (per year)	-0.15	-0.39 to 0.08	-0.09	-0.31 to 0.12
BMI (per Kg/m ²)	0.53	-0.12 to 1.18	0.55	-0.04 to 1.14
PKD	6.61	-4.6 to 17.81	11.57	-0.92 to 22.2
White Race	-0.55	-12.28 to 11.19	-0.27	-13.83 to 13.28
Number of Prior Abdominopelvic Surgeries	-0.67	-3.83 to 2.54	-0.3	-3.34 to 2.73
CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease				

Table 15. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Males - omission of five outlier/influential points.

Variable	All Observations, n=185		Omitting 5 Observations, n=180	
	Coefficient (β)	95% CI	Coefficient (β)	95% CI
Age (per year)	-0.16	-0.29 to -0.03	-0.15	-0.28 to 0.03
BMI (per Kg/m ²)	1.08	0.69 to 1.47	1.11	0.72 to 1.51
PKD	1.45	-6.74 to 9.65	8.19	-0.75 to 17.1
White Race	5.12	-1.07 to 11.31	4.45	-1.54 to 10.45
Number of Prior Abdominopelvic Surgeries	-2.23	-5.26 to 0.81	-1.75	-4.67 to 1.16
CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease				

Table 16. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Females - omission of six outlier/influential points.

Variable	All Observations, n=87		Omitting 6 Observations, n=81	
	Coefficient (β)	95% CI	Coefficient (β)	95% CI
Age (per year)	-0.13	-0.41 to 0.15	-0.14	-0.39 to 0.11
BMI (per Kg/m ²)	0.79	0.01 to 1.57	0.78	0.06 to 1.49
PKD	-6.91	-20.61 to 6.81	-11.61	-24.54 to 1.32
White Race	0.94	-13.37 to 15.24	4.29	-13.04 to 21.63
Number of Prior Abdominopelvic Surgeries	-3.44	-7.37 to 0.48	-2.75	-6.59 to 1.10
CI, Confidence Interval; BMI, Body Mass Index; PKD, Polycystic Kidney Disease				

Table 17. Characteristics of patients according to outcome of early peritoneal dialysis catheter flow dysfunction.

Characteristic	Early Catheter Flow Dysfunction		P Value
	No (n = 219)	Yes (n = 35)	
Age (years \pm SD)	61 \pm 16	58 \pm 19	0.29
BMI [median Kg/m ² (Q1-Q3)]	27 (24-31)*	29 (25-33)	0.12
Break-in Period [median days (Q1-Q3)]	38 (17-68)	38 (18-80)	0.77
Male, n (%)	153 (69)	22 (63)	0.26
White Race, n (%)	192 (87)	33 (94)	0.77
Cause of ESKD, n (%)			0.47
Diabetes	89 (40)	9 (25)	
Ischemic/Hypertension	38(17)	7 (20)	
Glomerulonephritis	32 (15)	7 (20)	
PKD	18 (8)	3 (9)	
Other	32 (15)	6 (17)	
Unknown	10 (5)	3 (9)	
Number of Prior Abdominopelvic Surgeries, n (%)			0.55
0	115 (52)	19 (54)	
1	74 (34)	10 (29)	
2	22 (10)	4 (11)	
3	4 (2)	2 (6)	
4	4 (2)	0	
SD, Standard Deviation BMI, Body mass index ESKD, End Stage Kidney Disease PKD, Polycystic Kidney Disease *n = 218			

Table 18. Characteristics of patients, comparing early peritoneal dialysis catheter flow dysfunction status and attrition for non-peritoneal dialysis catheter flow dysfunction reasons.

Characteristic	Early Catheter Dysfunction		Attrition, Non-Catheter Dysfunction	P Value
	No (n = 219)	Yes (n = 35)	(n = 32)	
Age (years \pm SD)	61 \pm 16	58 \pm 19	65 \pm 15	0.18
BMI [median Kg/m ² (Q1-Q3)]	27 (24-31)*	29 (25-33)	29 (26-31)	0.16
Break-in Period [median days (Q1-Q3)]	38 (17-68)	38 (18-80)	37 (19-75)	0.95
Male, n (%)	153 (69)	22 (63)	21 (66)	0.62
White Race, n (%)	192 (87)	33 (94)	26 (81)	0.47
Cause of ESKD, n (%)				0.72
Diabetes	89 (40)	9 (25)	16 (50)	
Ischemic/Hypertension	38(17)	7 (20)	5 (16)	
Glomerulonephritis	32 (15)	7 (20)	3 (9)	
PKD	18 (8)	3 (9)	2 (6)	
Other	32 (15)	6 (17)	4 (13)	
Unknown	10 (5)	3 (9)	2 (6)	
Number of Prior Abdominopelvic Surgeries, n (%)				0.62
0	115 (52)	19 (54)	17 (53)	
1	74 (34)	10 (29)	8 (25)	
2	22 (10)	4 (11)	6 (19)	
3	4 (2)	2 (6)	1 (3)	
4	4 (2)	0	0	
SD, Standard Deviation BMI, Body mass index ESKD, End Stage Kidney Disease PKD, Polycystic Kidney Disease *n = 218				

Table 19. Logistic regression model for early peritoneal dialysis catheter flow dysfunction using backward variable selection^a, n=242.

Early Catheter Flow Dysfunction	Odds Ratio	SE	95% CI	z	p value
BMI (per Kg/m ²)	1.09	0.04	1.01 to 1.17	2.32	0.02
Age (per year)	0.98	0.01	0.96 to 1	-1.35	0.17
Diabetic ESKD	0.39	0.18	0.16 to 0.95	-2.08	0.04
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; ESKD, End Stage Kidney Disease ^a Age, BMI, Sex, White Race, break in period, number of prior abdominopelvic surgeries, cause of ESKD: Diabetic, Ischemic, Glomerulonephritis, Polycystic Kidney Disease, Other, Unknown Interaction (#): BMI#Sex, Age, Diabetic ESKD; p=0.75 Age#Sex, BMI, Diabetic ESKD; p=0.34 Diabetic ESKD#Sex, BMI, Age; p=0.98					

Table 20. Logistic regression model for early peritoneal dialysis catheter flow dysfunction using backward variable selection^a; Inclusive of patients with non-peritoneal dialysis catheter flow dysfunction and attrition in first 3 months, n=272.

Early Catheter Flow Dysfunction	Odds Ratio	SE	95% CI	z	p value
BMI (per Kg/m ²)	1.08	0.04	1.01 to 1.16	2.24	0.03
Age (per year)	0.98	0.01	0.96 to 1.01	-1.46	0.14
Diabetic ESKD	0.39	0.17	0.16 to 0.93	-2.13	0.03
SE, Standard Error; CI, Confidence Interval; BMI, Body Mass Index; ESKD, End Stage Kidney Disease ^a Age, BMI, Sex, White Race, break in period, number of prior abdominopelvic surgeries, causes of ESKD: Diabetic, Ischemic, Glomerulonephritis, Polycystic Kidney Disease, Other, Unknown Interaction (#): BMI#Sex, Age, Diabetic ESKD; p=0.77 Age#Sex, BMI, Diabetic ESKD; p=0.31 Diabetic ESKD#Sex, BMI, Age; p=0.83					

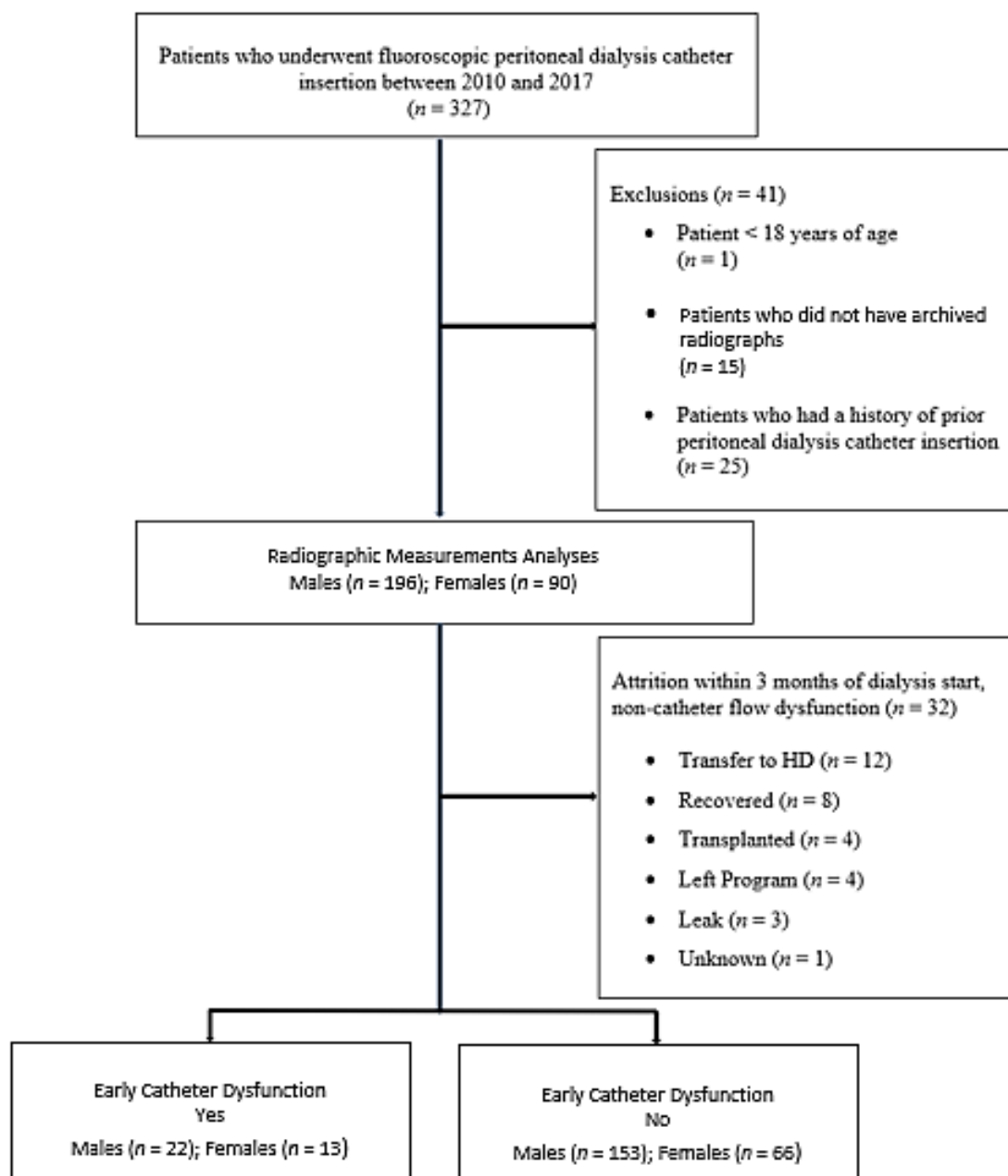


Figure 5. Selection of fluoroscopic peritoneal dialysis catheter insertion cohort (2010 to 2017) and outcome of peritoneal dialysis catheter flow dysfunction within 3 months of initiating peritoneal dialysis.

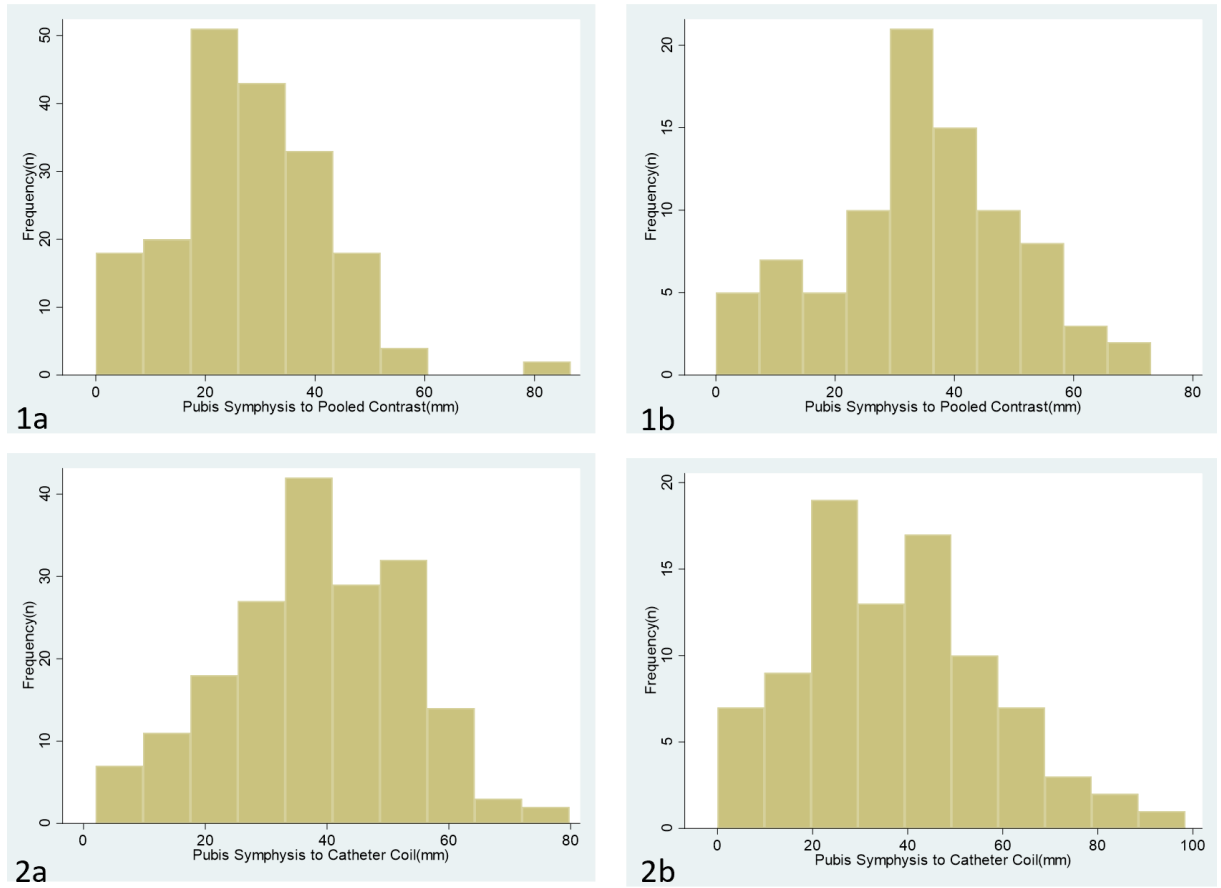


Figure 6. Frequency distribution of the distance (mm) between 1. Cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; 2. Cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip (coil); Males (a); Females (b).

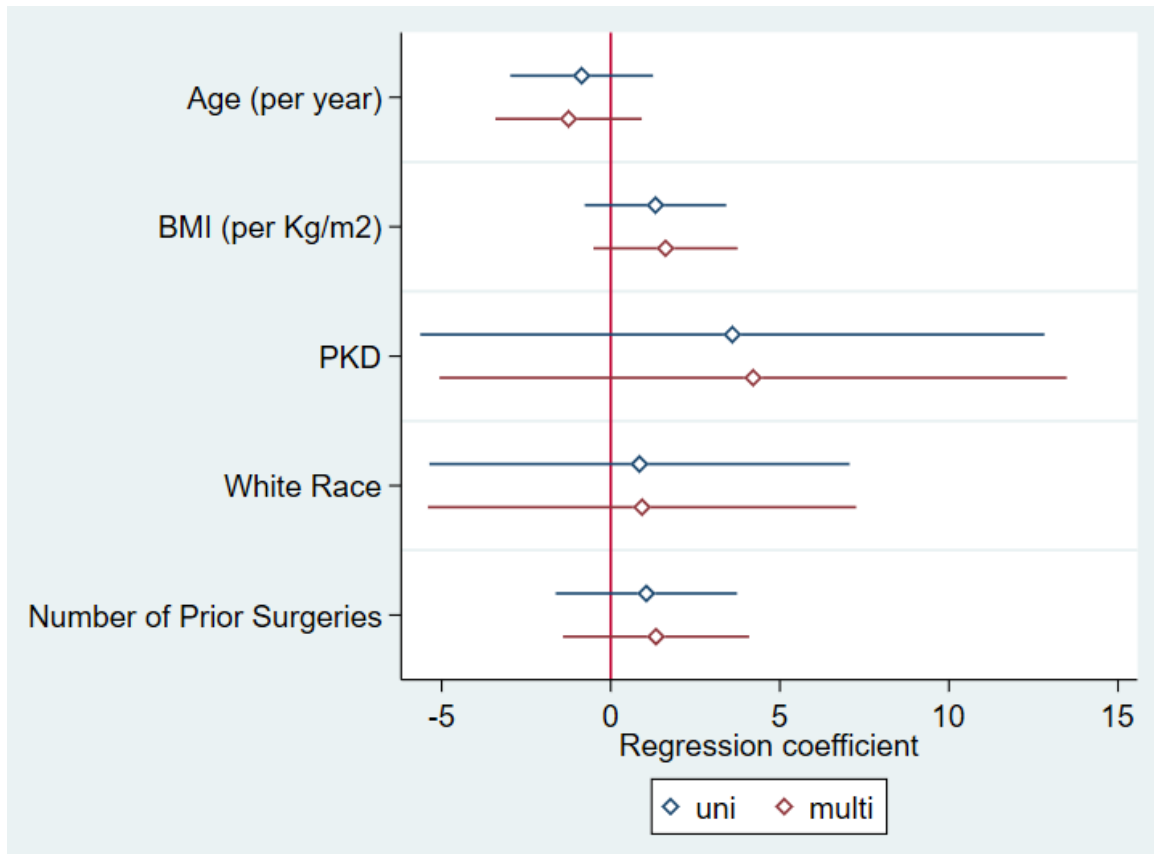


Figure 7. Regression coefficient estimates and 95% confidence intervals for single predictor (uni) and multiple linear regression models - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Males, n=189. BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

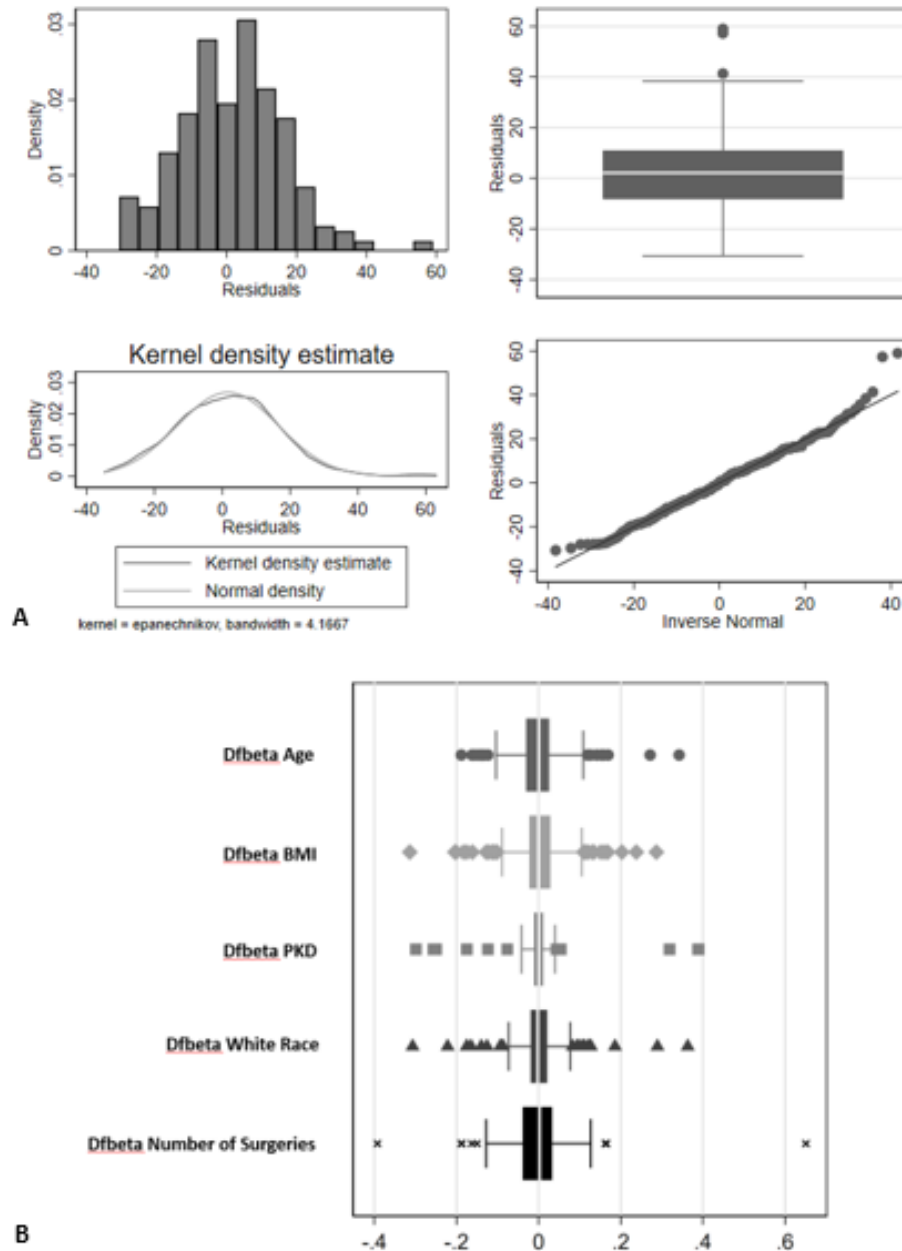


Figure 8. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Males, n=189; Test of model assumptions: A) Distribution of residuals & checks of normality B) Box & whisker plots - DFBETA values; BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

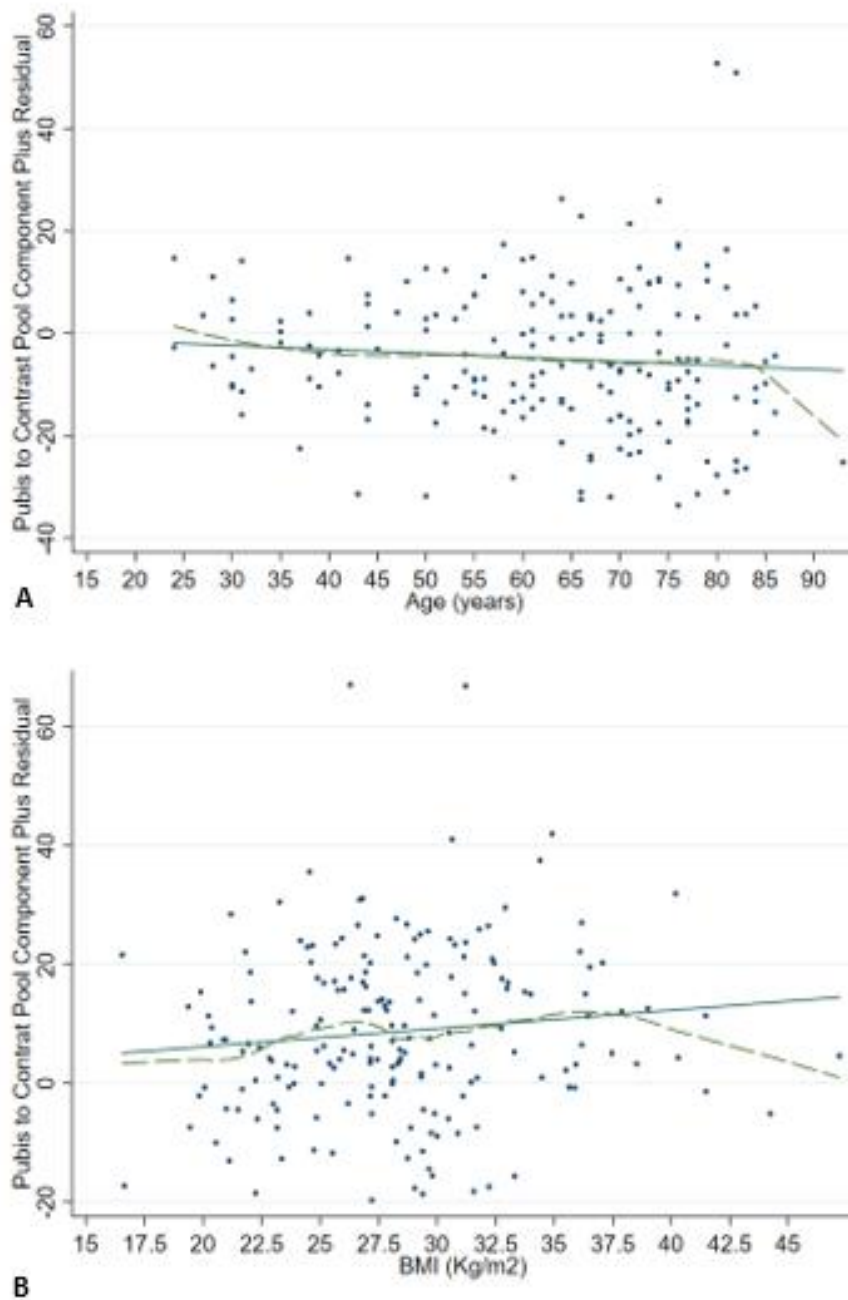


Figure 9. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Males, n=189; Test of model assumptions: A) Component-Plus-Residual Plot on Age. B) Component-Plus-Residual Plot on BMI. BMI, Body Mass Index.

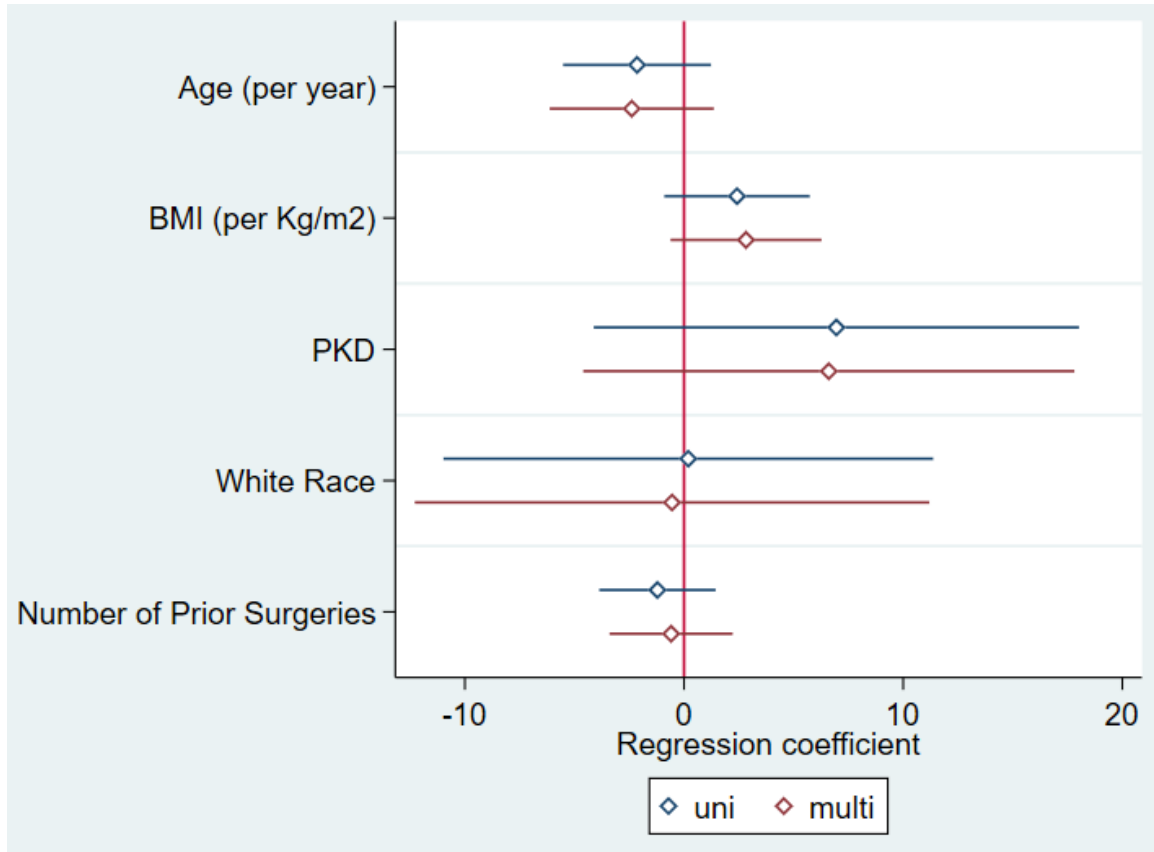


Figure 10. Regression coefficient estimates and 95% confidence intervals for single predictor (uni) and multiple (multi) linear regression models - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Females, n=85. BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

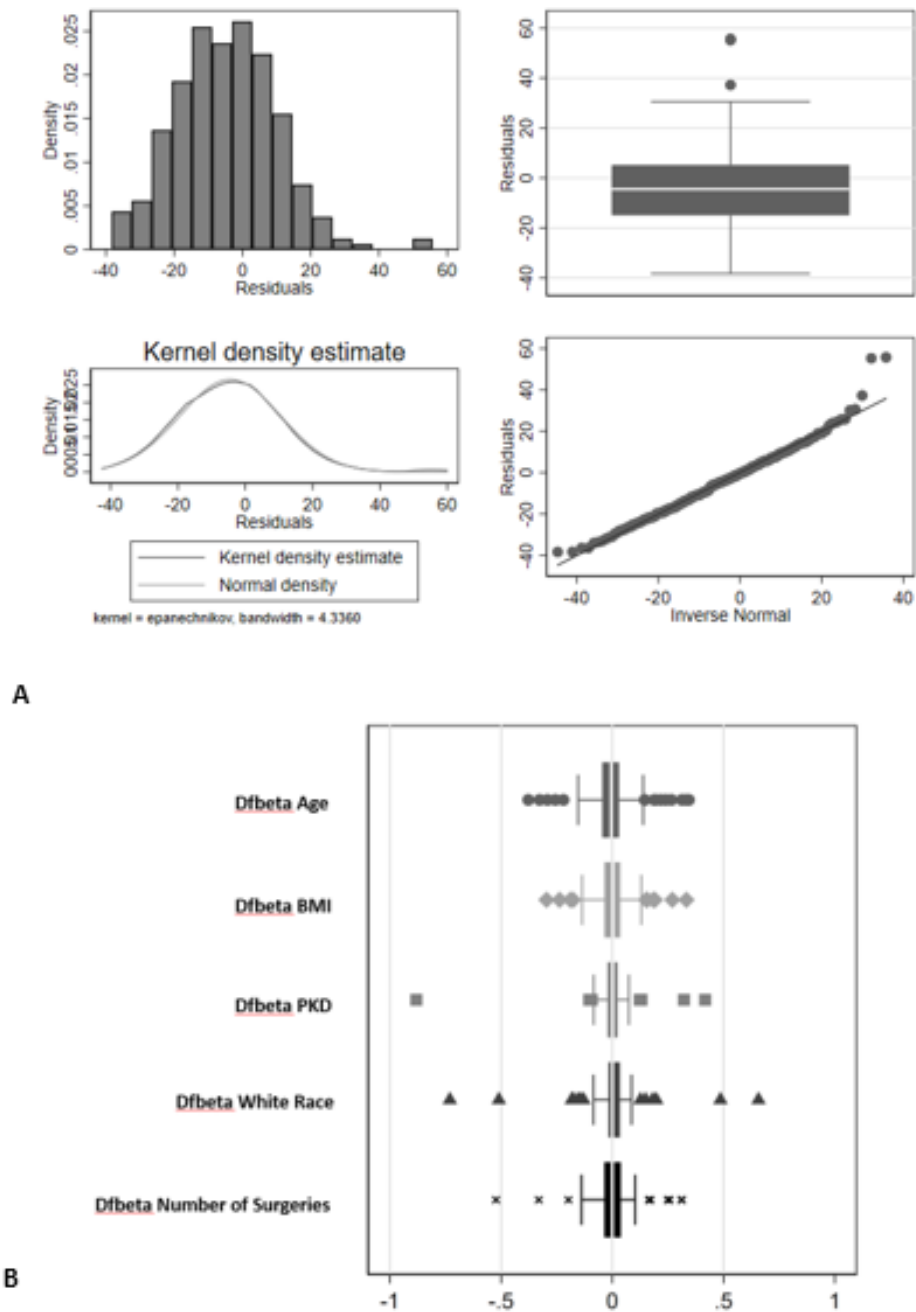


Figure 11. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Females, n=85; Test of model assumptions: A) Distribution of residuals & checks of normality B) Box & whisker plots - DFBETA values; BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

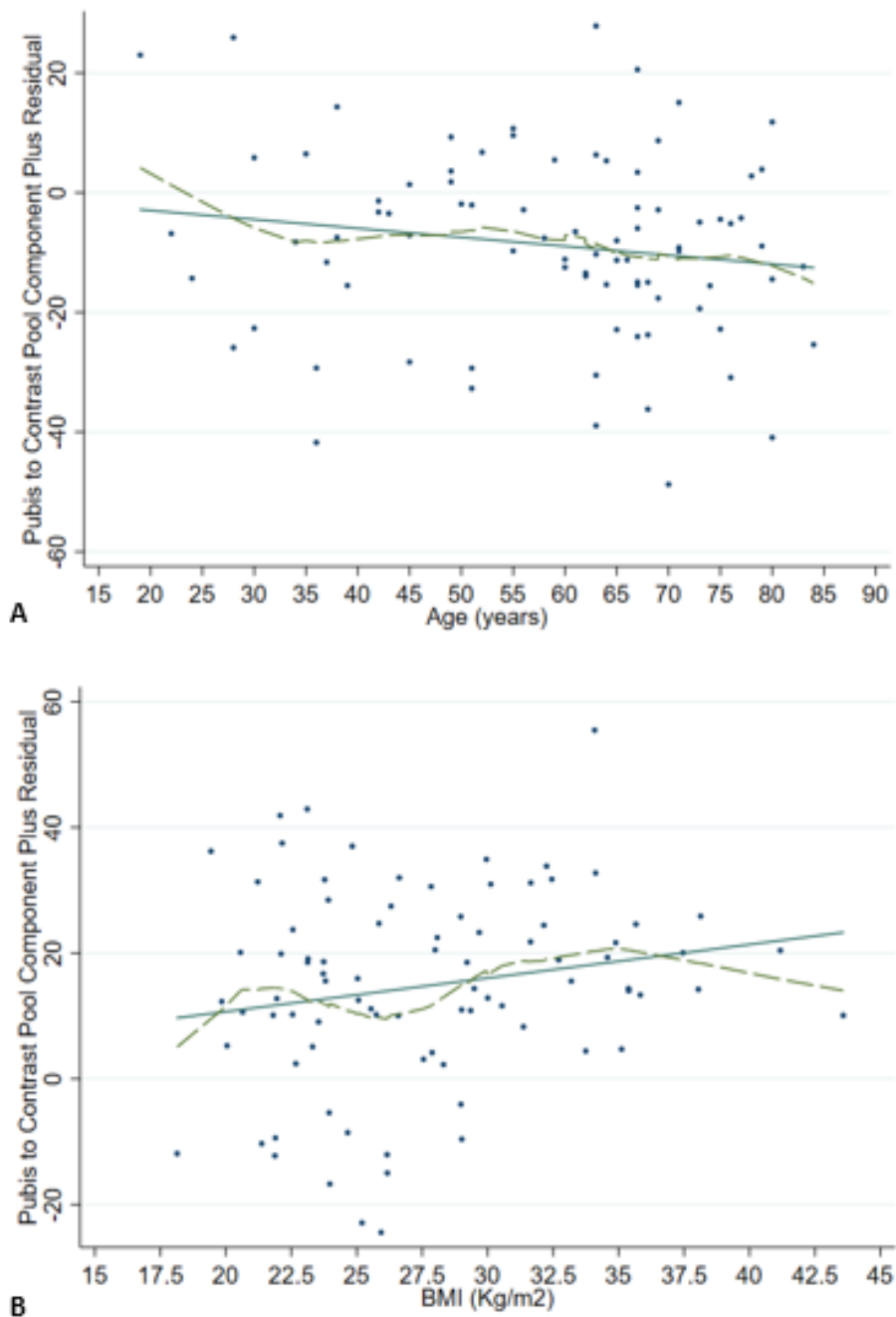


Figure 12. Multiple linear regression model - cranial border of pubic symphysis to caudal border of intraabdominal radiocontrast pooled in the deep pelvis; Females, n=85; Test of model assumptions: A) Component-Plus-Residual Plot on Age. B) Component-Plus-Residual Plot on BMI. BMI, Body Mass Index.

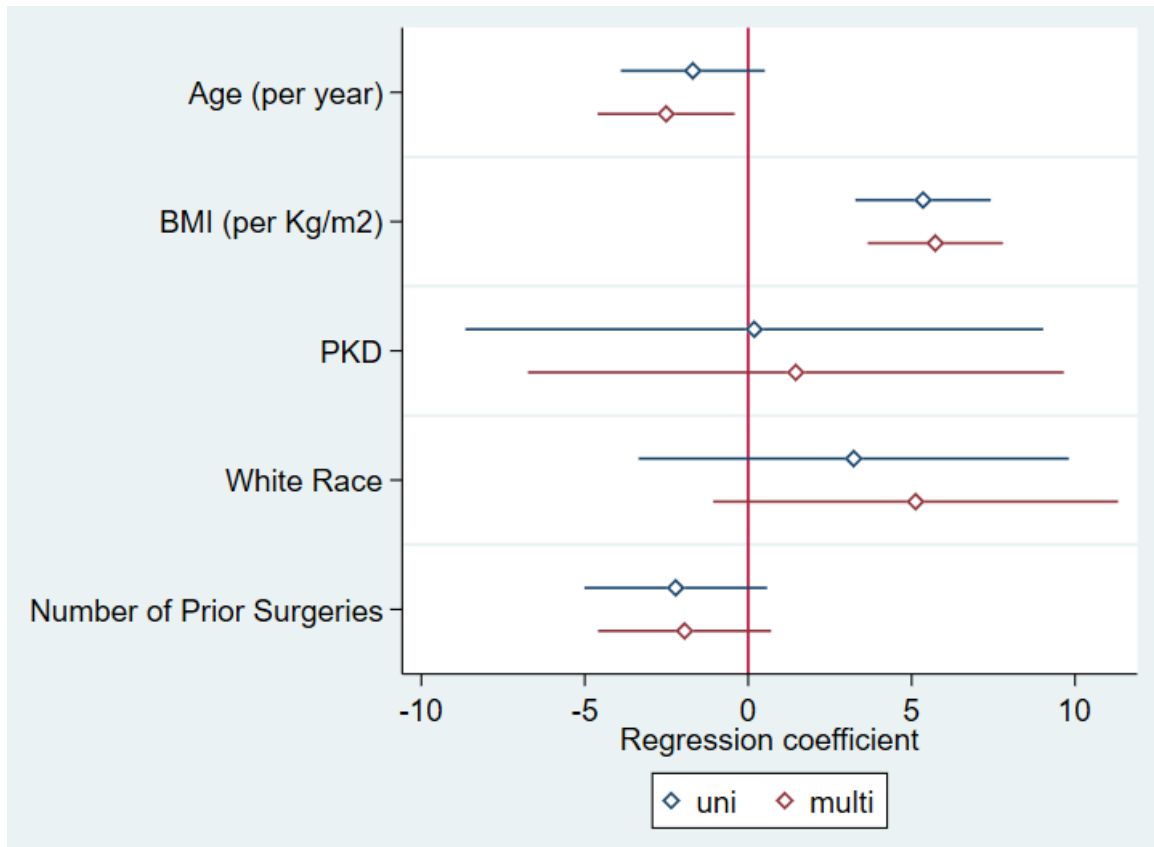


Figure 13. Regression coefficients and 95% confidence intervals for single predictor (uni) and multiple (multi) linear regression models - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Males, n=185. BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

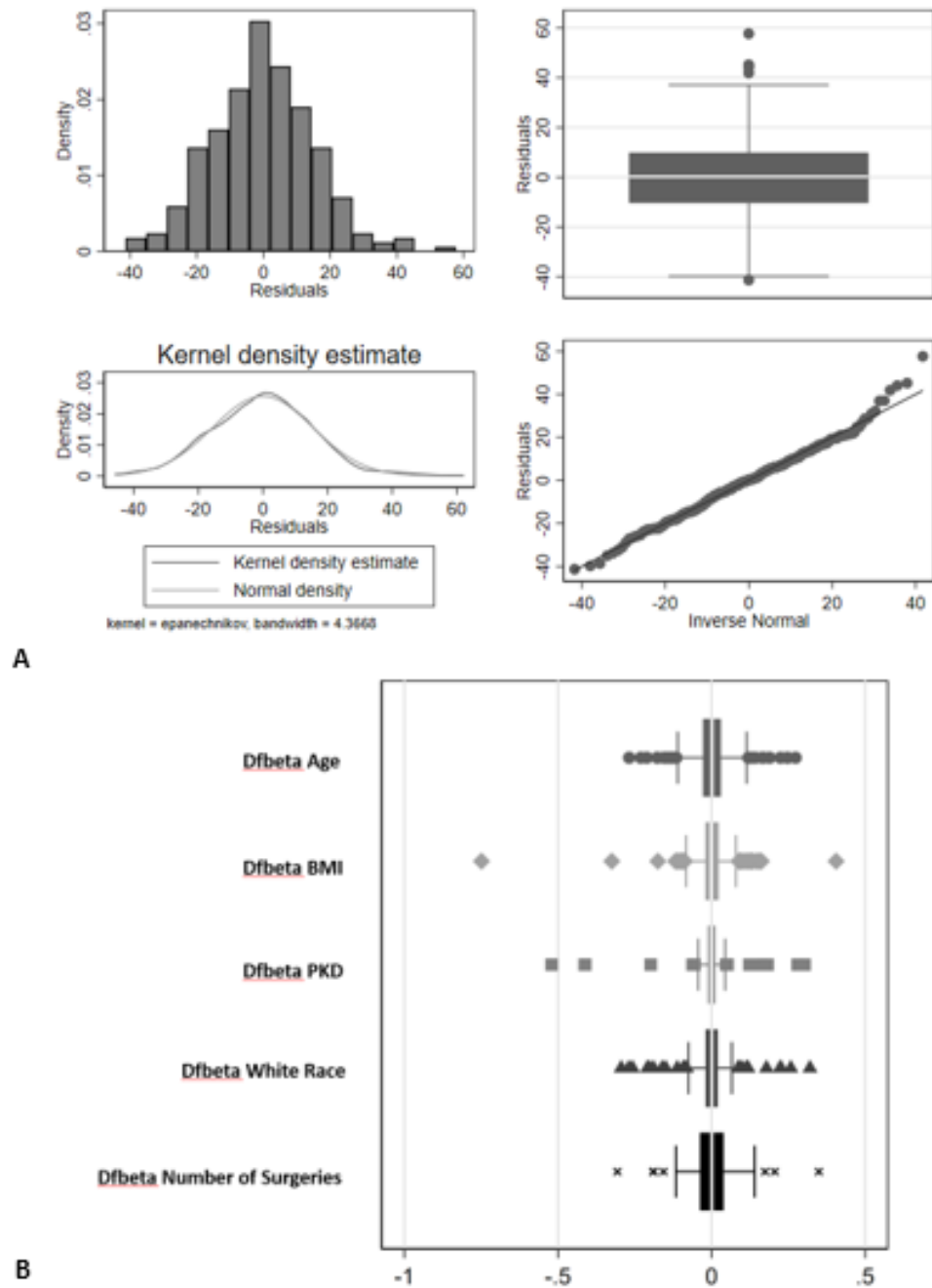


Figure 14. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Males, n=185; Test of model assumptions: A) Distribution of residuals & checks of normality B) Box & whisker plots - DFBETA values; BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

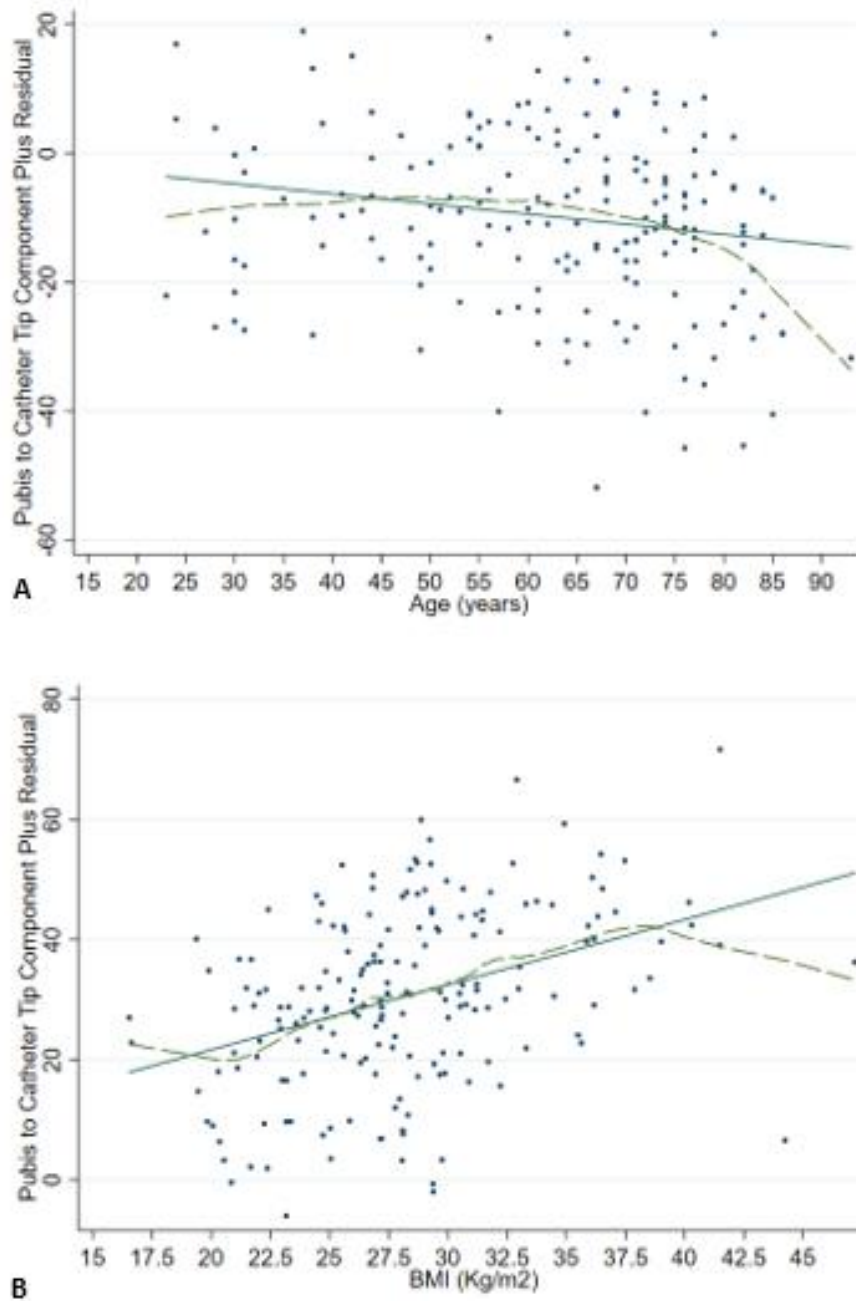


Figure 15. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Males, n=185; Test of model assumptions: A) Component-Plus-Residual Plot on Age. B) Component-Plus-Residual Plot on BMI. BMI, Body Mass Index.

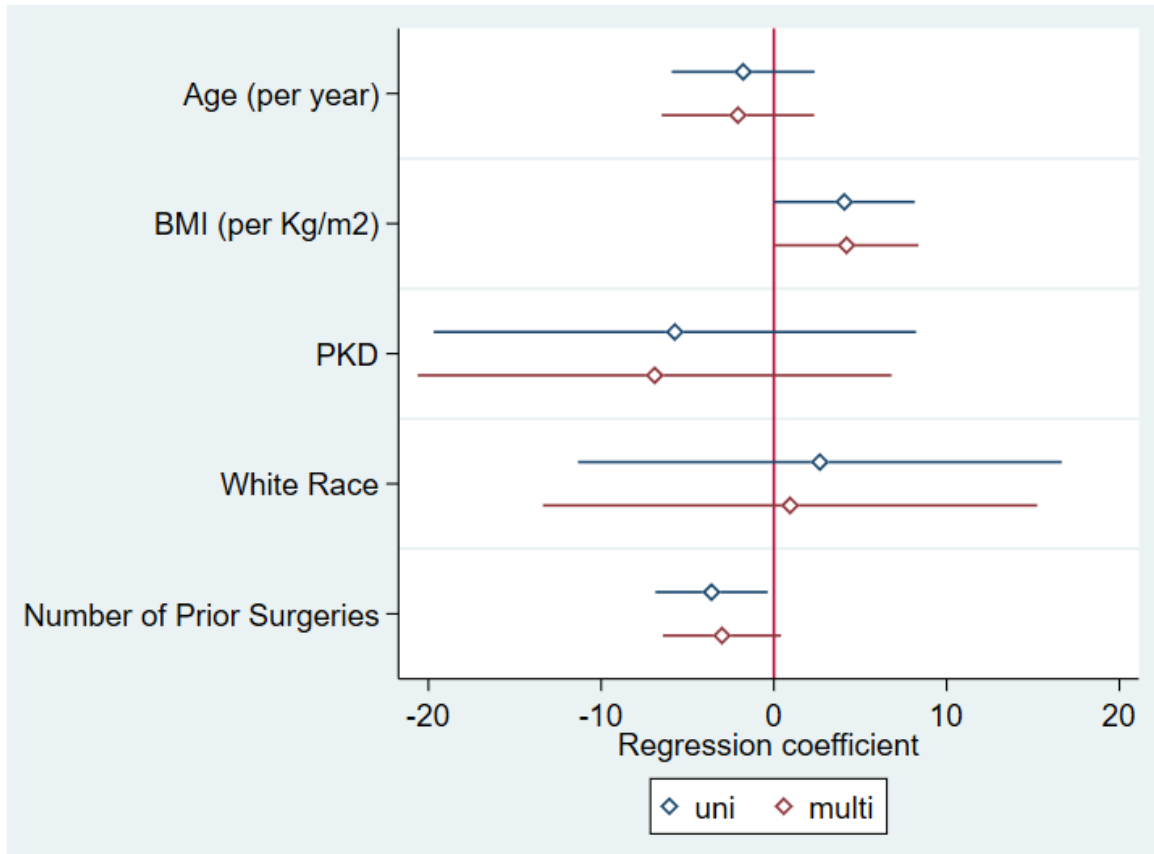


Figure 16. Regression coefficients and 95% confidence intervals for single predictor (uni) and multiple (multi) linear regression models - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip: Females, n=87. BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

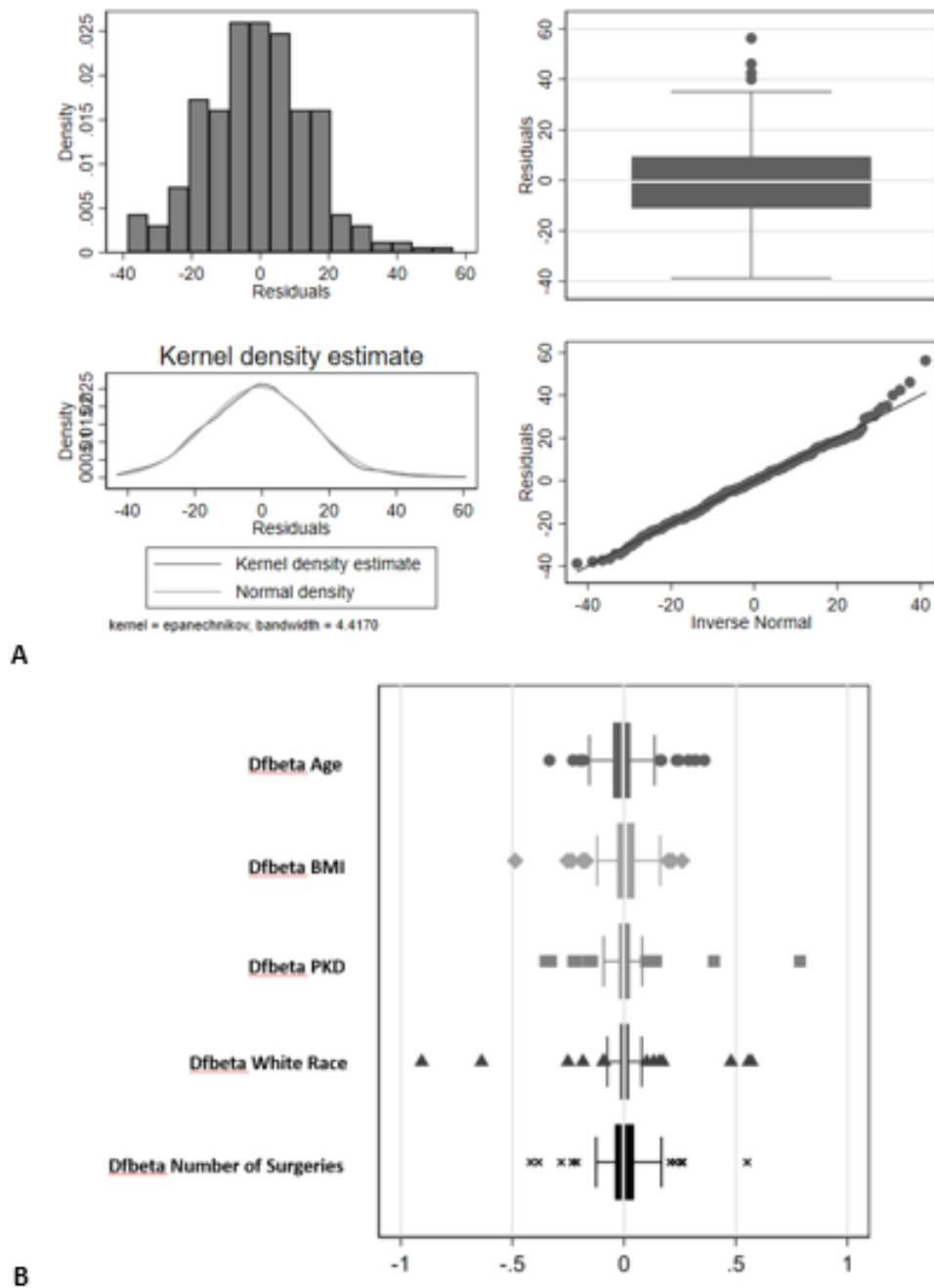


Figure 17. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Females, n=87; Test of model assumptions: A) Distribution of residuals & checks of normality B) Box & whisker plots - DFBETA values; BMI, Body Mass Index; PKD, Polycystic Kidney Disease.

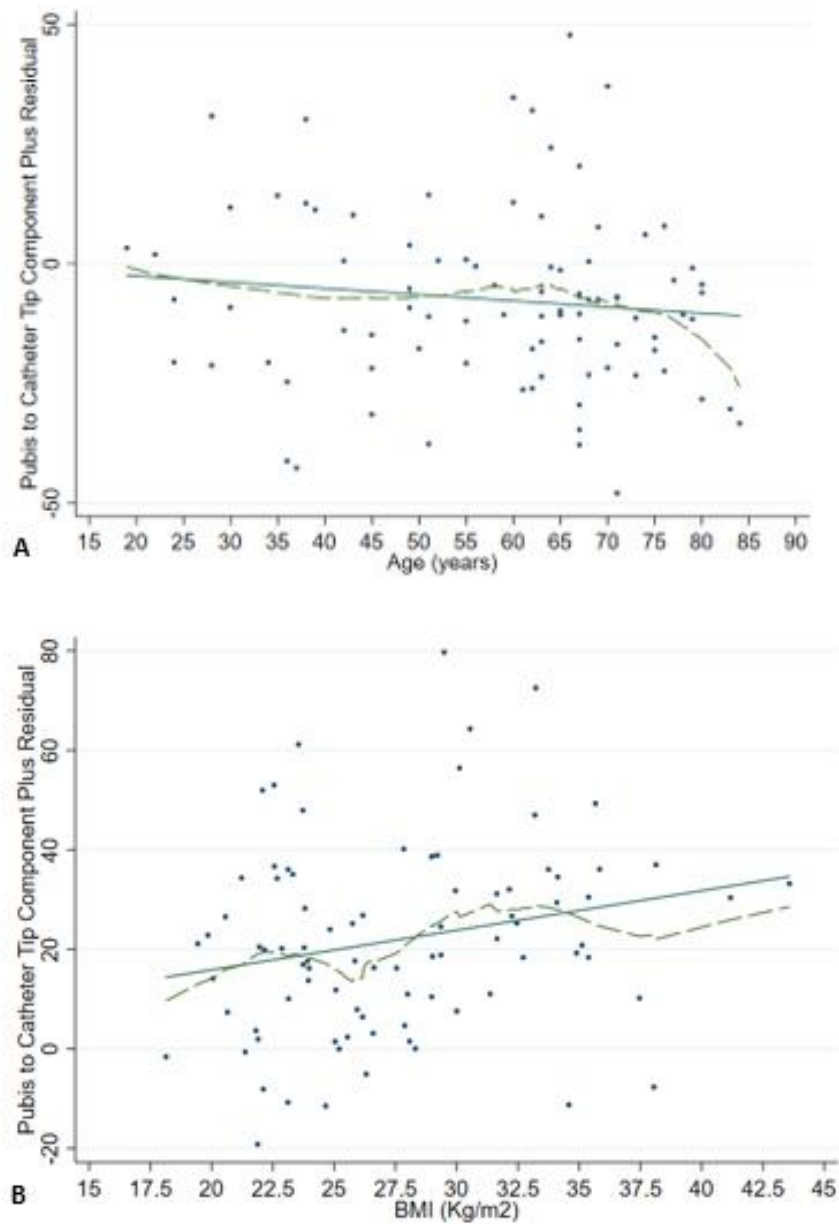


Figure 18. Multiple linear regression model - cranial border of pubic symphysis to bottom of the peritoneal dialysis catheter tip; Females, n=87; Test of model assumptions: A) Component-Plus-Residual Plot on Age. B) Component-Plus-Residual Plot on BMI. BMI, Body Mass Index.

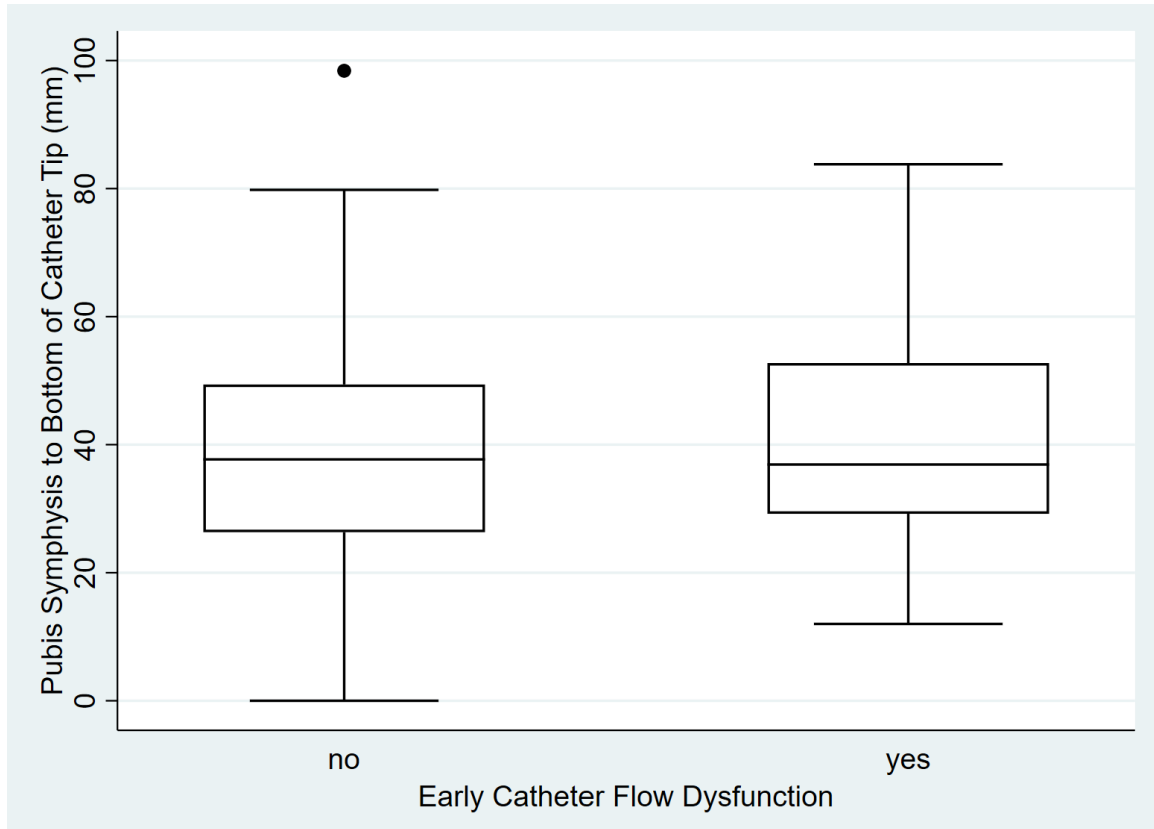


Figure 19. Box & whisker plots - cranial border of pubic symphysis to bottom of peritoneal dialysis catheter tip [median mm (Q1-Q3)] comparing those with early peritoneal dialysis catheter flow dysfunction (n=34) vs. not (n=208).

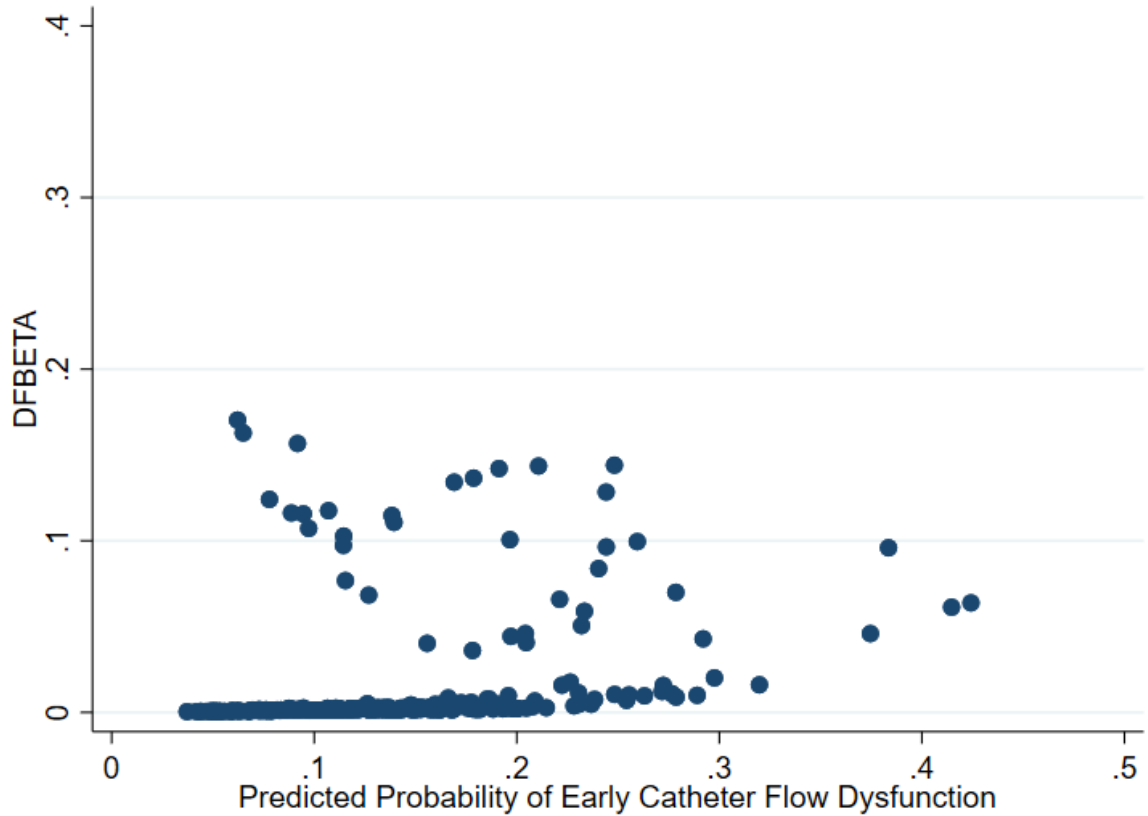


Figure 20. Influence DFBETA statistics for logistic regression model for early peritoneal dialysis catheter flow dysfunction using backward variable selection^a, n=242. ^aAge, BMI, Sex, White Race, break in period, number of prior abdominopelvic surgeries, cause of End Stage Kidney Disease: Diabetic, Ischemic, Glomerulonephritis, Polycystic Kidney Disease, Other, Unknown

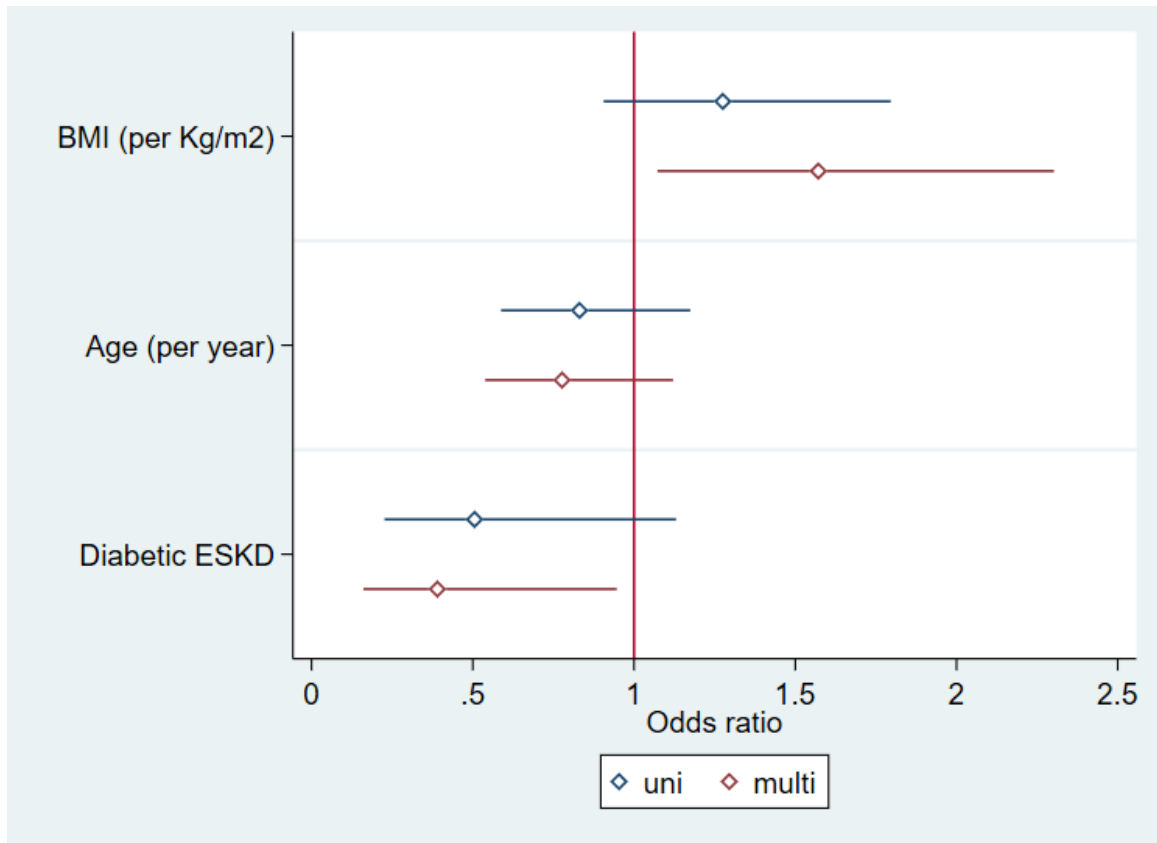


Figure 21. Odds Ratios and 95% confidence intervals for single predictor (uni) and multiple (multi) logistic regression models of early peritoneal dialysis catheter flow dysfunction (yes, n=34; no, n=208). BMI, Body Mass Index; ESKD, End Stage Kidney Disease.

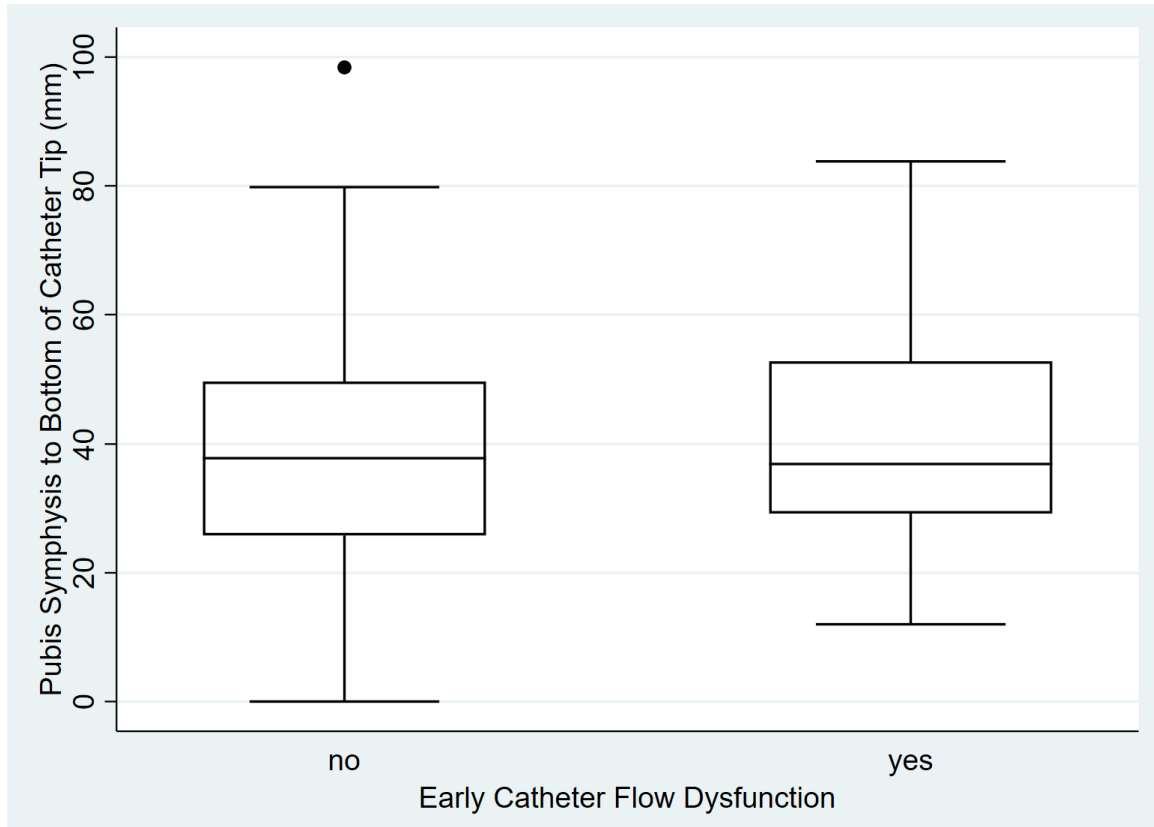


Figure 22. Box & whisker plots - cranial border of pubic symphysis to bottom of peritoneal dialysis catheter tip [median mm (Q1-Q3)] comparing those with early peritoneal dialysis catheter flow dysfunction (n=34) and not (inclusive of patients with non-peritoneal dialysis catheter flow dysfunction and attrition in first 3 months; n=239).

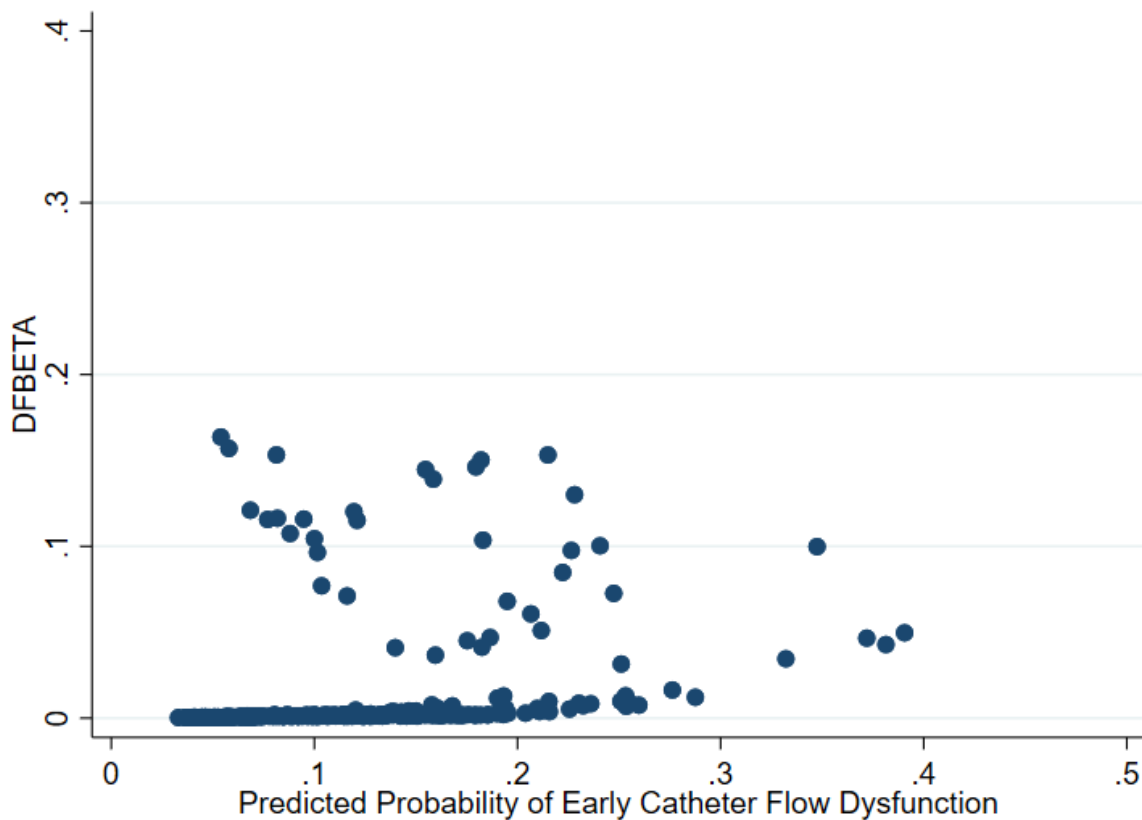


Figure 23. Influence DFBETA statistics for logistic regression model for early peritoneal dialysis catheter flow dysfunction using backward variable selection^a; Inclusive of patients with non-peritoneal dialysis catheter flow dysfunction and attrition in first 3 months, n=272. ^aAge, BMI, Sex, White Race, break in period, number of prior abdominopelvic surgeries, cause of End Stage Kidney Disease: Diabetic, Ischemic, Glomerulonephritis, Polycystic Kidney Disease, Other, Unknown.

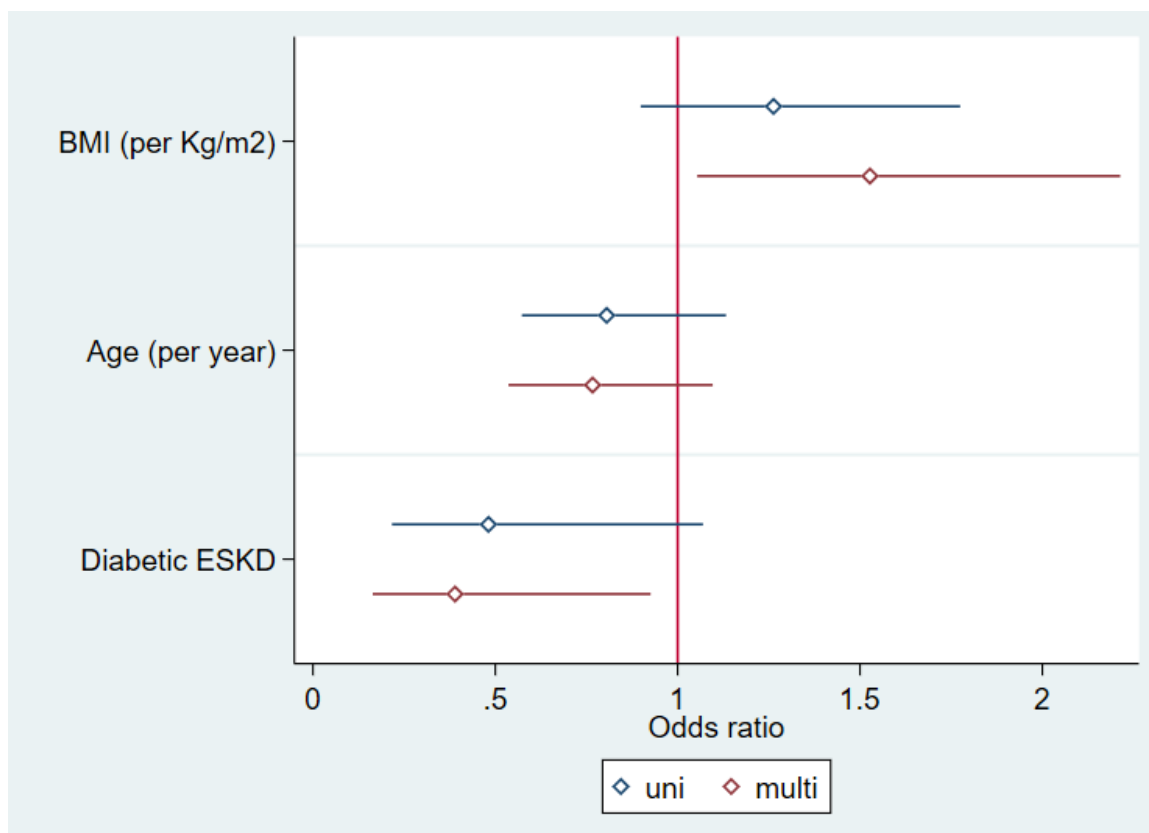


Figure 24. Odds ratios and 95% confidence intervals for single predictor (uni) and multiple (multi) logistic regression models of early peritoneal dialysis catheter flow dysfunction [yes, n=34; no, n=239 (inclusive of patients with non-peritoneal dialysis catheter flow dysfunction and attrition in first 3 months)]. BMI, Body Mass Index; ESKD, End Stage Kidney Disease.

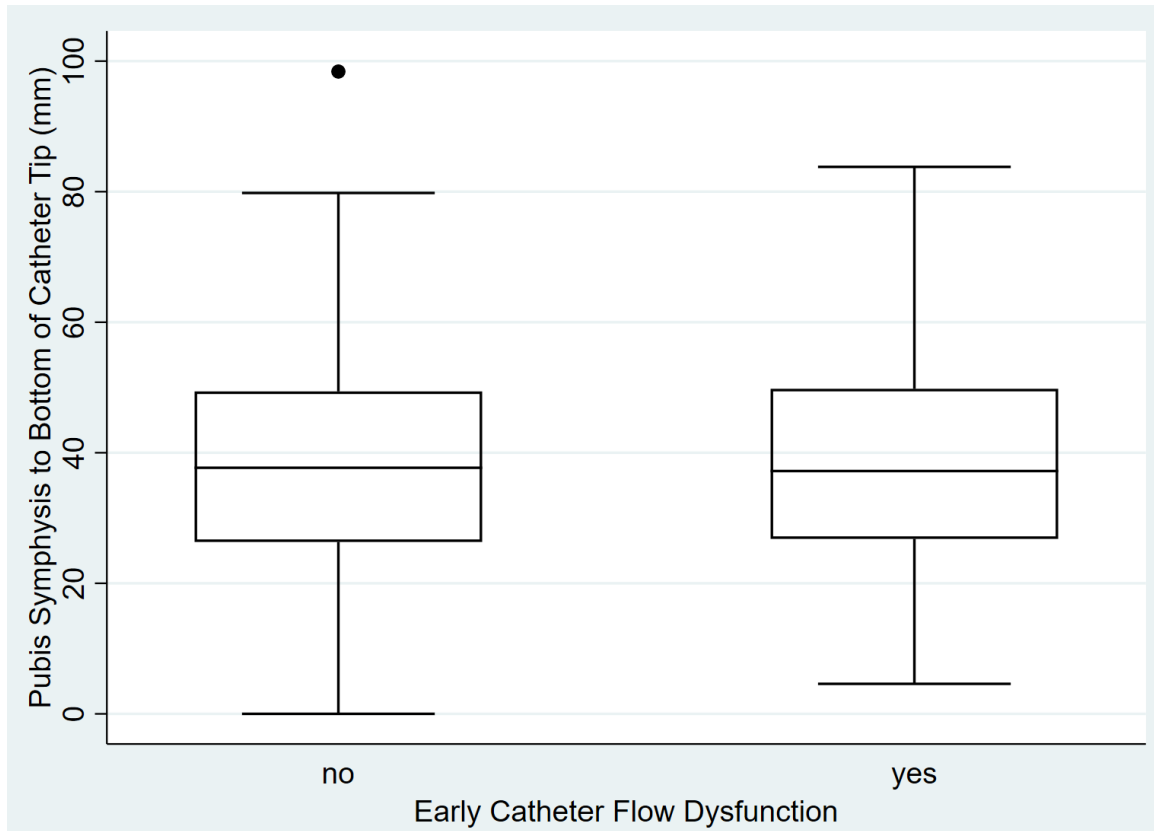


Figure 25. Box & whisker plots - cranial border of pubic symphysis to bottom of peritoneal dialysis catheter tip [median mm (Q1-Q3)] comparing those with early peritoneal dialysis catheter flow dysfunction (inclusive of patients with non-peritoneal dialysis catheter flow dysfunction and attrition in first 3 months and assumed to have outcome of interest (n=65), and not (n=208).

Chapter 7

7 Discussion

7.1 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Landmarking the True Pelvis & Final Catheter Tip Position

By analyzing procedural fluoroscopic radiographs from a retrospective cohort of patients who underwent incident fluoroscopic PDC insertion, we described the distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis (referencing midline in a standard-anterior posterior pelvic view, with the patient in the supine position; Figure 3). Overall, the variability of this distance was small (interquartile range of 1.8 cm in males and 2 cm in females). Similarly, the variability of the measured distance between the cranial border of the pubic symphysis and the bottom of the PDC tip (referencing midline in a standard anterior posterior pelvic view; Figure 4)) was also nominal (interquartile range of 1.9 cm in males and 2.5 cm in females).

Our results, indicating that the distance between the cranial border of the pubic symphysis and the caudal border of intraabdominal radiocontrast pooled in the deep pelvis being larger in females compared to males, aligned with our initial predictions regarding sex-related differences of pelvis structure and anatomy.^{115, 116} Although statistically different, the clinical significance between the two groups may be limited as the absolute difference in the median distance was less than one centimeter.

Our modeling did not suggest effects of Race-related differences of pelvis structure⁸⁹ on radiographic measurements. Acknowledging that our study cohort was vastly of White race, with other Racial minorities under-represented, this finding should be interpreted with caution. Increasing age (years) did associate with a smaller distance between the pubic symphysis and the bottom of the PDC tip in multiple regression models for males, but not in models for females. Studies examining sexual dimorphism and aging have noted exaggerated pelvic retroversion with aging in males versus females,⁹¹ which may offer an explanation for our findings. However, we would suggest replicating our results in larger cohorts prior to subjecting this theory to additional study, given that the

observed association did not persist in DFBETA analyses when five outlying/influential points were excluded from models.

As part of routine pre-procedural PDC mapping, optimal PDC positioning is suggested by first aligning the PDC tip with the pubic symphysis, with the patient in a supine position. This initial step defines deep cuff positioning and informs subsequent steps for exit site creation (Figure 1).^{38, 79} Of note, the length of the PDC segment that traverses the abdominal wall layers deep to the rectus fascia is often not accounted for during pre-procedural PDC mapping. Our findings, noting an association between increasing BMI and increasing distance between the pubic symphysis and the bottom of the PDC tip may be secondary to the unaccounted length of PDC traversing adipose tissue in the preperitoneal space, a common location of adipose tissue deposition in overweight adults.^{117, 118} Likewise, although rectus sheath tunneling was not common procedure for fluoroscopic PDC insertion at our center during the chosen study period (and thus not impacting these reported results), the technique has become incorporated into percutaneous PDC insertion methods and could also theoretically affect the final length of internal PDC segment and therefore PDC tip position. Unlike in surgical methods, which allow for PDC deep cuff insertion below the level of the anterior rectus sheath, the technique of rectus sheath tunneling when performed via a percutaneous approach impacts the internal PDC segment distal to the deep cuff which remains above the level of the rectus sheath.^{22, 34}

Our results did not suggest an association between the number of abdominopelvic surgeries and either the distance between the cranial border of the pubic symphysis and the caudal border of pooled intraperitoneal radiocontrast or the distance between the cranial border of the pubic symphysis and the bottom of the PDC tip. These findings were contrary to our original hypotheses and dispute the widespread belief that prior abdominopelvic surgeries risks development of adhesions^{42, 43, 119} and optimal PDC placement via percutaneous methods.⁷⁹

Evolving opinion regarding patient selection for methods of PDC insertion has acknowledged that patients with prior uncomplicated surgical history are appropriate for

fluoroscopic PDC placement when performed by operators with expertise in the technique.¹²⁰ Our center's experience aligns with this, noting a vast array of prior abdominopelvic surgeries for patients in our cohort, and reporting 40% of males and 63% of females having at least 1 prior abdominopelvic surgery. The higher reported incidence of inguinal surgeries in males versus females in our cohort also aligns with existing surgical literature reporting the frequency of this surgery by sex.¹²¹

Comparing our cohort to larger population registry studies characterizing incident PD patients in Ontario, Canada;^{91, 122} The average age and BMI in our study was similar, but the percentage ratio of male:female (69:31) deviated from expected (60:40). Although not specifically studied, it is likely that a higher percentage of female patients may have been directed toward laparoscopic PDC insertion acknowledging females had a higher number of past abdominopelvic surgeries and thus potentially heightened concern regarding adhesion risk in these individuals.

7.2 Fluoroscopic Peritoneal Dialysis Catheter Insertion: Final Catheter Tip Position and Early Catheter Flow Dysfunction

Our study found an incidence of early PDC flow dysfunction of 12% which is comparable to the 10-15% range reported from other centers utilizing fluoroscopic PDC insertion methods.^{106, 123} In both single and multiple predictor modelling, we did not observe an association between the measured distance - cranial border of the pubic symphysis to bottom of the PDC tip - and the outcome of early PDC flow dysfunction.

In a prior retrospective single-center study of 110 consecutive patients receiving a first PDC via open surgical technique, Bammens *et al.*⁶⁰ reviewed post-implantation posterior-anterior radiographs to study radiologic variables of PDC positioning and association with PDC flow dysfunction. To evaluate whether a "too high" or "too low" PDC position would influence function, they related the position of the PDC silicone bead (standard on swan neck double-cuff Missouri curled PDCs utilized; bead located just distal to the deep cuff) to the lumbar spine level (L1-2, L3-4, lower); reporting no association. The authors did query the impact of performing measurements on radiographs taken in the standing

position versus the fact that patients complete their PD exchanges sitting or supine, however, our radiographic analyses accounted for these issues, and notwithstanding procedural differences employed in our study (different PDC type, fluoroscopic insertion method), we too found no association.

Past attempts to study PDC dysfunction by analyzing PDC tip position in radiographs, have also called attention to the belief that PDC dysfunction is attributed to PDC malposition. Tanasiychuk *et al.*⁵⁹ analyzed 900 abdominal radiographs taken of 254 PD patients and assessed if the PDC tip was located below the level of the pelvic brim (ideal location) versus not (mal positioned). PDC function was then defined as normal or dysfunctional according to clinical records at a pre-defined time window, ranging from one week before to one week after the imaging study. They reported 74% of mal-positioned PDCs as functioning normally, while up to 35% of malfunctioning PDCs being in an ideal position. The authors concluded that malposition of a PDC does not necessarily predict abnormal functioning, querying instead that the PDC position being prominently impacted by its dynamic environment.⁵⁹

In our study, both single and multiple predictor modelling, analyses for other potential predictors of early PDC flow dysfunction yielded no associations with age, Race, sex, and number of prior abdominopelvic surgeries. This finding is consistent with prior studies.^{58, 124-126} Break in period also demonstrated no association with early PDC flow dysfunction. The median 38-day break in period observed for patients in our cohort reflects local practice, demonstrating the efficiency with which PDCs are inserted in our center. This efficiency results in a very low use of PDC embedding. In centers that do routinely embed PDCs, the risk of PDC flow dysfunction has not been demonstrated to increase until the embedded period goes beyond 5 months.⁵²

Our findings suggest an increased odds of early PDC flow dysfunction with increasing BMI which could be explained by undesired retraction forces exerted on the PDC by a shifting pannus. With changes in body position, specifically supine to recombinant, a downward shifting pannus could cause catheter retraction in a PDC with a lower abdominal exit site. To avoid this phenomenon, experts have suggested that pre-

procedure marking be also completed in the upright position.⁸³ This issue can be avoided by selecting obese patients with a shifting pannus for a surgical method of PDC insertion to facilitate creation of an upper abdominal or pre-sternal exit site.⁶¹

Another interesting observation of our study is the suggestion that diabetic ESKD is associated with decreased odds of early PDC flow dysfunction. Similarly, the association between diabetic ESKD (referent group – glomerulonephritis) and decreased risk for mechanical causes (hernia, PDC dysfunction, leak) of PD technique failure has also been reported in analyses from a large Australian and New Zealand dialysis registry.⁵³ The rationale for the association is unclear. Notably, in our study, the proportion of patients with diabetic ESKD who experienced attrition in the first three months for alternative reasons was also higher, which may in part explain our tests results. Furthermore, a sensitivity analysis which included patients who experienced attrition for non-PDC flow dysfunction reasons but analyzed as having the outcome of interest, no longer demonstrated the association between diabetic ESKD and early PDC flow dysfunction.

In a prior review of 138 PDCs placed via the open surgical method, Weber *et al.*¹²⁷ reported a 6% incidence of PDC malfunction associated omental wrapping within 1 year of PDC use. Comparatively, we report a 7% (20/279) incidence of PDC flow dysfunction within 3 months of PDC use associated with omental wrapping (excludes 4 patients who did not undergo repositioning and 3 who underwent fluoroscopic repositioning). These findings highlight the rationale for performing PDC insertion via advanced laparoscopic techniques including omentopexy.¹²⁸ A recent systematic review and meta-analysis comparing open surgical, basic laparoscopic, and advanced laparoscopic (including omentopexy and rectus sheath tunneling) PDC insertion methods reported significantly lower PDC obstruction and migration in the advanced laparoscopic group.¹²⁹ As already indicated, rectus sheath tunneling was not integrated into routine fluoroscopic PDC insertion during the study data collection period and may account for surgically confirmed cases of isolated PDC tip migration as a cause for early PDC flow dysfunction. Rectus sheath tunneling has been cited by experts as critical to maintaining pelvic orientation of the PDC and preventing PDC tip migration.³⁴

7.3 Limitations

Our study has some notable limitations. First, we acknowledge that we are reporting a retrospective, single-center study and utilized a convenience sampling method, which limits generalizability of our findings and risks residual confounding. Although the use of only one PDC type in our study strengthens homogeneity of our results, this practice, along with only having a single operator performing PDC insertion procedures, further limits generalizability. Caution should also be applied when generalizing our results to centers which do not have ready access to both fluoroscopic and surgical PDC insertion methods. Finally, our study cohort lacked racial diversity.

We conducted our analysis using hospital health administrative data which was not originally intended for clinical research and often maintained by administrative personnel without specialized medical training. Thus, misclassification of some variables may have occurred, however, in most cases, misclassification of such variables was expected to be non-differential. In the case of missing data, missing values were obtained from electronic medical records using a fixed lookback window to avoid information bias based on cohort entry date.

Although missing data for baseline demographics and predictors was minimal (<1%), missing data for radiographic measurements approximated 5% for females and 6% for males respectively. Missing data may have reduced statistical power; however, the lost data was deemed missing completely at random and thus not felt to introduce bias in the estimation of parameters.

Finally, the choice of radiographic measurements analyzed in this study were informed by literature review plus expert opinion and balanced study feasibility and the desired goal for potential implementation into procedural practice. Measures did not consider PDC resiliency,⁶⁰ the possible impacts of pelvic tilt,¹³⁰ and assumed continuity of the PDC tip with pooled radiocontrast as per the distorted appearance of contrast (by either guidewire or PDC tip) on a two-dimensional image. Performance/calculation of individual measurement values were not repeated which may have risked intra-observer variability, however interobserver variability was evaluated in a subset of 10 patients and

found to be minimal (data not shown). Given the exploratory nature of this research and small sample size, our results will require further study, ideally in larger multi-center prospective observational studies and/or controlled trials to validate findings.

7.4 Study Implications and Future Research

The findings from this thesis build upon existing research to improve our understanding of optimal PDC placement and risks for PDC flow dysfunction. Our results provide assurance that fluoroscopic techniques for optimal positioning of the PDC tip approximate pre-procedural methods which are considered universal and suggested for all approaches of PDC insertion. Furthermore, if utilizing fluoroscopic techniques to optimally position the PDC tip in the deep pelvis, the measured distance between the pubic symphysis and the PDC tip as seen on an anterior-posterior radiograph (in the supine patient), is not shown to associate with early PDC flow dysfunction.

Future research should seek to validate our findings, including performing fluoroscopic and laparoscopic techniques in tandem and comparing pre/post abdominal insufflation effects on injected radiocontrast. Additionally, studies could consider the possible impact of pelvic tilt¹³⁰ on radiographic measurements and attempt stereotactic imaging methods to better localize the pool of injected radio contrast and PDC tip. Furthermore, our results relating PDC tip position to early PDC flow dysfunction should be validated in larger, multi-center, prospective studies, and across commonly available PDC configurations, and considered in other patient populations, including pediatrics. Ideally, such efforts should also evaluate the potential association between PDC tip position and drain pain. Finally, using our suggested study approach (analyzing procedural fluoroscopic images), offers potential for future real-time procedural interventions and their evaluation, i.e., use of expanded PDC inventories with varying peritoneal PDC segment lengths.

7.5 Conclusions

This study utilized radiographic measurements to relate fluoroscopic techniques of landmarking the true pelvis and achieving deep pelvic position of the PDC tip to existing guideline practices which reference the pubic symphysis as a landmark for the true pelvis

to guide deep pelvic positioning of the PDC tip. The measured distance between the pubic symphysis and the final PDC tip position as visualized during fluoroscopy does not associate with early PDC flow dysfunction.

7.6 Knowledge Translation

The results from this thesis were presented in poster format at a local Department of Medicine Research Day. The completed thesis will result in two publications. The first will be a manuscript with the major findings of this study, which will be prepared and submitted to a relevant peer-reviewed journal. The second will be a review of Fluoroscopic PDC insertion that will contribute to a Canadian Society of Nephrology Endorsed Guideline of Percutaneous PDC Insertion in Canada, that will also be submitted to a relevant peer-reviewed journal. Additionally, the findings will be presented at a relevant research conference.

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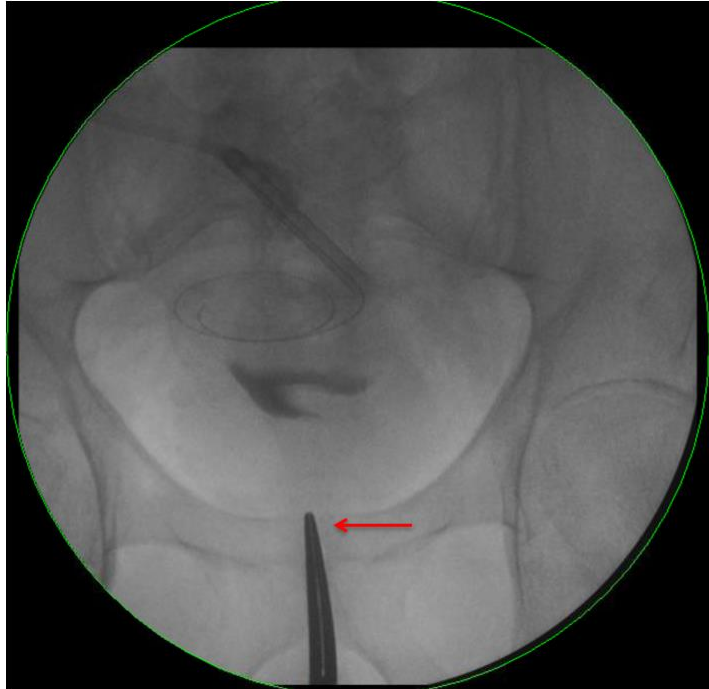
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Appendices

Appendix A. Fluoroscopic radiograph of peritoneal dialysis catheter insertion, demonstrating accuracy of physical examination palpation of cranial border of pubic symphysis in midline position: Examination method used to position tip of instrument and confirmed with fluoroscopy (solid arrow)



Appendix B: Study conduct and reporting follow guidelines (STROBE) for observational studies

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

Appendix C: Study Approval by the Western University Health Science Research Ethics Board, London, Ontario



Date: 17 December 2018

To: Dr. Arsh Jain

Project ID: 111385

Study Title: Fluoroscopic Guided Peritoneal Catheter Insertion: Radiology Anthropometric Analysis

Application Type: HSREB Initial Application

Review Type: Delegated

Meeting Date / Full Board Reporting Date: 15/Jan/2019

Date Approval Issued: 17/Dec/2018

REB Approval Expiry Date: 17/Dec/2019

Dear Dr. Arsh Jain

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
Local Database Form	Other Data Collection Instruments	03/Jun/2018	1.0
Radiology Anthropometric Analysis - Protocol Version 2.0	Protocol	12/Dec/2018	2.0

Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
References	References	17/Apr/2018	1

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB , except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

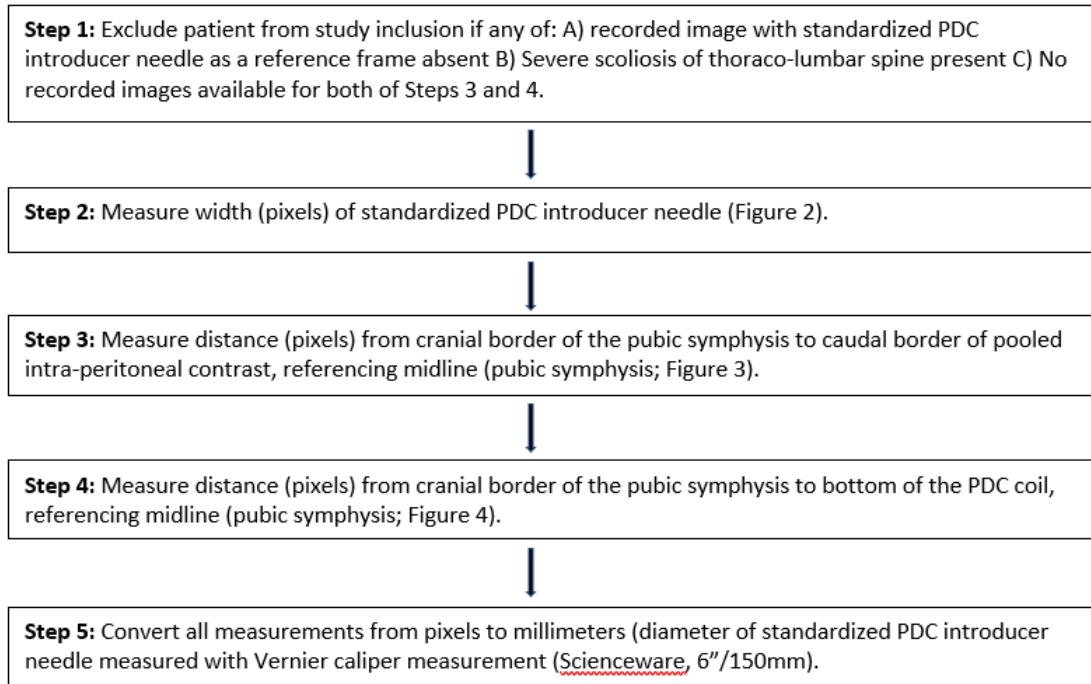
The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.
Sincerely,

Patricia Sargeant, Ethics Officer on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations)

Appendix D. Sequence protocol for radiographic measure analyses. PDC, Peritoneal Dialysis Catheter



Appendix E. Stata code file.

```

      (R)
Statistics/Data Analysis
User: STATA CODE FILE

```

User: STATA CODE FILE

*Thesis Do File

*David Clark

*Last update: June, 2023

*****PART 1 - Anthropometric Measures Analyses*****

capture log close

log using "C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic P
> D Catheter Insertion\Thesis\Thesis Statistics Do File Finale 2023", text replace

*****Descriptive Statistics*****

use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on

1

Entire Cohort Continuous Variables - Descriptive Stats & Normality Assessment

summarize ageatinsert bmi pubis_contrast_mid_mm pubis_coil_bottom_mm

summarize bmi, detail

histogram ageatinsert, bin(10) frequency

graph save histogram_ageatinsert, replace

histogram bmi, bin(10) frequency

graph save histogram_bmi, replace

histogram pubis_contrast_mid_mm, bin(10) frequency

graph save histogram_pubis_contrast_mid_mm, replace

histogram pubis_coil_bottom_mm, bin(10) frequency

graph save histogram_pubis_coil_bottom_mm, replace

2

Grouped by "Sex", Continuous Variables - Descriptive Stats & Normality Assessment

histogram ageatinsert if SEX == 0, bin(10) frequency

graph save histogram_ageatinsert_male, replace

swilk ageatinsert if SEX == 0

tabstat ageatinsert if SEX == 0, stat(mean sd skew k q)

sktest ageatinsert if SEX == 0

histogram ageatinsert if SEX == 1, bin(10) frequency

graph save histogram_ageatinsert_female, replace

swilk ageatinsert if SEX == 1

tabstat ageatinsert if SEX == 1, stat(mean sd skew k q)

sktest ageatinsert if SEX == 1


```

histogram bmi if SEX == 0, bin(10) frequency
graph save histogram_bmi_male, replace
swilk bmi if SEX == 0
tabstat bmi if SEX == 0, stat(mean sd skew k q)
sktest bmi if SEX == 0
histogram bmi if SEX == 1, bin(10) frequency
graph save histogram_bmi_female, replace
swilk bmi if SEX == 1
tabstat bmi if SEX == 1, stat(mean sd skew k q)
sktest bmi if SEX == 1

```

```

histogram pubis_contrast_mid_mm if SEX==0, bin(10) frequency ytitle(Frequency(n)) ylabel(,
nogrid) xtitle(Pubis Symphysis to Pooled Contrast(mm))
graph save histogram_pubis_contrast_mid_mm_male, replace
swilk pubis_contrast_mid_mm if SEX == 0
tabstat pubis_contrast_mid_mm if SEX == 0, stat(mean sd skew k q)
sktest pubis_contrast_mid_mm if SEX == 0
histogram pubis_contrast_mid_mm if SEX==1, bin(10) frequency ytitle(Frequency(n)) ylabel(,
nogrid) xtitle(Pubis Symphysis to Pooled Contrast(mm))
graph save histogram_pubis_contrast_mid_mm_female, replace
swilk pubis_contrast_mid_mm if SEX == 1
tabstat pubis_contrast_mid_mm if SEX == 1, stat(mean sd skew k q)
sktest pubis_contrast_mid_mm if SEX == 1
histogram pubis_coil_bottom_mm if SEX==0, bin(10) frequency ytitle(Frequency(n)) ylabel(,
nogrid) xtitle(Pubis Symphysis to Catheter Coil(mm))
graph save histogram_pubis_coil_bottom_mm_male, replace
swilk pubis_coil_bottom_mm if SEX == 0
tabstat pubis_coil_bottom_mm if SEX == 0, stat(mean sd skew k q)
sktest pubis_coil_bottom_mm if SEX == 0
histogram pubis_coil_bottom_mm if SEX==1, bin(10) frequency ytitle(Frequency(n)) ylabel(,
nogrid) xtitle(Pubis Symphysis to Catheter Coil(mm))
graph save histogram_pubis_coil_bottom_mm_female, replace
swilk pubis_coil_bottom_mm if SEX == 1
tabstat pubis_coil_bottom_mm if SEX == 1, stat(mean sd skew k q)
sktest pubis_coil_bottom_mm if SEX == 1

```

*****CONTINUOUSVARIABLES*****

```
bysort SEX: summ ageatinsert bmi pubis_contrast_mid_mm pubis_coil_bottom_mm
```

*****T-tests/Wilcoxin signed rank tests*****

```

ttest ageatinsert, by(SEX)
ranksum ageatinsert, by(SEX)
ttest bmi, by(SEX)
ranksum bmi, by(SEX)
ttest pubis_contrast_mid_mm, by(SEX)
ranksum pubis_contrast_mid_mm, by(SEX)
ttest pubis_coil_bottom_mm, by(SEX)
ranksum pubis_coil_bottom_mm, by(SEX)

```

```

*****Nominal Variables; Fisher Exact Testing*****
tabulate SEX transplant, exact
tabulate SEX Appendectomy, exact
tabulate SEX Chole, exact
tabulate SEX Other, exact
tabulate SEX Hysterectomy, exact
tabulate SEX Csection, exact
tabulate SEX tubal, exact
tabulate SEX Prostectomy, exact
tabulate SEX number_prior_surgeries, exact
tabulate SEX ESRD, exact
tabulate SEX White, exact

*****Spearman Rank Analysis*****

**True Pelvis - FEMALES**
spearman pubis_contrast_mid_mm ageatinsert if SEX == 1, stats(rho obs p)
spearman pubis_contrast_mid_mm bmi if SEX == 1, stats(rho obs p)
spearman pubis_contrast_mid_mm number_prior_surgeries if SEX == 1, stats(rho obs p)

**True Pelvis - MALES **
spearman pubis_contrast_mid_mm ageatinsert if SEX == 0, stats(rho obs p)
spearman pubis_contrast_mid_mm bmi if SEX == 0, stats(rho obs p)
spearman pubis_contrast_mid_mm number_prior_surgeries if SEX == 0, stats(rho obs p)

** Catheter Coil - FEMALES **
spearman pubis_coil_bottom_mm ageatinsert if SEX == 1, stats(rho obs p)
spearman pubis_coil_bottom_mm bmi if SEX == 1, stats(rho obs p)
spearman pubis_coil_bottom_mm number_prior_surgeries if SEX == 1, stats(rho obs p)

** Catheter Coil - MALES **
spearman pubis_coil_bottom_mm ageatinsert if SEX == 0, stats(rho obs p)
spearman pubis_coil_bottom_mm bmi if SEX == 0, stats(rho obs p)
spearman pubis_coil_bottom_mm number_prior_surgeries if SEX == 0, stats(rho obs p)

*****REGRESSION*****
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesistdatafilefinal2.dta", clear
set autotabgraphs on

*****Linear Regression By Sex*****
*****Univariate BY SEX*****
*Check each of predictor variables: ageatinsert, bmi, White, number_prior_surgeries
**Age
regress pubis_contrast_mid_mm ageatinsert if SEX == 0
regress pubis_contrast_mid_mm ageatinsert if SEX == 1
regress pubis_coil_bottom_mm ageatinsert if SEX == 0
regress pubis_coil_bottom_mm ageatinsert if SEX == 1
**BMI
regress pubis_contrast_mid_mm bmi if SEX == 0

```

```

regress pubis_contrast_mid_mm bmi if SEX == 1
regress pubis_coil_bottom_mm bmi if SEX == 0
regress pubis_coil_bottom_mm bmi if SEX == 1
**RACE
regress pubis_contrast_mid_mm White if SEX == 0
regress pubis_contrast_mid_mm White if SEX == 1
regress pubis_coil_bottom_mm White if SEX == 0
regress pubis_coil_bottom_mm White if SEX == 1
**PKD
regress pubis_contrast_mid_mm PKD if SEX == 0
regress pubis_contrast_mid_mm PKD if SEX == 1
regress pubis_coil_bottom_mm PKD if SEX == 0
regress pubis_coil_bottom_mm PKD if SEX == 1
**Number of prior surgeries
regress pubis_contrast_mid_mm number_prior_surgeries if SEX == 0
regress pubis_contrast_mid_mm number_prior_surgeries if SEX == 1
regress pubis_coil_bottom_mm number_prior_surgeries if SEX == 0
regress pubis_coil_bottom_mm number_prior_surgeries if SEX == 1

*****Multiple Linear Regression*****

***1a***
*Pubis to contrast & Male*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_surg
> eries if SEX == 0

** Coefficient Plots **
label variable White "White Race"
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
*Standardize Continuous covariables for plots*
qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
qui summ number_prior_surgeries
qui replace number_prior_surgeries = (number_prior_surgeries - r(mean))/r(sd)
eststo clear

foreach predictor in ageatinsert bmi PKD White number_prior_surgeries {
qui eststo `predictor': regress pubis_contrast_mid_mm `predictor' if SEX =
> = 0
}
qui eststo multi: regress pubis_contrast_mid_mm ageatinsert bmi PKD White c
> .number_prior_surgeries if SEX == 0
coefplot (ageatinsert\bmi\PKD\White\number_prior_surgeries, label (uni)) //

```

```

> /
(multi), drop (_cons) xline(0) msymbol(d) mfcolor(white) ///
title("Regression Coefficients")

*test of model assumptions"
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Catheter
Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on

*check of Collinearity*
*compare ageatinsert to BMI*
twayway (scatter ageatinsert bmi if SEX ==1)
twayway (scatter ageatinsert bmi if SEX ==0)
spearman ageatinsert bmi if SEX == 0, stats(rho obs p)
spearman ageatinsert bmi if SEX == 1, stats(rho obs p)
qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 0

*Linearity
cprplot ageatinsert, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_contrast_mid_mm Component Plus Residual") ///
xtitle("ageatinsert") xlabel(15(5)100) ///
name(pubis_contrast_mid_mm_age_males, replace)

cprplot bmi, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_contrast_mid_mm Component Plus Residual") ///
xtitle("bmi") xlabel(15(2.5)45) ///
name(pubis_contrast_mid_mm_bmi_males, replace)

*Normality
capture program drop eda
program define eda
set graphics off
set scheme slmono
quietly histogram `1', name(eda1, replace)
quietly graph box `1', name(eda2, replace)
quietly kdensity `1', ep normal name(eda3, replace)
quietly qnorm `1', name(eda4, replace)
set graphics on
graph combine eda1 eda2 eda3 eda4
end

qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 0
predict resid, resid
eda resid

```

```

*Constant Variance
gen residsq = resid ^ 2
predict fitted, xb
tab ageatinsert, sum(resid)
tab bmi, sum(resid)
tab PKD, sum(resid)
tab White, sum(resid)
tab number_prior_surgeries, sum(resid)
twoway ///
(scatter resid fitted, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
yline(0) ///
title("Residuals Versus Fitted Values") ///
ytitle("") ///
legend(off) ///
name(cv1, replace)
twoway ///
(scatter resid ageatinsert, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("ageatinsert") ///
xlabel(15(5)100) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv2, replace)
twoway ///
(scatter resid bmi, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("bmi") ///
xlabel(15(2.5)50) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv3, replace)
*Outlying, High Leverage, & Influential Points
label variable White "White Race"
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"

qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 0
qui dfbeta
rename _dfbeta_1 DFage
rename _dfbeta_2 DFbmi

```

```

rename _dfbeta_3 DFPKD
rename _dfbeta_4 DFWhite
rename _dfbeta_5 DFnumber_prior_surgeries
graph hbox DFage DFbmi DFPKD DFWhite DFnumber_prior_surgeries, showyvar leg
> (off)

eststo clear
eststo: qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.numbe
> r_prior_surgeries if SEX == 0 , nohe
eststo: qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.numbe
> r_prior_surgeries if SEX == 0 ///
  & DFage <= .3 & DFbmi <= .3 & DFPKD <= .3 & DFWhite <= .3 & DFnumbe
> r_prior_surgeries <= .3 & DFage >= -.3 & DFbmi >= -.3 & DFPKD >= -.3 & DF
> White >= -.3 & DFnumber_prior_surgeries >= -.3, nohe
esttab, label wide ///
title(Sensitivity analysis) ///
nonumbers mtitles("All Data" "Minus Potential Outliers")

regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_p
> rior_surgeries if SEX == 0 ///
  & DFage <= .3 & DFbmi <= .3 & DFPKD <= .3 & DFWhite <= .3 & DFnumbe
> r_prior_surgeries <= .3 & DFage >= -.3 & DFbmi >= -.3 & DFPKD >= -.3 & DF
> White >= -.3 & DFnumber_prior_surgeries >= -.3

***1B***
*Pubis to contrast & Female*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesistatafilefinal2.dta", clear
set autotabgraphs on
regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_surg
> eries if SEX == 1
** Coefficient Plots **
label variable White "White Race"
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
qui summ number_prior_surgeries
qui replace number_prior_surgeries = (number_prior_surgeries - r(mean))/r(sd)
eststo clear
foreach predictor in ageatinsert bmi PKD White number_prior_surgeries {
qui eststo `predictor': regress pubis_contrast_mid_mm `predictor' if SEX =
> = 1
}
qui eststo multi: regress pubis_contrast_mid_mm ageatinsert bmi PKD White n
> umber_prior_surgeries if SEX == 1
coefplot (ageatinsert\bmi\PKD\White\number_prior_surgeries, label (uni)) //

```

```

> /
(multi), drop (_cons) xline(0) msymbol(d) mfcolor(white) ///
title("Regression Coefficients")
*test of model assumptions"
qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 1

*Linearity
cprplot ageatinsert, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_contrast_mid_mm Component Plus Residual") ///
xtitle("ageatinsert") xlabel(15(5)100) ///
name(pubis_contrast_mid_mm_age_female, replace)

cprplot bmi, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_contrast_mid_mm Component Plus Residual") ///
xtitle("bmi") xlabel(15(2.5)45) ///
name(pubis_contrast_mid_mm_bmi_female, replace)

*Normality
capture program drop eda
program define eda
set graphics off
set scheme s1mono
quietly histogram `1', name(eda1, replace)
quietly graph box `1', name(eda2, replace)
quietly kdensity `1', ep normal name(eda3, replace)
quietly qnorm `1', name(eda4, replace)
set graphics on
graph combine eda1 eda2 eda3 eda4
end

qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 1
predict resid, resid
eda resid

*Constant Variance
gen residsq = resid ^ 2
predict fitted, xb
tab ageatinsert, sum(resid)
tab bmi, sum(resid)
tab PKD, sum(resid)
tab RACE, sum(resid)
tab number_prior_surgeries, sum(resid)
twoway ///
(scatter resid fitted, sort msymbol(circle) msize(large)) ///
, ///

```

```

plotregion(style(none)) ///
yline(0) ///
title("Residuals Versus Fitted Values") ///
ytitle("") ///
legend(off) ///
name(cv1, replace)
twoway ///
(scatter resid ageatinsert, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("ageatinsert") ///
xlabel(15(5)100) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv2, replace)

twoway ///
(scatter resid bmi, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("bmi") ///
xlabel(15(2.5)50) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv3, replace)
*Outlying, High Leverage, & Influential Points
qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_
> surgeries if SEX == 1
qui dfbeta
rename _dfbeta_1 DFage
rename _dfbeta_2 DFbmi
rename _dfbeta_3 DFPKD
rename _dfbeta_4 DFWhite
rename _dfbeta_5 DFnumber_prior_surgeries
graph hbox DFage DFbmi DFPKD DFWhite DFnumber_prior_surgeries, showyvar leg
> (off)
eststo clear
eststo: qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.numbe
> r_prior_surgeries if SEX == 1, nohe
eststo: qui regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.numbe
> r_prior_surgeries if SEX == 1 ///
& DFage <= .45 & DFbmi <= .45 & DFPKD <=.45 & DFWhite <=.45 & DFnum
> ber_prior_surgeries <= .45 & DFage >= -.45 & DFbmi >= -.45 & DFPKD >= -.4
> 5 & DFWhite >= -.45 & DFnumber_prior_surgeries >= -.45, nohe
esttab, label wide ///
title(Sensitivity analysis) ///
nonumbers mtitles("All data " "-potential outliers")

```



```

regress pubis_contrast_mid_mm ageatinsert bmi PKD White c.number_prior_surg
> eries if SEX == 1 ///
  & DFage <= .45 & DFbmi <= .45 & DFPKD <=.45 & DFWhite <=.45 & DFnum
> ber_prior_surgeries <= .45 & DFage >= -.45 & DFbmi >= -.45 & DFPKD >= -.4
> 5 & DFWhite >= -.45 & DFnumber_prior_surgeries >= -.45, nohe
***2a***
*Pubis to coil & Male*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_surge
> ries if SEX == 0
** Coefficient Plots **
label variable White "White Race"
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
qui summ number_prior_surgeries
qui replace number_prior_surgeries = (number_prior_surgeries - r(mean))/r(s
> d)
eststo clear
foreach predictor in ageatinsert bmi PKD White number_prior_surgeries {
qui eststo `predictor': regress pubis_coil_bottom_mm `predictor' if SEX ==
> 0
}
qui eststo multi: regress pubis_coil_bottom_mm ageatinsert bmi PKD White nu
> mber_prior_surgeries if SEX == 0
coefplot (ageatinsert\bmi\PKD\White\number_prior_surgeries, label (uni)) //
> /
(multi), drop (_cons) xline(0) msymbol(d) mfcolor(white) ///
title("Regression Coefficients")
*test of model assumptions"
qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 0
*Linearity
cprplot ageatinsert, ///
rlopts(clpat(solid)) Isopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msizes(vtiny) ///
ytitle("pubis_coil_bottom_mm Component Plus Residual") ///
xtitle("ageatinsert") xlabel(15(5)100) ///
name(pubis_coil_bottom_mm_age_males, replace)

cprplot bmi, ///
rlopts(clpat(solid)) Isopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msizes(vtiny) ///
ytitle("pubis_coil_bottom_mm Component Plus Residual") ///

```

```
xtitle("bmi") xlabel(15(2.5)45) ///
name(pubis_coil_bottom_mm_bmi_males, replace)
```

*Normality

```
capture program drop eda
program define eda
set graphics off
set scheme s1mono
quietly histogram `1', name(eda1, replace)
quietly graph box `1', name(eda2, replace)
quietly kdensity `1', ep normal name(eda3, replace)
quietly qnorm `1', name(eda4, replace)
set graphics on
graph combine eda1 eda2 eda3 eda4
end
```

```
qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 0
predict resid, resid
eda resid
```

*Constant Variance

```
Saturday July 1 21:27:34 2023 Page 12
gen residsq = resid ^ 2
predict fitted, xb
tab ageatinsert, sum(resid)
tab bmi, sum(resid)
tab PKD, sum(resid)
tab RACE, sum(resid)
tab number_prior_surgeries, sum(resid)
twoway ///
(scatter resid fitted, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
yline(0) ///
title("Residuals Versus Fitted Values") ///
ytitle("") ///
legend(off) ///
name(cv1, replace)
twoway ///
(scatter resid ageatinsert, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("ageatinsert") ///
xlabel(15(5)100) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv2, replace)
```

```

twoway ///
(scatter resid bmi, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("bmi") ///
xlabel(15(2.5)50) ///
yline(0) ///
ytile("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv3, replace)
*Outlying, High Leverage, & Influential Points

qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 0
qui dfbeta
rename _dfbeta_1 DFage
rename _dfbeta_2 DFbmi
rename _dfbeta_3 DFPKD
rename _dfbeta_4 DFWhite
rename _dfbeta_5 DFnumber_prior_surgeries
graph hbox DFage DFbmi DFPKD DFWhite DFnumber_prior_surgeries, showyvar leg
> (off)
eststo clear
eststo: qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number
> _prior_surgeries if SEX == 0, nohe
eststo: qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number
> _prior_surgeries if SEX == 0 ///
& DFage <= .4 & DFbmi <=.4 & DFPKD <= .4 & DFWhite <= .4 & DFnumber
> _prior_surgeries <= .4 & DFage >= -.4 & DFbmi >= -.4 & DFPKD >= -.4 & DFW
> hite >= -.4 & DFnumber_prior_surgeries >= -.4, nohe
esttab, label wide ///
title(Sensitivity analysis) ///
nonumbers mtitles("All data" "-potential outliers")

*Remove Influential Points*
regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_surge
> ries if SEX == 0 ///
& DFage <= .4 & DFbmi <=.4 & DFPKD <= .4 & DFWhite <= .4 & DFnumber
> _prior_surgeries <= .4 & DFage >= -.4 & DFbmi >= -.4 & DFPKD >= -.4 & DFW
> hite >= -.4 & DFnumber_prior_surgeries >= -.4, nohe

**Check for Interaction**
**Interaction age with each of bmi, PKD, White Race, Number of prior surger
> ies
regress pubis_coil_bottom_mm c.ageatinsert##c.bmi PKD White c.number_prior_
> surgeries if SEX == 0
regress pubis_coil_bottom_mm c.ageatinsert##i.PKD bmi White c.number_prior_
> surgeries if SEX == 0
regress pubis_coil_bottom_mm c.ageatinsert##i.White bmi PKD c.number_prior_
> surgeries if SEX == 0

```

```

regress pubis_coil_bottom_mm c.ageatinsert##c.number_prior_surgeries bmi PK
> D White if SEX == 0
**Interaction bmi with each of PKD, White Race, Number of prior surgeries
regress pubis_coil_bottom_mm ageatinsert c.bmi##i.PKD White c.number_prior_
> surgeries if SEX == 0
regress pubis_coil_bottom_mm ageatinsert c.bmi##i.White PKD c.number_prior_
> surgeries if SEX == 0
regress pubis_coil_bottom_mm ageatinsert c.bmi##c.number_prior_surgeries PK
> D White if SEX == 0

***2b***
*Pubis to coil & Female*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesistdatafilefinal2.dta", clear
set autotabgraphs on
regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_surge
> ries if SEX == 1
label variable White "White Race"
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
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qui summ number_prior_surgeries
qui replace number_prior_surgeries = (number_prior_surgeries - r(mean))/r(s
> d)
eststo clear
foreach predictor in ageatinsert bmi PKD White number_prior_surgeries {
qui eststo `predictor': regress pubis_coil_bottom_mm `predictor' if SEX ==
> 1
}
qui eststo multi: regress pubis_coil_bottom_mm ageatinsert bmi PKD White nu
> mber_prior_surgeries if SEX == 1
coefplot (ageatinsert\bmi\PKD\White\number_prior_surgeries, label (uni))//
> /
(multi), drop (_cons) xline(0) msymbol(d) mfcolor(white) ///
title("Regression Coefficients")
*test of model assumptions"
qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 1
*Linearity
cprplot ageatinsert, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_coil_bottom_mm Component Plus Residual") ///
xtitle("ageatinsert") xlabel(15(5)100) ///
name(pubis_coil_bottom_mm_age_female, replace)

```

```

cprplot bmi, ///
rlopts(clpat(solid)) lsopts(bw(.5) clpat(longdash)) ///
plotregion(style(none)) msize(vtiny) ///
ytitle("pubis_coil_bottom_mm Component Plus Residual") ///
xtitle("bmi") xlabel(15(2.5)45) ///
name(pubis_coil_bottom_mm_bmi_female, replace)

*Normality
capture program drop eda
program define eda
set graphics off
set scheme s1mono
quietly histogram `1', name(eda1, replace)
quietly graph box `1', name(eda2, replace)
quietly kdensity `1', ep normal name(eda3, replace)
quietly qnorm `1', name(eda4, replace)
set graphics on
graph combine eda1 eda2 eda3 eda4
end

qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 1
predict resid, resid
eda resid

*Constant Variance
gen residsq = resid ^ 2
predict fitted, xb
tab ageatinsert, sum(resid)
tab bmi, sum(resid)
tab PKD, sum(resid)
tab RACE, sum(resid)
tab number_prior_surgeries, sum(resid)
Saturday July 1 21:27:34 2023 Page 15
twoway ///
(scatter resid fitted, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
yline(0) ///
title("Residuals Versus Fitted Values") ///
ytitle("") ///
legend(off) ///
name(cv1, replace)
twoway ///
(scatter resid ageatinsert, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("ageatinsert") ///
xlabel(15(5)100) ///
yline(0) ///

```

```

ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv2, replace)
twoway ///
(scatter resid bmi, sort msymbol(circle) msize(large)) ///
, ///
plotregion(style(none)) ///
xtitle("bmi") ///
xlabel(15(2.5)50) ///
yline(0) ///
ytitle("") ///
title("Residuals Versus Predictor") ///
legend(off) ///
name(cv3, replace)

*Outlying, High Leverage, & Influential Points
qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_s
> urgeries if SEX == 1
qui dfbeta
rename _dfbeta_1 DFage
rename _dfbeta_2 DFbmi
rename _dfbeta_3 DFPKD
rename _dfbeta_4 DFWhite
rename _dfbeta_5 DFnumber_prior_surgeries
graph hbox DFage DFbmi DFPKD DFWhite DFnumber_prior_surgeries, showyvar leg
> (off)
eststo clear
eststo: qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number
> _prior_surgeries if SEX == 1, nohe
eststo: qui regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number
> _prior_surgeries if SEX == 1 ///
& DFage <= .5 & DFbmi <=.5 & DFPKD <= .5 & DFWhite <= .5 & DFnumber
> _prior_surgeries <= .5 & DFage >= -.5 & DFbmi >= -.5 & DFPKD >= -.5 & DF
> hite >= -.5 & DFnumber_prior_surgeries >= -.5, nohe
esttab, label wide ///
title(Sensitivity analysis) ///
nonumbers mtitles("All data " "-potential outliers")

*Remove Influential Points*

regress pubis_coil_bottom_mm ageatinsert bmi PKD White c.number_prior_surge
> ries if SEX == 1 ///
& DFage <= .5 & DFbmi <=.5 & DFPKD <= .5 & DFWhite <= .5 & DFnumber
> _prior_surgeries <= .5 & DFage >= -.5 & DFbmi >= -.5 & DFPKD >= -.5 & DF
> hite >= -.5 & DFnumber_prior_surgeries >= -.5
*Check for Interaction
regress pubis_coil_bottom_mm c.ageatinsert##c.bmi PKD White c.number_prior_
> surgeries if SEX == 1
regress pubis_coil_bottom_mm ageatinsert c.bmi##i.PKD White c.number_prior_
> surgeries if SEX == 1

```

```
regress pubis_coil_bottom_mm ageatinsert c.bmi##i.White PKD c.number_prior_
> surgeries if SEX == 1
regress pubis_coil_bottom_mm ageatinsert c.bmi##c.number_prior_surgeries PKD White if SEX
== 1
```

```
*****
```

PART 2 - Early Catheter Flow Dysfunction Analyses

```
*****
```

```
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesistadatafilefinal2.dta", clear
set autotabgraphs on
```

```
***Descriptive***
```

```
** Flow Chart **
```

```
codebook catheterdysfun3mon
tabulate reposition if catheterdysfun3mon==1
tabulate reasonrepo1 if catheterdysfun3mon==1
```

```
** Chart **
```

```
codebook EarlyTechFail_Noncath
tabulate reasonPDend if EarlyTechFail_Noncath==1
****A - Excluded patients****
**Supplemenatry Table of excluded EarlyTechFail_Noncath patients**
summarize ageatinsert if EarlyTechFail_Noncath==0, detail
summarize ageatinsert if EarlyTechFail_Noncath==1, detail
summarize bmi if EarlyTechFail_Noncath==0, detail
summarize bmi if EarlyTechFail_Noncath==1, detail
summarize SEX if EarlyTechFail_Noncath==0, detail
summarize SEX if EarlyTechFail_Noncath==1, detail
summarize White if EarlyTechFail_Noncath==0, detail
summarize White if EarlyTechFail_Noncath==1, detail
summarize ESRD if EarlyTechFail_Noncath==0, detail
summarize ESRD if EarlyTechFail_Noncath==1, detail
summarize PKD if EarlyTechFail_Noncath==0, detail
summarize PKD if EarlyTechFail_Noncath==1, detail
summarize Appendectomy if EarlyTechFail_Noncath==0, detail
summarize Appendectomy if EarlyTechFail_Noncath==1, detail
summarize Chole if EarlyTechFail_Noncath==0, detail
summarize Chole if EarlyTechFail_Noncath==1, detail
summarize Hysterectomy if EarlyTechFail_Noncath==0, detail
summarize Hysterectomy if EarlyTechFail_Noncath==1, detail
summarize Csection if EarlyTechFail_Noncath==0, detail
summarize Csection if EarlyTechFail_Noncath==1, detail
summarize tubal if EarlyTechFail_Noncath==0, detail
summarize tubal if EarlyTechFail_Noncath==1, detail
summarize Prosectomy if EarlyTechFail_Noncath==0, detail
summarize Prosectomy if EarlyTechFail_Noncath==1, detail
summarize transplant if EarlyTechFail_Noncath==0, detail
summarize transplant if EarlyTechFail_Noncath==1, detail
summarize Other if EarlyTechFail_Noncath==0, detail
summarize Other if EarlyTechFail_Noncath==1, detail
```

summarize pelvic_adhesion_risk if EarlyTechFail_Noncath==0, detail
 summarize pelvic_adhesion_risk if EarlyTechFail_Noncath==1, detail
 summarize virginabdo if EarlyTechFail_Noncath==0, detail
 summarize virginabdo if EarlyTechFail_Noncath==1, detail
 summarize abdosurgeryone if EarlyTechFail_Noncath==0, detail
 summarize abdosurgeryone if EarlyTechFail_Noncath==1, detail
 summarize abdosurgerytwo if EarlyTechFail_Noncath==0, detail
 summarize abdosurgerytwo if EarlyTechFail_Noncath==1, detail
 summarize abdosurgerythree if EarlyTechFail_Noncath==0, detail
 summarize abdosurgerythree if EarlyTechFail_Noncath==1, detail
 summarize abdosurgeryfour if EarlyTechFail_Noncath==0, detail
 summarize abdosurgeryfour if EarlyTechFail_Noncath==1, detail
 summarize pubis_coil_bottom_mm if EarlyTechFail_Noncath==1, detail
 summarize pubis_coil_bottom_mm if EarlyTechFail_Noncath==0, detail
 summarize coilminuscontrast if EarlyTechFail_Noncath==1, detail
 summarize coilminuscontrast if EarlyTechFail_Noncath==0, detail
 summarize breakinperiod if EarlyTechFail_Noncath==1, detail
 summarize breakinperiod if EarlyTechFail_Noncath==0, detail

***TESTING

*****FISHER'S Exact Testing*****

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tabulate EarlyTechFail_Noncath SEX, exact
 tabulate EarlyTechFail_Noncath White, exact
 tabulate EarlyTechFail_Noncath ESRD, exact
 tabulate EarlyTechFail_Noncath PKD, exact
 tabulate EarlyTechFail_Noncath Appendectomy, exact
 tabulate EarlyTechFail_Noncath Chole, exact
 tabulate EarlyTechFail_Noncath Hysterectomy, exact
 tabulate EarlyTechFail_Noncath Csection, exact
 tabulate EarlyTechFail_Noncath tubal, exact
 tabulate EarlyTechFail_Noncath Prostectomy, exact
 tabulate EarlyTechFail_Noncath transplant, exact
 tabulate EarlyTechFail_Noncath Other, exact

*****T-Testing/Rank SUM*****

ttest ageatinsert, by(EarlyTechFail_Noncath)
 ranksum ageatinsert, by(EarlyTechFail_Noncath)
 ttest bmi, by(EarlyTechFail_Noncath)
 ranksum bmi, by(EarlyTechFail_Noncath)
 ttest breakinperiod, by(EarlyTechFail_Noncath)
 ranksum breakinperiod, by(EarlyTechFail_Noncath)
 ttest pubis_coil_bottom_mm, by(EarlyTechFail_Noncath)
 ranksum pubis_coil_bottom_mm, by(EarlyTechFail_Noncath)

****B - Defined Cohort****

*** Generate a three way comparison table***

*** want to compare early catheter dysfunction yes/no with the 32 patients

> who had attrition for other reasons within the first 3 months***

replace attritionreason = 1 if(catheterdysfun3mon==1)

replace attritionreason = 2 if(EarlyTechFail_Noncath==1)


```

tostring attritionreason, generate(attritreason)
encode attritreason, gen(earlyattritionreason)
codebook earlyattritionreason
recode earlyattritionreason 1=0 2=1 3=2
codebook earlyattritionreason
label define earlyattritionreason 0 "no catheter dsyfunction" 1 "early cath
> eter dsyfunction" 2 "attrition other", replace
codebook earlyattritionreason
drop attritionreason attritreason

```

*** 3 way Table Creation ***

```

tabulate earlyattritionreason SEX, exact
tabulate earlyattritionreason White, exact
tabulate earlyattritionreason ESRD, exact
tabulate earlyattritionreason PKD, exact
tabulate earlyattritionreason Appendectomy, exact
tabulate earlyattritionreason Chole, exact
tabulate earlyattritionreason Hysterectomy, exact
tabulate earlyattritionreason Csection, exact
tabulate earlyattritionreason tubal, exact
tabulate earlyattritionreason Prostectomy, exact
tabulate earlyattritionreason transplant, exact
tabulate earlyattritionreason Other, exact
tabulate earlyattritionreason number_prior_surgeries, exact
summarize ageatinsert if earlyattritionreason==0, detail
summarize ageatinsert if earlyattritionreason==1, detail
summarize ageatinsert if earlyattritionreason==2, detail
oneway ageatinsert earlyattritionreason
summarize bmi if earlyattritionreason==0, detail
summarize bmi if earlyattritionreason==1, detail
summarize bmi if earlyattritionreason==2, detail
kwallis bmi, by(earlyattritionreason)
summarize breakinperiod if earlyattritionreason==0, detail
summarize breakinperiod if earlyattritionreason==1, detail
summarize breakinperiod if earlyattritionreason==2, detail
kwallis breakinperiod, by(earlyattritionreason)
summarize pubis_coil_bottom_mm if earlyattritionreason==0, detail
summarize pubis_coil_bottom_mm if earlyattritionreason==1, detail
summarize pubis_coil_bottom_mm if earlyattritionreason==2, detail
kwallis pubis_coil_bottom_mm, by(earlyattritionreason)

```

*****FISHER'S Eact Testing*****

```

drop if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon
tabulate catheterdysfun3mon SEX, co ro exact
tabulate catheterdysfun3mon White, co ro exact
tabulate catheterdysfun3mon ESRD, co ro exact
tabulate catheterdysfun3mon PKD, co ro exact
tabulate catheterdysfun3mon number_prior_surgeries, co ro exact
summarize ageatinsert if catheterdysfun3mon==0, detail
summarize ageatinsert if catheterdysfun3mon==1, detail

```

```

summarize bmi if catheterdysfun3mon==0, detail
summarize bmi if catheterdysfun3mon==1, detail
summarize breakinperiod if catheterdysfun3mon==1, detail
summarize breakinperiod if catheterdysfun3mon==0, detail
summarize pubis_coil_bottom_mm if catheterdysfun3mon==1, detail
summarize pubis_coil_bottom_mm if catheterdysfun3mon==0, detail

```

```
*****T-Testing/Rank SUM*****
```

```

ttest ageatinsert, by(catheterdysfun3mon)
ranksum ageatinsert, by(catheterdysfun3mon)
ttest bmi, by(catheterdysfun3mon)
ranksum bmi, by(catheterdysfun3mon)
ttest breakinperiod, by(catheterdysfun3mon)
ranksum breakinperiod, by(catheterdysfun3mon)
ttest pubis_coil_bottom_mm, by(catheterdysfun3mon)
ranksum pubis_coil_bottom_mm, by(catheterdysfun3mon)

```

```
***MODELING*****
```

```
***Main Analysis***
```

```

use "C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear

```

```
set autotabgraphs on
```

```
*** Drop all patients who had non-catheter dysfunction attrition by 3 months***
```

```
drop if EarlyTechFail_Noncath==1
```

```
codebook catheterdysfun3mon
```

```
**Univariate Logistic regression**
```

```
logistic catheterdysfun3mon pubis_coil_bottom_mm
```

```
logistic catheterdysfun3mon ageatinsert
```

```
logistic catheterdysfun3mon bmi
```

```
logistic catheterdysfun3mon SEX
```

```
logistic catheterdysfun3mon number_prior_surgeries
```

```
logistic catheterdysfun3mon breakinperiod
```

```
logistic catheterdysfun3mon PKD
```

```
logistic catheterdysfun3mon White
```

```
logistic catheterdysfun3mon i.ESRD
```

```
**Multiple Logistic Regression**
```

```
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
```

```
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
```

```
> nephropathy ischemic gn other unknown
```

```
**Interaction
```

```
logistic catheterdysfun3mon c.ageatinsert##c.bmi diabeticnephropathy
```

```
logistic catheterdysfun3mon ageatinsert c.bmi##i.diabeticnephropathy
```

```
logistic catheterdysfun3mon c.ageatinsert##i.diabeticnephropathy c.bmi
```

```
logistic catheterdysfun3mon c.ageatinsert c.bmi##i.SEX i.diabeticnephropathy
```

```
logistic catheterdysfun3mon c.ageatinsert##i.SEX c.bmi i.diabeticnephropathy
```

```
logistic catheterdysfun3mon c.ageatinsert c.bmi i.SEX##i.diabeticnephropathy
```

```
**COEFPLOTS**
```

```
use "C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
```

```

> ter Insertion\Thesis\Thesistatafilefinal2.dta", clear
set autotabgraphs on
*** Drop all patients who had non-catheter dysfunction attrition by 3 months***
drop if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon
label variable ageatinsert "Age(years)"
label variable bmi "BMI(Kg/m2)"
label variable diabeticnephropathy "Diabetic ESKD"

qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
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foreach predictor in bmi ageatinsert diabeticnephropathy {
qui eststo `predictor': logistic catheterdysfun3mon `predictor'
}
qui eststo multi: stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis
> _coil_bottom_mm ageatinsert SEX PKD breakinperiod bmi number_prior_surger
> ies White diabeticnephropathy ischemic gn other unknown
coefplot (bmi\ageatinsert\diabeticnephropathy, label (uni)) ///
(multi), drop (_cons) xline(1) eform xtitle (Odds ratio)

*** BOX PLOTS ***
bysort catheterdysfun3mon: summarize pubis_coil_bottom_mm
graph box pubis_coil_bottom_mm, ///
medtype(line) over(catheterdysfun3mon) ///
box(1, bfcolor(none) blcolor(black) blwidth(medium)) ///
mark(1, msize(medsmall) mcolor(black)) ///
caption("Early Catheter Flow Dysfunction", position(6)) ///
ytitle("Pubis Symphysis to Bottom of Catheter Tip (mm)") ///
plotregion(color(white)) ///
name(boxplot, replace)

**Multiple Logistic Regression**
**Pubis to Coil, checks of Model Adequacy**

*Variance*
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy ischemic gn other unknown
predict residual, rstandard
sort catheterdysfun3mon
scatter residual pubis_coil_bottom_mm, symbol(oh)
*Linearity*
bysort pubis_coil_bottom_mm: egen catheterdysfun3monprop = mean(catheterdys
> fun3mon)
gen lgtcatheterdysfun3mon = log(catheterdysfun3monprop / (1 - catheterdysfun
> 3monprop))
predict yhat, xb
gr twoway (line yhat pubis_coil_bottom_mm)(sc lgtcatheterdysfun3mon pubis_c

```

```

> oil_bottom_mm, msymbol(Oh))(lowess lgtcatheterdysfun3mon catheterdysfun3m
> on, bw(5)), ytitle(Log Odds of Catheter Dysfunction) leg(off)
*Variance*
predict residual2, rstandard
sort pubis_coil_bottom_mm
scatter residual2 pubis_coil_bottom_mm, symbol(oh)
*goodness of fit*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
drop if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy ischemic gn other unknown
estat gof
**The Hosmer–Lemeshow test**
estat gof, group(10)

```

****Sensitivity Analyses*******

A) will include patients who had early attrition as is; assumes no early
> catheter dysfunction in this sub-group***

*****Main Analysis*****

```

use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
codebook catheterdysfun3mon

```

****Univariate Logistic regression****

```

logistic catheterdysfun3mon pubis_coil_bottom_mm
logistic catheterdysfun3mon ageatinsert
logistic catheterdysfun3mon bmi
logistic catheterdysfun3mon SEX
logistic catheterdysfun3mon number_prior_surgeries
logistic catheterdysfun3mon breakinperiod
logistic catheterdysfun3mon PKD
logistic catheterdysfun3mon White
logistic catheterdysfun3mon i.ESRD

```

****Multiple Logistic Regression****

```

stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy ischemic gn other unknown
logistic catheterdysfun3mon c.ageatinsert c.bmi i.diabeticnephropathy

```

****Interaction**

```

logistic catheterdysfun3mon c.ageatinsert##c.bmi diabeticnephropathy
logistic catheterdysfun3mon ageatinsert c.bmi##i.diabeticnephropathy
logistic catheterdysfun3mon c.ageatinsert c.bmi##i.SEX i.diabeticnephropathy

```

```
logistic catheterdysfun3mon c.ageatinsert c.bmi i.SEX##i.diabeticnephropathy
```

```
**COEFPLOTS**
```

```
use "C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
label variable ESRD "Diabetic Nephropathy"
label variable White "White Race"
label variable diabeticnephropathy "Diabetic ESKD"
qui summ bmi
qui replace bmi = (bmi - r(mean))/r(sd)
qui summ ageatinsert
qui replace ageatinsert = (ageatinsert - r(mean))/r(sd)
foreach predictor in bmi ageatinsert diabeticnephropathy {
qui eststo `predictor': logistic catheterdysfun3mon `predictor'
}
qui eststo multi: stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis
> _coil_bottom_mm ageatinsert SEX PKD breakinperiod bmi number_prior_surger
> ies White diabeticnephropathy gn ischemic other unknown
coefplot (bmi\ageatinsert\diabeticnephropathy, label (uni)) ///
(multi), drop (_cons) xline(1) eform xtitle (Odds ratio)
```

```
*** BOX PLOTS ***
```

```
bysort catheterdysfun3mon: summarize pubis_coil_bottom_mm
graph box pubis_coil_bottom_mm, ///
medtype(line) over(catheterdysfun3mon) ///
box(1, bfcolor(none) blcolor(black) blwidth(medium)) ///
mark(1, msize(medsmall) mcolor(black)) ///
caption("Early Catheter Flow Dysfunction", position(6)) ///
ytitle("Pubis Symphysis to Bottom of Catheter Tip (mm)") ///
plotregion(color(white)) ///
name(boxplot, replace)
```

```
**Multiple Logistic Regression**
```

```
**Pubis to Coil, checks of Model Adequacy**
```

```
*Variance*
```

```
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy gn ischemic other unknown
```

```
predict residual, rstandard
```

```
sort catheterdysfun3mon
```

```
scatter residual pubis_coil_bottom_mm, symbol(oh)
```

```
*Linearity*
```

```
bysort pubis_coil_bottom_mm: egen catheterdysfun3monprop = mean(catheterdys
> fun3mon)
```

```
gen lgtcatheterdysfun3mon = log(catheterdysfun3monprop / (1 - catheterdysfun
```

```

> 3monprop))
predict yhat, xb
gr twoway (line yhat pubis_coil_bottom_mm)(sc lgtcatheterdysfun3mon pubis_c
> oil_bottom_mm, msymbol(Oh))(lowess lgtcatheterdysfun3mon catheterdysfun3m
> on, bw(5)), ytitle(Log Odds of Catheter Dysfunction) leg(off)
*Variance*
predict residual2, rstandard
sort pubis_coil_bottom_mm
scatter residual2 pubis_coil_bottom_mm, symbol(oh)
*goodness of fit*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy gn ischemic other
estat gof
**The Hosmer–Lemeshow test**
estat gof, group(10)

**Sensitivity Analysis*****

B) will include patients who had early attrition and assume all had catheter dysfunction**
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
replace catheterdysfun3mon = 1 if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon

**Univariate Logistic regression**
logistic catheterdysfun3mon pubis_coil_bottom_mm
logistic catheterdysfun3mon ageatinsert
logistic catheterdysfun3mon bmi
logistic catheterdysfun3mon SEX
logistic catheterdysfun3mon number_prior_surgeries
logistic catheterdysfun3mon breakinperiod
logistic catheterdysfun3mon PKD
logistic catheterdysfun3mon White
logistic catheterdysfun3mon i.ESRD

**Multiple Logistic Regression**
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy gn ischemic other unknown
**Interaction
logistic catheterdysfun3mon c.ageatinsert c.bmi##i.SEX i.diabeticnephropathy

**COEFPLOTS**
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on

```

```

replace catheterdysfun3mon = 1 if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon
label variable ageatinsert "Age(years)"
label variable PKD "PKD"
label variable number_prior_surgeries "Number of Prior Surgeries"
label variable bmi "BMI(Kg/m2)"
label variable ESRD "Diabetic Nephropathy"
label variable White "White Race"
label variable diabeticnephropathy "Diabetic ESKD"
foreach predictor in bmi ageatinsert diabeticnephropathy {
qui eststo `predictor': logistic catheterdysfun3mon `predictor'
}
qui eststo multi: stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis
> _coil_bottom_mm ageatinsert SEX PKD breakinperiod bmi number_prior_surger
> ies White diabeticnephropathy gn ischemic other unknown
coefplot (bmi\ageatinsert\diabeticnephropathy, label (uni)) ///
(multi), drop (_cons) xline(1) eform xtitle (Odds ratio)

*** BOX PLOTS ***
bysort catheterdysfun3mon: summarize pubis_coil_bottom_mm
graph box pubis_coil_bottom_mm, ///
medtype(line) over(catheterdysfun3mon) ///
box(1, bfcolor(none) blcolor(black) blwidth(medium)) ///
mark(1, msize(medsmall) mcolor(black)) ///
caption("Early Catheter Flow Dysfunction", position(6)) ///
ytitle("Pubis Symphysis to Bottom of Catheter Tip (mm)") ///
plotregion(color(white)) ///
name(boxplot, replace)

**Multiple Logistic Regression**
**Pubis to Coil, checks of Model Adequacy**
*Variance*
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy gn ischemic other unknown
predict residual, rstandard
sort catheterdysfun3mon
scatter residual pubis_coil_bottom_mm, symbol(oh)
*Linearity*
bysort pubis_coil_bottom_mm: egen catheterdysfun3monprop = mean(catheterdys
> fun3mon)
gen lgtcatheterdysfun3mon = log(catheterdysfun3monprop / (1 - catheterdysfun
> 3monprop))
predict yhat, xb
gr twoway (line yhat pubis_coil_bottom_mm)(sc lgtcatheterdysfun3mon pubis_c
> oil_bottom_mm, msymbol(Oh))(lowess lgtcatheterdysfun3mon catheterdysfun3m
> on, bw(5)), ytitle(Log Odds of Catheter Dysfunction) leg(off)
Saturday July 1 21:27:34 2023 Page 27
*Variance*
predict residual2, rstandard
sort pubis_coil_bottom_mm

```

```
scatter residual2 pubis_coil_bottom_mm, symbol(oh)
*goodness of fit*
use"C:\Users\bigco\OneDrive\Documents\Clin Epi\Thesis\Fluoroscopic PD Cathe
> ter Insertion\Thesis\Thesisdatafilefinal2.dta", clear
set autotabgraphs on
replace catheterdysfun3mon = 1 if EarlyTechFail_Noncath==1
codebook catheterdysfun3mon
stepwise, pr(.2) pe(.1):logistic catheterdysfun3mon pubis_coil_bottom_mm ag
> eatinsert SEX PKD breakinperiod bmi number_prior_surgeries White diabetic
> nephropathy gn ischemic other unknown
estat gof
**The Hosmer–Lemeshow test**
estat gof, group(10)
```


Curriculum Vitae

DAVID A CLARK MD FRCPC

EDUCATION

Degrees

1. *Master of Science, Clinical Epidemiology and Biostatistics* Candidate 2023
Faculty of Science, Western University
2. *Doctor of Medicine* September 2008-June 2012
Faculty of Medicine, University of Ottawa
3. *Bachelor of Science, BSc. Honors* September 2003-June 2007
Faculty of Science, Saint Francis Xavier University

Professional Training

1. *Home Dialysis Fellowship* July 2017-June 2019
London Health Sciences Center, Western University
London, Ontario
2. *Nephrology Fellowship* July 2015-June 2017
Queen Elizabeth II Hospital, Dalhousie University
Halifax, Nova Scotia
3. *Internal Medicine Residency* July 2012-June 2015
Queen Elizabeth II Hospital, Dalhousie University
Halifax, Nova Scotia

Professional Certification

1. *Specialist Certificate, Nephrology* November 2017
The Royal College of Physicians and Surgeons of Canada
2. *Fellow of the Royal College of Physicians of Canada* June 2016
The Royal College of Physicians and Surgeons of Canada
3. *Specialist Certificate, Internal Medicine* June 2016
The Royal College of Physicians and Surgeons of Canada
4. *Licentiate of the Medical Council of Canada* October 2013
Medical Council of Canada

Special Training

1. *GRADE – CSN GRADE Workshop Course* 2021
INGUIDE - Level 1: Guideline Panel Member Certification
2. *POCUS – Acute Care CORE Independent Practitioner Certification* 2021
IP # 21387, PoCUS East, Halifax NS
3. *Clinical Epidemiology: Introduction to Patient Oriented Health Research* 2017
Life Science Research Institute, Halifax NS
4. *Peritoneal Dialysis University – Certificate of Attendance* 2016
Toronto ON
5. *ECCU: Emergency & Critical Care Ultrasound Course* 2013
Queen Elizabeth Hospital II, Halifax NS

LICENSES

1. College of Physicians and Surgeons of Nova Scotia Medical License 2017-Present
2. College of Physicians and Surgeons of Ontario Independent Practice License 2019

ACADEMIC AFFILIATIONS

1. *Assistant Professor* 2019-Present
Department of Medicine, Dalhousie University
2. *Adjunct Professor* 2018-2019
Department of Medicine, Western University

PROFESSIONAL AFFILIATIONS

1. Canadian Society of Nephrology 2015-Present
2. American Society of Nephrology 2015-Present
3. International Society of Peritoneal Dialysis 2015-Present
4. Doctors of Nova Scotia 2012-Present

HONOURS AND AWARDS

1. *Department of Medicine Service Award* 2022
Five years' service
2. *Gold Medal – Medicine* 2012
Highest standing overall in Anglophone Medical class of 2012
University of Ottawa, Faculty of Medicine

- | | | |
|----|--|-----------|
| 3. | <i>Nomination for Outstanding Clinical Performance – Clerkship</i>
Pediatrics, Family Medicine, Emergency, Anesthesia, Psychiatry, Surgery.
University of Ottawa | 2011-2012 |
| 4. | <i>Alfred E. Coll Memorial Award</i>
Highest standing in pre-clerkship year 1 – Anglophone
University of Ottawa | 2009 |
| 5. | <i>Department of Biology Highest Academic Achievement Award</i>
Saint Francis Xavier University | 2005-2007 |
| 6. | <i>NSERC USRA</i>
<i>Natural Sciences & Engineering Research Council of Canada</i> | 2007-2008 |
| 7. | <i>Dean’s List, Faculty of Science</i>
Saint Francis Xavier University | 2003-2007 |

BOARDS AND COMMITTEES

Division of Nephrology

- | | | |
|----|---|--------------|
| 1. | Kidney Research Institute of Nova Scotia – <i>Member</i>
Halifax, NS | 2020-Present |
| 2. | <i>Medical Lead – Home Dialysis Program</i>
NSHA Renal Program, Central Zone | 2020-Present |
| 3. | <i>Lead – Percutaneous Peritoneal Dialysis Catheter Insertion Program</i>
NSHA Renal Program, Central Zone | 2019-Present |
| 4. | <i>Halifax Home Dialysis Fellowship – Program Director</i>
Division of Nephrology, Dalhousie University | 2020-Present |
| 5. | <i>Medical Lead - Home Dialysis Quality Review Program</i>
Division of Nephrology, Dalhousie University | 2022-Present |

Department of Medicine

- | | | |
|----|---|--------------|
| 1. | <i>Department of Medicine Research Committee - Member</i>
Department of Medicine, Dalhousie University | 2020-Present |
|----|---|--------------|

External

- | | | |
|----|---|-----------|
| 1. | CSN Executive Board – Representative for Atlantic Provinces
Canadian Society of Nephrology, Canada | 2023-2026 |
| 2. | CSN Clinical Practice Guidelines Committee – <i>Member</i>
Canadian Society of Nephrology, Canada | 2021-2024 |

3. CSN Scientific Committee – *Member* 2021-2023
Canadian Society of Nephrology, Canada
4. International Society of Nephrology Mentorship Program – *Mentor* 2021 - Present
5. *International Home Dialysis Round Table - Member* 2020
Advancing Home Dialysis - The Imperative from the Pandemic and Beyond
6. *Canadian Society of Nephrology COVID-19 Rapid Response Team* 2020
Canadian Society of Nephrology, Canada
7. *Peritoneal Dialysis: Attrition & Frailty Committee - Member* 2018-2019
Division of Nephrology, Western University

RESEARCH

Research Grants

1. Tennankore K (PI), Searle S, El-Feghi M, **Clark DA**, Vinson A, Sills L, Wilson J, Verdin N (2023). Assessing Cognition in Kidney Failure Using Virtual Reality Technology: Nova Scotia Health Authority Research Fund Competition: \$100,000 CAD.
2. Vinson, A (PI), **Clark DA**, Tennankore K. Gender-Based Barriers to Referral for Kidney Transplantation in Canada. The Kidney Foundation of Canada
3. Tennankore K. (PI), **Clark DA**, Leblanc J, Davis I, Bohm C, Shorter A (2021). Optimizing donor and recipient matching in deceased and live donor kidney transplantation using machine learning: Nova Scotia Health Authority Research Fund Competition: \$94,000 CAD
4. Vinson, A (PI), **Clark DA**, West K, Siddiqqi F, Skinner T, Tennankore K (2020). C-Peptide and Kidney Transplant Outcomes. UIMRF for Special Circumstance Grant Funding: \$24,976 CAD
5. Tennankore K. (PI), **Clark DA**, Leblanc J, Davis I, Bohm C, Shorter A (2020). Towards a better understanding of screening approaches and outcomes of COVID-19 infection in dialysis patients. Submitted to the Nova Scotia COVID-19 Health Research Coalition – 1 year (\$43,103.36)
6. Tennankore K (PI), **Clark DA**, Vinson A, Goldstein J. 2018. Validation of a Risk Prediction Model for Urgent Dialysis after Ambulance Transport to the Emergency Department. Nova Scotia Health Authority Research Fund Competition: \$24,744 CAD.

7. **Clark DA (PI)**, Crabtree J, Jain A. 2018. Fluoroscopic Guided Peritoneal Catheter Insertion: Radiology Anthropometric Analysis for Determining Optimal Catheter Position. Western University Division of Nephrology Divisional Academic Fund Grant Competition: \$10,800 CAD.
8. **Clark DA (PI)**, Tennankore K. 2017. Towards a Better Understanding of Hospitalization in Polycystic Kidney Disease. Investigator Initiated Research - Otsuka Canada Pharmaceuticals: \$15,000 CAD.
9. **Clark DA (PI)**, Tennankore K. 2016. Towards a Better Understanding of Measuring Hospitalization in Dialysis: A Cohort Study. Nova Scotia Health Authority Research Fund Competition: \$5,000 CAD.

Peer-Reviewed Publications

1. Baragar B, **Clark DA**, Harrison T, Hundemer G, Mathew A, Mustaf R, Ryz K, Schorr M, Verdin N, Woodlock, T. Identification and Prioritization of Canadian Society of Nephrology Clinical Practice Guideline Topics with Multidisciplinary Stakeholders and People Living with Kidney Disease: A Research Protocol. Submitted to CJKHD 2022.
2. Thanamyooran A, Nallbani M, Vinson A, **Clark DA**, Fok P, Goldstein J, More KM, Swain J, Wiemer H, Tennankore KK. Predictors of urgent dialysis following ambulance transport to the emergency department. Submitted to CJKHD 2022.
3. England E, Sheffield M, Poyah P, **Clark DA**, Wilson J. An Evaluation of Iron Isomaltoside Use in Non-Dialysis Dependent Chronic Kidney Disease and Peritoneal Dialysis Patients. Accepted to Canadian Journal of Hospital Pharmacy 2022.
4. Thorne J, **Clark DA**, Geldenhuys L, More Keigan, Vinson A, Tennankore K. AA Amyloidosis and nephropathy: presentation, diagnosis and emerging therapies. *Kidney Medicine*. 2022;4(8):100504.
5. Amanda J. Vinson, Wayel Zanjir, Megi Nallbani, Judah Goldstein, Janel Swain, **David A. Clark**, Keigan M. More, John R. Manderville, Patrick T. Fok, Hana Wiemer and Karthik K. Tennankore. Predictors of hyperkalemia among maintenance hemodialysis patients transported to the emergency department by ambulance. *Kidney360* February 2022, 10.34067/KID.0008132021; DOI:<https://doi.org/10.34067/KID.0008132021>
6. Alabbas, Abdullah; Harvey, Elizabeth; Kirpalani, Amrit; Teoh, Chia Wei; Mammen, Cherry; Pederson, Kristen; Nemecek, Rosaleen; Davis, T.; Mathew, Anna; McCormick, Brendan; Banks, Cheryl; Frenette, Charles; **Clark, David**; Zimmerman, Deborah; Qirjazi, Elena; Mac-Way, Fabrice; Vorster, Hans; Antonsen, John; Kappel, Joanne; MacRae, Jennifer; Hemmett, Juliya; Tennankore, Karthik; Moist, Louise; Copland, Michael; McCormick, Michael; Suri, Rita; Singh, Suneeet;

- Davison, Sara; Lemaire, Mathieu; Chanchlani, Rahul. Canadian Association of Paediatric Nephrologists COVID-19 Rapid Response: Home and In-Centre Dialysis Guidance. Canadian Journal of Kidney Health and Disease. September 2021.
7. Pratt R, **Clark DA**, Vinson A, Green R, Tennankore K. Outcomes of major trauma among patients with chronic kidney disease and receiving dialysis in Nova Scotia: a retrospective analysis. *Trauma Surgery & Acute Care Open* 2021;6:e000672. doi: 10.1136/tsaco-2020-000672 *Trauma Surgery & Acute Care*.
 8. Vinson A, Skinner T, Kiberd B, **Clark D**, Tennankore K. The differential impact of size mismatch in live versus deceased donor kidney transplant. *Clin Transplant*. 2021;00:e14310
 9. Vinson A, Skinner T, Kiberd B, **Clark DA**, Tennankore K. The differential impact of size mismatch in live versus deceased donor kidney transplant. *Clin Transplant*. 2021;00:e14310.
 10. **Clark DA**, West KA, Tennankore KK. Feasibility of Twice Weekly Hemodialysis: Contingency Planning for COVID-19 *Kidney Med*. 2021 Mar-Apr;3(2):314-316. doi: 10.1016/j.xkme.2020.12.005. Epub 2021 Feb 5. PMID: 33585809; PMCID: PMC7863757.
 11. **Clark DA**, Matheson K, West B, Vinson A, West K, Jain A, Rockwood K, Tennankore K. Frailty Severity and Hospitalization after Dialysis Initiation. *Canadian Journal of Kidney Health and Disease*. January 2021. doi:10.1177/20543581211023330.
 12. Gale J, **Clark DA**, Bohm C, et al. COVID-19 Status, Symptom Burden, and Characteristics of Dialysis Patients Residing in Areas of Community Transmission: Research Letter. *Canadian Journal of Kidney Health and Disease*. January 2020. doi:10.1177/2054358120964178
 13. Rita S. Suri, John E. Antonsen, Cheryl Banks, **David Clark**, Sara N. Davison, Charles Frenette, Joanne Kappel, Jennifer McRae, Fabrice Mac-Way, Anna Mathew, Louise Moist Elena Qirjazi, Karthik Tennakore Hans Vorster. Management of Outpatient Hemodialysis During the COVID-19 Pandemic: Recommendations From the Canadian Society of Nephrology COVID-19 Rapid Response Team. *Canadian Journal of Kidney Health and Disease*. January 2020. doi: 10.1177/2054358120938564
 14. A. J. Vinson, J. Bartolacci, J. Goldstein, J. Swain, **D. A. Clark** & K. K. Tennankore (2020). Predictors of Need for First and Recurrent Emergency Medical Service Transport to Emergency Department after Dialysis Initiation, Prehospital Emergency Care, DOI: 10.1080/10903127.2019.1701157

15. Vinson A, Bartolacci J, Goldstein J, Swain J, **Clark DA**, Kiberd B, Tennankore K. Optimizing Ambulance Transport of Hemodialysis Patients to the Emergency Department: A Cohort Study. March 2019 CJKHD.
16. Bartolacci J, Goldstein J, Kiberd B, Swain J, Vinson A, **Clark DA**, Tennankore K. Burden of Emergency Medical Services Usage by Dialysis Patients. Prehosp Emerg Care. 2018 Apr 19:1-7.
17. **Clark DA**, Turner C, Dixon A, Moorhouse P, Khan U, Moffatt H, Tennankore KK. Perceptions of Frailty by Caregivers, Patients and Practitioners. BMC Nephrol. 18(1):148, 2017.

Accepted Conference Abstracts

1. Sophie Gaube, Dylan Cooper, Annie-Claire Nadeau-Fredette, **David Clark**, Karthik Tennankore. FRAILITY AND MORTALITY AMONG INCIDENT PERITONEAL DIALYSIS PATIENTS: A COHORT STUDY.
 - a. Poster - Canadian Society of Nephrology AGM 2023
 - b. Poster - 2023 Dalhousie Faculty of Medicine Research Day
2. Dylan Cooper, Sophie Gaube, Annie-Claire Nadeau-Fredette, Karthik Tennankore, **David Clark**. PATIENT CHARACTERISTICS AND MORTALITY IN A CANADIAN INCREMENTAL PERITONEAL DIALYSIS COHORT.
 - a. Poster – Canadian Society of Nephrology AGM 2023
 - b. Poster - 2023 Dalhousie Faculty of Medicine Research Day
3. Meghan Day, Leah Cahill, Annie-Claire Nadeau-Fredette, Cindy Feng, Emilie Trinh, Jeffrey Perl, Christopher Chan, **David Clark**, Karthik Tennankore. A comparison of hospitalization outcomes between peritoneal dialysis and home hemodialysis patients in Canada.
 - a. Abstract – Canadian Society of Nephrology AGM 2023
4. Worthen G, Vinson A, **Clark DA**, More K, Tennankore K. The Impact of Late Initiation of Chronic Dialysis on Mortality: A National Retrospective Cohort Study
 - a. Poster – American Society of Nephrology Kidney Week 2021
5. England E, Wilson J, Sheffield M, Poyah P, **Clark DA**, Robinson S, Elbourne K, Seo L. An Evaluation of Iron Isomaltoside Use in Non-Dialysis Dependent Chronic Kidney Disease and Peritoneal Dialysis Patients.
 - a. Poster – 2021 Dalhousie Student Research Symposium
 - b. Poster – 2022 Department of Medicine Quality Day
6. Vinson A, **Clark DA**, Kiberd B, Tennankore K. The Association of Pre-Kidney Transplant C-Peptide Level with Post Transplant Outcomes.
 - a. Abstract – 2021 American Transplant Congress

7. Goodwin, Josh; Vinson, Amanda; **Clark, David**; More, Keigan; Tennankore, Karthik. Frailty and the probability of wait listing for kidney transplantation
 - a. Poster at the 2020 Dalhousie Faculty of Medicine Research Day
8. Zanjir, Wayel; Vinson, Amanda; **Clark, David**; More, Keigan; Tennankore, Karthik. Predictors of hyperkalemia among chronic hemodialysis patients transported to the emergency department.
 - a. Poster at the 2020 Dalhousie Faculty of Medicine Research Day
9. **Clark DA**, Meherzad K, Tennankore K, Jain, A. Fluoroscopic Guided Peritoneal Catheter Insertion: Radiology Anthropometric Analysis For Determining Optimal Catheter Position.
 - a. Poster at the 2020 Canadian Society of Nephrology Annual meeting 2020
 - b. Poster at the 2020 American Society of Nephrology Kidney Week 2020
 - c. Poster at the 2020 Dalhousie Faculty of Medicine Research Day
10. **Clark DA**, West K, Tennankore K (2020). Contingency Planning for COVID-19: Feasibility of Twice Weekly Hemodialysis in a Large Canadian Center.
 - a. Poster at the 2020 American Society of Nephrology Kidney Week 2020
 - b. Poster at the 2021 Dalhousie Faculty of Medicine Research Day
11. **Clark DA**, Tennankore K. Cumulative Time in Hospital After Initiation of Dialysis: A Cohort Study.
 - a. Poster at the 2018 American Society of Nephrology Annual Meeting 2018
12. **Clark DA**, Tennankore K. Frailty and Hospitalization in Dialysis: Evaluation of the Clinical Frailty Scale.
 - a. ePoster oral presentation at the Canadian Society of Nephrology Annual Meeting 2018
 - b. Poster at the 2018 Dalhousie Faculty of Medicine Research Day
 - c. Poster at the 2018 Western Faculty of Medicine Research Day
13. Vinson A, Bartolacci J, Goldstein J, Swain J, **Clark DA**, Kiberd B, Tennankore K. Emergency Medical Services for Dialysis Patients: Predictors and Outcomes
 - a. Poster at the Canadian Society of Nephrology Annual Meeting 2018
 - b. Poster at the 2018 Dalhousie Faculty of Medicine Research Day
14. Bartolacci J, Goldstein J, Kiberd B, **Clark DA**, Tennankore K. The Burden of Emergency Medical Services Care for Dialysis Patients.
 - a. Poster at the National Association of EMS Physicians Annual Meeting 2017
15. Bartolacci J, Goldstein J, Kiberd B, **Clark DA**, Swain J, Tennankore K. Predictors of Emergency Medical Services Usage by Dialysis Patients.
 - a. Poster at the Annual Dialysis Conference 2017
 - b. Poster at the National Association of EMS Physicians Annual Meeting 2017
 - c. Poster at the Canadian Society of Nephrology Annual Meeting 2017

16. **Clark DA**, Turner C, Dixon A, Moorhouse P, Khan U, Moffatt H, Tennankore K. Perceptions of Frailty by Caregivers, Patients and Practitioners.
 - a. Poster at the 2016 Dalhousie Faculty of Medicine Research Day
17. **Clark DA**, Tran A, Hobbs H, Haroon B. Internal Medicine Boot Camp - Easing the Transition from Clinical Clerk to Junior Resident
 - a. Poster at the 2014 Dalhousie Faculty of Medicine Research Day
 - b. Poster at the 2013 Simulation Summit, Royal College of Physicians and Surgeons
18. **Clark DA**, Dyck, T, Lantz, A, Demont E. Undergraduate Degree Honours Thesis: Impact of mechanical vibration on the viscera and health of the male American lobster (*Homarus americanus*).
 - a. Poster at the 2006 Annual Lobster Science Workshop

Current Research Efforts

1. Fluoroscopic Guided Peritoneal Dialysis Catheter Insertion
 - a. **Clark DA (PI)**, Meherzad K, Crabtree J, Jain A. Fluoroscopic Guided Peritoneal Catheter Insertion: Radiology Anthropometric Analysis for Determining Optimal Catheter Position.
2. Outcomes of CKD, Dialysis and Kidney Transplant Recipients with COVID-19
 - a. **Clark DA**, Tennankore K (PI)
3. Towards a Better Understanding of Outcomes of Peritoneal Dialysis Catheter Insertion: A Cohort Study
 - a. **Clark DA (PI)**, Vinson A, Skinner T, Walsh M, Tennankore K.
4. Hospitalization in Renal Disease/Dialysis Populations
 - a. **Clark DA (PI)**, Tennankore K. Hospitalization Patterns in Polycystic Kidney Disease Patients.
 - b. Gaube S, **Clark DA**, Tennankore K. Impact of frailty on short/long-term outcomes after PD initiation.
5. Incremental Peritoneal Dialysis
 - a. Cooper D, Tennankore K, **Clark DA (SI)**. Towards a Better Understanding of Outcomes of Incremental Peritoneal Dialysis
 - b. PDOPPS Executive – Incremental PD; Co-Investigator

Research Trainees Under Supervision

1. Dylan Cooper – Co-supervisor May 2022 – present
Undergraduate Dalhousie Sciences Student – Honors Thesis
2. Sophie Gaube – Co-Supervisor Jan 2022 – present
Research in Medicine Student

Guidelines Development

1. Co-Lead of the Canadian Peritoneal Catheter Insertion Consensus Workshop – May 2018.
2. Co-Lead for guideline development for percutaneous peritoneal dialysis catheter insertion in Canada – Canadian Society of Nephrology Guideline

CADTH Review

1. CADTH Reimbursement Review: Difelikefalin; Indication: Treatment of chronic kidney disease associated pruritus

Books/Chapters

1. International Applications of Home Hemodialysis: Barriers and How They Can Be Overcome. Jordan Thorne, **David Clark**, Karthik Tennankore

Peer Review

1. Canadian Journal of Kidney Health and Disease
2. BMJ Open
3. Journal of the American Society of Nephrology
4. Clinical Journal of the American Society of Nephrology

EDUCATIONAL DELIVERY**Nephrology Core Fellows - Longitudinal Clinic Supervisor**

1. Dr. Wayel Zanjir Jan – Aug 2022

Home Dialysis Fellows – Fellowship Program Supervisor

1. Dr. Gaeth Al’Zaneen Sept 2022 - Present
2. Dr. Mohamed Elbokl July 2020 – Dec 2021

Presentations

1. Home Dialysis Therapies – Patient Selection and Myth Busting
Nova Scotia Renal Program – Truro, NS June 2023
2. Home Dialysis Therapies – Patient Selection and Myth Busting
Nova Scotia Renal Program – Halifax, NS May 2023
3. Peritoneal Dialysis – Pre-course Education Program
Canadian Society of Nephrology Annual General Meeting May 2023
4. NxSTAGE
Halifax Home Dialysis Education Series, Atlantic Canada April 2023
5. Journal Club – Urgent Peritoneal Dialysis
Halifax Nephrology Divisional Rounds March 2023

6. Peritoneal Dialysis Catheter Insertion
Halifax Home Dialysis Education Series, Atlantic Canada March 2023
7. Nephrotic Syndrome & Glomerulonephritis
Dalhousie Core Internal Medicine Academic Half Day January 2023
8. Introduction to Acid/Base Disorders
Dalhousie Undergraduate Curriculum – Med 2 Metabolic Unit January 2023
9. History of Peritoneal Dialysis
Halifax Home Dialysis Education Series, Atlantic Canada January 2023
10. Home Dialysis – Who, Why, & Myths
2022 NS Renal Program Meeting – Planning for Home Therapies November 2022
11. Nephrologist-Led Percutaneous Peritoneal Dialysis Catheter Insertion
2022 Atlantic Canada PD Symposium October 2022
12. Interesting Case Rounds – Nephrogenic Diabetes Insipidus
Halifax Nephrology Divisional Rounds September 2022
13. Innovation Rounds – Home Dialysis Advancements
Halifax Nephrology Divisional Rounds June 2022
14. Updates in Acute Peritoneal Dialysis
Canadian Society of Nephrology Annual General Meeting May 2022
15. Interesting Case Rounds – PD Catheter Mechanical Complications
Halifax Nephrology Divisional Rounds April 2022
16. Acute Kidney Injury & Renal Biopsy
Dalhousie Internal Medicine Academic Half Day February 2022
17. Journal Club FIGARO-DKD Trial
Halifax Nephrology Evening Journal Club February 2022
18. Bedside Peritoneal Dialysis Catheter Insertion
Peritoneal Dialysis Atlantic Nursing Symposium, Baxter Canada November 2021
19. Interesting Case Rounds - Paroxysmal Nocturnal Hemoglobinuria
Halifax Nephrology Divisional Rounds October 2021
20. Innovation Rounds - POCUS for Nephrologists
Halifax Nephrology Divisional Rounds September 2021
21. Journal Club - Frailty & Dialysis Modality April 2021

- Halifax Nephrology Divisional Rounds
22. Peritoneal Dialysis – There and Back Again
Department of Medicine Grand Rounds – Dalhousie University April 2021
 23. Nephrotic Syndrome & Glomerulonephritis
Dalhousie Core Internal Medicine Academic Half Day February 2021
 24. Urgent Start Peritoneal Dialysis
Eastern Zone Renal Program, Cape Breton NS February 2021
 25. Nephrology Curriculum - Complications of Peritoneal Dialysis
Halifax Nephrology Fellowship Educational Rounds October 2020
 26. Journal Club - STARTAKI Trial
Halifax Nephrology Divisional Rounds June 2022
 27. Coronavirus Pandemic & Dialysis Care: Dilemmas and Challenges
Department of Medicine Grand Rounds – Dalhousie University May 2020
 28. Journal Club - Risk for Nephrotic Syndrome for NSAID Users
Halifax Nephrology Evening Journal Club September 2019
 29. Interesting Case Rounds - Do It Yourself Plumbing
Halifax Nephrology Divisional Rounds August 2019
 30. Tackling Knowledge Gaps in Peritoneal Dialysis
Home Dialysis Fellow – Invited Presentation – Halifax Nephrology March 2018
 31. Frailty Measurement in Dialysis Patients
Home Dialysis Fellow – Invited Presentation – Western Nephrology February 2018